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NOTE

from :	General Secretariat
to :	Delegations
No. prev. doc. :	15472/05 COMPET 282 ENV 587 CHIMIE 72 CODEC 1152 OC 938 + COR 1 (en)
No. Cion prop. :	15409/03 COMPET 75 ENV 651 CHIMIE 3 CODEC 1692 + ADD 1 + ADD 2 + ADD 3 + ADD 4 + ADD 5 + ADD 6
Subject :	Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} Proposal for a Directive of the European Parliament and of the Council amending Council Directive 67/548/EEC in order to adapt it to Regulation (EC) of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals

Following the agreement on the recitals by the Permanent Representatives Committee at its meeting on 8 March 2006, delegations will find enclosed the complete consolidated text of the proposed Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

This document consists of the text of the enacting terms agreed by the Council (Competitiveness) at its meeting on 13 December 2005 (doc.15921/05), the text of the recitals set out in document 6888/06, the corrections to Articles 3 and 13 agreed by the Ad-hoc Working Party on Chemicals at its meeting on 13 and 14 February 2006, and Annexes XII and XIII from the Commission proposal (doc. 15409/03). This document will serve as a basis for the preparation of the text of the Council's Common Position by the legal-linguistic experts.

The complete consolidated text incorporates the following annexes: I, Ia, Ic, II, III, IV, V, VI, VII, VIII, IX, XI, XII, XIII, XIV, XV and XVI. Of these, annex XVI is set out in ADD 1 to this document. Annexes Ib, X and XVII of the Commission Proposal have been deleted.

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Presidency Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],
Whereas:

(1) The purpose of the Regulation is to ensure a high level of protection of health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation.

(2) The efficient functioning of the internal market for substances within the Community can be achieved only if requirements for substances do not differ significantly from Member State to Member State.

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(3) A high level of health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development; that legislation should be applied in a non-discriminatory manner whether chemical substances are traded on the internal market or internationally.

(3a) Pursuant to the implementation plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development, the European Union is aiming to achieve that, by 2020, chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment.

(3b) The Regulation shall apply without prejudice to Community workplace and environment legislation.

(3c) The Strategic Approach to International Chemical Management (SAICM) was adopted on 6 February 2006 in Dubai and this Regulation should contribute to its fulfilment.

(4) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers, and the environment, it is necessary to ensure that manufacturing of substances in the Community comply with Community law, even if those substances are exported.

(4a) Special account should be taken of the potential impact of the Regulation on small- and medium-sized enterprises (SMEs) and the need to avoid any discrimination against them.

(5) The assessment[4] of the operation of the four main legal instruments governing chemicals in the Community (Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances[5], Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[6] (in the meantime replaced by Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations[7]), Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances[8] and Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations[9]) identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field, and the need to do more to protect public health and the environment in accordance with the Precautionary Principle.

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4 Commission Working Document SEC(1998) 1986 final, referred to in White paper Strategy for a future Chemicals Policy, COM(2001) 88 final, 27.2.2001.

5 OJ 196, 16.8.1967, p. 1. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

6 OJ L 187, 16.7.1988, p. 14.

7 OJ L 200, 30.7.1999, p. 1. Directive as amended by Commission Directive 2001/60/EC (OJ L 226, 22.8.2001, p. 5).

8 OJ L 84, 5.4.1993, p. 1.

9 OJ L 262, 27.9.1976, p. 201. Directive as last amended by Directive 2003/53/EC of the European Parliament and of the Council (OJ L 178, 17.7.2003, p. 24).

(6) Substances under customs supervision which are in temporary storage, in free zones or free warehouses with a view to re-exportation or in transit are not used within the meaning of this Regulation and are therefore to be excluded from its scope. The carriage of dangerous substances and of dangerous preparations by rail, road, inland waterways, sea or air should also be excluded from its scope as specific legislation already applies to such carriage.

(6a) To ensure workability and to maintain the incentives for recycling and recovery of wastes, such wastes should not be regarded as substances, preparations or articles within the meaning of the Regulation.

(7) An important objective of the new system to be established by this Regulation is to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available. This Regulation does not affect the application of Directives on worker protection and the environment, especially Council Directive 2004/37/EC of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)[10] and Council Directive 98/24/EC under which employers are required to eliminate dangerous substances, wherever technically possible, or to substitute dangerous substances with less dangerous substances.

(8) Responsibility for the management of the risks of substances should lie with the natural or legal persons that manufacture, import, place on the market or use these substances. Information on the implementation of REACH should be easily accessible, in particular for small and medium-sized enterprises.

[10] OJ L196, 26.7.1990, p. 1. Directive as last amended by Directive 1999/38/EC (OJ L 138, 1.6.1999, p. 66).

(9) For these reasons, the registration provisions require manufacturers and importers to generate data on the substances they manufacture or import, use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration requires them to submit a dossier containing all this information to the Agency to be established by this Regulation. Registered substances should be allowed to circulate on the internal market.

(10) The evaluation provisions provide for follow-up to registration, by allowing for checks whether registrations are in compliance with the requirements of this Regulation and if necessary by allowing for generation of more information on the properties of substances. If the Agency in co-operation with the Member States considers that there are grounds for considering that a substance constitutes a risk to health or the environment, the Agency should, after having included them in the Community rolling action plan, relying on the competent authorities of Member States, ensure that these substances are evaluated.

(11) Although the information yielded on substances through evaluation should be used in the first place by manufacturers and importers to manage the risks related to their substances, it may also be used to initiate the authorisation or restrictions procedures under this Regulation or risk management procedures under other Community legislation; therefore it should be ensured that this information is available to the appropriate authorities and may be used by them for the purpose of such procedures.

(12) The aim of the authorisation provisions is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled. Authorisations for the placing on the market and use will be granted by the Commission only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.

(13) The restrictions provisions allow the manufacturing, placing on the market and use of substances presenting risks that need to be addressed, to be made subject to total or partial bans or other restrictions, based on an assessment of those risks.

(14) There is a need to assure effective management of the technical, scientific and administrative aspects of the present Regulation at Community level. A central entity should therefore be created to fulfil this role.

(15) A feasibility study on the resource requirements for a central entity concluded that an independent central entity offered a number of long-term advantages over other options. A European Chemicals Agency, hereinafter referred to as "the Agency", should therefore be established.

(15a) In preparation for REACH, the Commission has launched REACH implementation projects (RIPs), involving relevant experts from stakeholder groups. Some of those projects aim at developing draft guidelines and tools which should help the Commission, the Agency, Member States, manufacturers, importers and downstream users of substances to fulfil, in concrete terms, their obligations under the new Regulation. This work should enable the Commission and the Agency to make available appropriate technical guidance, in due time, with regard to the deadlines introduced by REACH.

(16) The responsibility to assess the risks and hazards of chemical substances should be given, in the first place, to the natural or legal persons that manufacture or import substances, but only when they do so in quantities exceeding a certain volume, to enable them to carry the associated burden. Natural or legal persons handling chemicals should take the necessary risk management measures in accordance with the assessment of the risks of substances and pass on relevant recommendations along the supply chain. This includes describing, documenting and notifying in an appropriate and transparent fashion the risks stemming from the production, use and disposal of each substance.

(17) In order to undertake chemical safety assessments of substances effectively, manufacturers and importers of substances should obtain information on these substances, if necessary by performing new tests.

(18) For purposes of enforcement and evaluation and for reasons of transparency, the information on these substances, as well as related information, including on risk management measures, should normally be submitted to authorities.

(19) Scientific research and development normally takes place in quantities below 1 tonne per year, there is no need to exempt such research and development because substances in those quantities do not have to be registered in any case. However, in order to encourage innovation, research on products and process oriented research and development should be exempted from the obligation to register for a certain time period where a substance is not yet intended to be placed on the market to an indefinite number of customers because its application in preparations or articles still requires further research and development performed by the potential registrant himself or in cooperation with a limited number of known customers. In addition, it is appropriate to provide a similar exemption to downstream users using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.

(20) Since producers and importers of articles should be responsible for their articles, it is appropriate to impose a registration requirement on substances which are intended to be released from articles and have not been registered for that use. In the case of substances of very high concern which are present in articles above tonnage and concentration thresholds, where exposure to the substance cannot be excluded and where the substance has not been registered by any person for this use, the Agency should be notified. The Agency should also be empowered to request that a registration be submitted if it has grounds for suspecting that the release of a substance from the article may present a risk to human health or the environment and the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year. Following the deadline for applications for authorisation for the use of substances of very high concern, the Agency should consider the need for a proposal for a restriction where it considers that the use of such substances in articles poses a risk to human health or the environment that is not adequately controlled.

(21) The requirements for undertaking chemical safety assessments by manufacturers and importers should be prescribed in detail in a technical annex to allow them to meet their obligations. To achieve fair burden sharing with their customers, manufacturers and importers should in their chemical safety assessment address not only their own uses and the uses for which they place their substances on the market, but also all uses which their customers ask them to address.

(21a) The Commission, in close co-operation with industry, Member States and other relevant stakeholders, should develop guidance to fulfil the requirements under REACH related to preparations (in particular with regard to safety data sheets incorporating exposure scenarios) including assessment of substances incorporated into special preparations – such as metals incorporated in alloys; in doing so, the Commission should take full account of the work that will have been carried out within the framework of the REACH Implementation Projects (RIPs) and should include the necessary guidance on this matter in the overall REACH guidance package. This guidance should be available before the entry into operation of the Regulation.

(22) A chemical safety assessment should not need to be performed for substances in preparations in certain very small concentrations which are considered as not giving rise to concern. Substances in preparations in such low concentrations should also be exempt from authorisation. These provisions should apply equally to preparations that are solid mixtures of substances until a specific shape is given to such a preparation that transforms it into an article.

(23) Joint submission and the sharing of information on substances should be provided for in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals. One of a group of multiple registrants should submit information on behalf of the others according to rules which ensure that all the required information is submitted, while allowing sharing of the costs burden. A registrant should be able to submit information directly to the Agency in certain specified cases.

(24) Requirements for generation of information on substances should be tiered according to the volume of manufacture or importation of a substance, because these provide an indication of the potential for exposure of man and the environment to the substances, and should be described in detail; to reduce the possible impact on low volume substances, new toxicological and ecotoxicological information should only be required for priority substances between 1 and 10 tonnes; for other substances in that quantity range there should be incentives to encourage manufacturers and importers to provide this information.

(24a) The Member States, the Agency and all interested parties should take full account of the results of the REACH Implementation Projects, in particular with regard to the registration of naturally occurring substances.

(24b) It is necessary to consider the application of Articles 2(4)(a) and (b) and Annex IX to substances derived from mineralogical processes and the review of Annexes II and III should fully take this into account.

(25) If tests are performed, they should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes[11], and, in the case of ecotoxicological and toxicological tests, good laboratory practice, set out in Council Directive 2004/10/EC of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances[12].

(26) The generation of information by alternative means offering equivalence to prescribed tests and test methods should also be allowed, for example when this information comes from valid qualitative or quantitative structure activity models or from structurally related substances. To this end the Agency, in cooperation with Member States and interested parties, should develop appropriate guidance. It should also be possible not to submit certain information if appropriate justification can be provided. Based on experience gained through REACH Implementation Projects, criteria should be developed defining what constitutes such justification.

(26a) In order to help companies, and in particular SMEs, to comply with the requirements of this Regulation, Member States, in addition to the operational guidance documents provided by the Agency, should establish national helpdesks.

(27) Internationally accepted test methods should be recognised and other test methods should be adopted by the Commission and revised as appropriate, in particular to refine, reduce or replace animal testing.

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[11] OJ L 358, 18.12.1986, p. 1. Directive as amended by Directive 2003/65/EC of the European Parliament and of the Council (OJ L 230, 16.9.2003, p. 32).

[12] OJ L 50, 20.2.2004, p.44

(28) For reasons of workability and because of their special nature, specific registration requirements should be laid down for intermediates; polymers should be exempted from registration and evaluation until those that need to be registered due to the risks posed to human health or the environment can be selected in a practicable and cost-efficient way on the basis of sound technical and valid scientific criteria.

(29) To avoid overloading authorities and natural or legal persons with the work arising from the registration of phase-in substances already on the internal market, that registration should be spread over an appropriate period of time, without introducing undue delay. Deadlines for the registration of these substances should therefore be set.

(30) Data for substances already notified in accordance with Directive 67/548/EEC should be eased into the system and should be upgraded when the next tonnage quantity threshold is reached.

(31) In order to provide a harmonised, simple system, all registrations should be submitted to the Agency. To ensure a consistent approach and efficient use of resources, it should perform a completeness check on all registrations and take responsibility for any final rejections of registrations.

(31a) EINECS included certain complex substances in a single entry, UVCB substances (substances of unknown or variable composition, complex reaction products or biological materials) may be registered as a single substance under REACH, despite their variable composition, provided that the hazardous properties do not differ significantly and warrant the same classification.

(32) To ensure that the information gathered through the registration is kept up-to-date, an obligation on registrants to inform the Agency of certain changes to the information should be introduced.

(33) [Deleted.]

(34) It is necessary to reduce to a minimum the number of vertebrate animals used for experimental purposes in accordance with the provisions of Directive 86/609/EEC; wherever possible the use of animals should be avoided by recourse to alternative methods validated by the European Centre for Validation of Alternative Testing Methods or other international bodies and recognised by the Commission or the Agency as appropriate.

(35) This Regulation should be without prejudice to the full and complete application of the Community competition rules.

(36) In order to avoid duplication of work, and in particular to reduce testing involving vertebrate animals, the provisions concerning preparation and submission of registrations and updates should require sharing of information where this is requested by any registrant. If the information concerns vertebrate animals, the registrant should be obliged to request it.

(37) It is in the public interest to ensure the quickest possible circulation of test results on the human health or environmental hazards of certain substances to those natural or legal persons which use them, in order to limit any risks associated with their use. Sharing of information should occur where this is requested by any registrant, in particular in the case of information involving tests on vertebrate animals under conditions that ensure a fair compensation for the company that has undertaken the tests.

(37a) In order to strengthen the competitiveness of Community industry and to ensure that this Regulation is applied as efficiently as possible, it is appropriate to make provision for the sharing of data between registrants on the basis of fair compensation.

(38) In order to respect the legitimate property rights of those generating testing data, the owner of such data should, for a period of 10 years, be able to claim compensation from those registrants who benefit from that data.

(39) In order to allow a potential registrant to proceed with his registration, even if he cannot reach agreement with a previous registrant, the Agency, on request, should allow use of any summary or robust study summary of tests already submitted. The registrant who receives these data should be obliged to pay a contribution to the costs to the owner of the data.

(40) In order to avoid duplication of work, and in particular to avoid duplication of testing, registrants of phase-in substances should pre-register as early as possible with a database managed by the Agency. A system should be established in order to provide for the establishment of Substance Information Exchange Fora (SIEF) to help registrants to find other registrants. In order to ensure the smooth functioning of that system they should fulfil certain obligations. If a member of a SIEF does not fulfil his obligations, he is breaching the Regulation and should be penalised accordingly but other members should be enabled to continue preparing their own registration.

(41) Part of the responsibility of manufacturers or importers for the management of the risks of substances is the communication of information on these substances to other professionals such as downstream users or distributors; this important responsibility also applies throughout the supply chain to enable all actors to meet their responsibility in relation to management of risks arising from the use of substances.

(42) As the existing safety data sheet is already being used as a communication tool within the supply chain of substances and preparations, it is appropriate to develop it further and make it an integral part of the system established by this Regulation.

(43) In order to have a chain of responsibilities, downstream users should be responsible for assessing the risks arising from their uses of substances if those uses are not covered by a safety data sheet received from their suppliers, unless the downstream user concerned takes more protective measures than those recommended by his supplier or unless his supplier was not required to assess those risks or provide him with information on those risks; for the same reason, downstream users should manage the risks arising from their uses of substances. In addition, it is appropriate that any producer or importer of an article containing a substance of very high concern should provide sufficient information to allow safe use of such an article.

(44) The requirements for undertaking chemical safety assessments by downstream users should also be prescribed in detail to allow them to meet their obligations. This requirement should only apply above a total quantity of 1 tonne of substance or preparation. In any case, however, the downstream users should consider the use and identify and apply appropriate risk management measures. Downstream users should report certain basic information on use to the Agency.

(45) For enforcement and evaluation purposes, downstream users of substances should be required to report to the Agency certain basic information if their use is outside the conditions of the exposure scenario detailed in the safety data sheet communicated by their original manufacturer or importer and to keep such reported information up-to-date.

(46) For reasons of workability and proportionality, it is appropriate to exempt downstream users using low quantities of a substance from such reporting.

(46a) Communication up and down the supply chain should be facilitated, the Commission shall develop a system categorising brief general descriptions of uses taking into account the outcomes of the REACH Implementation Projects

(47) It is also necessary to ensure that generation of information is tailored to real information needs; to this end evaluation should require the Agency to decide on the programmes of testing proposed by manufacturers and importers for such substances. In cooperation with Member States, the Agency should give priority to certain substances, for instance those which may be of very high concern.

(48) In addition, it is necessary to instil confidence in the general quality of registrations and to ensure that the public at large as well as all stakeholders in the chemicals industry have confidence that natural or legal persons are meeting the obligations placed upon them; accordingly, it is appropriate for provisions to be made for recording which information has been reviewed by an assessor possessing appropriate experience, and for a percentage of registrations to be checked for compliance by the Agency.

(49) The Agency should also be empowered to require further information from manufacturers, importers or downstream users on substances suspected of posing a risk to health or the environment, including by reason of their presence on the internal market in high volumes, on the basis of evaluations performed. Based on the criteria for prioritising substances developed by the Agency in co-operation with the Member States a Community rolling action plan for substance evaluation should be established, relying on Member State competent authorities to evaluate substances included therein. If a risk equivalent to the level of concern arising from the use of substances subject to authorisation arises from the use of isolated intermediates on site, the competent authorities of the Member States should also be allowed to require further information, when justified.

(50) Collective agreement within the Agency's Member State Committee on their draft decisions provides the basis for an efficient system that respects the principle of subsidiarity, while maintaining the internal market. If one or more Member States or the Agency do not agree to a draft decision, it should be made subject to a centralised procedure. If the Member States Committee fails to reach unanimous agreement, the Commission should adopt a decision in accordance with a Committee procedure.

(51) Evaluation may lead to the conclusion that action should be taken under the restriction or authorisation procedures or that risk management action should be considered in the framework of other appropriate legislation. Information on the progress of evaluation proceedings should therefore be made public.

(52) To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorization demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorized if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.

(52a) Methodologies to establish thresholds for carcinogenic and mutagenic substances may be developed taking into account the outcomes of REACH Implementation Projects. In accordance with article 130(3), Annex I section 6.4 may be amended on the basis of these methodologies to allow thresholds where appropriate to be used in the context of authorising the use of carcinogenic and mutagenic substances.

(52b) To support the aim of eventual replacement of substances of very high concern by suitable alternative substances or technologies, all applicants of authorisations should provide an analysis of alternatives considering their risks and the technical and economical feasibility of substitution. Furthermore, authorisations should be subject to time-limited review whose duration would be determined on a case by case basis and normally be subject to conditions, including monitoring.

(53) Experience at the international level shows that substances with characteristics rendering them persistent, liable to bioaccumulate and toxic, or very persistent and very liable to bioaccumulate, present a very high concern, while criteria have been developed allowing the identification of such substances. For certain other substances concerns are sufficiently high to address them in the same way on a case-by-case basis.

(54) In view of workability and practicality considerations, both as regards natural or legal persons, who have to prepare application files and take appropriate risk management measures, and as regards the authorities, who have to process authorisation applications, only a limited number of substances should be subjected to the authorisation procedure at the same time and realistic deadlines should be set for applications, while allowing certain uses to be exempted. Substances identified as meeting the criteria for authorisation should be included in a candidate list for eventual inclusion in the authorisation procedure. Within this list, substances on the Agency´s work program should be clearly identified.

(55) The Agency should provide advice on the prioritisation of substances to be made subject to the authorisation procedure, to ensure that decisions reflect the needs of society as well as scientific knowledge and developments.

(56) A total ban on a substance would mean that none of its uses could be authorised. It would therefore be pointless to allow the submission of applications for authorisation; in such cases the substance should be removed from the list of substances for which applications can be submitted and added to the list of restricted substances.

(56a) The proper interaction between the provisions on authorisation and restriction must be ensured in order to preserve the efficient functioning of the internal market and the protection of health, safety and the environment. Restrictions that exist when the substance in question is added to the list of substances for which applications for authorisation can be submitted, should be maintained for that substance. The Agency should consider whether the risk from substances in articles is adequately controlled and, if it is not, prepare a dossier in relation to introduction of further restrictions for substances for which the use requires authorisation.

(57) In order to provide a harmonised approach to the authorisation of the uses of particular substances, the Agency should issue opinions on the risks arising from those uses and on any socio-economic analysis submitted to it by third parties.

(58) To allow effective monitoring and enforcement of the authorisation requirement, downstream users benefiting from an authorisation granted to their supplier should inform the Agency of their use of the substance.

(59) In order to accelerate the current system the restriction procedure should be restructured and should replace Directive 76/769/EEC, which has been substantially amended and adapted several times. The *acquis* of the harmonised rules under the Annex to that Directive should be taken over in a recast version in the interests of clarity and as a starting point for this new accelerated restriction procedure. This recast follows the rules set out within the Interinstitutional Agreement concerning recasting techniques.

(59a) In relation to Annex XVI Member States are allowed to maintain for a transitional period of six years more stringent restrictions, provided that these restrictions have been notified according to the Treaty. This concerns substances on their own, substances in preparations and substances in articles, the manufacturing, the placing on the market and the use of which is restricted. Within two years, the Commission should compile and publish an inventory of these restrictions. This will provide an opportunity for the Commission to review the measures concerned with a view to possible harmonisation

(60) It is the responsibility of the manufacturer, importer and the downstream user to identify the appropriate risk management measures needed to ensure a high level of protection for human health and the environment from the manufacturing, placing on the market or use of a substance on its own, in a preparation or in an article. However, where this is considered to be insufficient and where Community legislation is justified, appropriate restrictions should be laid down.

(61) In order to protect human health and the environment, restrictions on the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article may include any condition for, or prohibition of, the manufacture, placing on the market or use. Therefore it is necessary to list such restrictions and any amendments thereto.

(62) In order to prepare a restrictions proposal and in order for such legislation to operate effectively, there should be good co-operation, co-ordination and information between the Member States, the Agency, other bodies of the Community, the Commission and the interested parties.

(63) In order to give Member States the opportunity to submit proposals to address a specific risk for human health and the environment, they should prepare a dossier in conformity with detailed requirements. The dossier should set out the justification for Community-wide action.

(64) In order to provide a harmonised approach to restrictions, the Agency should fulfil a role as co-ordinator of this procedure, for example by appointing the relevant rapporteurs and verifying conformity with the requirements of the relevant Annexes. The Agency should maintain a list of substances for which a restriction dossier is being prepared.

(65) In order to give the Commission the opportunity to address a specific risk for human health and the environment that needs to be addressed Community wide, it should be able to entrust the Agency with the preparation of a restriction dossier.

(66) For reasons of transparency, the Agency should publish the relevant dossier including the suggested restrictions while requesting comments.

(67) In order to finalise the procedure in due time, the Agency should submit its opinions on the suggested action and its impact on the basis of a draft opinion prepared by a rapporteur.

(68) In order to speed up the procedure for restrictions, the Commission should prepare its draft amendment within three months of receiving the Agency's opinions.

(69) The Agency should be central to ensuring that the chemicals law and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public. It should also play a pivotal role in co-ordinating communication around REACH and in its implementation. The confidence in the Agency of the Community institutions, the Member States, the general public and interested parties is therefore essential. For this reason, it is vital to ensure its independence, high scientific, technical and regulatory capacities, transparency and efficiency.

(70) The structure of the Agency should be suitable for the tasks that it should fulfil. Experience with similar Community agencies provides some guidance in this respect but the structure should be adapted to meet the specific needs of this Regulation.

(71) In the interests of efficiency, the staff of the Agency Secretariat should perform essentially technical-administrative and scientific tasks without calling on the scientific and technical resources of the Member States; the Executive Director should ensure the efficient execution of the Agency's tasks in an independent manner. To ensure that the Agency fulfils its role, the composition of the Management Board should be designed to represent each Member State, the Commission, interested parties appointed by the Commission, and secure the highest standard of competence and a broad range of relevant expertise in chemicals safety or the regulation of chemicals, whilst ensuring that there is relevant expertise in the field of general financial and legal matters.

(72) The Agency should have the means to perform all the tasks required to enable it to carry out its role.

(72a) A Commission Regulation should specify the structure and amounts of fees, including specifying the circumstances under which a proportion of the fees will be transferred to the relevant Member State Competent Authority

(73) The Management Board should have the necessary powers to establish the budget, check its implementation, draw up internal rules, adopt financial regulations and appoint the Executive Director.

(74) It is appropriate for the Management Board of the Agency to include representatives from other interested parties in order to ensure the involvement of stakeholders.

(75) Through the Committee for Risk Assessment and the Committee for Socio-economic Analysis, the Agency should take over the role of the Scientific Committees attached to the Commission in issuing scientific opinions in its field of competence.

(76) Through the Member States Committee, the Agency should aim to reach agreement amongst Member States authorities on specific issues which require a harmonised approach.

(77) It is necessary to ensure close co-operation between the Agency and the competent authorities working within the Member States so that the scientific opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis are based on the broadest possible scientific and technical expertise appropriate which is available within the Community; to the same end, the Committees should be able to rely on additional particular expertise.

(78) In light of the increased responsibility of natural or legal persons for ensuring safe use of chemicals enforcement needs to be strengthened. The Agency should therefore provide a Forum for Member States to exchange information on and to co-ordinate their activities related to the enforcement of chemicals legislation. The currently informal co-operation between Member States in this respect would benefit from a more formal framework.

(79) A Board of Appeal should be set up within the Agency to guarantee processing of appeals for any natural or legal person affected by decisions taken by the Agency.

(80) The Agency should be financed partly by fees paid by natural or legal persons and partly by the general budget of the European Communities. The Community budgetary procedure should remain applicable as far as any subsidies chargeable to the general budget of the European Communities are concerned. Moreover, the auditing of accounts should be undertaken by the Court of Auditors in accordance with Article 91 of Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities[13].

(81) Where the Commission and Agency consider it appropriate, it should be possible for representatives of third countries to participate in the work of the Agency.

(82) The Agency should contribute, through co-operation with organisations having interests in the harmonisation of international regulations, to the role of the Community and the Member States in such harmonisation activities. To promote broad international consensus the Agency should take account of existing and emerging international standards in the regulation of chemicals such as the Globally Harmonised System (GHS) of classification and labeling of chemicals.

(83) The Agency should provide the infrastructure needed for natural or legal persons to meet their obligations under the data-sharing provisions.

[13] OJ L 357, 31.12.2002, p. 72.

(84) It is important to avoid confusion between the mission of the Agency and the respective missions of the European Medicines Agency (EMEA) established by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[14], the European Food Safety Authority (EFSA) established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety[15] and the Advisory Committee on Safety, Hygiene and Health Protection at Work set up by Council Decision 2003/913/EC[16]. Consequently, the Agency should establish rules of procedure where co-operation with the EFSA or the Advisory Committee on Safety, Hygiene and Health Protection at Work is necessary. It is necessary to establish that this Regulation is otherwise without prejudice to the competence conferred on the EMEA, the EFSA and the Advisory Committee on Safety, Hygiene and Health Protection at Work by Community legislation.

(85) [deleted]

(86) In order to achieve the functioning of the internal market for substances on their own or in preparations, while at the same time ensuring a high level of protection for human health and the environment, rules should be established for a classification and labelling inventory.

(87) The classification and labelling for any substance either subject to registration or covered by Article 1 of Directive 67/548/EEC and placed on the market should therefore be notified to the Agency to be included in the inventory.

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[14] OJ L 136, 30.4.2004, p.1.

[15] OJ L 31, 1.2.2002 p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245,29.9.2003, p. 4).

[16] OJ C 218, 13.9.2003, p. 1.

(88) To ensure a harmonised protection for the general public, and, in particular, for persons who come into contact with certain substances, and the proper functioning of other Community legislation relying on the classification and labelling, an inventory should record the classification in accordance with Directive 67/548/EEC and Directive 1999/45/EC agreed by manufacturers and importers of the same substance, if possible, as well as decisions taken at Community level to harmonise the classification and labelling of some substances. This should take full account of the work and experience accumulated in connection to the activities under Directive 67/548/EEC, including the classification and labelling of specific substances or groups of substances listed in Annex I to this directive.

(89) Resources should be focused on substances of the highest concern. A substance should therefore be added to Annex I of Directive 67/548/EEC if it meets the criteria for classification as carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, as a respiratory sensitiser, or in respect of other effects on a case-by-case basis. Provision should be made to enable competent authorities to submit proposals to the Agency. The Agency should give its opinion on the proposal while parties concerned should have an opportunity to comment. The Commission should take a decision subsequently.

(90) Regular reports by the Member States and the Agency on the operation of this Regulation will be an indispensable means of monitoring the implementation of this Regulation as well as trends in this field; conclusions drawn from findings in the reports will be useful and practical tools for reviewing the Regulation and, where necessary, for formulating proposals for amendments.

(91) Community citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. A transparent means of achieving this is to grant them free and easy access to basic data held in the Agency's database, including brief profiles of hazardous properties, labelling requirements and relevant Community legislation including authorised uses and risk management measures. The Agency and Member States should allow access to information in accordance with Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information[1], Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents[2] and with the UNECE Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (the 'Aarhus Convention'), to which the European Community is a party.

(92) Apart from their participation in the implementation of Community legislation, Member State competent authorities should, because of their closeness to stakeholders in the Member States, play a role in the exchange of information on risks of substances and on the obligations of natural or legal persons under chemicals legislation; at the same time, close co-operation between the Agency, the Commission and the competent authorities of the Member States is necessary to ensure the coherence and efficiency of the global communication process.

(93) In order for the system established by this Regulation to operate effectively, there must be good co-operation, co-ordination and exchange of information between the Member States, the Agency and the Commission regarding enforcement.

(94) In order to ensure compliance with this Regulation, Member States should put in place effective monitoring and control measures. The necessary inspections should be planned, carried out and their results should be reported.

(95) In order to ensure transparency, impartiality and consistency in the level of enforcement activities by Member States, it is necessary for Member States to set up an appropriate framework for sanctions with a view to imposing effective, proportionate and dissuasive sanctions for non-compliance, as non-compliance can result in damage to human health and the environment.

(96) [Deleted.]

(97) The measures necessary for the implementation of this Regulation and certain amendments to it should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[17].

(98) It is essential that chemicals be regulated in an effective and timely manner during the transition to full applicability of the provisions of this Regulation and, in particular, during the start-up period of the Agency; provision should therefore be made for the Commission to provide the necessary support towards the setting up of the Agency, including the conclusion of contracts and the appointment of an Executive Director *ad interim* until the Agency's Management Board can appoint an Executive Director itself.

(99) To take full advantage of the work performed under Regulation (EEC) No 793/93 as well as under Directive 76/769/EEC and to avoid such work being lost, the Commission should be empowered during the start-up period to initiate restrictions based on that work without following the full restrictions procedure laid down in this Regulation. All those elements should be used, as soon as REACH enters into force, to support risk reduction measures.

[17] OJ L 184, 17.7.1999, p. 23.

(100) It is appropriate for the provisions of this Regulation to enter into force in a staggered way to smooth the transition to the new system; moreover, a gradual entry into force of the provisions should allow all parties involved, authorities, natural or legal persons as well as stakeholders, to focus resources in the preparation for new duties at the right times.

(101) This Regulation replaces Council Directive 76/769/EEC of 27 July 1976, Commission Directive 91/155/EEC of 5 March 1991 defining and laying down the detailed arrangements for the system of specific information relating to dangerous preparations in implementation of Article 10 of Directive 88/379/EEC, Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC[18], Commission Directive 93/105/EEC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC[19], Commission Directive 2000/21/EC of 25 April 2000 concerning the list of Community legislation referred to in the fifth indent of Article 13(1) of Council Directive 67/548/EEC[20], Council Regulation (EEC) No 793/93 of 23 March 1993 and Commission Regulation (EC) No 1488/94 of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93[21].

(102) For the sake of consistency, Directive 1999/45/EC which already addresses matters covered by this Regulation should be amended.

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18 OJ L 227, 8.9.1993, p. 9.
19 OJ L 294, 30.11.1993, p. 21.
20 OJ L 103, 28.4.2000, p. 70.
21 OJ L 161, 29.6.1994, p. 3.

(103) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of this Regulation to lay down rules for chemical substances and to establish a European Chemicals Agency. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty.

(104) The Regulation observes the fundamental rights and principles which are acknowledged in particular in the Charter of Fundamental Rights of the European Union[22]. In particular, it seeks to ensure full compliance with the principles of environmental protection and sustainable development guaranteed by its Article 37,

HAVE ADOPTED THIS REGULATION:

[22] OJ C 364, 18.12.2000, p. 1.

TITLE I
GENERAL ISSUES

Chapter 1
Aim, Scope and Application

Article 1

Aim and scope

1. The purpose of this Regulation is to ensure a high level of protection of health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

1bis. This Regulation lays down provisions on substances and preparations within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in preparations or in articles and to the placing on the market of preparations, if so stated.

2. [deleted]

3. This Regulation is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle[23].

[23] As set out in the Communication from the Commission on the precautionary principle, COM(2000) 1 final.

Article 2

Application

1. This Regulation shall not apply to:

(a) radioactive substances within the scope of Council Directive 96/29/Euratom[24];

(b) substances, on their own, in a preparation or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;

(c) non-isolated intermediates;

(d) the carriage of dangerous substances and dangerous substances in dangerous preparations by rail, road, inland waterway, sea or air.

1bis. Waste as defined in Council Directive 75/442/EEC and the amendments thereto, is not a substance, preparation or article within the meaning of Article 3 of this Regulation.

1ter. Member States may allow for exemptions from the Regulation in specific cases for certain substances, on their own, in a preparation or in an article, where necessary in the interests of defence.

[24] OJ L 159, 29.6.1996, p. 1.

2. This Regulation shall apply without prejudice to Community workplace and environmental legislation, including:

(a) Council Directive 89/391/EEC[25];

(b) Council Directive 90/394/EEC;

(c) Council Directive 98/24/EC[26];

(d) Council Directive 96/61/EC[27];

(e) Council Directive 2000/60/EC[28].

3. The provisions of Title II, V, VI and VII shall not apply to the extent that a substance is used:

(a) in medicinal products for human or veterinary use within the scope of Regulation (EEC) No 2309/93, Directive 2001/82/EC of the European Parliament and of the Council[29] and Directive 2001/83/EC of the European Parliament and of the Council[30];

(b) in food or feedingstuffs according to Regulation (EC) No 178/2002 of the European Parliament and of the Council including used:

(i) as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC;

(ii) as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC and Commission Decision 1999/217/EC;

(iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council ;

(iv) in animal nutrition within the scope of Council Directive 82/471/EEC.

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25 OJ L 183, 29.6.1989, p. 1.
26 OJ L 131, 5.5.1998, p. 11.
27 OJ L257, 10.10.1996, p. 26.
28 OJ L327, 22.12.2000, p. 1.
29 OJ L 311, 28.11.2001, p. 1.
30 OJ L 311, 28.11.2001, p. 67.

3bis. The provisions of Title IV shall not apply to the following preparations in the finished state, intended for the final user:

(a) medicinal products for human or veterinary use, within the scope of Regulation (EEC) No 2309/93, Directive 2001/82/EC of the European Parliament and of the Council and as defined in Directive 2001/83/EC of the European Parliament and of the Council;

(b) cosmetic products as defined in the scope of Directive 76/768/EEC;

(c) medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and preparations which ensure the same level of information provision and protection as Directive 1999/45/EC;

(d) food or feedingstuffs according to Regulation (EC) No 178/2002 of the European Parliament and of the Council including used:

(i) as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC;

(ii) as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC and Commission Decision 1999/217/EC;

(iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council;

(iv) in animal nutrition within the scope of Council Directive 82/471/EEC.

4. The following shall be exempted from Title II, V and VI:

(a) substances included in Annex II, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;

(b) substances covered by Annex III, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the aims of this Regulation;

(c) substances on their own or in preparations, registered in accordance with Title II, exported from the Community by an actor in the supply chain and re-imported into the Community by the same or another actor in the same supply chain who shows that:

(i) the substance being re-imported is the same as the exported substance;

(ii) he has been provided with the information in accordance with Articles 29 or 30 relating to the exported substance.

(d) Substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:

(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and

(ii) the establishment undertaking the recovery has available the information required by Articles 29 or 30 relating to the substance that has been registered in accordance with Title II.

5. On-site isolated intermediates or transported isolated intermediates shall be exempted from:

(i) Chapter 2 of Title II, with the exception of Article 7; and

(ii) Title VII.

6. The provisions of Titles II and VI shall not apply to polymers.

Chapter 2

Definitions and general provision

Article 3

Definitions

For the purposes of this Regulation:

1. *Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

2. *Preparation* means a mixture or solution composed of two or more substances;

3. *Article* means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

4. *Polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
   (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
   (b) less than a simple weight majority of molecules of the same molecular weight.

   In the context of this definition a 'monomer unit' means the reacted form of a monomer substance in a polymer;

4a. *Monomer* means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

5. *Registrant* means the manufacturer or the importer or the producer or importer of an article submitting a registration for a substance;

6. *Manufacturing* means production or extraction of substances in the natural state;

7. *Manufacturer* means any natural or legal person established within the Community who manufactures a substance within the Community;

8. *Import* means the physical introduction into the customs territory of the Community;

9. *Importer* means any natural or legal person established within the Community who is responsible for import;

10. *Placing on the market* means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;

11. *Downstream user* means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(4)(c) shall be regarded as a downstream user;

12. *Use* means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

13. *Distributor* means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;

14. *Intermediate* means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter called *synthesis*):
    (a) *non-isolated intermediate* means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
    (b) *on-site isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one more legal entities;
    (c) *transported isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

15. *Site* means a single location, in which, if there is more than one manufacturer of
    (a) substance(s), certain infrastructure and facilities are shared;

16. *Actors in the supply chain* means all manufacturers and/or importers and/or downstream users in a supply chain;

17. [deleted]

18. [deleted]

19. *Competent authority* means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

20. *Phase-in substance* means a substance which meets at least one of the following criteria:
    (a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
    (b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this regulation.
    (c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 May 2004, and between 18 September 1981 and 31 October 1993 inclusive it was also placed on the market by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC, as amended by Directive 79/831/EEC, but does not meet the definition of a polymer set out in Directive 67/548/EEC, as amended by Directive 92/32/EEC;

    provided the manufacturer or importer has documentary evidence of this.

21. *Notified substance* means a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC;

22. *Product and process orientated research and development* means any scientific development related to product development, the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;

23. *Scientific research and development* means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year;

24. *Registrant's own use* means an industrial or professional use by the registrant;

25. *Identified use* means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;

26. [deleted]

26a. *Full study report* means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed;

27. *Robust study summary* means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;

27a. *Study summary* means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study for hazard assessment;

28. *Per year* means per calendar year unless stated otherwise;

29. *Restriction* means any condition for or prohibition of the manufacture, use or placing on the market;

30. *Supplier* of a substance or a preparation means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;

31. *Recipient* of a substance or a preparation means a downstream user or a distributor being supplied with a substance or a preparation;

31a. *Recipient* of an article means an industrial or professional user being supplied with an article but does not include consumers.

32. *Small and Medium Enterprise (SME)* means small and medium-sized enterprises according to the definition contained in Commission Recommendation concerning the definition of micro, small and medium-sized enterprises[31];

33. *Exposure scenario* means the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

34. *Use and exposure category* means an exposure scenario covering a wide range of processes or uses;

35. *Substances which occur in nature* means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means; by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

36. *Not chemically modified substance* means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities.

[31] OJ L124 20.5.2003 p. 36.

36a. *Alloy* means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they can not be readily separated by mechanical means.

Article 3a

General Provision

Any manufacturer, importer, or where relevant a downstream user, may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all proceedings under Articles 10, 17, Title III and Article 50 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.

TITLE II
REGISTRATION OF SUBSTANCES

Chapter 1
Scope

[deleted]

Article 4

Scope

[deleted]

Chapter 2

General obligation to register and information requirements

Article 4a

No data, no market

Subject to Articles 6, 19 and 21, substances on their own, in preparations or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

Article 5

General obligation to register substances on their own or in preparations

1. Save where this Regulation provides otherwise, any manufacturer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency.

   Save where this Regulation provides otherwise, any importer of a substance, either on its own or in one or more preparation(s), in quantities of 1 tonne or more per year shall submit a registration to the Agency.

2. For monomers that are used as on-site isolated intermediates or transported isolated intermediates, Articles 15 and 16 shall not apply.

3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:
   (a) the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);

(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year.

4. A submission for registration shall be accompanied by the fee in accordance with Title VIIIa.

Article 6

Registration and notification of substances in articles

1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles**,** if all the following conditions are met:
   (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
   (b) [deleted];
   (c) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

A submission for registration shall be accompanied by the fee in accordance with Title VIIIa.

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 3, if a substance meets the criteria in Article 54 and is identified according to Article 56(1), if all the following conditions are met:
   (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
   (b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w).
   (c) [deleted]
   (d) [deleted]

2bis. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article in accordance with Article 30(4).

3. The information to be notified shall include the following:
   (a) the identity and contact details of the producer or importer as specified in section 1 of Annex IV, with the exception of the use sites;
   (b) the registration number(s) referred to in Article 18 (1), if available;
   (c) the identity of the substance(s) as specified in section 2.1 to 2.3.4 of Annex IV;
   (d) the classification of the substance as specified in sections 4.1 and 4.2 of Annex IV;
   (e) a brief description of the use(s) of the substance in the article as specified in section 3.5 of Annex IV and of the uses of the article(s);
   (f) the tonnage range of the substance, such as 1-10 tonnes, 10-100 tonnes and so on.

4. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:
   (a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
   (b) the Agency has grounds for suspecting that:
      (i) the substance is released from the articles, and
      (ii) the release of the substance from the articles presents a risk to human health or the environment;
   (c) the substance is not subject to paragraph 1.

   A submission for registration shall be accompanied by the fee in accordance with Title VIIIa.

5. Paragraphs 1 to 4 shall not apply to substances that have already been registered for that use.

6. Paragraphs 2, 2bis and 3 shall apply 6 months after a substance is identified according to Article 56(1), provided that 6 months have elapsed from the deadline specified in Article 21(1).

7. Any measures for the implementation of paragraphs 1 to 6 shall be adopted in accordance with the procedure referred to in Article 130(3).

Article 6a

Only representative of a non-Community manufacturer

1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.

2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 33, he shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet.

3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community exporter shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

Article 7

Exemption from the general obligation to register for product and process orientated research and development (PPORD)

1. Articles 4a, 5, 6, 15, 16 and 19 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development by a manufacturer or importer, by himself or in co-operation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.

2. For the purpose of paragraph 1, the manufacturer or importer shall notify the Agency of the following information:
   (a) the identity of the manufacturer or importer as specified in section 1 of Annex IV;
   (b) the identity of the substance, as specified in section 2 of Annex IV;
   (c) the classification of the substance as specified in section 4 of Annex IV, if any;
   (d) the estimated quantity as specified in section 3.1 of Annex IV;
   (e) the list of customers referred to in paragraph 1, including their names and addresses.
   (f) [deleted]

   The notification shall be accompanied by the fee in accordance with Title VIIIa.

   The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.

3. The Agency shall check the completeness of the information supplied by the notifier and Article 18(2) shall apply adapted as necessary. The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to the manufacturer or importer concerned. The Agency shall also communicate this information to the competent authority of the Member State(s) concerned.

4. The Agency may decide to impose conditions with the aim of ensuring that the substance or the preparation or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time either on its own or in a preparation or article and that remaining quantities will be re-collected for disposal after the exemption period.

   In such cases, the Agency may ask the notifier to provide additional necessary information.

5. In the absence of any indication to the contrary, the manufacturer or importer of the substance may manufacture or import the substance not earlier than two weeks after the notification.

6. The manufacturer or importer shall comply with any conditions imposed by the Agency in accordance with paragraph 4.

7. The Agency may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be used exclusively in the development of medicinal products for human or veterinary use, for a further maximum of 10 years, upon request if the manufacturer or importer can demonstrate that such an extension is justified by the research and development programme.

8. The Agency shall forthwith communicate any draft decisions to the competent authorities of each Member State in which the manufacture, import or product and process orientated research takes place.

   When taking decisions as provided for in paragraphs 4 and 7, the Agency shall take into account any comments made by such competent authorities.

9. The Agency and the competent authorities of the respective Member States shall always keep confidential the information submitted in accordance with paragraphs 1 to 8.

10. An appeal may be brought, in accordance with Articles 87, 88 and 89, against Agency decisions under paragraphs 4 and 7.

Article 8

Substances in plant protection and biocidal products

[deleted]

Article 9

Information to be submitted for general registration purposes

A registration required by Article 5 or by Article 6(1) or (4) shall include all the following information:

(a) a technical dossier including:

(i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex IV;

(ii) the identity of the substance as specified in section 2 of Annex IV;

(iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex IV; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;

(iv) the classification and labelling of the substance as specified in section 4 of Annex IV;

(v) guidance on safe use of the substance as specified in Section 5 of Annex IV;

(vi) study summaries of the information derived from the application of Annexes V to IX;

(vii) robust study summaries of the information derived from the application of Annexes V to IX, if required under Annex I;

(viia) an indication as to which of the information submitted under Article 9(a)(iii), (iv), (vi), (vii) or (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;

(viii) [deleted];

(ix) proposals for testing where listed in Annexes VII and VIII;

(ixa) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex IV;

(x) [deleted];

(xa) a request as to which of the information in Article 116(1bis) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 73(2)(d), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

Subject to Article 23(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration

(b) a chemical safety report when required under Article 13. Sections 5 and 6 of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.

Article 10

Joint submission of data by multiple registrants

1. When a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, the following shall apply.

Subject to paragraph 2bis, the information specified in Article 9(a)(iv), (vi), (vii) and (ix), and any relevant indication under Article 9(a)(viia) shall first be submitted by the one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s) ("the lead registrant").

Each registrant shall subsequently submit separately the information specified in Article 9(a)(i), (ii), (iii) and (ixa), and any relevant indication under Article 9(a)(viia).

The registrants may decide themselves whether to submit the information specified in Article 9(a)(v) and (b) and any relevant indication under (a)(viia) separately or whether one manufacturer or importer is to submit this information on behalf of the others.

2. Each manufacturer or importer need only comply with paragraph 1 for items of information specified in Article 9(a)(iv), (vi), (vii) and (ix) that are required for the purposes of registration within his tonnage band in accordance with Article 11.

2bis. A manufacturer or importer may submit the information referred to in Article 9(a) (iv), (vi), (vii) or (ix) separately if:

(a) it would be disproportionately costly for him to submit this information jointly; or

(b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

(c) he disagrees with the lead registrant on the selection of this information.

If paragraphs (a), (b) or (c) apply, the manufacturer or importer shall submit along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.

3. A submission for registration shall be accompanied by the fee in accordance with Title VIIIa.

Article 11

Information to be submitted depending on tonnage

1. The technical dossier referred to in Article 9 (a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:

(a) the information specified in Annex V for non-phase-in substances, and for phase-in substances meeting one or both of the criteria specified in Annex Ic, manufactured or imported in quantities of 1 tonne or more per year per manufacturer or importer;

(abis) the information on physicochemical properties specified in Annex V, section 5 for phase-in substances manufactured or imported in quantities of 1 tonne or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex Ic;

(b) the information specified in Annexes V and VI for substances manufactured or imported in quantities of 10 tonnes or more per year per manufacturer or importer;

(c) the information specified in Annexes V and VI and testing proposals for the provision of the information specified in Annex VII for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;

(d) the information specified in Annexes V and VI and testing proposals for the provision of the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 1 000 tonnes or more per year per manufacturer or importer.

2. As soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the Agency immediately of the additional information he would require under paragraph 1. Article 24 paragraphs (5) and (6) shall apply adapted as necessary.

Article 12

General requirements for generation of information on intrinsic properties of substances

1. Information on intrinsic properties of substances may be generated by means other than tests, in particular through the use of qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across), provided that the conditions set out in Annex IX are met. Testing in accordance with Annex VI, section 6.6 and 6.7, Annex VII and Annex VIII may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex IX(3).

2. Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation adopted in accordance with the procedure referred to in Article 130(3), which shall be revised as appropriate in particular to refine, reduce or replace animal testing, or other international test methods recognised by the Commission or the Agency as appropriate.

   Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex IX are met.

3. Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.

4. If a substance has already been registered, a new registrant shall be entitled to refer to the study summaries or robust study summaries, for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) has given permission to refer to the full study reports for the purpose of registration.

5. However, a new registrant shall not refer to such studies in order to provide the information required in section 2 of Annex IV.

Article 13

Chemical safety report and duty to apply and recommend risk reduction measures

1. Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter if the registrant manufactures or imports such a substance in quantities of 10 tonnes or more per year.

   The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a preparation or a group of substances.

2. A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a preparation if the concentration of the substance in the preparation is less than the lowest of any of the following:
   (a) the applicable concentrations defined in the table of Article 3(3) of Directive 1999/45/EC;
   (b) the concentration limits given in Annex I to Directive 67/548/EEC;
   (c) the concentration limits given in Part B of Annex II to Directive 1999/45/EC;
   (d) the concentration limits given in Part B of Annex III to Directive 1999/45/EC;
   (e) the concentration limits given in an agreed entry in the classification and labelling inventory established under Title X;
   (f) 0.1 % weight by weight (w/w), if the substance meets the criteria in Annex XII.

3. A chemical safety assessment of a substance shall include the following steps:
   (a) human health hazard assessment;
   (b) physicochemical hazard assessment;
   (c) environmental hazard assessment;
   (d) PBT and vPvB assessment.

4. If, as a result of carrying out steps (a) to (d) of paragraph 3, the manufacturer or importer concludes that the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:

   (a) exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;

   (b) risk characterisation.

   The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and the risk characterisation shall address all identified uses of the manufacturer or importer.

5. The chemical safety report need not include consideration of the risks to human health from the following end uses:

   (a) in food contact materials within the scope of Regulation (EC) 1935/2004[32];"

   (b) in cosmetic products within the scope of Council Directive 76/768/EEC[33].

6. Any manufacturer or importer shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 29.

7. Any manufacturer or importer required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

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[32] OJ L338, 13.11.2004, p. 4.

[33] OJ L 262 , 27.9.1976, p. 169.

Chapter 2a

Substances regarded as being registered

Article 13a

Substances in plant protection and biocidal products

1. Active substances and co-formulants manufactured or imported for use in plant protection products only and included either in Annex I to Council Directive 91/414/EEC[34] or in Commission Regulation (EEC) No 3600/92[35], Commission Regulation (EC) No 703/2001[36], Commission Regulation (EC) No 1490/2002[37], Commission Decision 2003/565/EC[38] and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 2, 6 and of Article 20.

2. Active substances manufactured or imported for use in biocidal products only and included either in Annexes I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council[39] or in Commission Regulation (EC) No …/… {Second Review Regulation}[40], until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 2, 6 and of Article 20.

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34 OJ L 230, 19.8.1991, p. 1.
35 OJ L 366, 15.12.1992, p. 10.
36 OJ L 98, 7.4.2001, p. 6.
37 OJ L 224, 21.8.2002, p. 23.
38 OJ L 192, 31.7.2003, p. 40.
39 OJ L 123, 24.4.1998, p. 1.
40 OJ L

Article 13b

Duties of the Commission, the Agency and registrants of substances regarded as being registered

1. The Commission or the relevant Community body shall make information equivalent to that required by Article 9 available to the Agency for substances registered according to Article 13a. The Agency shall include this information or a reference thereto in its databases and notify the Competent Authorities thereof by the deadline in Article 26(2).

2. Articles 19, 20, 23, 24, 25, 26, shall not apply to uses of substances registered according to Article 13a.

Chapter 3
Registration of polymers

[deleted]

Article 14

Polymers

[deleted]

Chapter 4
Obligation to register and information requirements for certain types of isolated intermediates

Article 15

Registration of on-site isolated intermediates

1. Any manufacturer of an on-site isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the on-site isolated intermediate.

2. A registration for an on-site isolated intermediate shall include all the following information, to the extent that the manufacturer is able to submit it without any additional testing:
   (a) the identity of the manufacturer as specified in section 1 of Annex IV;
   (b) the identity of the intermediate as specified in section 2.1 to 2.3.4 of Annex IV ;
   (c) the classification of the intermediate as specified in section 4 of Annex IV;
   (d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
   (e) a brief general description of the use, as specified in section 3.5 of Annex IV;
   (f) details of the risk management measures applied.

   Subject to Article 23(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

   The registration shall be accompanied by a fee in accordance with Title VIIIa.

3. Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure.

   If these conditions are not fulfilled, the registration shall include the information specified in Article 9.

Article 16

Registration of transported isolated intermediates

1. Any manufacturer or importer of a transported isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.

2. A registration for a transported isolated intermediate shall include all the following information:

   (a) the identity of the manufacturer or importer as specified in section 1 of Annex IV;

   (b) the identity of the intermediate as specified in section 2.1 to 2.3.4 of Annex IV;

   (c) the classification of the intermediate as specified in section 4 of Annex IV;

   (d) any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;

   (e) a brief general description of the use, as specified in section 3.5 of Annex IV;

   (f) information on risk management measures applied and recommended to the user in accordance with paragraph 4.

   Subject to Article 23(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

   The registration shall be accompanied by a fee in accordance with Title VIIIa.

3. A registration for a transported isolated intermediate in quantities of more than 1 000 tonnes per year per manufacturer or importer shall include the information specified in Annex V in addition to the information required under paragraph 2.

   For the generation of this information, Article 12 shall apply.

4. Paragraphs 2 and 3 shall apply only to transported isolated intermediates if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:

(a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;

(b) Procedural and control technologies shall be used that minimise emission and any resulting exposure;

(c) only properly trained and authorised personnel handle the substance;

(d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;

(e) [deleted];

(f) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;

(g) substance-handling procedures are well documented and strictly supervised by the site operator;

(h) [deleted].

If the conditions listed in the first subparagraph are not fulfilled, the registration shall include the information specified in Article 9.

Article 17

Joint submission of data on isolated intermediates by multiple registrants

1. When an on-site isolated intermediate or transported isolated intermediate is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, the following shall apply.

Subject to paragraph 1bis, the information specified in Article 15(2)(c) and (d) and 16(2)(c) and (d) shall first be submitted by one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s) ("the lead registrant").

Each registrant shall subsequently submit separately the information specified in Article 15(2)(a), (b), (e) and (f) and Article 16(2)(a) (b), (e) and (f).

1bis. A manufacturer or importer may submit the information referred to in Article 15(2)(c) or (d) and 16(2)(c) or (d) separately if:

(a) it would be disproportionately costly for him to submit this jointly; or

(b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

(c) he disagrees with the lead registrant on the selection of this information.

If paragraphs (a), (b) or (c) apply, the manufacturer or importer shall submit along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the disagreement, as the case may be.

2. A submission for registration shall be accompanied by the fee in accordance with Title VIIIa.

Chapter 5
Common provisions for all registrations

Article 18
Duties of the Agency

1. The Agency shall assign a submission number to each registration, which is to be used for all correspondence regarding the registration until the registration is deemed to be complete, and a submission date, which shall be the date of receipt of the registration at the Agency.

2. The Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 9 and 11 or under Articles 15 or 16, as well as the registration fee referred to in Articles 5(4), 6(1), 6(4), 15(2) or 16(2), have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.

The Agency shall undertake the completeness check within three weeks of the submission date, or within three months of the relevant deadline of Article 21, as regards registrations of phase-in substances submitted in the course of the 2-month period immediately preceding that deadline.

If a registration is incomplete, the Agency shall inform the registrant, before expiry of the three week or three month period referred to in the previous subparagraph, as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant shall update his registration and submit it to the Agency within the deadline set. The Agency shall confirm the submission date of the further information to the registrant. The Agency shall perform a further completeness check, considering the further information submitted.

The Agency shall reject the registration if the registrant fails to complete his registration within the deadline set. The registration fee shall not be reimbursed in such cases.

2bis. Once the registration is complete, the Agency shall assign a registration number to the substance concerned and a registration date, which shall be the same as the submission date. The Agency shall without delay communicate the registration number and registration date to the registrant concerned. The registration number should be used for all subsequent correspondence regarding registration.

3. The Agency shall notify the competent authority of the relevant Member State within 30 days of the submission date, that the following information is available in the Agency database: the registration dossier together with the submission or registration number, the submission or registration date, the result of the completeness check and any request for further information and deadline set in accordance with the third subparagraph of paragraph 2. The relevant Member State shall be the Member State within which the manufacture takes place or the importer is established.

   If the manufacturer has production sites in more than one Member State, the relevant Member State shall be the one in which the head office of the manufacturer is established. The other Member States where the production sites are established shall also be notified.

   The Agency shall forthwith notify the competent authority of the relevant Member State(s) when any further information submitted by the registrant is available on the Agency database.

4. An appeal may be brought, in accordance with Articles 87, 88 and 89, against Agency decisions under paragraph 2 of this Article .

5. Where additional information for a particular substance is submitted to the Agency by a new registrant, the Agency shall notify the existing registrants that this information is available on the database for the purposes of Article 20.

Article 19

Manufacturing and import of substances

1. A registrant may start or continue the manufacture or import of a substance, if there is no indication to the contrary from the Agency in accordance with Article 18(2) within the three weeks after the submission date, without prejudice to Article 25(8).

In the case of registrations of phase-in substances, a registrant may continue the manufacture or import of the substance, if there is no indication to the contrary from the Agency in accordance with Article 18(2) within the three weeks after the submission date or if submitted within the 2-month period before the relevant deadline of Article 21, if there is no indication to the contrary from the Agency in accordance with Article 18(2) within the 3 months from that deadline, without prejudice to Article 25(8).

In the case of an update of a registration according to Article 20 a registrant may continue the manufacture or import of a substance, if there is no indication to the contrary from the Agency in accordance with Article 18(2) within the three weeks after the update date, without prejudice to Article 25(8).

2. If the Agency has informed the registrant that he is to submit further information in accordance with the third subparagraph of Article 18(2), the registrant may start the manufacture or import if there is no indication to the contrary from the Agency, within the three weeks after receipt by the Agency of the further information necessary to complete his registration, without prejudice to Article 25(8).

3. If one manufacturer or importer submits parts of the registration on behalf of other manufacturers and/or importers, as provided for in Articles 10 or 17, those other manufacturers and/or importers may manufacture the substance in the Community or import it only after the expiry of the time-limit laid down in paragraph 1 or 2 of this Article and provided that there is no indication to the contrary from the Agency in respect of the registration of the one manufacturer or importer acting on behalf of others.

4. Paragraphs 1, 2 and 3 shall also apply to on-site isolated intermediates or transported isolated intermediates.

Article 20

Further duties of registrants

1. Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency in the following cases:
   (a) any change in his status, such as being a manufacturer or an importer, or in his identity, such as his name or address;
   (b) any change in the composition of the substance as given in section 2 of Annex IV;
   (c) changes in the annual or total quantities manufactured or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;
   (d) new identified uses and new uses advised against as in section 3.7 of Annex IV for which the substance is manufactured or imported;
   (e) new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;
   (f) any change in the classification and labelling of the substance;
   (g) any update or amendment of the chemical safety report or section V of Annex IV;
   (h) the registrant identifies the need to perform a test listed in Annex VII or VIII, in which cases a testing proposal shall be developed;
   (i) any change in the access granted to information in the registration.

   The Agency shall communicate this information to the competent authority of the relevant Member State.

1bis. A registrant shall submit to the Agency an update of the registration containing the information required by the decision made in accordance with Articles 39, 40 or 44 or take into account a decision made in accordance with articles 57 and 70, within the deadline specified in that decision. The Agency shall notify the competent authority of the relevant Member State that the information is available on its database.

1ter The Agency shall undertake a completeness check according to Article 18(2) first and second subparagraphs of each updated registration. In cases where the update is in accordance with article 11(2) and 20(1)(c) then the Agency shall check the completeness of the information supplied by the registrant and Article 18(2) subparagraph 1 first sentence and third sentence, second subparagraph and third subparagraph shall apply adapted as necessary.

2. In cases covered by Articles 10 or 17, each registrant shall submit separately the information specified in paragraph 1(c).

2bis. An update shall be accompanied by the relevant part of the fee required in accordance with Title VIIIa.

Chapter 6
Transitional provisions applicable to phase-in substances and notified substances

Article 21

Specific provisions for phase-in substances

1. Articles 4a, 5, 6(1) and 19 shall not apply to the following substances for a period of 3 years after the entry into force of this Regulation:
   (a) phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC and manufactured in the Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation;
   (b) phase-in substances classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50-53) in accordance with Directive 67/548/EEC, and manufactured in the Community or imported in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation;

(c) phase-in substances manufactured in the Community or imported, in quantities reaching 1 000 tonnes or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation.

2. Articles 4a, 5, 6(1) and 19 shall not apply for a period of 6 years after entry into force of this Regulation to phase-in substances manufactured in the Community or imported, in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation.

3. Articles 4a, 5, 6(1) and 19 shall not apply for a period of 11 years after entry into force of this Regulation to phase-in substances manufactured in the Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation.

Article 22

Notified substances

1. A notification in accordance with Directive 67/548/EEC shall be regarded as a registration for the purposes of this Title and the Agency shall assign a registration number within 18 months of entry into force of this Regulation.

2. If the quantity of a notified substance manufactured or imported per manufacturer or importer reaches the next tonnage threshold under Article 11, the additional required information corresponding to that tonnage threshold, as well as to all the lower tonnage thresholds, shall be submitted in accordance with Articles 9 and 11, unless it has already been submitted in accordance with those Articles.

TITLE III
DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING

Chapter 1
Objectives and general rules

Article 23

Objectives and general rules

1. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.

2. The sharing and joint submission of information in accordance with this Regulation shall concern technical data and in particular information related to the intrinsic properties of substances. Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares.

3. Any study summaries or robust study summaries of studies submitted in the framework of a registration under this Regulation at least 10 years previously can be used for the purposes of registration by another manufacturer or importer.

Chapter 2

rules for non-phase-in substances and registrants of phase-in substances who have not pre-registered

Article 24

Duty to inquire prior to registration

1. [deleted]

2. [deleted]

3. The potential registrant of a non-phase-in substance, or the potential registrant of a phase-in substance who has not pre-registered in accordance with Article 26 shall inquire from the Agency whether a registration has already been submitted for the same substance. He shall submit all the following information to the Agency with the inquiry:
   (a) his identity as specified in section 1 of Annex IV, with the exception of the use sites;
   (b) the identity of the substance, as specified in section 2 of Annex IV;
   (c) which information requirements would require new studies involving vertebrate animals to be carried out by him;
   (d) which information requirements would require other new studies to be carried out by him.

4. If the same substance has previously not been registered, the Agency shall inform the potential registrant accordingly.

5. If the same substance has previously been registered less than 10 years earlier, the Agency shall inform the potential registrant without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries, as the case may be, already submitted by them

Those studies involving vertebrate animals shall not be repeated.

The Agency shall simultaneously inform the previous registrants of the name and address of the potential registrant. The available studies shall be shared with the potential registrant in accordance with Article 25.

6. If several potential registrants have made an inquiry in respect of the same substance, the Agency shall inform all potential registrants without delay of the name and address of the other potential registrants.

Article 25

Sharing of existing data in the case of registered substances

1. Where a substance has previously been registered less than 10 years earlier as referred to in Article 24(5), the potential registrant:
   (a) shall, in the case of information involving tests on vertebrate animals, and
   (b) may, in the case of information not involving tests on vertebrate animals,
   request from the previous registrant(s) the information he requires with respect to Article 9(a)(vi) and (vii) in order to register.

2. When a request for information has been made according to paragraph 1, the potential and the previous registrant(s) as referred to in paragraph 1 shall make every effort to reach an agreement to make available the information requested by the potential registrant(s) with respect of Article 9(a)(vi) and (vii). Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order.

2bis. The previous registrant and potential registrant(s) shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following cost sharing guidance based on those principles and which is adopted by the Agency in accordance with Article 73(2)(f). Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

3. On agreement on the sharing of the information, the new registrant shall have permission to refer to this information in his registration dossier.

4. If there is failure to reach such an agreement, the potential registrant(s) shall inform the Agency and the previous registrant(s) thereof at least 1 month after receipt, from the Agency, of the name and address of the previous registrant(s).

5. Within one month from the receipt of the information referred to in paragraph 4, the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier. Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.

6. [deleted]

7. An appeal may be brought, in accordance with Articles 87, 88 and 89, against Agency decisions under paragraph 5 of this Article.

8. The registration waiting period in accordance with Article 19 (1) for the new registrant shall be extended by a period of 4 months, if the previous registrant so requests.

Chapter 3

Rules for phase-in-substances

Article 26

Duty to pre-register for phase-in substances

1. In order to benefit from the transitional regime provided for in Article 21 each potential registrant of a phase-in substance manufactured or imported in quantities of 1 tonne or more per year, including without limitation intermediates, shall submit all the following information to the Agency:
   (a) the name of the substance as specified in section 2 of Annex IV , including its EINECs and CAS number or, if not available, any other identity codes;
   (b) his name and address and the name of the contact person and, where appropriate, the name and address of the person representing him in accordance with Article 27(3) as specified in section 1 of Annex IV;
   (c) the envisaged deadline for the registration/tonnage band;
   (cbis) the name(s) of substance(s) as specified in section 2 of Annex IV, including their EINECs and CAS number or, if not available, any other identity codes, for which the available information is relevant for the application of Annex IX paragraphs 1.3 and 1.5.
   (d) [deleted]
   (e) [deleted]

2. The information referred to in paragraph 1 shall be submitted within a time period starting 12 months and ending 18 months after entry into force of this Regulation.

3. Registrants who do not submit the information required under paragraph 1 shall not be able to rely on Article 21.

3bis. Potential registrants who manufacture or import for the first time a phase-in substance in quantities of 1 tonne or more per year after the deadline in paragraph 2 has elapsed, shall be entitled to rely on Article 21 provided that they submit the information referred to in paragraph 1 to the Agency within 6 months of first manufacturing or importing the substance and no later than 12 months before the relevant deadline in Article 21.

4. [deleted]

5. The Agency shall, within one month of the expiry of the deadline referred to in paragraph 2, publish on its website a list of the substances referred to in paragraphs 1(a) and (cbis). That list shall comprise only the names of the substances, including their EINECs and CAS number if available and other identity codes.

6. Manufacturers or importers of phase-in substances in quantities of less than 1 tonne per year, as well as downstream users and third parties, that appear on the list published by the Agency in accordance with paragraph 5, may submit the information referred to in paragraph 26(1) or any other relevant information to the Agency with the intention of being part of the substance information exchange forum as referred to in Article 27.

Article 26a

Submission of information to the Agency following publication of lists

[deleted]

Article 27

Substance Information Exchange Fora

1. All manufacturers and importers who have submitted information to the Agency in accordance with Article 26 for the same phase-in substance shall be participants in a substance information exchange forum (SIEF).

2. The aim of each SIEF shall be to:

(i) facilitate for the purposes of registration, the exchange of the information specified in Article 9(a) (vi) and (vii) between manufacturers and importers, thereby avoiding the duplication of studies; and

(ii) agree classification and labelling where there is a difference in the classification and labelling of the substance.

SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies and arrange for them to be carried out. Each SIEF shall be operational until 11 years after entry into force of this Regulation.

3. [deleted]

Article28

Sharing of data involving tests

1. Before testing is carried out in order to meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving tests on vertebrate animals is available within the SIEF, a participant of that SIEF shall request that study within two months of the deadline set in Article 26(2). If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study within two months of the deadline set in Article 26(2).

Within two weeks of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 73(2)(f). If they cannot reach such an agreement, the cost shall be shared equally. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

2. If a relevant study involving tests is not available within the SIEF, only one study shall be conducted per information requirement within each SIEF by one of its members acting on behalf of the others. They shall take all reasonable steps to reach an agreement within a deadline set by the Agency as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to the Agency. If no agreement is reached, the Agency shall specify which registrant or downstream user shall perform the test. All participants of the SIEF who require a study shall contribute to the costs for the elaboration of the study with a share corresponding to the number of participating potential registrants. Those participants that do not carry out the study themselves shall have the right to receive the full study report within two weeks following payment to the participant that carried out the study.

3. If the owner of a study as referred to in paragraph 1 which involves testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to another participant(s), he shall not be able to proceed with registration until he provides the information to the other participants(s). The other participant(s) shall proceed with registration without fulfilling the relevant information requirement, explaining the reason for this in the registration dossier. The study shall not be repeated unless within 12 months of the date of registration of the other participant(s), the owner of this information has not provided it to them and the Agency decides that the test should be repeated by them. However, if a registration containing this information has already been submitted by another registrant, the Agency shall give the other participant(s) permission to refer to the information in his registration dossier(s). The other registrant shall have a claim on the other participant(s) for an equal share of the cost, provided he makes the full study report available to the other participant(s),which shall be enforceable in the national courts.

3bis. If the owner of a study as referred to in paragraph 1 which does not involve testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to another participant(s), the other members of the SIEF shall proceed with registration as if no relevant study was available in the SIEF.

4. An appeal may be brought, in accordance with Articles 87, 88 and 89, against Agency decisions under paragraph 3 of this Article.

5. The owner of the study who has refused to provide either the costs or the study itself, as referred to in paragraph 3 or 3bis, shall be penalised in accordance with Article 123.

TITLE IV
INFORMATION
IN THE SUPPLY CHAIN

Article 29

Requirements for Safety Data Sheets

1. The supplier shall provide the recipient with a safety data sheet compiled in accordance with Annex Ia:
   (a) where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC, or
   (b) where a substance is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XII.

2. Any actor in the supply chain who is required, under Articles 13 or 34, to carry out a chemical safety assessment for a substance shall ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a preparation and the actor in the supply chain has prepared a chemical safety assessment for the preparation, it is sufficient if the information in the safety data sheet is consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation.

3. The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex Ia, where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains:
   (a) in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0.2 % by volume for gaseous preparations at least one substance posing health or environmental hazards, or
   (b) in an individual concentration of ≥ 0.1 % by weight for non-gaseous preparations at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XII, or

(c) one substance for which there are Community workplace exposure limits.

4. The safety data sheet need not be supplied where dangerous substances or preparations offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of health, safety and the environment, unless requested by a downstream user or distributor.

5. The safety data sheet shall be supplied in an official language of the Member State(s) where the substance or preparation is placed on the market, unless the Member State provides otherwise.

6. The safety data sheet shall be dated and shall contain the following headings:
   1. identification of the substance/preparation and of the company/undertaking;
   2. hazards identification;
   3. composition/information on ingredients;
   4. first-aid measures;
   5. fire-fighting measures;
   6. accidental release measures;
   7. handling and storage;
   8. exposure controls/personal protection;
   9. physical and chemical properties;
   10. stability and reactivity;
   11. toxicological information;
   12. ecological information;
   13. disposal considerations;
   14. transport information;
   15. regulatory information;
   16. other information.

7. Any actor in the supply chain who is required to prepare a chemical safety report according to Article 13 or 34 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Annex IX(3).

   Any downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses.

   Any distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information according to Article 34(2).

8. A safety data sheet shall be provided free of charge on paper or electronically.

9. Suppliers shall update it without delay on the following occasions:
   (a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
   (b) [deleted];
   (c) once an authorisation has been granted or refused;
   (d) once a restriction has been imposed.

   The new, dated version of the information, identified as "Revision: (date)", shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or preparation within the preceding 12 months. Any updates following registration shall include the registration number.

10. [deleted]

Article 30

Duty to communicate information down the supply chain for substances on their own or in preparations for which a safety data sheet is not required

1. Any supplier of a substance on its own or in a preparation who does not have to supply a safety data sheet in accordance with Article 29 shall provide the recipient with the following information:
   (a) the registration number(s) referred to in Article 18 (2bis), if available, for any substances for which information is communicated under Article 30(1)(b), (c) or (d);
   (b) whether the substance is subject to authorisation and details of any authorisation granted or denied under Title VII in this supply chain;
   (c) details of any restriction imposed under Title VIII;
   (d) any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions resulting from the application of Annex IX(3).

2. This information shall be communicated free of charge on paper or electronically at the latest at the time of the first delivery of a substance on its own or in a preparation following the entry into force of this Regulation.

3. Suppliers shall update this information without delay on the following occasions:
   (a) as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
   (b) [deleted];
   (c) once an authorisation has been granted or refused;
   (d) once a restriction has been imposed.

   In addition, the updated information shall be provided free of charge on paper or electronically to all former recipients to whom they have supplied the substance or preparation within the preceding 12 months. Any updates following registration shall include the registration number.

4. Any producer or importer of an article containing a substance meeting the criteria in Article 54 and identified according to Article 56(1) in a concentration above 0.1 % (w/w), shall provide the recipient of the article with sufficient information to allow safe use of the article including, as a minimum, the name of the substance. This obligation shall extend to all recipients of articles in the supply chain.

Article 31

Duty to communicate information on substances and preparations up the supply chain

Any actor in the supply chain of a substance or a preparation shall communicate the following information to the next actor or distributor up the supply chain:

(a) new information on hazardous properties, regardless of the uses concerned;

(b) any other information that might call into question the appropriateness of the risk management measures identified in a safety data sheet supplied to him, which shall be communicated only for identified uses.

Distributors shall pass on that information to the next actor or distributor up the supply chain.

Article 32

Access to information for workers

Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 29 and 30 in relation to substances or preparations that they use or may be exposed to in the course of their work.

Article 33

Obligation to keep information

1. Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or preparation. That manufacturer, importer, downstream user or distributor shall submit this information or make it available without delay upon request to any competent authority, of the Member State in which he is established or to the Agency, without prejudice to Titles II and VI.

2. In the event of a registrant ceasing activity, or transferring part or all of his operations to a third party, the party responsible for liquidating the registrant's undertaking or assuming responsibility for marketing the substance or preparation concerned, shall be bound by the obligation in Article 33(1) in place of the registrant.

TITLE V
DOWNSTREAM USERS

Article 34

Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures

1. A downstream user or distributor may provide information to assist in the preparation of a registration.

2. Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a preparation with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.

   Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.

3. For registered substances, the manufacturer, importer or downstream user shall comply with the obligation laid down in Article 13 before he next supplies the substance on its own or in a preparation to the downstream user making the request referred to in paragraph 2, provided that the request was made at least one month before the supply, or within 1 month after the request, whichever is the later.

For phase-in substances, the manufacturer, importer or downstream user shall comply with this request and with the obligations laid down in Article 13 before the relevant deadline in Article 21, provided that the downstream user makes his request at least 12 months before the deadline in question.

Where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 13, is unable to include it as an identified use for reasons of protection of health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 29 or 30. Any manufacturer or importer shall include this use in Annex IV, section 3.7 in his update of the registration in accordance with Article 20(1)(d).

4. A downstream user of a substance on its own or in a preparation shall prepare a chemical safety report in accordance with Annex XI for any use outside the conditions described in an exposure scenario or if appropriate a use and exposure category communicated to him in a safety data sheet or for any use his supplier advises against.

A downstream user need not prepare such a chemical safety report in any of the following cases:

(a) a safety data sheet is not required to be communicated with the substance or preparation in accordance with Article 29;

(b) a chemical safety report is not required to be completed by his supplier in accordance with Article 13;

(bbis) the downstream user uses the substance or preparation in a total quantity of less than 1 tonne per year;

(c) the downstream user implements or recommends an exposure scenario which includes as a minimum the conditions described in the exposure scenario communicated to him in the safety data sheet;

(d) the substance is present in a preparation in a concentration lower than any of the concentrations set out in Article 13(2);

(e) the downstream user is using the substance for the purposes of product and process oriented research and development, provided that the risks to human health and the environment are adequately controlled in accordance with the requirements of legislation for the protection of workers and the environment.

5. Any downstream user shall identify, apply and where suitable, recommend, appropriate measures to adequately control risks identified in any of the following:

(a) the safety data sheet(s) supplied to him;

(b) his own chemical safety assessment;

(c) any information on risk management measures supplied to him in accordance with Article 30.

5bis. Where a downstream user does not prepare a chemical safety report in accordance with Article 34(4)(bbis), he shall consider the use(s) of the substance and identify and apply any appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled. Where necessary, this information shall be included in any safety data sheet prepared by him.

6. Downstream users shall keep their chemical safety report up to date and available.

7. A chemical safety report prepared in accordance with paragraph 4 need not include consideration of the risks to human health from the end uses set out in Article 13(5).

Article 35

Obligation for downstream users to report information

1. Before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain in accordance with Articles 5 or 16, the downstream user shall report to the Agency the information specified in paragraph 2 of this Article, in the following cases:
   (a) the downstream user has to prepare a chemical safety report in accordance with Article 34(4); or
   (b) the downstream user is relying on the exemption in Articles 34(4)(bbis) and 34(4)(e).

2. The information reported by the downstream user shall include the following:
   (a) his identity and contact details as specified in section 1.1 of Annex IV;
   (b) the registration number(s) referred to in Article 18(2bis), if available;
   (c) the identity of the substance(s) as specified in section 2.1 to 2.3.4 of Annex IV;
   (d) the identity of the manufacturer(s) or the importer(s) or other supplier as specified in section 1.1 of Annex IV;
   (e) a brief general description of the use(s), as specified in section 3.5 of Annex IV, and of the conditions of use(s);
   (f) a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.

3. The downstream user shall update this information without delay in the event of a change in the information reported in accordance with paragraph 1.

4. A downstream user shall report to the Agency if his classification of a substance is different to that of his supplier.

5. Reporting in accordance with paragraphs 1 to 4 shall not be required in respect of a substance, on its own or in a preparation, used by the downstream user in quantities of less than 1 tonne per year for that particular use.

Article 36

Application of downstream user obligations

1. Downstream users shall be required to comply with the requirements of Article 34 at the latest 12 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

2. Downstream users shall be required to comply with the requirements of Article 35 at the latest 6 months after receiving a registration number communicated to them by their suppliers in a safety data sheet.

TITLE VI
EVALUATION

Chapter 1
scope

[deleted]

Article 37

Scope

[deleted]

Chapter 2
Dossier Evaluation

Article 38

Competent authority

[deleted]

Article 39

Examination of testing proposals

1. The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes VII and VIII for a substance. Priority should be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or CMR properties, or substances classified as dangerous according to Directive 67/548/EEC above 100 tonnes per year with uses resulting in widespread and diffuse exposure.

2. On the basis of the examination under paragraph 1, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 48 and 49:

(a) a decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the summary of the test result, or the robust study summary if required by Annex I;

(b) a decision in accordance with point (a), but modifying the conditions under which the test is to be carried out;

(bbis) a decision in accordance with point (a) or (b) but requiring registrant(s) or downstream user(s) to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes VII, VIII and IX;

(c) a decision rejecting the testing proposal;

(d) a decision in accordance with point (a), (b) or (bbis), if several registrants of the same substance have submitted proposals for the same test, giving them the opportunity to reach an agreement on who will perform the test on behalf of all of them and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants to perform the test on behalf of all of them.

3. The registrant or downstream user shall submit the information required to the Agency by the deadline set.

Article 40

Compliance check of registrations

1. The Agency may examine any registration in order to verify any of the following:

(a) that the information in the technical dossier(s) submitted pursuant to Article 9 complies with the requirements of Articles 9, 11 and 12 and with Annexes Ic, IV to VIII;

(b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes V to VIII and with the general rules set out in Annex IX;

(c) that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate.

(d) that any explanation(s) submitted in accordance with Article 10(2bis) or Article 17(1bis) have an objective basis.

1bis. The list of dossiers being checked for compliance by the Agency shall be made available to Member States competent authorities.

2. On the basis of an examination made pursuant to paragraph 1, the Agency may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Articles 48 and 49.

3. The registrant shall submit the information required to the Agency by the deadline set.

4. To ensure that registration dossiers comply with the Regulation, the Agency shall select a percentage of those dossiers, no lower than 5 % of the total received by the Agency for each tonnage band, for compliance checking. The Agency shall give priority, but not exclusively, to dossiers meeting at least one of the following criteria:

(a) the dossier contains information in Article 9(a)(iv), (vi) and/or (vii) submitted separately as per Article 10(2bis); or

(b) the dossier is for a substance manufactured or imported in quantities of 1 tonne or more per year and does not meet the requirements of Annex V applying under either Article 11(1)(a) or 11(1)(abis), as the case may be; or

(c) [deleted];

(d) the dossier is for a substance listed in the Community rolling action plan referred to in Article 43a.

5. Any third party may electronically submit information to the Agency relating to substances that appear on the list referred to in Article 26(5). The Agency shall consider this information together with the information submitted according to Article 121 when checking and selecting dossiers.

6. The Commission may, after consulting with the Agency, take a decision to vary the percentage of dossiers selected and amend or include further criteria in paragraph 4 in accordance with the procedure referred to in Article 130(3).

Article 41

Check of information submitted and follow-up to dossier evaluation

1. The Agency shall examine any information submitted in consequence of a decision taken under Articles 39 or 40, and draft any appropriate decisions in accordance with Article 39 or 40, if necessary.

2. Once the dossier evaluation is completed, the Agency shall notify the Commission and the competent authorities of the Member States of the information obtained and any conclusions made. The competent authorities shall use the information obtained from this evaluation for the purposes of Articles 43a *bis* (5), 56(3) and 66(2).The Agency shall use the information obtained from this evaluation for the purposes of Article 43a.

Article 42

Procedure and time periods for examination of testing proposals

1. [deleted]

2. In the case of non phase-in substances, the Agency shall prepare a draft decision in accordance with Article 39(2) within 180 days of receiving a registration or downstream user report containing a testing proposal.

3. In the case of phase-in substances, the Agency shall prepare the draft decisions in accordance with Article 39(2):

   (a) within 5 years of the entry into force of this Regulation for all registrations received within the deadline referred to in Article 21 (1) containing proposals for testing in order to fulfil the information requirements in Annexes VII and VIII;

   (b) within 9 years of the entry into force of this Regulation for all registrations received within the deadline referred to in Article 21 (2) containing proposals for testing in order to fulfil the information requirements in Annex VII only;

   (c) within 15 years of the entry into force of this Regulation for any registrations containing testing proposals received within the deadline referred to in Article 21 (3).

4. The list of registration dossiers being evaluated under Article 39 shall be made available to Member States.

Article 43

Procedure and time periods for compliance check

[deleted]

Chapter 3

substance evaluation

Article 43a

Criteria for substance evaluation

1. In order to provide a harmonised approach, the Agency shall in co-operation with the Member States develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria shall consider;

(a) hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;

(b) exposure information;

(c) tonnage, including aggregated tonnage from the registrations submitted by several registrants.

2. The Agency shall use the criteria in paragraph 1 for the purpose of compiling a draft Community rolling action plan which shall cover a period of three years and shall specify substances to be evaluated each year. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to health or the environment. The Agency shall submit the first draft rolling action plan to the Member States within 4 years of entry into force of this Regulation. The Agency shall submit draft annual updates to the rolling action plan to the Member States by 28 February each year.

The Agency shall adopt the final Community rolling action plan on the basis of an opinion from the Member States Committee and shall publish the plan on its website, identifying the Member State who will carry out the evaluation of the substances listed therein as determined according to Article 43a bis.

Article 43a bis

Competent authority

1. The Agency shall be responsible for co-ordinating the substance evaluation process and ensuring that substances on the Community rolling action plan are evaluated. In doing so, the Agency shall rely on the competent authorities of Member States. In carrying out an evaluation of a substance, the competent authorities may appoint another body to act on their behalf.

2. A Member State may choose a substance(s) from the Community rolling action plan, with the aim of becoming a competent authority for the purposes of Articles 44-46. In the case of a substance from the Community rolling action plan not being chosen by any Member State, the Agency shall ensure that the substance is evaluated.

3. In cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree who should be the competent authority, the competent authority for the purposes of Articles 44, 45 and 46 shall be determined in accordance with the following procedure.
The Agency shall refer the matter to the Member State Committee provided for in Article 72(1)(e), hereinafter "the Member State Committee", in order to agree which authority shall be the competent authority, taking into account the Member State in which the manufacturer(s) or importer(s) is located, the respective proportions of total Community gross domestic product, the number of substances already being evaluated by a Member State and the expertise available.

If, within 60 days of the referral, the Member State Committee reaches unanimous agreement, the Member States concerned shall adopt substances for evaluation accordingly.

If the Member State Committee fails to reach a unanimous agreement, the Agency shall submit the conflicting opinions to the Commission, which shall decide which authority shall be the competent authority, in accordance with the procedure referred to in Article 130(3), and the Member States concerned shall adopt substances for evaluation accordingly.

4. The competent authority identified in accordance with paragraphs 2 and 3 shall evaluate the allocated substances in accordance with this Chapter.

5. A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. The Agency shall decide whether to add this substance to the Community rolling action plan on the basis of an opinion from the Member States Committee. If the substance is added to the Community rolling action plan, the proposing Member State, or another Member State who agrees, shall evaluate that substance.

Article 44

Requests for further information and check of information submitted

1. If the competent authority considers that further information is required, including, if appropriate, information not required in Annexes V to VIII, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission. A draft decision shall be prepared within 12 months of the publication of the Community rolling action plan on the Agency's website for substances to be evaluated that year. The decision shall be taken in accordance with the procedure laid down in Articles 48 and 49a.

2. The registrant shall submit the information required to the Agency by the deadline set.

3. The competent authority shall examine any information submitted, and shall draft any appropriate decisions in accordance with this Article, if necessary, within 12 months of the information being submitted.

4. The competent authority shall finish its evaluation activities within 12 months of the start of the evaluation of the substance or within 12 months of the information being submitted under paragraph 2, and notify the Agency accordingly. If this deadline is exceeded, the evaluation shall be deemed to be finished.

Article 45

Coherence with other activities

1. An evaluation of a substance shall be based on all relevant information submitted on that particular substance and on any previous evaluation under this Title. Where information on intrinsic properties of a substance has been generated by reference to structurally related substance(s), the evaluation may also cover these related substances. In cases where a decision on an evaluation has been previously taken in accordance with Article 49 and 49a, any draft decision requiring further information under Article 44 may be justified only by a change of circumstances or acquired knowledge.

2. In order to ensure a harmonised approach to requests for further information, the Agency shall monitor draft decisions under Article 44 and shall develop criteria and priorities. Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article 130(3).

Article 46

Follow-up to substance evaluation

Once the substance evaluation has been completed, the competent authority shall consider how to use the information obtained from this evaluation for the purposes of Articles 56(3), 66(2) and 112(1). The competent authority shall inform the Agency of its conclusions as to whether or how to use the information obtained. The Agency shall in turn inform the Commission, the registrant and the competent authorities of the other Member States.

Chapter 4

Evaluation of intermediates

Article 47

Further information on on-site isolated intermediates

For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation shall apply. However, where the competent authority of the Member State in whose territory the site is located considers that a risk to human health or the environment equivalent to the level of concern arising from the use of substances meeting the criteria in Article 54, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, it may:

(a) require the registrant to submit further information directly related to the risk identified. This request shall be accompanied by a written justification;

(b) examine any information submitted and, if necessary, recommend any appropriate risk reduction measures to address the risks identified in relation to the site in question.

The procedure provided for in the first paragraph may be undertaken only by the competent authority referred to therein. The competent authority shall inform the Agency of the results of such an evaluation, which shall then inform the competent authorities of other Member States and make the results available to them.

Chapter 5

Common provisions

Article 48

Registrants' and downstream users' rights

1. The Agency shall notify any draft decision under Articles 39, 40 or 44 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 44) and the Agency (for decisions taken under Articles 39 and 40) shall take any comments received into account and may amend the draft decision accordingly.

2. If a registrant has ceased the manufacture or import of the substance, he shall inform the Agency of this fact with the consequence that the registered volume in his registration shall be put to zero and no further information may be requested with respect to that substance, unless the registrant notifies the restart of the manufacture or import of the substance. The Agency shall inform the competent authority of the Member State in which the manufacturer or importer is located.

3. The registrant may cease the manufacture or import of the substance upon receipt of the draft decision. In such cases, he shall inform the Agency of this fact with the consequence that his registration shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration. The Agency shall inform the competent authority of the Member State in which the manufacturer or importer is located.

4. Notwithstanding paragraphs 2 and 3, further information may be required in accordance with Article 44 in either or both of the following cases:

   (a) where the competent authority prepares a dossier in accordance with Annex XIV concluding that there is a potential long-term risk to human health or the environment justifying the need for further information;

   (b) where the exposure to the substance manufactured or imported by the registrant(s) concerned contributes significantly to that risk.

   The procedure in Articles 66 to 70 shall apply *mutatis mutandis*.

Article 49

Adoption of decisions under dossier evaluation

1. The Agency shall notify its draft decision in accordance with Articles 39 or 40, together with the comments of the registrant or downstream user, to the competent authorities of the Member States.

2. Within 30 days of circulation, the Member States may propose amendments to the draft decision to the Agency.

3. If the Agency does not receive any proposals, it shall take the decision in the version notified under paragraph 1.

4. If the Agency receives a proposal for amendment, it may modify the draft decision. The Agency shall refer a draft decision, together with any amendments proposed, to the Member State Committee within 15 days of the end of the 30-day period referred to in paragraph 2.

5. The Agency shall forthwith communicate any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days. The Member State Committee shall take any comments received into account.

6. If, within 60 days of the referral, the Member State Committee reaches a unanimous agreement on the draft decision, the Agency shall take the decision accordingly.

7. If the Member States Committee fails to reach unanimous agreement, the Commission shall prepare a draft decision to be taken in accordance with the procedure referred to in Article 130(3).

8. An appeal may be brought, in accordance with Articles 87, 88 and 89, against Agency decisions under paragraphs 3 and 6.

Article 49a

Adoption of decisions under substance evaluation

1. The competent authority shall circulate its draft decision in accordance with Article 44, together with any comments by the registrant or downstream user, to the Agency and to the competent authorities of the other Member States.

2. The provisions of Article 49(2) to (8) shall apply *mutatis mutandi*

Article 50

Cost sharing for tests without an agreement between registrants and/or downstream users

1. Where registrants or downstream users are required to perform a test as a result of a decision taken under this Title, those registrants or downstream users shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants or downstream users and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users to perform the test on behalf of all of them.

2. If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally.

3. In the case referred to in paragraph 1, the registrant or downstream user who performs the test shall provide each of the others concerned with a copy of the full study report.

4. The person performing and submitting the study shall have a claim against the others accordingly. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the full study report of the study performed. All claims shall be enforceable in the national courts. Any person may choose to submit their claims for remuneration to an arbitration board and accept the arbitration order.

Article 51

Publication of information on evaluation

By 28 February of each year, the Agency shall publish on its website a report on the progress made over the previous calendar year towards discharging the obligations incumbent upon it in relation to evaluation. This report shall include, in particular, recommendations to potential registrants in order to improve the quality of future registrations.

TITLE VII
AUTHORISATION

Chapter 1
Authorisation requirement

Article 52

Aim of authorisation

The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are eventually replaced by suitable alternative substances or technologies where these are economically and technically viable.

Article 53

General provisions

1. A manufacturer, importer or downstream user shall not place on the market a substance for a use or use it himself if that substance is included in Annex XIII, unless:
   (a) the use(s) of that substance on its own, in a preparation or the incorporation of a substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 57 to 61; or
   (b) the use(s) of that substance on its own, in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIII itself in accordance with Article 55(2); or
   (c) the date referred to in Article 55(1)(c)(i) has not been reached; or
   (d) the date referred to in Article 55(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or

(e) in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.

2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.

3. [deleted]

4. Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIII shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.

5. Paragraphs 1 and 2 shall not apply to the following uses of substances:
   (a) uses in plant protection products within the scope of Directive 91/414/EEC;
   (b) uses in biocidal products within the scope of Directive 98/8/EC;
   (c) [deleted]
   (d) [deleted]
   (e) [deleted]
   (f) [deleted]
   (g) [deleted]
   (h) use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council[41];
   (i) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.

6. In the case of substances that are subject to authorisation only because they meet the criteria in Article 54(a), (b) and (c) or because they are identified in accordance with Article 54(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:

[41] OJ L 350, 28.12.1998, p. 58.

(a) uses in cosmetic products within the scope of Directive 76/768/EEC;

(b) uses in food contact materials within the scope of Directive 89/109/EEC.

7. Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations:

(a) for substances referred to in Article 54(d), (e) and (f), below a concentration limit of 0.1 % weight by weight (w/w);

(b) for all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in Annex I to Directive 67/548/EEC which result in the classification of the preparation as dangerous.

Article 54

Substances to be included in Annex XIII

The following substances may be included in Annex XIII in accordance with the procedure laid down in Article 55:

(a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;

(b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;

(c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XII;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XII;

(f) substances, such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) and (e), and for which there is scientific evidence of probable serious effects to humans or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 56.

Article 55

Inclusion of substances in Annex XIII

1. Whenever a decision is taken to include in Annex XIII substances referred to in Article 54, such a decision shall be taken in accordance with the procedure referred to in Article 130(3). It shall specify for each substance:
   (a) the identity of the substance as specified in section 2 of Annex IV;
   (b) the intrinsic property (properties) of the substance referred to in Article 54;
   (c) transitional arrangements:
      (i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted, hereinafter "the sunset date", which should take account, where appropriate, the production cycle specified for that use;
      (ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;
   (d) review periods for certain uses, if appropriate;
   (e) uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

2. Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.

3. Prior to a decision to include substances in Annex XIII, the Agency shall, taking into account the opinion of the Member States Committee, recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:

   (a) PBT or vPvB properties;

   (b) wide dispersive use; or

   (c) high volumes.

   The number of substances included in Annex XIII and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for. The Agency shall make its first recommendation of priority substances to be included in Annex XIII no later than 2 years after entry into force of the Regulation. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIII.

4. Before the Agency sends its recommendation to the Commission it shall make it publicly available on its website, clearly indicating the date of publication, taking into account Articles 115 and 116 on access to information. The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement.

   The Agency shall update its recommendation, taking into account the comments received.

5. Subject to paragraph 5bis, after inclusion of a substance in Annex XIII, this substance shall not be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance on its own, in a preparation or incorporation of a substance in an article arising from the intrinsic properties specified in Annex XIII.

5bis. A substance listed in Annex XIII may be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance in article(s).

6. Substances for which all uses have been prohibited under Title VIII or by other Community legislation shall not be included in Annex XIII or shall be removed from it.

7. Substances which as a result of new information no longer meet the criteria of Article 54 (a)-f), shall be removed from Annex XIII in accordance with the procedure referred to in Article 130(3).

Article 56

Identification of substances referred to in Article 54

1. The procedure set out in paragraphs 2 to 9 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 54 and establishing a candidate list for eventual inclusion in Annex XIII. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 79(3)(e).

2. The Commission may ask the Agency to prepare a dossier in accordance with relevant sections of Annex XIV for substances which in its opinion meet the criteria set out in Article 54. The dossier may be limited, if appropriate, to a reference to an entry in Annex I of Directive 67/548/EEC. The Agency shall make this dossier available to the Member States.

3. Any Member State may prepare a dossier in accordance with Annex XIV for substances which in its opinion meet the criteria set out in Article 54 and forward it to the Agency. The dossier may be limited, if appropriate, to a reference to an entry in Annex I of Directive 67/548/EEC. The Agency shall make this dossier available within 30 days of receipt to the other Member States.

3bis. The Agency shall publish on its website a notice that an Annex XIV dossier has been prepared for a substance. The Agency shall invite all interested parties to submit comments within a specified deadline to the Agency.

4. Within 60 days of circulation, the other Member States or the Agency may comment on the identification of the substance in relation to the criteria in Article 54 in the dossier to the Agency.

5. If the Agency does not receive any comments, it shall include this substance on the list referred to in paragraph 1. The Agency may include this substance in its recommendations under Article 55(3).

6. Upon receipt of comments from another Member State or other interested party or on its own initiative, the Agency shall refer the dossier to the Member State Committee within 15 days of the end of the 60-day period referred to in paragraph 4.

7. If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, the Agency shall include the substance in the list referred to in paragraph 1. The Agency may include that substance in its recommendations under Article 55(3).

8. If the Member States Committee fails to reach a unanimous agreement, the Commission shall prepare a draft proposal on the identification of the substance within 3 months of receipt of the opinion of the Member State Committee. A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article 130(3).

9. The Agency shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.

Chapter 2
The granting of authorisations

Article 57

The granting of authorisations

1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.

2. Without prejudice to paragraph 2bis, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII is adequately controlled in accordance with Annex I, section 6.4, and as documented in the applicant's chemical safety report. The Commission shall take into account all discharges, emissions and losses known at the time of decision.

   The Commission shall not consider the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC[42], Council Directive 93/42/EEC[43] or Directive 98/79/EC of the European Parliament and of the Council[44].

[42] OJ L 189, 20.7.1990, p. 17.
[43] OJ L 169, 12.7.1993, p. 1.
[44] OJ L 331, 7.12.1998, p. 1.

2bis. Paragraph 2 shall not apply to:

(i) substances meeting the criteria in Article 54 (a), (b), (c) and (f) for which it is not possible to determine a threshold in accordance with Annex I, section 6.4;
(ii) substances meeting the criteria in Article 54 (d) and (e).

3. If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 2bis, an authorisation may be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements:
(a) the risk posed by the uses of the substance;
(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;
(c) the analysis of the alternatives submitted by the applicant under Article 59(4) and any third party contributions submitted under Article 61(2);
(d) available information on the health or environmental risks of any alternative substances or technologies.

4. A use shall not be authorised if this would constitute a relaxation of a restriction set out in Annex XVI.

5. An authorisation shall be granted only if the application is made in conformity with the requirements of Article 59.

5bis. Where an application for authorisation includes the information specified in Article 59(5)(b), this information will be considered in determining the duration of the time-limited review period in Article 57(6).

6. Authorisations shall be subject to a time-limited review (whose duration will be determined on a case-by-case basis) without prejudice to any decision on a future review period and shall normally be subject to conditions, including monitoring.

7. The authorisation shall specify:
   (a) the person(s) to whom the authorisation is granted;
   (b) the identity of the substance(s);
   (c) the use(s) for which the authorisation is granted;
   (d) any conditions under which the authorisation is granted;
   (e) the time-limited review period;
   (f) any monitoring arrangement.

8. Notwithstanding any conditions of an authorisation, the holder shall ensure that the level of exposure is reduced to as low as is technically and practically possible.

Article 58

Review of authorisations

1. Authorisations granted in accordance with Article 57 shall be regarded as valid until the Commission decides to amend or withdraw the authorisation in the context of a review, provided that the holder of the authorisation submits a review report at least 18 months before the expiry of the time-limited review period. Rather than re-submitting all elements of the original application for the current authorisation, the holder of an authorisation may submit only the number of the current authorisation, subject to the second, third and fourth subparagraphs.

A holder of an authorisation granted in accordance with Article 57 shall submit an update of any substitution plan included in his application. If the holder cannot demonstrate that the risk is adequately controlled, he shall submit an update of the socio-economic analysis, analysis of alternatives and substitution plan contained in the original application.

If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report.

If any other elements of the original application have changed, he shall also submit updates of these element(s).

2. Authorisations may be reviewed at any time if:
   (i) the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact; or,
   (ii) new information on possible substitutes becomes available.

   The Commission shall set a reasonable deadline by which the holder(s) of the authorisation may submit further information necessary for the review and indicate by when it will take a decision in accordance with Article 61.

3. In its review decision the Commission may, taking into account proportionality, amend the authorisation or withdraw the authorisation from the time of the decision, if under the changed circumstances it would not have been granted.

   In cases where there is a serious and immediate risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account proportionality.

4. If an environmental quality standard referred to in Directive 96/61/EC is not met, the authorisations granted for the use of the substance concerned may be reviewed.

5. If the environmental objectives as referred to in Article 4(1) of Directive 2000/60/EC are not met, the authorisations granted for the use of the substance concerned in the relevant river basin may be reviewed.

6. If a use of a substance is subsequently restricted or prohibited in Regulation 850/2004, the Commission shall withdraw the authorisation for that use.

Article 59

Applications for authorisations

1. An application for an authorisation shall be made to the Agency.

2. Applications for authorisation may be made by the manufacturer(s), importer(s) and/or downstream user(s) of the substance. Applications may be made by one or several persons.

3. Applications may be made for one or several substances, and for one or several uses. Applications may be made for the applicant's own use(s) and/or for uses for which he intends to place the substance on the market.

4. An application for authorisation shall include the following information:
   (a) the identity of the substance(s), as referred to in section 2 of Annex IV;
   (b) the name and contact details of the person or persons making the application;
   (c) a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in preparations and/or the incorporation of the substance in articles, where this is relevant;
   (d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIII;

(dbis) an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution.

4bis. [deleted]

5. The application may include:

(a) a socio-economic analysis conducted in accordance with Annex XV;

(b) where appropriate a substitution plan, including research and development and a timetable for proposed actions by the applicant.

(c) a justification for not considering risks to human health and the environment arising either from:

(i) emissions of a substance from an installation for which a permit was granted in accordance with Council Directive 96/61/EC; or

(ii) discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC of the European Parliament and the Council and legislation adopted under Article 16 of that Directive.

6. The application shall not include the risks to human health arising from the use of a substance in a medical device regulated by Directives 90/385/EEC, 93/42/EEC or 98/79/EC.

7. An application for an authorisation shall be accompanied by the fee in accordance with Title VIIIa.

Article 60

Subsequent applications for authorisation

1. If an application has been made for a use of a substance, a subsequent applicant may refer to the parts of the previous application submitted in accordance with Article 59(4)(d) and (5)(a) and (b), provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application.

2. If an authorisation has been granted for a use of a substance, a subsequent applicant may refer to the parts of the holder's application submitted in accordance with Article 59(4)(d) and (5)(a) and (b), provided that the subsequent applicant has permission from the holder of the authorisation to refer to these parts of the application.

Article 61

Procedure for authorisation decisions

1. The Agency shall acknowledge the date of receipt of the application. The Agency's Committees for Risk Assessment and Socio-economic Analysis shall give their draft opinions within ten months of the date of receipt of the application.

2. The Agency shall make available on its web-site broad information on uses, taking into account Articles 115 and 116 on access to information, for which applications have been received, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.

3. In preparing its opinion, each Committee referred to in paragraph 1 shall first check that the application includes all the information specified in Article 59 that is relevant to its remit. If necessary, the Committees shall, in consultation with each other, make a joint request to the applicant for additional information to bring the application into conformity with the requirements of Article 59. The Socio-economic Analysis Committee may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. Each Committee shall also take into account any information submitted by third parties.

4. The draft opinions shall include the following elements:

   (a) Risk Assessment Committee: an assessment of the risk to health and/or the environment arising from the use(s) of the substance as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;

   (b) Socio-economic Analysis Committee: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 59(5).

5. The Agency shall send these draft opinions to the applicant by the end of the deadline set out in paragraph 1. Within 1 month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. The draft opinion shall be deemed to have been received 7 days after the Agency has sent it.

   If the applicant does not wish to comment, the Agency shall send these opinions to the Commission, the Member States and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment.

   If the applicant wishes to comment, he shall send his written argumentation to the Agency within 2 months of the receipt of the draft opinion. The Committees shall consider the comments and adopt their final opinions within 2 months of receipt of the written argumentation, taking this argumentation into account where appropriate. Within a further 15 days the Agency shall send the opinions, with the written argumentation attached, to the Commission, the Member States and the applicant.

6. The Agency shall determine in accordance with Articles 115 and 116 which parts of its opinions and parts of any attachments thereto should be made publicly available on its website.

7. In cases covered by Article 60(1), the Agency shall treat the applications together, provided the deadlines for the first application can be met.

8. The Commission shall prepare a draft authorisation decision within 3 months of receipt of the opinions from the Agency. A final decision granting or refusing the authorisation shall be taken in accordance with the procedure referred to in Article 130(2).

9. Summaries of the Commission decisions, including the authorisation number, shall be published in the Official Journal of the European Union and shall be made publicly available in a database established and kept up to date by the Agency.

10. In cases covered by Article 60(2), the deadline set out in paragraph 1 of this Article shall be shortened to 5 months.

Chapter 3
Authorisations in the supply chain

Article 62

Obligation of holders of authorisations

Holders of an authorisation, as well as downstream users including the substances in a preparation, shall include the authorisation number on the label before they place the substance or a preparation containing the substance on the market for an authorised use without prejudice to Directive 67/548/EEC and Directive 99/45/EC. This should be done without delay once the authorisation number has been made publicly available in accordance with Article 61(9).

Article 63

Downstream Users

1. Downstream users using a substance in accordance with Article 53(2) shall notify the Agency within 3 months of the first supply of the substance.

2. The Agency shall establish and keep up to date a register of downstream users who have made a notification in accordance with paragraph 1. The Agency shall grant access to this register to the competent authorities of the Member States.

TITLE VIII
RESTRICTIONS ON THE MANUFACTURING, MARKETING AND USE OF CERTAIN DANGEROUS SUBSTANCES AND PREPARATIONS

Chapter 1
General Issues

Article 64

General provisions

1. A substance on its own, in a preparation or in an article, for which Annex XVI contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development. Annex XVI shall specify if the restriction shall not apply to product and process orientated research and development, as well as the maximum quantity exempted.

2. [deleted]

3. [deleted]

4. Article 64(1) shall not apply to the use of substances in cosmetic products, as defined by Directive 76/768/EC, with regard to restrictions addressing the risks to human health within the scope of that Directive.

5. Up until 6 years after entry into force of the Regulation, a Member State may maintain any existing and more stringent restrictions in relation to Annex XVI on the manufacture, placing on the market or use of a substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions within 2 years of entry into force of this Regulation.

Chapter 2

The restrictions process

Article 65

Introducing new and amending current restrictions

1. When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVI shall be amended in accordance with the procedure referred to in Article 130(3) by adopting new restrictions, or amending current restrictions in Annex XVI, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 66 to 70. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.

   The first subparagraph shall not apply to the use of a substance as an on-site isolated intermediate.

2. For a substance on its own, in a preparation or in an article which meet the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVI shall be amended in accordance with the procedure referred to in Article 130(3). Articles 66 to 70 shall not apply.

3. [deleted]

4. [deleted]

Article 66

Preparation of a proposal

1. If the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall ask the Agency to prepare a dossier which conforms to the requirements of Annex XIV.

1bis. After the date referred to in Article 55(1)(c)(i) for a substance listed in Annex XIII, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XIV.

1ter. Within 12 months of the receipt of the request from the Commission in paragraph 1 and 1bis and if this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Agency shall suggest restrictions, in order to initiate the restrictions process.

2. If a Member State considers that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed it shall notify the Agency that it proposes to prepare a dossier which conforms to the requirements of the relevant sections of Annex XIV. If the substance is not on the list maintained by the Agency referred to in paragraph (2bis) below, the Member State shall prepare a dossier which conforms to the requirements of Annex XIV within 12 months of the notification to the Agency. If this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in the format outlined in Annex XIV, in order to initiate the restrictions process.

The Agency or Member States shall refer to any dossier, chemical safety report or risk assessment submitted to the Agency or Member State under this Regulation. The Agency or Member States shall also refer to any relevant risk assessment submitted for the purposes of other Community Regulations or Directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Agency or Member State concerned on request.

The Committee for Risk Assessment and the Committee for Socio-economic Analysis shall check whether the dossier submitted conforms to the requirements of Annex XIV. Within 30 days of receipt, the respective Committee shall inform the Agency or the Member State suggesting restrictions, as to whether the dossier conforms. If the dossier does not conform, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Chapter shall be terminated. The Agency shall publish without delay the intention of the Commission or of a Member State to instigate a restriction procedure for a substance and shall inform those who submitted a registration for that substance.

2bis. The Agency shall maintain a list of substances for which a dossier conforming to the requirements of Annex XIV is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction. If a substance is on the list, no other such dossier shall be prepared. If it is proposed by either a Member State or the Agency that an existing restriction listed in Annex XVI should be re-examined a decision on whether to do so shall be taken in accordance with the procedure referred to in Article 130(2) based on evidence presented by the Member State or the Agency.

3. Without prejudice to Articles 115 and 116, the Agency shall make publicly available on its website all dossiers conforming with Annex XIV including the restrictions suggested pursuant to paragraphs 1 and 2 without delay, clearly indicating the date of publication. The Agency shall invite all interested parties to submit individually or jointly within 6 months of the date of publication:

(a) comments on dossiers and the suggested restrictions;

(b) a socio-economic analysis, or information which can contribute to one, of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions. It shall conform to the requirements in Annex XV.

Article 67

Agency opinion: Committee for risk assessment

Within 9 months of the date of publication referred to in Article 66(3), the Committee for Risk Assessment shall formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the Member State dossier or of the dossier prepared by the Agency at the request of the Commission, and the views of interested parties referred to in point (a) of Article 66(3).

Article 68

Agency opinion: Committee for socio-economic analysis

1. Within 12 months of the date of publication referred to in Article 66(3), the Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to point (b) of Article 66(3), if there are any. The Agency shall publish the draft opinion on its website without delay. The Agency shall invite interested parties to give their comments on the draft opinion no later than 60 days from the publication of that draft opinion.

2. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set. This opinion shall take account of the comments and socio-economic analyses of interested parties submitted under point (b) of Article 66 (3) and under Article 68 (1).

3. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions suggested by a Member State or the Commission, the Agency may postpone the deadline for the opinion of the Committee for Socio-economic Analysis by a maximum of 90 days.

Article 69

Submission of an opinion to the Commission

1. The Agency shall submit to the Commission without delay the opinions of the Committees for Risk Assessment and Socio-economic Analysis on restrictions suggested for substances on their own, in preparations or in articles. If one or both of the Committees do not formulate an opinion by the deadline set in Articles 67(1) and 68(1) the Agency shall inform the Commission accordingly, stating the reasons.

2. Without prejudice to Articles 115 and 116 the Agency shall publish the opinions of the two Committees on its website without delay.

3. The Agency shall provide the Commission and/or Member State on request with all documents and evidence submitted to or considered by it.

Article 70

Commission decision

1. If the conditions laid down in Article 65 are fulfilled, the Commission shall prepare a draft amendment to Annex XVI, within 3 months of receipt of the opinion of the Committee for Socio Economic analysis or the end of the deadline established under Article 68 if that Committee does not form an opinion, whichever is the earlier.

   Where the draft amendment diverges from the original proposal or if it does not take the opinions from the Agency into account, the Commission shall annex a detailed explanation of the reasons for the differences.

2. A final decision shall be taken in accordance with the procedure referred to in Article 130(3). The Commission shall send the draft amendment to the Member States at least 45 days before voting.

TITLE VIIIa
FEES AND CHARGES

Article 70a

Fees and charges

1. The fees that are required according to Articles 5(4), 6(1), 6(4), 7(2), 10(3), 15(2), 16(2), 17(2), 39, 59(7) and 88(3) shall be specified in a Commission Regulation adopted in accordance with the procedure referred to in Article 130(3) within one year of the entry into force of this Regulation.

1bis. A fee need not be paid for a registration of a substance in a quantity of between 1 and 10 tonnes where the registration dossier contains the full information in Annex V.

2. The structure and amount of the fees referred to in paragraph 1 shall take account of the work required by this Regulation to be carried out by the Agency and the competent authority and shall be fixed at such a level as to ensure that the revenue derived from them when combined with other sources of the Agency's revenue pursuant to Article 93(1) is sufficient to cover the cost of the services delivered. The fees set for registration shall take into account the work that may be done pursuant to Title VI.

In the case of Articles 5(4), 6(1), 6(4), 7(2), 10(3), 15(2), 16(2), the structure and amount of fees shall take account of the tonnage range of the substance being registered.

In all cases, a reduced fee shall be set for SMEs.

In the case of Article 10(3), the structure and amount of fees shall take into account whether information has been submitted jointly or separately.

In the case of a request made under Article 9(a)(xa), the structure and amount of fees shall take into account the work required by the Agency in assessing the justification.

3. The Commission Regulation referred to in paragraph 1 shall specify the circumstances under which a proportion of the fees will be transferred to the relevant Member State Competent Authority.

4. The Agency may collect charges for other services provided by the Agency.

TITLE IX
AGENCY

Article 71

Establishment and review

1. A European Chemicals Agency (the Agency) is established for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of REACH and to ensure consistency at Community level in relation to these aspects.

2. The Agency shall be subject to a review 5 years after entry into force of this Regulation.

Article 72

Composition

1. The Agency shall comprise:
   (a) a Management Board, which shall exercise the responsibilities set out in Article 74;
   (b) an Executive Director, who shall exercise the responsibilities set out in Article 79;
   (c) a Committee for Risk Assessment, which shall be responsible for preparing the opinion of the Agency on evaluations, applications for authorisation, proposals for restrictions and proposals for classification and labelling under Title X and any other questions that arise from the operation of this Regulation relating to risks to human health or the environment;
   (d) a Committee for Socio-economic Analysis, which shall be responsible for preparing the opinion of the Agency on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of this Regulation relating to the socio-economic impact of possible legislative action on substances;
   (e) a Member State Committee, which shall be responsible for resolving potential divergences of opinions on draft decisions proposed by the Agency or the Member States under Title VI and proposals for identification of substances of very high concern to be subjected to the authorisation procedure under Title VII;

(f) a Forum for Exchange of Information on Enforcement, hereinafter "the Forum", which shall co-ordinate a network of Member States authorities responsible for enforcement of this Regulation;

(g) a Secretariat, which shall work under the leadership of the Executive Director and provide technical, scientific and administrative support for the Committees and the Forum and ensure appropriate co-ordination between them. It shall also undertake the work required of the Agency under the procedures for pre-registration, registration and evaluation as well as preparation of guidance, database maintenance and information provision;

(h) a Board of Appeal, which shall decide on appeals against decisions taken by the Agency.

2. The Committees referred to in points (c), (d) and (e) of paragraph 1, hereinafter "the Committees", and the Forum may each establish working groups. For this purpose they shall adopt, in accordance with their rules of procedure, precise arrangements for delegating certain tasks to these working groups.

3. The Committees and the Forum may, if they consider it appropriate, seek advice on important questions of a general scientific or ethical nature from appropriate sources of expertise.

Article 73

Tasks

1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of the present Regulation.

2. The Secretariat shall undertake the following tasks:

(a) performing the tasks allotted to it under Title II; including facilitating the efficient registration of imported substances, in a way consistent with the Community's international trading obligations towards third countries;

(b) performing the tasks allotted to it under Title III;

(c) performing the tasks allotted to it under Title VI;

(d) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list. It shall make the information identified in Article 116(1), and in Article 116(1bis) except where a request made under Article 9(a)(xa) is considered justified, in the data base(s) publicly available, free of charge, over the Internet. The Agency shall make other information in the databases available on request in accordance with Article 115;

(e) making publicly available information as to which substances are being, and have been evaluated within 90 days of receipt of the information at the Agency, in accordance with Article 116(1);

(f) providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports (in accordance with Articles 13, 29(1) and 34(4)) and application of Article 9(a)(viia), 10(2bis) and 17(1bis) by industry and especially by Small and Medium sized Enterprises (SMEs);

(g) providing technical and scientific guidance on the operation of this Regulation for Member State competent authorities and providing support to the help desks established by Member States under Title XII;

(gbis) providing advice and assistance to manufacturers and importers registering a substance in accordance with Article 11(1);

(h) preparing explanatory information on this Regulation for other stakeholders;

(i) at the Commission's request, providing technical and scientific support for steps to improve co-operation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;

(j) keep a Manual of Decisions and Opinions based on conclusions from the Member States Committee regarding interpretation and implementation of this Regulation;

(k) notification of decisions taken by the Agency;

(l) provision of formats for submission of information to the Agency.

3. The Committees shall undertake the following:

(a) performing the tasks allotted to them under Title VI;

(b) performing the tasks allotted to them under Title VII;

(c) performing the tasks allotted to them under Title VIII;

(d) performing the tasks allotted to them under Title X;

(e) at the Commission's request, providing technical and scientific support for steps to improve co-operation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;

(f) at the Commission's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or articles.

4. The Forum shall undertake the following tasks:

(a) spreading good practice and highlighting problems at Community level;

(b) proposing, co-ordinating and evaluating harmonised enforcement projects and joint inspections;

(c) co-ordinating exchange of inspectors;

(d) identifying enforcement strategies, as well as best practice in enforcement;

(e) developing working methods and tools of use to local inspectors;

(f) developing an electronic information exchange procedure;

(g) liaising with industry and other stakeholders, including relevant international organisations, as necessary;

(h) examine proposals for restrictions with a view to advising on enforceability.

Article 74

Powers of the Management Board

The Management Board shall appoint the Executive Director pursuant to Article 80 and an accounting officer in accordance with Article 43 of Regulation (EC, Euratom) No 2343/2002.
It shall adopt:

(a) by 30 April each year, the general report of the Agency for the previous year and forward it by 15 June at the latest to the Member States, the European Parliament, the Council, the Commission, the European Economic and Social Committee and the Court of Auditors;

(b) by 31 October each year the work programme of the Agency for the coming year and forward it to the Member States, the European Parliament, the Council and the Commission;

(c) the final budget of the Agency pursuant to Article 93 of this Regulation before the beginning of the financial year, adjusting it, where necessary, according to the Community contribution and any other revenue of the Agency;

(d) a multi-annual work programme, which shall be regularly revised.

It shall adopt the internal rules and procedures of the Agency. The rules shall be made public.

It shall perform its duties in relation to the Agency's budget pursuant to Articles 93, 94 and 101.

It shall exercise disciplinary authority over the Executive Director.

It shall adopt its rules of procedure.

It shall appoint the Chairman, the members and alternates of the Board of Appeal in accordance with Article 85.

It shall appoint the members of the Agency committees as set out in Article 81.

It shall forward annually to the budgetary authority in accordance with Article 93(6) any information relevant to the outcome of the evaluation procedures.

Article 75

Composition of the Management Board

1. The Management Board shall be composed of one representative from each Member State nominated by the Council and a maximum of six representatives appointed by the Commission, including three individuals from interested parties without voting rights. Each Member State shall nominate a member to the Management Board. The members thus nominated shall be appointed by the Council.

2. Members shall be appointed on the basis of their relevant experience and expertise in the field of chemical safety or the regulation of chemicals whilst ensuring there is relevant expertise amongst the board members in the fields of general, financial and legal matters.

3. The duration of the term of office shall be four years. The term of office may be renewed once. However, for the first mandate, the Commission shall identify half of its appointees, and the Council shall identify 12 of its appointees, for whom this period shall be six years.

Article 76

Chairmanship of the Management Board

1. The Management Board shall elect a Chairman and a Deputy-Chairman from among the members with voting rights. The Deputy-Chairman shall automatically take the place of the Chairman if he is prevented from attending to his duties.

2. The terms of the office of the Chairman and the Deputy-Chairman shall be two years and shall expire when they cease to be members of the Management Board. The term of office shall be renewable once.

Article 77

Meetings of the Management Board

1. The meetings of the Management Board shall be convened by the invitation of its Chairman or at the request of at least one third of the Board members.

2. The Executive Director shall take part in the meetings of the Management Board, without voting rights.

3. The Chairmen of the Committees or the Chairman of the Forum, as referred to in Article 72(1)(c) to (f), are entitled to attend the meetings of the Management Board without voting rights.

Article 78

Voting of the Management Board

The Management Board shall adopt rules of procedure for voting, including the conditions for a member to vote on behalf of another member. The Management Board shall act by a two-thirds majority of all members with the right to vote.

Article 79

Duties and powers of the Executive Director

1. The Agency shall be managed by its Executive Director, who shall perform his duties in the interests of the Community, and independently of any specific interests.

2. The Executive Director shall be the legal representative of the Agency. He shall be responsible for:
   (a) the day-to-day administration of the Agency;
   (b) managing all the Agency resources necessary for carrying out its tasks;

(c) ensuring that the time-limits laid down in Community legislation for the adoption of opinions by the Agency are complied with;

(d) ensuring appropriate and timely co-ordination between the Committees and the Forum;

(e) concluding and managing necessary contracts with service providers;

(f) the preparation of the statement of revenue and expenditure and the execution of the budget of the Agency pursuant to Article 93;

(g) all staff matters;

(h) providing the secretariat for the Management Board;

(i) preparing draft opinions of the Management Board concerning the proposed rules of procedure of the Committees and of the Forum;

(j) making arrangements, upon request from the Management Board, for the execution of any further function(s) (within the remit of Article 73) allotted to the Agency by delegation from the Commission;

(k) determining the terms and conditions for use of software packages.

3. Each year, the Executive Director shall submit the following to the Management Board for approval:

(a) a draft report covering the activities of the Agency in the previous year, including information about the number of registration dossiers received, the number of substances evaluated, the number of applications for authorisation received, the number of proposals for restriction received by the Agency and opined upon, the time taken for completion of the associated procedures, and the substances authorised, dossiers rejected, substances restricted; complaints received and the action taken; an overview of the activities of the Forum;

(b) a draft programme of work for the coming year;

(c) the draft annual accounts;

(d) the draft forecast budget for the coming year;

(e) a draft multi-annual work programme.

Article 80

Appointment of the Executive Director

1. The Commission shall propose candidates for the post of the Executive Director based on a list following publication of the post in the Official Journal of the European Union and other press or internet sites as appropriate.

2. The Executive Director of the Agency shall be appointed by the Management Board on the grounds of merit and documented administrative and management skills, as well as his relevant experience in the fields of chemical safety or regulation. The Management Board shall take its decision by a two-thirds majority of all members with a right to vote.

   Power to dismiss the Executive Director shall lie with the Management Board, in accordance with the same procedure.

3. The term of the office of the Executive Director shall be 5 years. It may be prolonged by the Management Board once for another period of up to 5 years.

Article 81

Establishment of the Committees

1. Each Member State may nominate candidates to membership of the Risk Assessment Committee. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Members shall be appointed for their role and experience in performing the tasks specified in Article 73(3).

2. Each Member State may nominate candidates to membership of the Socio-economic Analysis Committee. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Members shall be appointed for their role and experience in performing the tasks specified in Article 73(3).

3. Each Member State shall appoint one member to the Member State Committee.

4. The Committees should aim to have a broad range of relevant expertise among their members. To this end the Committees may co-opt a maximum of five additional members chosen on the basis of their specific competence.

   Members of the Committees shall be appointed for a term of three years which shall be renewable.

   The members of the Management Board may not be members of the Committees.

   The members of each Committee may be accompanied by advisers on scientific, technical or regulatory matters.

   The Executive Director or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Committees and working groups convened by the Agency or its committees as observers. Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of the Committee members, or the Management Board.

5. The members of each Committee appointed following nomination by a Member State shall ensure that there is appropriate co-ordination between the tasks of the Agency and the work of their Member State competent authority.

6. The members of the Committees shall be supported by the scientific and technical resources available to the Member States. To this end, Member States shall provide adequate scientific and technical resources to the members of the Committees that they have nominated. Each Member State competent authority shall facilitate the activities of the Committees and their working groups.

7. The Member States shall refrain from giving the members of the Risk Assessment Committee or of the Socio-Economic Analysis Committee, or their scientific and technical advisers and experts, any instruction which is incompatible with the individual tasks of those persons or with the tasks, responsibilities and independence of the Agency.

8. When preparing an opinion, each Committee shall use its best endeavours to reach a consensus. If such a consensus cannot be reached, the opinion shall consist of the position of the majority of members and the minority position(s), with their grounds.

9. Each Committee drafts a proposal for its own rules of procedure, to be approved by the Management Board, within 6 months of the Committees first being appointed.

These rules shall in particular lay down the procedures for replacing members, the procedures for delegating certain tasks to working groups, the creation of working groups and the establishment of a procedure for the urgent adoption of opinions. The Chairman of each Committee shall be an employee of the Agency.

Article 82

Establishment of the Forum

1. Each Member State shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State competent authorities.

The Forum should aim to have a broad range of relevant expertise among its members. To this end the Forum may co-opt a maximum of five additional members chosen on the basis of their specific competence. These members shall be appointed for a term of three years, which shall be renewable.

The members of the Forum may be accompanied by scientific and technical advisers.

The Executive Director of the Agency or his representative and representatives of the Commission shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of Forum members, or the Management Board.

2. The members of the Forum appointed by a Member State shall ensure that there is appropriate co-ordination between the tasks of the Forum and the work of their Member State competent authority.

3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups. The Member States shall refrain from giving the Forum members, or their scientific and technical advisers and experts any instruction which is incompatible with the individual tasks of those persons or with the tasks and responsibilities of the Forum.

4. The Forum shall draft a proposal for its own rules of procedure, to be adopted by the Management Board, within 6 months of the Forum first being appointed.

These rules shall in particular lay down the procedures for appointing and replacing the Chairman, replacing members and the procedures for delegating certain tasks to working groups.

Article 83

Rapporteurs of Committees and use of experts

1. Where, in accordance with Article 73, a Committee is required to take a decision, provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XIV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing.
A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case.
The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

2. Member States shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 73, who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise.

   The Agency shall keep an up-to-date list of experts. The list shall include the experts referred to in the first subparagraph and other experts identified directly by the Secretariat.

3. The provision of services by Committee members or any expert serving on a working group of the Committees or Forum, or performing any other task for the Agency shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.

   The person concerned, or his employer, shall be remunerated by the Agency in accordance with a scale of fees to be included in the financial arrangements established by the Management Board. Where the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration.

4. The provision of services for which there are several potential providers may require a call for an expression of interest:
   (i) if the scientific and technical context allows, and
   (ii) if it is compatible with the duties of the Agency, in particular the need to provide a high level of protection of human health and the environment.

   The Management Board shall adopt the appropriate procedures on a proposal from the Executive Director.

5. The Agency may use the services of experts for the discharge of other specific tasks for which it is responsible.

Article 84

Qualification and interests of members of committees and boards

1. The membership of the Committees and of the Forum shall be made public. Individual members may request that their names not be made public if they believe that such publication could place them at risk. The Executive Director shall decide whether to agree to such requests. When each appointment is published, the professional qualifications of each member shall be specified.

2. Members of the Management Board, the Executive Director and members of the Committees and of the Forum shall make a declaration of commitment to fulfil their duties and a declaration of interests which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing.

3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees and of the Forum and any experts participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall not participate in any voting on the relevant agenda point.

Article 85

Establishment of the Board of Appeal

1. The Board of Appeal shall consist of a Chairman and two other members.

2. The Chairman and the two members shall have alternates who shall represent them in their absence.

3. The Chairman, the other members and the alternates shall be appointed by the Management Board on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures from a list of qualified candidates adopted by the Commission.

   The Management Board may appoint additional members and their alternates, on recommendation by the Executive Director, following the same procedure, if this is necessary to ensure that the appeals can be processed at a satisfactory rate.

4. The qualifications required for the members of the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article 130(3).

5. The Chairman and the members shall have equal voting rights.

Article 86

Members of the Board of Appeal

1. The term of office of the members of the Board of Appeal, including the Chairman and the alternates shall be 5 years. It may be prolonged once.

2. The Members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions.

3. The members of the Board of Appeal may not perform any other duties in the Agency. The function of the Members may be a part-time function.

4. The members of the Board of Appeal may not be removed either from office or from the list during their respective terms, unless there are serious grounds for such removal and the Commission, after obtaining the opinion of the Management Board, takes a decision to this effect.

5. Members of the Board of Appeal may not take part in any appeal proceedings if they have any personal interest therein, or if they have previously been involved as representatives of one of the parties to the proceedings, or if they participated in the decision under appeal.

6. If a member of the Board of Appeal considers for reasons mentioned in paragraph 5 that he must not take part in any appeal proceedings, he shall inform the Board of Appeal accordingly. Members of the Board may be objected to by any party to the appeal proceedings on any of the grounds mentioned in paragraph 5, or if suspected of partiality. No objection may be based on the nationality of members.

7. The Board of Appeal shall decide as to the action to be taken in the cases specified in paragraphs 5 and 6 without the participation of the member concerned. For the purposes of taking this decision, the member concerned shall be replaced on the Board of Appeal by an alternate.

Article 87

Decisions subject to appeal

1. An appeal may be brought against decisions of the Agency taken pursuant to Article 7, Article 18, Article 25(5),Article 28(2) and (3), Article 49.

2. An appeal lodged pursuant to paragraph 1 shall have suspensive effect.

Article 88

Persons entitled to appeal, time-limits, fees and form

1. Any natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former.

2. The appeal, together with the statements of the grounds thereof, shall be filed in writing to the Agency within 3 months of the notification of the decision to the person concerned, or in the absence thereof, of the day on which it became known to the latter, unless otherwise provided in this Regulation.

3. A fee may be payable by persons bringing an appeal against an Agency decision, in accordance with Title VIIIa.

Article 89

Examination and decisions on appeal

1. If, after consultation with the Chairman of the Board of Appeal, the Executive Director considers the appeal to be admissible and well founded he may rectify the decision within 30 days of the appeal being filed in accordance with Article 88(2).

2. In cases other than those referred to in paragraph 1, the Chairman of the Board of Appeal shall examine whether the appeal is admissible within 30 days of the appeal being filed in accordance with Article 88(2). In the affirmative, the appeal shall be remitted to the Board of Appeal for examination of the grounds. Parties to the appeal proceedings shall be entitled to make an oral presentation during the procedure.

3. The Board of Appeal may exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.

4. The procedures for the Board of Appeal shall be determined by the Commission in accordance with the procedure referred to in Article 130(3).

Article 90

Actions before the European Court of First Instance and the Court of Justice of the European Communities

1. An action may be brought before the European Court of First Instance or the Court of Justice of the European Communities, in accordance with Articles 225 or 230 of the Treaty, contesting a decision taken by the Board of Appeal or, in cases where no right of appeal lies before the Board, by the Agency.

2. Should the Agency fail to take a decision, proceedings for failure to act may be brought before the European Court of First Instance or the Court Justice of the European Communities in accordance with Articles 225 or 232 of the Treaty.

3. The Agency shall be required to take the necessary measures to comply with the judgment of the European Court of First Instance or the Court of Justice of the European Communities.

Article 91

Complaints to the Ombudsman

[deleted]

Article 92

Conflicts of opinion with other bodies

1. The Agency shall take care to ensure early identification of potential sources of conflict between its opinions and those of other bodies established under Community law, including Community Agencies, carrying out a similar task in relation to issues of common concern.

2. Where the Agency identifies a potential source of conflict, it shall contact the body concerned in order to ensure that any relevant scientific or technical information is shared and to identify the scientific or technical points which are potentially contentious.

3. Where there is a fundamental conflict over scientific or technical points and the body concerned is a Community Agency or a scientific committee, the Agency and the body concerned shall work together either to solve the conflict or to submit a joint document to the Commission clarifying the scientific and/or technical points of conflict.

Article 93

The budget of the Agency

1. The revenues of the Agency shall consist of:
   (a) a subsidy from the Community, entered in the general budget of the European Communities (Commission Section);
   (b) the fees paid by undertakings;
   (c) any voluntary contribution from the Member States.

2. The expenditure of the Agency shall include the staff, administrative, infrastructure and operational expenses.

3. By 15 February of each year at the latest, the Executive Director shall draw up a preliminary draft budget covering the operational expenditure and the programme of work anticipated for the following financial year, and shall forward this preliminary draft to the Management Board together with an establishment plan accompanied by a provisional list of posts.

4. Revenue and expenditure shall be in balance.

5. Each year the Management Board, on the basis of a draft drawn up by the Executive Director, shall produce an estimate of revenue and expenditure for the Agency for the following financial year. This estimate, which shall include a draft establishment plan, shall be forwarded by the Management Board to the Commission by 31 March at the latest.

6. The estimate shall be forwarded by the Commission to the European Parliament and the Council, hereinafter "the budgetary authority", together with the preliminary draft budget of the European Communities.

7. On the basis of the estimate, the Commission shall enter in the preliminary draft budget of the European Communities the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.

8. The budgetary authority shall authorise the appropriations for the subsidy to the Agency.

   The budgetary authority shall adopt the establishment plan for the Agency.

9. The budget of the Agency shall be adopted by the Management Board. It shall become final following final adoption of the general budget of the European Communities. Where appropriate, it shall be adjusted accordingly.

10. Any modification to the budget, including the establishment plan, shall follow the procedure referred to above.

11. The Management Board shall, without delay, notify the budgetary authority of its intention to implement any project which may have significant financial implications for the funding of its budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

    Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Management Board within a period of 6 weeks from the date of notification of the project.

Article 94

Implementation of the Agency's budget

1. The Executive Director shall perform the duties of the authorising officer and shall implement the Agency's budget.

2. Monitoring of the commitment and payment of all the Agency's expenditure and of the establishment and recovery of all the Agency's revenue shall be carried out by the Accounting Officer of the Agency.

3. By 1 March at the latest following each financial year, the Agency's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of Council Regulation (EC, Euratom) No 1605/2002[45].

4. By 31 March at the latest following each financial year, the Commission's accounting officer shall forward the Agency's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for that financial year shall also be forwarded to the European Parliament and the Council.

5. On receipt of the Court of Auditors' observations on the Agency's provisional accounts, pursuant to Article 129 of Regulation (EC, Euratom) No 1605/2002, the Director shall draw up the Agency's final accounts under his own responsibility and forward them to the Management Board for an opinion.

6. The Management Board shall deliver an opinion on the Agency's final accounts.

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[45] OJ L 248, 16.9.2002, p. 1.

7. By 1 July of the following year at the latest, the Executive Director shall send the final accounts, together with the opinion of the Management Board, to the European Parliament, the Council, the Commission and the Court of Auditors.

8. The final accounts shall be published.

9. The Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He shall also send this reply to the Management Board.

10. The European Parliament, upon a recommendation from the Council, shall, before 30 April of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

Article 95

Fees

[deleted]

Article 96

Combating fraud

1. In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council[46] shall apply without restrictions to the Agency.

2. The Agency shall be bound by Interinstitutional Agreement 1999/1074/Euratom[47] concerning internal investigations by the European Anti-Fraud Office (OLAF) and shall issue, without delay, the appropriate provisions applicable to all of its staff.

[46] OJ L 136, 31.5.1999, p. 1.
[47] OJ L 136, 31.5.1999, p. 15.

3. The decisions concerning funding and the implementing agreements and instruments resulting from them shall explicitly stipulate that the Court of Auditors and OLAF may carry out, if necessary, on-the-spot checks of the recipients of the Agency's funding and the agents responsible for allocating it.

Article 97

Financial regulation

The financial rules applicable to the Agency shall be adopted by the Management Board after the Commission has been consulted. They may not depart from Regulation (EC, Euratom) No 2343/2002 unless specifically necessary for the Agency's operation and with the Commission's prior consent.

Article 98

Legal personality of the Agency

1. The Agency shall be a body of the Community and shall have legal personality. In each Member State it shall enjoy the most extensive legal capacity accorded to legal persons under their laws. In particular it may acquire and dispose of movable and immovable property and may be a party to legal proceedings.

2. The Agency shall be represented by its Executive Director.

Article 99

Liability of the Agency

1. The contractual liability of the Agency shall be governed by the law applicable to the contract in question. The Court of Justice of the European Communities shall have jurisdiction pursuant to any arbitration clause contained in a contract concluded by the Agency.

2. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or by its servants in the performance of their duties.

The Court of Justice of the European Communities shall have jurisdiction in any dispute relating to compensation for such damages.

3. The personal financial and disciplinary liability of its servants towards the Agency shall be governed by the relevant rules applying to the staff of the Agency.

Article 100

Privileges and immunities of the Agency

The Protocol on the Privileges and Immunities of the European Communities shall apply to the Agency.

Article 101

Staff rules and regulations

1. The staff of the Agency shall be subject to the Regulations and Rules applicable to officials and other servants of the European Communities. In respect of its staff, the Agency shall exercise the powers which have been devolved to the appointing authority.

2. The Management Board shall, in agreement with the Commission, adopt the necessary implementing provisions.

3. The Agency's staff shall consist of officials assigned or seconded by the Commission or Member States on a temporary basis and of other servants recruited by the Agency as necessary to carry out its tasks. The Agency shall recruit its personnel on the basis of a staffing plan to be included in the multi-annual work programme referred to in Article 74(d).

Article 101a

Languages

1. The provisions laid down in Regulation No 1 of 15 April 1958 determining the languages to be used in the European Economic Community shall apply to the Agency.

2. The translation services required for the functioning of the Agency shall be provided by the Translation Centre of the bodies of the European Union.

Article 102

Duty of confidentiality

Members of the Management Board, members of the Committees and of the Forum, experts and officials and other servants of the Agency, shall be required, even after their duties have ceased, not to disclose information of the kind covered by the duty of professional secrecy.

Article 103

Participation of third countries

The Management Board may, in agreement with the relevant Committee or the Forum, invite representatives of third countries to participate in the work of the Agency.

Article 104

Participation of international organisations

The Management Board may, in agreement with the relevant Committee or the Forum, invite representatives of international organisations with interests in the field of chemicals regulation to participate as observers in the work of the Agency.

Article 105

Contacts with stakeholder organisations

The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and relevant stakeholder organisations.

Article 106

Rules on transparency

To ensure transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in preparations or in articles which is not of a confidential nature.

Article 107

Relations with relevant Community Bodies

1. The Agency shall co-operate with other Community bodies to ensure mutual support in the accomplishment of their respective tasks in particular to avoid duplication of work.

2. The Executive Director, having consulted the Committee on Risk Assessment and the European Food Safety Authority, shall establish rules of procedure concerning substances for which an opinion has been sought in a food safety context. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.

   This Title shall not otherwise affect the competences vested in the European Food Safety Authority.

3. This Title shall not affect the competences vested in the European Agency for the Evaluation of Medicinal Products.

4. The Executive Director, having consulted the Committee on Risk Assessment, the Committee on Socio-economic Analysis and the Advisory Committee on Safety, Hygiene and Health Protection at Work, shall establish rules of procedure concerning worker protection issues. These rules of procedure shall be adopted by the Management Board, in agreement with the Commission.

This Title shall not affect the competences vested in the Advisory Committee on Safety, Hygiene and Health Protection at Work and the European Agency for Health and Safety at Work.

Article 108

Formats and software for submission of information to the Agency

The Agency shall specify formats and make them available free of charge, and software packages and make them available on its website for any submissions to the Agency. Member States, manufactures, importers, distributors or downstream users shall use these formats and packages in their submissions to the Agency pursuant to this Regulation. In particular, the Agency shall make available software tools to facilitate the submission of all information relating to substances registered in accordance with Article 11(1).

For the purposes of registration, the format of the technical dossier referred to in Article 9(a) shall be IUCLID. The Agency shall co-ordinate the further development of this format with the OECD to ensure maximum harmonisation.

TITLE X
CLASSIFICATION AND LABELLING INVENTORY

Article 109

Scope

This Title shall apply to:

(a) substances subject to registration by a manufacturer or importer;

(b) substances within the scope of Article 1 of Directive 67/548/EEC, which meet the criteria for classification as dangerous in accordance with that Directive, and which are placed on the market either on their own, or in a preparation above the concentration limits specified in Directive 1999/45/EC, where relevant, which results in the classification of the preparation as dangerous.

Article 110

Obligation to notify the Agency

1. Any importer or manufacturer, or group of importers or manufacturers, who place on the market a substance within the scope of Article 109, shall notify to the Agency the following information in order for it to be included in the inventory in accordance with Article 111, unless submitted as part of the registration:
   (a) the identity of the manufacturer or importer responsible for placing the substance(s) on the market as specified in section 1 of Annex IV;
   (b) the identity of the substance(s) as specified in part 2.1 to 2.3.4 of Annex IV;
   (c) the hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;
   (d) the resulting hazard label for the substance(s), resulting from application of Article 23 (c) to (f), of Directive 67/548/EEC;
   (e) specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.

2. [deleted]

3. Where the obligation under paragraph 1 results in different entries on the inventory for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory.

4. The information listed in paragraph 1 shall be updated by the notifier(s) whenever:
   (a) any new scientific or technical information is generated which results in a change to the classification and labelling of the substance;
   (b) notifiers and registrants of differing entries for a single substance come to an agreed entry in accordance with paragraph 3.

Article 111

The classification and labelling inventory

1. A classification and labelling inventory, listing the information referred to in Article 110(1), both for information notified under Article 110(1) as well as for information submitted as part of a registration, shall be established and maintained by the Agency in the form of a database. The information in this database identified in Article 116(1) shall be publicly accessible. The Agency shall grant access to the other data on each substance in the inventory to the notifiers and registrants who have submitted information on that substance in accordance with Article 27(1).

   The Agency shall update the inventory when it receives updated information in accordance with Article 110(4).

2. In addition to the information referred to in paragraph 1, the Agency shall record the following information, where appropriate, against each entry:
   (a) whether, in respect of the entry, there is a harmonised classification and labelling at Community level by inclusion in Annex I of Directive 67/548/EEC;
   (abis) whether, in respect of the entry, it is a joint entry between registrants of the same substance as per Article 10(1);

(b) if the entry differs from another entry on the inventory for the same substance;

(c) the relevant registration number(s), if available.

Article 112

Harmonisation of classification and labelling

1. Harmonised classification and labelling at Community level shall, from the entry into force of this Regulation, normally be added to Annex I of Directive 67/548/EEC for classification of a substance as carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, or as a respiratory sensitiser. Harmonised classification and labelling for other effects may also be added to Annex I of Directive 67/548/EEC on a case-by-case basis if justification is provided demonstrating the need for action at Community level. To this end, Member State competent authorities may submit proposals to the Agency for harmonised classification and labelling in accordance with Annex XIV.

2. The Risk Assessment Committee shall adopt an opinion on the proposal, giving parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission, which shall take a decision in accordance with Article 4(3) of Directive 67/548/EEC.

Article 113

Transitional arrangements

The obligations set out in Article 110 shall apply from the deadline established under Article 21(1).

TITLE XI
INFORMATION

Article 114

Reporting

1. Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 124.

   The first report shall be submitted three years after the entry into force of this Regulation.

2. Every five years, the Agency shall submit to the Commission a report on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 10 and an overview of the explanations given for submitting information separately.

   However, the first report shall be submitted four years after entry into force of this Regulation.

3. Every five years, the Commission shall publish a general report on the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1 and 2.

   However, the first report shall be published five years after entry into force of this Regulation.

Article 115

Access to information

1. Regulation (EC) No 1049/2001 of the European Parliament and the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents shall apply to documents held by the Agency.

1bis. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person:

(a) details of the full composition of a preparation;
(b) the precise use, function or application of a substance or preparation;
(c) the precise tonnage of the substance or preparation manufactured or placed on the market;
(d) links between a manufacturer or importer and his downstream users.

Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph.

2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 within 12 months of entry into force of this Regulation.

3. Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the Treaty respectively.

5. [deleted]

6. [deleted]

7. [deleted]

Article 116

Electronic Public Access

1. The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 73(2)(d):

(a) the trade name(s) of the substance;

(b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC;

(c) if applicable, the name of the substance as given in EINECs;

(cbis) the classification and labelling of the substance;

(d) physicochemical data concerning the substance and on pathways and environmental fate;

(e) the result of each toxicological and ecotoxicological study;

(f) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;

(g) [delete]

(h) the guidance on safe use provided in accordance with section 4 and 5 of Annex IV;

(i) [deleted]

(j) analytical methods if requested in accordance with Annex VII or VIII which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

(k) [deleted]

(l) [deleted]

1bis. The following information on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 73(2)(d) except where a party submitting the information submits a justification in accordance with Article 9(a)(xa), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

(a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;

(b) the total tonnage band (i.e. 1-10 tonnes, 10-100 tonnes, 100-1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;

(c) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);

(d) information, other than that listed in subparagraphs (a) – (h), (j) and (k) of paragraph 1 above, contained in the safety data sheet.

2. [deleted]

Article 117

Cooperation with third countries and international organisations

Notwithstanding Articles 115 and 116, information received by the Agency under this Regulation may be disclosed to any government or national authority of a third country or an international organisation in accordance with an agreement concluded between the Community and the third party concerned under Regulation (EC) No 304/2003 of the European Parliament and of the Council[48] or under Article 181a (3) of the Treaty, provided that both the following conditions are met:

(a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;

(b) the third party protects the confidential information as mutually agreed.

[48] OJ L 63, 6.3.2003, p. 1.

TITLE XII
COMPETENT AUTHORITIES

Article 118

Appointment

Member States shall appoint the competent authority or competent authorities responsible for performing the tasks allotted to competent authorities under this Regulation and for co-operating with the European Commission and the Agency in the implementation of this Regulation. Member States shall place adequate resources at the disposal of the competent authorities to enable them, in conjunction with any other available resources, to fulfil their tasks under this Regulation in a timely and effective manner.

Article 119

Co-operation between competent authorities

The competent authorities shall co-operate with each other in the performance of their tasks under this Regulation and shall give the competent authorities of other Member States all the necessary and useful support to this end.

Article 120

Communication to the public of information on risks of substances

The competent authorities of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The Commission shall draw up guidelines in accordance with Article 130(3) with a view to co-ordinating Member States in these activities.

Article 121

Other responsibilities of the competent authorities

Competent authorities shall electronically submit any available information to the Agency that they hold on substances registered in accordance with Article 11(1) whose dossiers do not contain the full information referred to in Annex V, in particular whether enforcement or monitoring activities have identified suspicions of risk. The competent authority shall update this information as appropriate.

Member States shall establish national helpdesks to provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation, in particular in relation to the registration of substances in accordance with Article 11(1), in addition to the operational guidance documents provided by the Agency under Article 73(2)(f).

TITLE XIII
ENFORCEMENT

Article 122

Tasks of the Member States

Member States shall maintain a system of official controls and other activities as appropriate to the circumstances.

Article 123

Sanctions for non-compliance

1. The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of the present Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission no later than eighteen months after entry into force of this Regulation and shall notify it without delay of any subsequent amendment affecting them.

2. [deleted]

Article 124

Report

The report referred to in Article 114(1) shall, in relation to enforcement, include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken pursuant to Articles 122 and 123 during the previous reporting period. The common issues to be covered in the reports shall be agreed by the Forum. The Agency shall make these reports available to the Commission and the Forum.

TITLE XIV

TRANSITIONAL AND FINAL PROVISIONS

Article 125

Free movement clause

1. Subject to paragraph 2, Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a preparation or in an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.

2. Nothing in this Regulation shall prevent Member States from maintaining or laying down national rules to protect workers, health and the environment applying in cases where this Regulation does not harmonise the requirements on manufacture, placing on the market or use.

Article 126

Safeguard Clause

1. Where a Member State has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance, on its own, in a preparation or in an article, even if satisfying the requirements of this Regulation, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based.

2. The Commission shall take a decision in accordance with the procedure referred to in Article 130(3) within 60 days of receipt of the information from the Member State. This decision shall either:

(a) authorise the provisional measure for a time period defined in the decision; or

(b) require the Member State to revoke the provisional measure.

3. If, in the case of a decision as referred to in point (a) of paragraph 2, the provisional measure taken by the Member State consists in a restriction on the placing on the market or use of a substance, the Member State concerned shall initiate a Community restrictions procedure by submitting to the Agency a dossier, in accordance with Annex XIV, within 3 months of the date of the Commission decision.

4. In the case of a decision as referred to in point (a) of paragraph 2, the Commission shall consider whether the present Regulation needs to be adapted.

Article 127

Statement of reasons for decisions

The Competent Authorities, the Agency and the Commission shall state the reasons for all decisions they take under this Regulation.

Article 128

Amendments to the Annexes

The Annexes may be amended in accordance with the procedure referred to in Article 130(3).

Article 129

Implementing legislation

The measures necessary for the efficient implementation of this Regulation shall be adopted in accordance with the procedure referred to in Article 130(3).

Article 130

Committee procedure

1. The Commission shall be assisted by a Committee composed of representatives of the Member States and chaired by the representative of the Commission.

2. Where reference is made to this paragraph, the advisory procedure laid down in Article 3 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

3. Where reference is made to this paragraph, the regulatory procedure laid down in Article 5 of Decision 1999/468/EC shall apply, in compliance with Article 7(3) and Article 8 thereof.

4. The period provided for in Article 5(6) of Decision 1999/468/EC shall be three months.

Article 131

Transitional measures regarding the Agency

1. The Commission shall provide the necessary support towards the setting up of the Agency.

1bis. For that purpose, until such time as the Executive Director is appointed in accordance with Article 80, the Commission, on behalf of the Agency, thereby using the budget provided for the latter, may appoint personnel, including a person who shall fulfil the administrative functions of the Executive Director on an interim basis, and conclude other contracts.

2. [deleted]

3. [deleted]

Article 131bis

Transitional measures regarding notified substances

1. The requests to notifiers to provide further information to the competent authority in accordance with Article 16(2) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 49.

2. A request to a notifier to provide further information for a substance in accordance with Article 16(1) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 49a.

   Such substance shall be regarded as being included in the Community rolling action plan in accordance with Article 43a(2) and shall be regarded as being chosen in accordance with Article 43abis(2) by the Member State whose competent authority has requested further information in accordance with Article 16(1) of Directive 67/548/EEC.

Article 131ter

Transitional measures regarding existing substances

1. The requests to manufacturers and importers to submit information to the Commission made by a Commission Regulation in application of Article 10(2) of Regulation (EEC) No 793/93, shall be considered as decisions adopted in accordance with Article 49a.

   The competent authority for the substance shall be the competent authority from the Member State identified as rapporteur in accordance with Article 10(1) of Regulation (EEC) No 793/93 and shall carry out the tasks of Article 44(2) and 46.

2. The requests to manufacturers and importers to submit information to the Commission made by a Commission Regulation in application of Article 12(2) of Regulation (EEC) No 793/93, shall be considered as decisions adopted in accordance with Article 49a.The Agency shall identify the competent authority for the substance to carry out the tasks of Article 44(2) and 46.

3. A Member State whose rapporteur has not forwarded within 12 months of entry into force of this Regulation, the risk evaluation and, where appropriate, the strategy for limiting the risks, in accordance with Article 10(3) of Regulation (EEC) No 793/93, shall:
   (a) document information on hazard and risk in accordance with Annex XIV, Part B;
   (b) apply Article 66(2) on the basis of the dossier referred to in (a); and
   (c) prepare a documentation of how it considers that any other risks identified would need to be addressed by action other than an amendment of Annex XVI.

   The information referred to above shall be submitted to the Agency within 18 months of entry into force of this Regulation.

Article 132

Transitional measures regarding restrictions

1. Within 18 months of the entry into force of this Regulation, the Commission shall, if necessary, prepare a draft amendment to Annex XVI in accordance with either of the following:
   (a) any risk evaluation and recommended strategy for limiting risks that has been adopted at Community level in accordance with Article 11 of Regulation (EEC) No 793/93 as far as it includes proposals for restrictions in accordance with Title VIII but for which a decision under Directive 76/769/EEC has not yet been taken;
   (b) any proposal, which has been submitted to the relevant institutions but has not yet been adopted, concerning the introduction of restrictions under Directive 76/769/EEC.

2. Until 18 months after the entry into force of this Regulation, any dossier referred to in Article 126(3) shall be submitted to the Commission. The Commission shall, if necessary, prepare a draft amendment to Annex XVI.

Article 133

Review

1. Twelve years after entry into force of this Regulation, the Commission shall carry out a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. On the basis of this review, the Commission may, if appropriate, present legislative proposals to extend this obligation.

2. The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:
   (a) the risks posed by polymers in comparison with other substances;
   (b) the need, if any, of registering certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of health and the environment on the other.

3. The report, referred to in Article 114(3), on the experience acquired with the operation of this Regulation shall include a review of the requirements relating to registration of substances manufactured or imported only in quantities starting at 1 tonne but less than 10 tonnes per year per manufacturer or importer. On the basis of that review, the Commission may present legislative proposals to modify the information requirements for substances manufactured or imported in quantities of 1 tonne or more up to 10 tonnes per year per manufacturer or importer, taking into account the latest developments, for example in relation to alternative testing and (quantitative) structure-activity relationships ((Q)SARs).

3bis. The Commission shall carry out a review of Annexes I, II and III within 12 months after entry into force of this Regulation, with a view to proposing amendments, if appropriate, to them in accordance with Article 130(3).

Article 134

Repeal

Directives 76/769/EEC and 91/155/EEC are repealed.

Directives 93/105/EEC and 2000/21/EC and Regulations (EEC) No 793/93 and (EC) No 1488/94 are repealed on the day falling twelve months after entry into force of this Regulation.

Directive 93/67/EEC is repealed on the day falling 14 months after entry into force of this Regulation. References to the repealed acts shall be construed as references to this Regulation.

Article 135

Amendment of Directive 1999/45/EC

Article 14 of Directive 1999/45/EC is deleted.

Article 136

Amendment of Regulation (EC) No 850/2004

[deleted]

Article 137

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

2. Titles II, III, V, VI, VII, X and XI as well as Article 125 shall apply from the day falling twelve months after the entry into force of this Regulation.

3. [deleted]

4. Articles 66 to 70 shall apply from the day falling 18 months after the entry into force of this Regulation.

4bis. Article 131bis shall apply from the day falling 14 months after entry into force of this Regulation, Article 131ter shall apply from the day falling twelve months after the entry into force of this Regulation.

5. [deleted]

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, […]

For the European Parliament	For the Council
The President	The President
[…]	[…]

ANNEX I

GENERAL PROVISIONS FOR ASSESSING SUBSTANCES AND PREPARING CHEMICAL SAFETY REPORTS

0. INTRODUCTION

0.1. The purpose of this Annex is to set out how manufacturers and importers are to assess and document that the risks arising from the substance they manufacture or import are adequately controlled during manufacture and their own use(s) and that others further down the supply chain can adequately control the risks.

0.1a The chemical safety assessment shall be prepared by one or more competent person(s) who have appropriate experience and received appropriate training, including refresher training.

0.2. The chemical safety assessment of a manufacturer shall address the manufacture of a substance and all the identified uses. The chemical safety assessment of an importer shall address all identified uses. The chemical safety assessment shall consider the use of the substance on its own (including any major impurities and additives), in a preparation and in an article, as defined by the identified uses. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions.

0.3. Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or "category" of substances. If the manufacturer or importer considers that the chemical safety assessment carried out for one substance is sufficient to assess and document that the risks arising from another substance or from a group or "category" of substances are adequately controlled then he can use that chemical safety assessment for the other substance or group or "category" of substances. The manufacturer or importer shall provide a justification for this.

0.4. The chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. Manufacturers or importers submitting a proposal for testing in accordance with Annexes VII and VIII shall record this under the relevant heading of the chemical safety report. Available information from assessments carried out under other international and national programmes shall be included. Where available and appropriate, an assessment carried out under Community legislation (e.g. risk assessments completed under Regulation 793/93) shall be taken into account in the development of, and reflected in, the chemical safety report. Deviations from such assessments shall be justified.

Thus the information to be considered includes information related to the hazards of the substance, the exposure arising from the manufacture or import, the identified uses of the substance, operational conditions and risk management measures applied or recommended to downstream users to be taken into account.

In accordance with Annex IX, Section 3, in some cases, it may not be necessary to generate missing information, because risk management measures and operational conditions which are necessary to control a well-characterised risk may also be sufficient to control other potential risks, which will not therefore need to be characterised precisely.

If the manufacturer or importer considers that further information is necessary for producing his chemical safety report and that this information can only be obtained by performing tests in accordance with Annex VII or VIII, he shall submit a proposal for a testing strategy, explaining why he considers that additional information is necessary and record this in the chemical safety report under the appropriate heading. While waiting for results of further testing, he shall record in his chemical safety report, and include in the exposure scenario developed, the interim risk management measures that he has put in place and those he recommends to downstream users intended to manage the risks being explored.

0.5. A chemical safety assessment performed by a manufacturer or an importer for a substance shall include the following steps in accordance with the respective sections of this Annex:

1. Human health hazard assessment
2. Human health hazard assessment of physicochemical properties
3. Environmental hazard assessment
4. PBT and vPvB assessment

If as a result of steps 1 to 4 the manufacturer or importer concludes that the substance or the preparation meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB, the chemical safety assessment shall also consider the following steps:

5. Exposure assessment

5.1 The generation of exposure scenario(s) or the generation of relevant use and exposure categories if appropriate

5.2 Exposure estimation

6. Risk characterisation

A summary of all the relevant information used in addressing the points above, shall be presented under the relevant heading of the chemical safety report (Section 7).

0.6. The main element of the exposure part of the chemical safety report is the description of the exposure scenario(s) implemented for the manufacturer's production, the manufacturer or importer's own use, and those recommended by the manufacturer or importer to be implemented for the identified use(s).

An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These sets of conditions contain a description of both the risk management measures and operational conditions which the manufacturer or importer has implemented or recommends to be implemented by downstream users.

If the substance is placed on the market, the relevant exposure scenario(s), including the risk management measures and operational conditions shall be included in an annex to the safety data sheet in accordance with Annex Ia.

0.7. The level of detail required in describing an exposure scenario will vary substantially from case to case, depending on the use of a substance, its hazardous properties and the amount of information available to the manufacturer or importer. Exposure scenarios may describe the appropriate risk management measures for several individual processes or uses of a substance. An exposure scenario may thereby cover a large range of processes or uses. Exposure scenarios covering a wide range of processes or uses may be referred to as Exposure Categories. Further mention of Exposure Scenario in Annex I and Ia includes Exposure Categories if they are developed.

0.8. [deleted]

0.9. Where information is not necessary in accordance with Annex IX , this fact shall be stated under the appropriate heading of the chemical safety report and a reference shall be made to the justification in the technical dossier. This fact that no information is required shall also be stated in the safety data sheet.

0.10. In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in Sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and summarised in the safety data sheet.

0.10a When assessing the risk of the use of one or more substances incorporated into a special preparation (for instance alloys), the way the constituent substances are bonded in the chemical matrix shall be taken into account.

0.11. Where the methodology described in this Annex is not appropriate, details of alternative methodology used shall be explained and justified in the chemical safety report.

0.12. Part A of the chemical safety report shall include a declaration that the risk management measures outlined in the relevant exposure scenarios for the manufacturer's or importer's own use(s) are implemented by the manufacturer or importer and that those exposure scenarios for the identified uses are communicated to distributors and downstream users in the safety data sheet(s).

1. HUMAN HEALTH HAZARD ASSESSMENT

1.0. Introduction

1.0.1. The objective of the human health hazard assessment shall be:

- to determine the classification and labelling of a substance in accordance with Directive 67/548/EEC; and
- to derive levels of exposure to the substance above which humans should not be exposed. This level of exposure is known as the Derived No-Effect Level (DNEL).

1.0.2. The human health hazard assessment shall consider the toxicokinetic profile (i.e.; absorption, metabolism, distribution and elimination) of the substance and the following groups of effects, (1) acute effects (acute toxicity, irritation and corrosivity), (2) sensitisation, (3) repeated dose toxicity and (4) CMR effects (carcinogenity, mutagenicity and toxicity for reproduction). Based on all the available information, other effects shall be considered when necessary.

1.0.3. The hazard assessment shall comprise the following four steps:

Step 1. Evaluation of non-human information

Step 2. Evaluation of human information

Step 3. Classification and Labelling

Step 4. Derivation of Derived No-Effect Levels (DNELs)

1.0.4. The first three steps shall be undertaken for every effect for which information is available and shall be recorded under the relevant section of the Chemical Safety Report and where required and in accordance with Article 29, summarised in the Safety Data Sheet under headings 2 and 11.

1.0.5. For any effect for which no relevant information is available, the relevant section shall contain the sentence "*This information is not available*". The justification, including reference to any literature search carried out, shall be included in the technical dossier.

1.0.6. Step 4 of the human health hazard assessment shall be undertaken by integrating the results from the first three steps and shall be included under the relevant heading of the Chemical Safety Report and summarised in the Safety Data Sheet under heading 8.1.

1.1. Step 1: Evaluation of non-human information

1.1.1. The evaluation of non-human information shall comprise:

– the hazard identification for the effect based on all available non-human information;

– the establishment of the quantitative dose (concentration) – response (effect) relationship.

1.1.2. When it is not possible to establish the quantitative dose (concentration) – response (effect) relationship, then this should be justified and a semi-quantitative or qualitative analysis shall be included. For instance, for acute effects it is usually not possible to establish the quantitative dose (concentration) – response (effect) relationship on the basis of the results of a test conducted in accordance with Annex X. In such cases it suffices to determine whether and to which degree the substance has an inherent capacity to cause the effect.

1.1.3. All non-human information used to assess a particular effect on humans and to establish the dose (concentration) – response (effect) relationship, shall be briefly presented, if possible in the form of a table or tables, distinguishing between *in vitro*, *in vivo* and other information. The relevant test results (e.g., LD50, NO(A)EL or LO(A)EL) and test conditions (e.g., test duration, route of administration) and other relevant information shall be presented, in internationally recognised units of measurement for that effect.

1.1.4 If one study is available then a robust study summary should be prepared for that study. If there are several studies addressing the same effect, then, having taken into account possible variables (e.g. conduct, adequacy, relevance of test species, quality of results etc.), normally the study or studies giving rise to the highest concern shall be used to establish the Derived No-Effect Levels and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment. If the study or studies giving rise to the highest concern are not used, then this shall be fully justified and included as part of the technical dossier, not only for the study being used but also for all studies demonstrating a higher concern than the study being used. It is important irrespective of whether hazards have been identified or not that the validity of the study be considered.

1.2. Step 2: Evaluation of human information

If no human information is available, this part shall contain the statement "*No human information is available*". However, if human information is available, it shall be presented, if possible in the form of a table.

1.3. Step 3: Classification and Labelling

1.3.1. The appropriate classification and labelling developed in accordance with the criteria in Directive 67/548/EEC shall be presented and justified. Where applicable Specific Concentration limits, resulting from the application of Article 4 (4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC, shall be presented and, if they are not included in Annex I to Directive 67/548/EEC, justified. The assessment should always include a statement as to whether the substance fulfils or does not fulfil the criteria given in Directive 67/548/EEC for CMR, categories 1 and 2.

1.3.2. If the information is inadequate to decide whether a substance should be classified for a particular end-point, the registrant shall indicate and justify the action or decision he has taken as a result.

1.4. Step 4: Identification of Derived No-Effect Level(s) (DNEL(s))

1.4.1. Based on the outcomes of steps 1 to 2, a Derived No-Effect Level(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. For some endpoints, especially mutagenicity and carcinogenicity, the available information may not enable a threshold, and therefore a DNEL, to be established. If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the available information and the exposure scenario(s) in Section 5 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g., workers, consumers and humans liable to exposure indirectly via the environment) and possibly for certain vulnerable sub-populations (e.g. children, pregnant women) and for different routes of exposure. A full justification shall be given specifying, *inter alia*, the choice of the information used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. If more than one route of exposure is likely to occur, then a DNEL shall be established for each route of exposure and for the exposure from all routes combined. When establishing the DNEL, the following factors shall, *inter alia*, be taken into account:

(i) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;

(ii) the nature and severity of the effect;

(iii) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies.

1.4.2. If it is not possible to identify a DNEL, then this shall be clearly stated and fully justified.

2. PHYSICOCHEMICAL HAZARD ASSESSMENT

2.1. The objective of the hazard assessment for physicochemical properties shall be to determine the classification and labelling of a substance in accordance with Directive 67/548/EEC.

2.2. As a minimum, the potential effects to human health shall be assessed for the following physicochemical properties:

– explosivity,
– flammability,
– oxidising potential.

If the information are inadequate to decide whether a substance should be classified for a particular end-point, the registrant shall indicate and justify the action or decision he has taken as a result.

2.3. The assessment of each effect shall be presented under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 29, summarised in the Safety Data Sheet under headings 2 and 9.

2.4. For every physicochemical property, the assessment shall entail an evaluation of the inherent capacity of the substance to cause the effect resulting from the manufacture and identified uses.

2.5. The appropriate classification and labelling developed in accordance with the criteria in Directive 67/548/EEC shall be presented and justified.

3. ENVIRONMENTAL HAZARD ASSESSMENT

3.0. Introduction

3.0.1. The objective of the environmental hazard assessment shall be to determine the classification and labelling of a substance in accordance with Directive 67/548/EEC and to identify the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur. This concentration is known as the Predicted No-Effect Concentration (PNEC).

3.0.2. The environmental hazard assessment shall consider the potential effects on the environment, comprising the (1) aquatic (including sediment), (2) terrestrial and (3) atmospheric compartments, including the potential effects that may occur (4) via food-chain accumulation. In addition, the potential effects on the (5) microbiological activity of sewage treatment systems shall be considered. The assessment of the effects on each of these five environmental spheres shall be presented under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 29, summarised in the Safety Data Sheet under headings 2 and 12.

3.0.3. For any environmental sphere, for which no effect information is available, the relevant section of the chemical safety report shall contain the sentence "*This information is not available* ". The justification, including reference to any literature research carried out, shall be included in the technical dossier. For any environmental sphere for which information is available, but the manufacturer or importer believes that it is not necessary to conduct the hazard assessment, the manufacturer or importer shall present a justification, with reference to pertinent information, under the relevant heading of the Chemical Safety Report (Section 7) and where required and in accordance with Article 29, summarised in the Safety Data Sheet under heading 12.

3.0.4. The hazard assessment shall comprise the following three steps, which shall be clearly identified as such in the Chemical Safety Report:

Step 1. Evaluation of information

Step 2. Classification and Labelling

Step 3. Derivation of the Predicted No-Effect Concentration (PNEC).

3.1. Step 1: Evaluation of information

3.1.1. The evaluation of all available information shall comprise:

- the hazard identification based on all available information;
- the establishment of the quantitative dose (concentration) – response (effect) relationship.

3.1.2. When it is not possible to establish the quantitative dose (concentration) – response (effect) relationship, then this should be justified and a semi-quantitative or qualitative analysis shall be included.

3.1.3. All information used to assess the effects on a specific environmental sphere shall be briefly presented, if possible in the form of a table or tables. The relevant test results (e.g. LC50 or NOEC) and test conditions (e.g. test duration, route of administration) and other relevant information shall be presented, in internationally recognised units of measurement for that effect.

3.1.4. All information used to assess the environmental fate of the substance shall be briefly presented, if possible in the form of a table or tables. The relevant test results and test conditions and other relevant information shall be presented, in internationally recognised units of measurement for that effect.

3.1.5. If one study is available then a robust study summary should be prepared for that study. Where there are more than one studies addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies and included as part of the technical dossier. Robust summaries will be required of all key data used in the hazard assessment. If the study or studies giving rise to the highest concern are not used, then this shall be fully justified and included as part of the technical dossier, not only for the study being used but also for all studies reaching a higher concern than the study being used. For substances where all available studies indicate no hazards an overall assessment of the validity of all studies should be performed.

3.2. Step 2: Classification and Labelling

3.2.1. The appropriate classification and labelling developed in accordance with the criteria in Directive 67/548/EEC shall be presented and justified. Where applicable Specific Concentration limits, resulting from the application of Article 4 (4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC, shall be presented and, if they are not included in Annex I to Directive 67/548/EEC, justified.

3.2.2. If the information are inadequate to decide whether a substance should be classified for a particular end-point, the registrant shall indicate and justify the action or decision he has taken as a result.

3.3. Step 3: Identification of the Predicted No-Effect Concentration

3.3.1. Based on the available information, the PNEC for each environmental sphere shall be established. The PNEC may be calculated by applying an appropriate assessment factor to the effect values (e.g. LC50 or NOEC) . An assessment factor expresses the difference between effects values derived for a limited number of species from laboratory tests and the PNEC for the environmental sphere[49].

3.3.2. If it is not possible to derive the PNEC, then this shall be clearly stated and fully justified.

[49] In general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor. An assessment factor of 1 000 is typically applied to the lowest of three short term L(E)C50 values derived from species representing different trophic levels and a factor of 10 to the lowest of three long-term NOEC values derived from species representing different trophic levels.

4. PBT AND VPVB ASSESSMENT

4.0. Introduction

4.0.1. The objective of the PBT and vPvB assessment shall be to determine if the substance fulfils the criteria given in Annex XII and if so, to characterise the potential emissions of the substance. A hazard assessment in accordance with Sections 1 and 3 of this Annex addressing all the long-term effects and the estimation of the long-term exposure of humans and the environment as carried out in accordance with Section 5 (Exposure Assessment), step 2 (Exposure Estimation), cannot be carried out with sufficient reliability for substances satisfying the PBT and vPvB criteria in Annex XII. Therefore, a separate PBT and vPvB assessment is required.

4.0.2. [deleted]

4.0.3. The PBT and vPvB assessment shall comprise the following two steps, which shall be clearly identified as such in Part C, Section 4 of the Chemical Safety Report:

Step 1. Comparison with the Criteria

Step 2. Emission Characterisation

The assessment shall also be summarised in the Safety Data Sheet under heading 12.

4.1. Step 1: Comparison with the Criteria

This part of the PBT and vPvB assessment shall entail the comparison of the available information, which is submitted as part of the technical dossier, with the criteria given in Annex XII and a statement of whether the substance fulfils or does not fulfil the criteria.

If the available information is not sufficient to decide whether the substance fulfils the criteria in Annex XII, then other evidence like monitoring data available for the registrant and giving rise to an equivalent level of concern shall be considered on a case-by-case basis.

If the technical dossier contains for one or more endpoints only information as required in Annexes V and VI, the registrant shall consider information relevant for screening for P, B and T properties to decide whether further information needs to be generated to fulfil the objective of the PBT and vPvB assessment. In case the generation of further information is necessary and would require testing on vertebrate animals, the registrant shall submit a testing proposal. However, such further information does not need to be generated if the registrant implements or recommends sufficient risk management measures and operational conditions that enable derogation according to Annex IX, section 3 from testing relevant for PBT and vPvB assessment.

4.2. Step 2: Emission Characterisation

If the substance fulfils the criteria an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. In particular it shall contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance.

5. EXPOSURE ASSESSMENT

5.0. Introduction

The objective of the exposure assessment shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the hazards identified in sections 1 to 4. The exposure assessment shall entail the following two steps, which shall be clearly identified as such in the chemical safety report:

Step 1. Generation of exposure scenario(s) or the generation of relevant use and exposure categories

Step 2. Exposure Estimation.

Where required and in accordance with Article 29, the exposure scenario shall also be included in an annex to the safety data sheet.

5.1. Step 1: Development of exposure scenarios

5.1.1. Exposure scenarios as described in sections 0.6 and 0.7 shall be generated. Exposure scenarios are the core of the process to carry out a chemical safety assessment. The chemical safety assessment process may be iterative. The first assessment will be based on the required minimum and all available hazard information and on the exposure estimation that corresponds to the initial assumptions about the operating conditions and risk management measures (an initial exposure scenario). If the initial assumptions lead to a risk characterisation indicating that risks to human health and the environment are not adequately controlled, then it is necessary to carry out an iterative process with amendment of one or a number of factors in hazard or exposure assessment with the aim to demonstrate adequate control. The refinement of hazard assessment may require generation of additional hazard information. The refinement of exposure assessment may involve appropriate alteration of the operational conditions or risk management measures in the exposure scenario or more precise exposure estimation. The exposure scenario, resulting from the final iteration (a final exposure scenario), shall be included in the chemical safety report and attached to the safety data sheet in accordance with Article 29.

The final exposure scenario shall be presented under the relevant heading of the chemical safety report, and included in an annex to the safety data sheet, using an appropriate short title giving a brief general description of the use, consistent with those given in Annex IV section 3.5. Exposure scenarios shall cover any manufacture in the Community and all identified uses.

In particular, an exposure scenario includes, where relevant, a description of:

Operational conditions

– the processes involved, including the physical form in which the substance is manufactured, processed and/or used;
– the activities of workers related to the processes and the duration and frequency of their exposure to the substance;
– the activities of consumers and the duration and frequency of their exposure to the substance;
– the duration and frequency of emissions of the substance to the different environmental compartments and sewage treatment systems and the dilution in the receiving environmental compartment.

Risk management measures

– the risk management measures to reduce or avoid direct and indirect exposure of humans (including workers and consumers) and the different environmental compartments to the substance;
– the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste, disposal and/or recycling.

5.1.2. Where a manufacturer, importer or downstream user applies for an application for an authorisation for a specific use, exposure scenarios need only be developed for that use and the subsequent life-cycle steps.

5.2. Step 2: Exposure Estimation

5.2.1. The exposure shall be estimated for each exposure scenario developed and shall be presented under the relevant heading of the chemical safety report and where required and in accordance with Article 29, summarised in an annex to the safety data sheet. The exposure estimation entails three elements: (1) emission estimation; (2) assessment of chemical fate and pathways; and (3) estimation of exposure levels.

5.2.2. The emission estimation shall consider the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses. The life-cycle stages resulting from the manufacture of the substance cover, where relevant, the waste stage. The life-cycle stages resulting from identified uses cover, where relevant, the service-life of articles and the waste stage. The emission estimation shall be performed under the assumption that the risk management measures and operational conditions described in the exposure scenario have been implemented.

5.2.3. A characterisation of possible degradation, transformation, or reaction processes and an estimation of environmental distribution and fate shall be performed.

5.2.4 An estimation of the exposure levels shall be performed for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is known or reasonably foreseeable. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes and sources of exposure) shall be addressed. Such estimations shall take account of spatial and temporal variations in the exposure pattern. In particular, the exposure estimation shall take account of:

- adequately measured, representative exposure data,
- any major impurities and additives in the substance,
- the quantity in which the substance is produced and/or imported,
- the quantity for each identified use,
- implemented or recommended risk management, including the degree of containment,
- duration and frequency of exposure according to the operational conditions,
- the activities of workers related to the processes and the duration and frequency of their exposure to the substance,
- the activities of consumers and the duration and frequency of their exposure to the substance,
- the duration and frequency of emissions of the substance to the different environmental compartments and the dilution in the receiving environmental compartment,

– the physicochemical properties of the substance,
– transformation and/or degradation products,
– the likely routes of exposure of and potential for absorption in humans,
– the likely pathways to the environment and environmental distribution and degradation and/or transformation (see also Section 3 Step 1),
– scale (geographical) of exposure,
– matrix dependent release/migration of the substance.

5.2.5 Where adequately measured representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Appropriate models can be used for the estimation of exposure levels. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties can also be considered.

6. RISK CHARACTERISATION

6.1 The risk characterisation shall be carried out for each exposure scenario and shall be presented under the relevant heading of the Chemical Safety Report.

6.2 The risk characterisation shall consider the human populations (exposed as workers, consumers or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonably foreseeable, under the assumption that the risk management measures described in the exposure scenarios in the previous Section have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

6.3 The risk characterisation consists of:

– a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL;
– a comparison of the predicted environmental concentrations in each environmental sphere with the PNECs; and
– an assessment of the likelihood and severity of an event occurring due to the physicochemical properties of the substance.

6.4 For any exposure scenario, the risk to humans and the environment can be considered to be adequately controlled, throughout the lifecycle of the substance that results from manufacture or identified uses, if:

– the exposure levels estimated in Section 6.2 do not exceed the appropriate DNEL or the PNEC, as determined in Sections 1 and 3, respectively, and;
– the likelihood and severity of an event occurring due to the physicochemical properties of the substance as determined in Section 2 is negligible.

6.5 For those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the exposure scenario shall be carried out.

For substances satisfying the PBT and vPvB criteria, the manufacturer or importer shall use the information as obtained in Section 5, Step 2 when implementing on its site, and recommending for downstream users, risk management measures which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses.

7. CHEMICAL SAFETY REPORT FORMAT

The Chemical Safety Report shall include the following headings:

CHEMICAL SAFETY REPORT FORMAT
PART A
1. SUMMARY OF RISK MANAGEMENT MEASURES **2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED** **3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED**
PART B
1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES **2. MANUFACTURE AND USES** **2.1. Manufacture** **2.2 Identified uses** **2.3 Uses advised against** **3. CLASSIFICATION AND LABELLING** **4. ENVIRONMENTAL FATE PROPERTIES** **4.1. Degradation** **4.2. Environmental distribution** **4.3. Bioaccumulation** **4.4 Secondary Poisoning** **5. HUMAN HEALTH HAZARD ASSESSMENT** **5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)** **5.2. Acute toxicity** **5.3. Irritation** 5.3.1. *Skin* 5.3.2. *Eye* 5.3.3. *Respiratory Tract* **5.4. Corrosivity**

5.5. Sensitisation

5.5.1. *Skin*

5.5.2. *Respiratory system*

5.6. Repeated dose toxicity

5.7. Mutagenicity

5.8. Carcinogenicity

5.9. Toxicity for reproduction

5.9.1. *Effects on fertility*

5.9.2. *Developmental Toxicity*

5.10 Other effects

5.11 Derivation of DNEL(s)

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

6.2. Flammability

6.3. Oxidising potential

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic Compartment (including sediment)

7.2. Terrestrial Compartment

7.3. Atmospheric Compartment

7.4. Microbiological Activity in Sewage Treatment Systems

8. PBT AND VPVB ASSESSMENT

9. EXPOSURE ASSESSMENT

9.1. [Title of Exposure Scenario 1]

9.1.1. *Exposure Scenario*

9.1.2. *Exposure Assessment*

9.2. [Title of Exposure Scenario 2]

9.2.1. *Exposure Scenario*

9.2.2. *Exposure Assessment*

[etc.]

CHEMICAL SAFETY REPORT FORMAT

10. RISK CHARACTERISATION

10.1. [Title of Exposure Scenario 1]

10.1.1. *Human Health*

10.1.1.1. *Workers*

10.1.1.2. *Consumers*

10.1.1.3. *Indirect exposure to humans via the environment*

10.1.2. *Environment*

10.1.2.1. *Aquatic Compartment (incl. Sediment)*

10.1.2.2. *Terrestrial Compartment*

10.1.2.3. *Atmospheric Compartment*

10.1.2.4. *Microbiological Activity in Sewage Treatment Systems*

10.2. [Title of Exposure Scenario 2]

10.2.1. *Human Health*

10.2.1.1. *Workers*

10.2.1.2. *Consumers*

10.2.1.3. *Indirect exposure to humans via the environment*

10.2.2. *Environment*

10.2.2.1. *Aquatic Compartment (incl. Sediment)*

10.2.2.2. *Terrestrial Compartment*

10.2.2.3. *Atmospheric Compartment*

10.2.2.4. *Microbiological Activity in Sewage Treatment Systems*

[etc.]

10.x. Overall exposure (combined for all relevant emission/release sources)

10.x.1 Human health (combined for all exposure routes)

10.x.1.1

10.x.2 Environment (combined for all emission sources)

10.x.2.1

ANNEX Ia

GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS

This Annex sets out the requirements for a Safety Data Sheet that is provided for a substance or a preparation in accordance with Article 29. The Safety Data Sheet provides a mechanism for transmitting appropriate safety information on classified substances and preparations, including information from the relevant Chemical Safety Report(s) down the supply chain to the immediate downstream user(s). The information provided in the Safety Data Sheet shall be consistent with the information in the chemical safety report, where one is required. Where a chemical safety report has been performed, the relevant exposure scenario(s) shall be placed into an annex of the safety data sheet, to make reference to them under the relevant headings of the safety data sheet easier.

The purpose of this Annex is to ensure consistency and accuracy in the content of each of the mandatory headings listed in Article 29, so that the resulting safety data sheets will enable users to take the necessary measures relating to protection of health and safety at the workplace, and protection of the environment.

The information provided by safety data sheets shall also meet the requirements set out in Council Directive 98/24/EC[50] on the protection of the health and safety of workers from the risks related to chemical agents at work. In particular, the safety data sheet shall enable the employer to determine whether any hazardous chemical agents are present in the workplace, and to assess any risk to the health and safety of workers arising from their use.

The information in the Safety Data Sheet shall be written in a clear and concise manner. The safety data sheet shall be prepared by a competent person who shall take into account the specific needs of the user audience, as far as it is known. Persons placing substances and preparations on the market shall ensure that competent persons have received appropriate training, including refresher training.

[50] OJ L 131, 5.5.1998, p. 11.

For preparations not classified as dangerous, but for which a safety data sheet is required according to Article 29, proportionate information shall be provided under each heading.

Additional information may be necessary in some cases in view of the wide range of properties of the substances and preparations. If in other cases it emerges that information on certain properties is of no significance or that it is technically impossible to provide, the reasons for this shall be clearly stated under each heading. Information shall be provided for each hazardous property. If it is stated that a particular hazard does not apply, clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available.

Give the date of issue of the safety data sheet on the first page. When a safety data sheet has been revised, the changes shall be brought to the attention of the recipient and identify it as 'Revision: (date).

Note

Safety data sheets are also required for certain special substances and preparations (e.g. metals in massive form, alloys, compressed gases etc.) listed in chapters 8 and 9 of Annex VI to Directive 67/548/EEC, for which there are labelling derogations.

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Identification of the substance or preparation

The term used for identification shall be identical to that provided on the label as set out in Annex VI to Directive 67/548/EEC.

For substances subject to registration, the term shall be consistent with that provided under registration and the registration number assigned under Article 18(1) of this Regulation shall also be indicated.

Other means of identification available may also be indicated.

1.2. Use of the substance/preparation

Indicate the uses of the substance or preparation as far as they are known. Where there are many possible uses, only the most important or common uses need to be listed. This shall include a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc.

Where a chemical safety report is required, the safety data sheet shall contain information on all the identified uses relevant to the recipient of the safety data sheet. This information shall be consistent with the identified uses and exposure scenarios set out in the annex to the safety data sheet.

1.3. Company/undertaking identification

Identify the person responsible for placing the substance or preparation on the market within the Community, whether it is the manufacturer, importer or distributor. Give the full address and telephone number of this person as well as the e-mail address of the competent person responsible for the safety data sheet.

In addition, where this person is not located in the Member State where the substance or preparation is placed on the market, give a full address and telephone number for the person responsible in that Member State, if possible.

For registrants, the person identified shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.

1.4. Emergency telephone

In addition to the above mentioned information, supply the emergency telephone number of the company and/or relevant official advisory body (this may be the body responsible for receiving information relating to health, which is referred to in Article 17 of Directive 1999/45/EC). Specify if this phone number is available only during office hours.

2. HAZARDS IDENTIFICATION

Give here the classification of the substance or preparation which arises from application of the classification rules in Directives 67/548/EEC or 1999/45/EC. Indicate clearly and briefly the hazards the substance or preparation presents to man and the environment.

Distinguish clearly between preparations which are classified as dangerous and preparations which are not classified as dangerous according to Directive 1999/45/EC.

Describe the most important adverse physicochemical, human health and environmental effects and symptoms relating to the uses and possible misuses of the substance or preparation that can reasonably be foreseen.

It may be necessary to mention other hazards, such as dustiness, cross-sensitisation, suffocation, freezing, high potency for odour or taste or environmental effects such as hazards to soil-dwelling organisms, ozone depletion, photochemical ozone creation potential etc., which do not result in classification but which may contribute to the overall hazards of the material.

The information shown on the label shall be given under heading 15.

The classification of the substance shall be consistent with the classification provided to the classification and labelling inventory according to Title X.

3. COMPOSITION/INFORMATION ON INGREDIENTS

The information given shall enable the recipient to identify readily the hazards of the components of the preparation. The hazards of the preparation itself shall be given under heading 2.

3.1. It is not necessary to give the full composition (nature of the ingredients and their concentration), although a general description of the components and their concentrations can be helpful.

3.2. For a preparation classified as dangerous according to Directive 1999/45/EC, the following substances shall be indicated, together with their concentration or concentration range in the preparation:

(i) substances presenting a health or environmental hazard within the meaning of Directive 67/548/EEC, if they are present in concentrations equal to or greater than the lowest of:

- the applicable concentrations defined in the table of Article 3 (3) of European Parliament and Council Directive 1999/45/EC, or
- the concentration limits given in Annex I to Council Directive 67/548/EEC, or
- the concentration limits given in Part B of Annex II to European Parliament and Council Directive 1999/45/EC, or
- the concentration limits given in Part B of Annex III to European Parliament and Council Directive 1999/45/EC, or
- the concentration limits given in Annex V to European Parliament and Council Directive 1999/45/EC, or
- the concentration limits given in an agreed entry in the classification and labelling inventory established under Title X,

(ii) and substances for which there are Community workplace exposure limits, which are not already included under (i).

(iii) substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XII, if the concentration of an individual substance is equal to or greater than 0.1 %.

3.3. For a preparation not classified as dangerous according to Directive 1999/45/EC, the substances shall be indicated, together with their concentration or concentration range, if they are present in an individual concentration of either:

(a) ≥ 1 % by weight for non-gaseous preparations and ≥ 0,2 % by volume for gaseous preparations and

- the substances present a health or environmental hazard within the meaning of Directive 67/548/EEC[51]; or
- the substances are assigned Community workplace exposure limits;

(b) ≥0.1 % by weight and the substances are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XII.

3.4. The classification (derived either from Articles 4 and 6 of Directive 67/548/EEC, from Annex I to Directive 67/548/EEC or from an agreed entry in the classification and labelling inventory established under Title X) of the above substances shall be given, including the symbol letters and R phrases which are assigned in accordance with their physicochemical, health and environmental hazards. The R phrases do not need to be written out in full here: reference shall be made to heading 16, where the full text of each relevant R phrase shall be listed. If the substance does not meet the classification criteria, the reason for indicating the substance in section 3 shall be described, such as "PBT-substance" or "substance with a Community workplace exposure limit".

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[51] Where the person responsible for placing the preparation on the market can demonstrate that the disclosure in the safety data sheet of the chemical identity of a substance which is exclusively classified as: - irritant with the exception of those assigned R41 or irritant in combination with one or more of the properties mentioned in point 2.3.4 of Article 10 of Directive 1999/ 45/EC; or – harmful or harmful in combination with one or more of the properties mentioned in point 2.3.4 of Article 10 of Directive 1999/45/EC presenting acute lethal effects alone; will put at risk the confidential nature of his intellectual property, he may, in accordance with the provisions of Part B of Annex VI to Directive 1999/45/EC, refer to that substance either by means of a name that identifies the most important functional chemical groups, or by means of an alternative name.

3.5. The name and the Registration number, assigned under Article 18(1) of this Regulation, EINECs or ELINCs number, if available, of the above substances shall be given in accordance with Directive 67/548/EEC. The CAS number and IUPAC name (if available) may also be helpful. For substances listed by a generic name, according to Article 15 of Directive 1999/45/EC or the footnote to point 3.3 of this Annex, a precise chemical identifier is not necessary.

3.6. If, in accordance with the provisions of Article 15 of Directive 1999/45/EC or the footnote to point 3.3 of this Annex, the identity of certain substances is to be kept confidential, their chemical nature shall be described in order to ensure safe handling. The name used shall be the same as that which derives from the above procedures.

4. FIRST AID MEASURES

Describe the first-aid measures.

Specify first whether immediate medical attention is required.

The information on first aid shall be brief and easy to understand by the victim, bystanders and first-aiders. The symptoms and effects shall be briefly summarised. The instructions shall indicate what is to be done on the spot in the case of an accident and whether delayed effects can be expected after exposure.

Subdivide the information according to the different routes of exposure, i.e. inhalation, skin and eye contact and ingestion, under different subheadings.

Indicate whether professional assistance by a doctor is needed or advisable.

For some substances or preparations it may be important to emphasise that special means to provide specific and immediate treatment shall be available at the workplace.

5. FIRE-FIGHTING MEASURES

Refer to requirements for fighting a fire caused by the substance or preparation, or arising in its vicinity by indicating:

– suitable extinguishing media,
– extinguishing media which shall not be used for safety reasons,
– special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases,
– special protective equipment for fire-fighters.

6. ACCIDENTAL RELEASE MEASURES

Depending on the substance or preparation involved, information may be needed on:
personal precautions such as:

- removal of ignition sources, provision for sufficient ventilation/respiratory protection, control of dust, prevention of skin and eye contact,

environmental precautions such as:

- keeping away from drains, surface- and ground-water and soil, possible need to alert the neighbourhood,

methods for cleaning up such as:

- use of absorbent material (e.g. sand, diatomaceous earth, acid binder, universal binder, sawdust, etc.), reduction of gases/fumes with water, dilution.

Also consider the need for indications such as: "never use, neutralise with ...".

Note
If appropriate refer to headings 8 and 13.

7. HANDLING AND STORAGE

Note

Information in this section shall relate to the protection of health, safety and the environment. It shall assist the employer in devising suitable working procedures and organisational measures according to Article 5 of Directive 98/24/EC.

Where a chemical safety report or a registration is required, the information in this section shall be consistent with the information given, for the identified uses and exposure scenarios set out in the annex to the safety data sheet.

7.1. Handling

Specify precautions for safe handling including advice on technical measures such as:

- containment, local and general ventilation, measures to prevent aerosol and dust generation and fire, measures required to protect the environment (e.g. use of filters or scrubbers on exhaust ventilation, use in a bunded area, measures for collection and disposal of spillages, etc.) and any specific requirements or rules relating to the substance or preparation (e.g. procedures or equipment which are prohibited or recommended) and if possible give a brief description.

7.2. Storage

Specify the conditions for safe storage such as: specific design for storage rooms or vessels (including retention walls and ventilation), incompatible materials, conditions of storage (temperature and humidity limit/range, light, inert gas, etc.) special electrical equipment and prevention of static electricity.

Give advice if relevant on quantity limits under storage conditions. In particular indicate any special requirements such as the type of material used in the packaging/containers of the substance or preparation.

7.3. Specific use(s)

For end products designed for specific use(s), recommendations shall refer to the identified use(s) and be detailed and operational. If possible, reference shall be made to industry – or sector – specific approved guidance.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure limit values

Specify currently applicable specific control parameters including occupational exposure limit values and/or biological limit values. Values shall be given for the Member State where the substance or preparation is placed on the market. Give information on currently recommended monitoring procedures.

Where a chemical safety report is required, the relevant DNELs and PNECs for the substance shall be given for the exposure scenarios set out in the annex to the safety data sheet.

For preparations, it is useful to provide values for those constituent substances which are required to be listed in the safety data sheet according to heading 3.

8.2. Exposure controls

For the purposes of this document exposure control means the full range of specific risk management measures to be taken during use in order to minimise worker and environmental exposure. Where a chemical safety report is required, a summary of the risk management measures shall be given in section 8 of the safety data sheet for the identified uses set out in the safety data sheet.

8.2.1. Occupational exposure controls

This information will be taken into account by the employer in carrying out an assessment of risk to the health and safety of workers for the substance or preparation under Article 4 of Directive 98/24/EC, which requires, in the order of priority:

– design of appropriate work processes and engineering controls, the use of adequate equipment and materials;
– the application of collective protection measures at source, such as adequate ventilation and appropriate organisational measures, and
– where exposure cannot be prevented by other means the use of individual protection measures, such as personal protection equipment.

Therefore provide suitable and adequate information on these measures to enable a proper risk assessment to be carried out under Article 4 of Directive 98/24/EC. This information shall complement that already given under heading 7.1.

Where individual protection measures are needed, specify in detail which equipment will provide adequate and suitable protection. Take into account Council Directive 89/686/EEC[52] and make reference to the appropriate CEN standards:

(a) Respiratory protection

For dangerous gases, vapours or dust, specify the type of protective equipment to be used, such as self contained breathing apparatus, adequate masks and filters.

(b) Hand protection

– Specify clearly the type of gloves to be worn when handling the substance or preparation, including:
  – the type of material,
  – the breakthrough time of the glove material, with regard to the amount and duration of dermal exposure.

If necessary indicate any additional hand protection measures.

[52] OJ L 399, 30.12.1989, p. 18.

(c) Eye protection

Specify the type of eye protection equipment required such as: safety glasses, safety goggles, face shield.

(d) Skin protection

If it is necessary to protect a part of the body other than the hands, specify the type and quality of protection equipment required, such as:

– apron, boots and full protective suit.

If necessary, indicate any additional skin protection measures and specific hygiene measures.

8.2.2. Environmental exposure controls

Specify the information required by the employer to fulfil his commitments under Community environmental protection legislation.

Where a chemical safety report is required, a summary of the risk management measures that adequately control exposure of the environment to the substance shall be given for the exposure scenarios set out in the annex to the safety data sheet.

9. PHYSICAL AND CHEMICAL PROPERTIES

To enable proper control measures to be taken, provide all relevant information on the substance or preparation, particularly the information listed under heading 9.2. The information in this section shall be consistent with the information provided in a registration where one is required.

9.1. General information

Appearance

Indicate the physical state (solid, liquid, gas) and the colour of the substance or preparation as supplied.

Odour

If odour is perceptible, give a brief description of it.

9.2. Important health, safety and environmental information

pH

Indicate the pH of the substance or preparation as supplied or of an aqueous solution; in the latter case, indicate the concentration.

Boiling point/boiling range:

Flash point:

Flammability (solid, gas):

Explosive properties:

Oxidising properties:

Vapour pressure:

Relative density:

Solubility:

Water solubility:

Partition coefficient: n-octanol/water:

Viscosity:

Vapour density:

Evaporation rate:

9.3. Other information

Indicate other important safety parameters, such as, miscibility, fat solubility (solvent – oil to be specified), conductivity, melting point/melting range, gas group (useful for European Parliament and Council Directive 94/9/EC)[53], auto-ignition temperature etc.

[53] OJ L 100, 19.4.1994, p. 1.

Note 1

The above properties shall be determined in accordance with the specifications of Part A of Annex X or any other comparable method.

Note 2

For preparations, information shall normally be given on the properties of the preparation itself. However, if it is stated that a particular hazard does not apply, clearly differentiate between cases where no information is available to the classifier, and cases where negative test results are available. If it is considered necessary to give information about the properties of individual components, please indicate clearly what the data refers to.

10. STABILITY AND REACTIVITY

State the stability of the substance or preparation and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment.

10.1. Conditions to avoid

List those conditions such as temperature, pressure, light, shock, etc., which may cause a dangerous reaction and if possible give a brief description.

10.2. Materials to avoid

List materials such as water, air, acids, bases, oxidising agents or any other specific substance which may cause a dangerous reaction and if possible give a brief description.

10.3. Hazardous decomposition products

List hazardous materials produced in dangerous amounts upon decomposition.

Note

Address specifically:

– the need for and the presence of stabilisers,
– the possibility of a hazardous exothermic reaction,
– safety significance, if any, of a change in physical appearance of the substance or preparation,
– hazardous decomposition products, if any, formed upon contact with water,
– possibility of degradation to unstable products.

11. TOXICOLOGICAL INFORMATION

This section deals with the need for a concise but complete and comprehensible description of the various toxicological (health) effects, which can arise if the user comes into contact with the substance or preparation.

The information shall include dangerous-to-health effects from exposure to the substance or preparation, based on the conclusion from, for example, test data and experience. The information shall also include, where appropriate, delayed, immediate and chronic effects from short- and long-term exposure: for example sensitisation, narcosis, carcinogenicity, mutagenicity and reproductive toxicity (developmental toxicity and fertility). It shall also include information on the different routes of exposure (inhalation, ingestion, skin and eye contact), and describe the symptoms related to the physical, chemical and toxicological characteristics.

Taking account of the information already provided under heading 3, composition/information on ingredients, it may be necessary to make reference to specific health effects of certain substances in the preparation.

The information in this section shall be consistent with the information provided for in a registration where required and/or in a chemical safety report where required and shall give information on the following groups of potential effects:

– toxicokinetics, metabolism and distribution,
– acute effects (acute toxicity, irritation and corrosivity),
– sensitisation,
– repeated dose toxicity, and
– CMR effects (carcinogenity, mutagenicity and toxicity for reproduction).

For substances subject to registration, summaries of the information derived from the application of Annexes V to IX of this Regulation shall be given. The information shall also include the result of the comparison of the available data with the criteria given in Directive 67/548/EEC for CMR, categories 1 and 2, following Paragraph 1.3.1 of Annex I.

12. ECOLOGICAL INFORMATION

Describe the possible effects, behaviour and environmental fate of the substance or preparation in air, water and/or soil. Where available, give relevant test data (e.g. LC50 fish ≤ 1 mg/l).

The information in this section shall be consistent with the information provided for in a registration where required and/or in a chemical safety report where required.

Describe the most important characteristics likely to have an effect on the environment owing to the nature of the substance or preparation and likely methods of use. Information of the same kind shall be supplied for dangerous products arising from the degradation of substances and preparations. This may include the following:

12.1. Ecotoxicity

This shall include relevant available data on aquatic toxicity, both acute and chronic for fish, crustaceans, algae and other aquatic plants. In addition, toxicity data on soil micro- and macro-organisms and other environmentally relevant organisms, such as birds, bees and plants, shall be included when available. Where the substance or preparation has inhibitory effects on the activity of micro-organisms, the possible impact on sewage treatment plants shall be mentioned.

For substances subject to registration, summaries of the information derived from the application of Annexes V to IX of this Regulation shall be included.

12.2. Mobility

The potential of the substance or the appropriate constituents of a preparation[54], if released to the environment, to transport to groundwater or far from the site of release.

Relevant data might include:

– known or predicted distribution to environmental compartments,
– surface tension,
– absorption/desorption.

For other physicochemical properties see heading 9.

[54] This information cannot be given for the preparation because it is substance specific. It should therefore be given, where available and appropriate, for each constituent substance in the preparation which is required to be listed in the safety data sheet according to the rules under heading 3 of this Annex.

12.3. Persistence and degradability

The potential of the substance or the appropriate constituents of a preparation[6] to degrade in relevant environmental media, either through biodegradation or other processes such as oxidation or hydrolysis. Degradation half lives shall be quoted where available. The potential of the substance or appropriate constituents of a preparation[6] to degrade in sewage treatment plants shall also be mentioned.

12.4. Bioaccumulative potential

The potential of the substance or the appropriate constituents of a preparation[6] to accumulate in biota and, eventually, to pass through the food chain, with reference to the octanol-water partition coefficient (Kow) and bioconcentration factor (BCF), if available.

12.5. Results of PBT assessment

Where a chemical safety report is required, the results of the PBT assessment as set in the Chemical Safety Report shall be given.

12.6 Other adverse effects

If available, include information on any other adverse effects on the environment, e.g. ozone depletion potential, photochemical ozone creation potential, endocrine disrupting potential and/or global warming potential.

Remarks

Ensure that information relevant to the environment is provided under other headings of the safety data sheet, especially advice for controlled release, accidental release measures, transport and disposal considerations under headings 6, 7, 13, 14 and 15.

13. DISPOSAL CONSIDERATIONS

If the disposal of the substance or preparation (surplus or waste resulting from the foreseeable use) presents a danger, a description of these residues and information on their safe handling shall be given.

Specify the appropriate methods of disposal of both the substance or preparation and any contaminated packaging (incineration, recycling, landfilling, etc.)

Where a chemical safety report is required, the information on the waste management measures that adequately control exposure of humans and the environment to the substance shall be consistent with the exposure scenarios set out in the annex to the safety data sheet.

Note
Refer to any relevant Community provisions relating to waste. In their absence, it is useful to remind the user that national or regional provisions may be in force.

14. TRANSPORT INFORMATION

Indicate any special precautions which a user needs to be aware of or needs to comply with in connection with transport or conveyance either within or outside his premises. Where relevant, provide information on the transport classification for each of the modal regulations: IMDG (sea), ADR (road, Council Directive 94/55/EC(9)), RID (rail, Council Directive 96/49/EC(10)), ICAO/IATA (air). This might include inter alia:

– UN number,
– class,
– proper shipping name,
– packing group,
– marine pollutant,
– other applicable information.

15. REGULATORY INFORMATION

Give the health, safety and environmental information shown on the label according to Directives 67/548/EEC and 1999/45/EC.

If the substance or preparation covered by this safety data sheet is the subject of specific provisions in relation to protection of man or the environment at Community level (e.g. authorisations given under Title VII or restrictions under Title VIII) these provisions shall, as far as is possible, be stated.

Also mention, where possible, the national laws which implement these provisions and any other national measures that may be relevant.

16. OTHER INFORMATION

Indicate any other information which the supplier assesses as being of importance for the health and safety of the user and for the protection of the environment, for example:

– list of relevant R phrases. Write out the full text of any R phrases referred to under headings 2 and 3 of the safety data sheet,
– training advice,
– recommended restrictions on use (i.e. non-statutory recommendations by supplier),
– further information (written references and/or technical contact point),
– sources of key data used to compile the data sheet.

For a revised safety data sheet, indicate clearly the information, which has been added, deleted or revised (unless this has been indicated elsewhere).

ANNEX Ib

CHEMICAL SAFETY ASSESSMENTS FOR PREPARATIONS

[deleted]

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ANNEX Ic

CRITERIA FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES

Criteria for substances registered between 1 and 10 tonnes, with reference to Articles 11(1a) and (abis):

(a) substances for which it is predicted (ie; by the application of (Q)SARs or other evidence) that they are likely to meet the criteria for category 1 or 2 classification for carcinogenicity, mutagenicity or reproductive toxicity or the criteria in Annex XII.

(b) substances:
   (i) with dispersive or diffuse use(s) particularly where such substances are used in consumer preparations or incorporated into consumer articles; and
   (ii) for which it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any human health or environmental effects endpoints under Directive 67/548/EEC.

ANNEX II

EXEMPTIONS FROM OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(4)(a)

EINECs no	Name/Group	CAS no
200-061-5	D-glucitol $C_6H_{14}O_6$	50-70-4
200-066-2	Ascorbic acid $C_6H_8O_6$	50-81-7
200-075-1	Glucose $C_6H_{12}O_6$	50-99-7
200-294-2	L-lysine $C_6H_{14}N_2O_2$	56-87-1
200-312-9	Palmitic acid, pure $C_{16}H_{32}O_2$	57-10-3
200-313-4	Stearic acid, pure $C_{18}H_{36}O_2$	57-11-4
200-334-9	Sucrose, pure $C_{12}H_{22}O_{11}$	57-50-1
200-405-4	α-tocopheryl acetate $C_{31}H_{52}O_3$	58-95-7
200-432-1	DL-methionine $C_5H_{11}NO_2S$	59-51-8
200-711-8	D-mannitol $C_6H_{14}O_6$	69-65-8
201-771-8	1-sorbose $C_6H_{12}O_6$	87-79-6
204-007-1	Oleic acid, pure $C_{18}H_{34}O_2$	112-80-1
204-664-4	Glycerol stearate, pure $C_{21}H_{42}O_4$	123-94-4
204-696-9	Carbon dioxide CO_2	124-38-9
205-278-9	Calcium pantothenate, D-form $C_9H_{17}NO_{5.1/2}Ca$	137-08-6
205-582-1	Lauric acid, pure $C_{12}H_{24}O_2$	143-07-7
205-590-5	Potassium oleate $C_{18}H_{34}O_2K$	143-18-0
205-756-7	DL-phenylalanine $C_9H_{11}NO_2$	150-30-1
208-407-7	Sodium gluconate $C_6H_{12}O_{7.}Na$	527-07-1
212-490-5	Sodium stearate, pure $C_{18}H_{36}O_{2.}Na$	822-16-2
215-279-6	Limestone A noncombustible solid characteristic of sedimentary rock. It consists primarily of calcium carbonate	1317-65-3
215-665-4	Sorbitan oleate $C_{24}H_{44}O_6$	1338-43-8
216-472-8	Calcium distearate, pure $C_{18}H_{36}O_{2.1/2}Ca$	1592-23-0
231-147-0	Argon Ar	7440-37-1

EINECs no	Name/Group	CAS no
231-153-3	Carbon C	7440-44-0
231-783-9	Nitrogen N_2	7727-37-9
231-791-2	Water, distilled, conductivity or of similar purity H_2O	7732-18-5
231-955-3	Graphite C	7782-42-5
232-273-9	Sunflower oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, and oleic. *(Helianthus annuus, Compositae*).	8001-21-6
232-274-4	Soybean oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic (*Soja hispida, Leguminosae*).	8001-22-7
232-276-5	Safflower oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acid linoleic (*Carthamus tinctorius, Compositae*).	8001-23-8
232-278-6	Linseed oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, linolenic and oleic (*Linum usitatissimum, Linaceae*).	8001-26-1
232-281-2	Corn oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmitic and stearic. *(Zea mays, Gramineae).*	8001-30-7
232-293-8	Castor Oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acid ricinoleic *(Ricinus communis, Euphorbiaceae).*	8001-79-4

EINECs no	Name/Group	CAS no
232-299-0	Rape oil Extractives and their physically modified derivatives. It consists primarily of the glycerides of the fatty acids erucic, linoleic and oleic *(Brassica napus, Cruciferae)*.	8002-13-9
232-307-2	Lecithins The complex combination of diglycerides of fatty acids linked to the choline ester of phosphoric acid.	8002-43-5
232-436-4	Syrups, hydrolyzed starch A complex combination obtained by the hydrolysis of cornstarch by the action of acids or enzymes. It consists primarily of d-glucose, maltose and maltodextrins.	8029-43-4
232-442-7	Tallow, hydrogenated	8030-12-4
232-675-4	Dextrin	9004-53-9
232-679-6	Starch High-polymeric carbohydrate material usually derived form cereal grains such as corn, wheat and sorghum, and from roots and tubers such as potatoes and tapioca. Includes starch which has been pregelatinised by heating in the presence of water.	9005-25-8
232-940-4	Maltodextrin	9050-36-6
234-328-2	Vitamin A	11103-57-4
238-976-7	Sodium D-gluconate $C_6H_{12}O_7.xNa$	14906-97-9
248-027-9	D-glucitol monostearate $C_{24}H_{48}O_7$	26836-47-5
262-988-1	Fatty acids, coco, Me esters	61788-59-8
262-989-7	Fatty acids, tallow, Me esters	61788-61-2
263-060-9	Fatty acids, castor-oil	61789-44-4
263-129-3	Fatty acids, tallow	61790-37-2
265-995-8	Cellulose Pulp	65996-61-4

EINECs no	Name/Group	CAS no
266-925-9	Fatty acids, C_{12-18} This substance is identified by SDA Substance Name: *C_{12}-C_{18} alkyl carboxylic acid* and SDA Reporting Number: 16-005-00.	67701-01-3
266-928-5	Fatty acids C_{16-18} This substance is identified by SDA Substance Name: *C_{16}-C_{18} alkyl carboxylic acid* and SDA Reporting Number: 19-005-00.	67701-03-5
266-929-0	Fatty acids, C_{8-18} and C_{18}-unsatd. This substance is identified by SDA Substance Name: *C_8-C_{18} and C_{18} unsaturated alkyl carboxylic acid* and SDA Reporting Number: 01-005-00.	67701-05-7
266-930-6	Fatty acids, C_{14-18} and C_{16-18}-unsatd. This substance is identified by SDA Substance Name: *C_{14}-C_{18} and C_{16}-C_{18} unsaturated alkyl carboxylic acid* and SDA Reporting Number: 04-005-00	67701-06-8
266-932-7	Fatty acids, C_{16}-C_{18} and C_{18}-unsatd. This substance is identified by SDA Substance Name: *C_{16}-C_{18} and C_{18} unsaturated alkyl carboxylic acid* and SDA Reporting Number: 11-005-00	67701-08-0
266-948-4	Glycerides, C_{16-18} and C_{18}-unsatd. This substance is identified by SDA Substance Name: *C_{16}-C_{18} and C_{18} unsaturated trialkyl glyceride* and SDA Reporting Number: 11-001-00.	67701-30-8
267-007-0	Fatty acids, C_{14-18} and C_{16-18}-unsatd., Me esters This substance is identified by SDA Substance Name: *C_{14}-C_{18} and C_{16}-C_{18} unsaturated alkyl carboxylic acid methyl ester* and SDA Reporting Number: 04-010-00.	67762-26-9
267-013-3	Fatty acids, C_{6-12} This substance is identified by SDA Substance Name: *C_6-C_{12} alkyl carboxylic acid* and SDA Reporting Number: 13-005-00.	67762-36-1

EINECs no	Name/Group	CAS no
268-099-5	Fatty acids, C_{14-22} and C_{16-22} unsatd. This substance is identified by SDA Substance Name: *C_{14}-C_{22}* and *C_{16}-C_{22} unsaturated alkyl carboxylic acid* and SDA Reporting Number: 07-005-00	68002-85-7
268-616-4	Syrups, corn, dehydrated	68131-37-3
269-657-0	Fatty acids, soya	68308-53-2
269-658-6	Glycerides, tallow mono- , di- and tri-, hydrogenated	68308-54-3
270-298-7	Fatty acids, C_{14-22}	68424-37-3
270-304-8	Fatty acids, linseed-oil	68424-45-3
270-312-1	Glycerides, C_{16-18} and C_{18}-unsatd. mono- and di- This substance is identified by SDA Substance Name: *C_{16}-C_{18} and C_{18} unsaturated alkyl and C_{16}-C_{18} and C_{18} unsaturated dialkyl glyceride* and SDA Reporting Number: 11-002-00.	68424-61-3
288-123-8	Glycerides, C_{10-18}	85665-33-4
292-771-7	Fatty acids, C_{12-14}	90990-10-6
292-776-4	Fatty acids, C_{12-18} and C_{18}-unsatd.	90990-15-1
296-916-5	Fatty acids, rape-oil, erucic acid-low	93165-31-2

ANNEX III

EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(4)(b)

2. Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight;

3. Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article;

4. Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market;

5. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:

   (i) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended, or

   (ii) a substance solely intended to provide a specific physicochemical characteristic functions as intended;

6. By-products, unless they are imported or placed on the market themselves;

7. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption;

8. The following substances which occur in nature, if they are not chemically modified: Minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke;

8a. Substances occurring in nature other than those listed under paragraph 8, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC;

9. Basic elemental substances for which hazards and risks are already well known: hydrogen, oxygen, noble gases (argon, helium, neon, xenon), nitrogen.

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ANNEX IV

INFORMATION REQUIREMENTS REFERRED TO IN ARTICLE 9

GUIDANCE NOTE
ON FULFILLING THE REQUIREMENTS OF ANNEXES IV TO IX

Annexes IV to IX specify the information that shall be submitted for registration and evaluation purposes according to Articles 9, 11 and 12, 39, 40 and 44. For the lowest tonnage level, the standard requirements are in Annex V, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.

STEP 1 – GATHER AND SHARE EXISTING INFORMATION

The registrant should gather all existing available test data on the substance to be registered, this would include a literature search for relevant information on the substance. Wherever practicable, registrations should be submitted jointly, in accordance with Article 10 or 17. This will enable test data to be shared, thereby avoiding unnecessary testing and reducing costs. The registrant should also collect all other available and relevant information on the substance regardless whether testing for a given endpoint is required or not at the specific tonnage level. This should include information from alternative sources (e.g. from (Q)SARs, read-across from other substances, in vivo and in vitro testing, epidemiological data) which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests. In addition, information on exposure, use and risk management measures in accordance with Article 9 and this Annex should be collected. Considering all this information together, the registrant will be able to determine the need to generate further information.

STEP 2 – CONSIDER INFORMATION NEEDS

The registrant shall identify what information is required for the registration. First, the relevant Annex or Annexes to be followed shall be identified, according to tonnage. These Annexes set out the standard information requirements, but shall be considered in conjunction with Annex IX, which allows variation from the standard approach, where it can be justified. In particular, information on exposure, use and risk management measures shall be considered at this stage in order to determine the information needs for the substance.

STEP 3 – IDENTIFY INFORMATION GAPS

The registrant shall then compare the information needs for the substance with the information already available and identify where there are gaps. It is important at this stage to ensure that the available data is relevant and has sufficient quality to fulfil the requirements.

STEP 4 – GENERATE NEW DATA/PROPOSE TESTING STRATEGY

In some cases it will not be necessary to generate new data. However, where there is an information gap that needs to be filled, new data shall be generated (Annexes V and VI), or a testing strategy shall be proposed (Annexes VII and VIII), depending on the tonnage. New tests on vertebrates shall only be conducted or proposed as a last resort when all other data sources have been exhausted. In some cases, the rules set out in Annex V to IX may require certain tests to be undertaken earlier than or in addition to the standard requirements.

NOTES

Note 1: If it is not technically possible, or if it does not appear scientifically necessary to give information, the reasons shall be clearly stated, in accordance with the relevant provisions.

Note 2: The registrant may wish to declare that certain information submitted in the registration dossier is commercially sensitive and its disclosure might harm him commercially. If this is the case, he shall list the items and provide a justification.

INFORMATION REFERRED TO IN ARTICLE 9(a) (i) TO (v)

1. GENERAL REGISTRANT INFORMATION

1.1. Registrant

1.1.1. Name, address, telephone number, fax number and e-mail address

1.1.2. Contact person

1.1.3. Location of the registrant's production and own use site(s), as appropriate

1.2. Joint submission of data

Articles 10 or 17 foresee that parts of the registration may be submitted by one manufacturer or importer on behalf of other manufacturers or importers.

In this case, that manufacturer or importer shall identify the other manufacturer or importers specifying:

– their name, address, telephone number, fax number and e-mail address,

– parts of the present registration which apply to other manufacturers or importers.

Mention the number(s) given in Annex IV, V, VI, VII or VIII, as appropriate.

Any other manufacturers or importers shall identify the manufacturer/importer submitting on his behalf specifying:

– his name, address, telephone number, fax number and e-mail address,

– parts of the registration which are submitted by those manufacturer(s) or importer(s).

Mention the number(s) given in Annex IV, V, VI, VII or VIII, as appropriate.

2. IDENTIFICATION OF THE SUBSTANCE

For each substance, the information given in this section shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more of the items below, the reasons shall be clearly stated.

2.1. Name or other identifier of each substance

2.1.1. Name(s) in the Iupac nomenclature or other international chemical name(s)

2.1.2. Other names (usual name, trade name, abbreviation)

2.1.3. EINECs or ELINCs number (if available and appropriate)

2.1.4. CAS name and CAS number (if available)

2.1.5. Other identity code (if available)

2.2. Information related to molecular and structural formula of each substance

2.2.1. Molecular and structural formula (including Smiles notation, if available)

2.2.2 Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)

2.2.3. Molecular weight or molecular weight range

2.3. Composition of each substance

2.3.1. Degree of purity (%)

2.3.2. Nature of impurities, including isomers and by-products

2.3.3. Percentage of (significant) main impurities

2.3.4. Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)

2.3.5. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)

2.3.6. High-pressure liquid chromatogram, gas chromatogram

2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

3. INFORMATION ON MANUFACTURE AND USE(S) OF THE SUBSTANCE(S)

3.1. Overall manufacture and/or imports in tonnes per manufacturer or importer per year in:

3.1.1. The calendar year of the registration (estimated quantity)

3.2. In case of a manufacturer: Brief description of the technological process used in manufacture

Precise details of the process, particularly those of a commercially sensitive nature, are not required.

3.3. An indication of the tonnage used for his own use(s)

3.4. Form (substance, preparation or article) and/or physical state under which the substance is made available to downstream users. Concentration or concentration range of the substance in preparations made available to downstream users and quantities of the substance in articles made available to downstream users.

3.5. Brief general description of the identified use(s)

3.6. Information on waste quantities and composition of waste resulting from production and identified uses

3.7. Uses advised against (see safety data sheet heading 16)

Where applicable, an indication of the uses, which the registrant advises against and why (i.e. non-statutory recommendations by supplier). This need not be an exhaustive list.

4. CLASSIFICATION AND LABELLING

4.1. The hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;

In addition, for each entry, the reasons why no classification is given for an endpoint should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification);

4.2. The resulting hazard label for the substance(s), resulting from the application of Articles 23 to 25 of Directive 67/548/EEC;

4.3. Specific concentration limits, where applicable, resulting from the application of Article 4 (4) of Directive 67/548/EEC and Articles 4 to 7 of Directive 1999/45/EC.

5. GUIDANCE ON SAFE USE CONCERNING:

This information shall be consistent with that in the Safety Data Sheet, where such a Safety Data Sheet is required according to Article 29 of this Regulation.

5.1. First-aid measures (safety data sheet heading 4)

5.2. Fire-fighting measures (safety data sheet heading 5)

5.3. Accidental release measures (safety data sheet heading 6)

5.4. Handling and Storage (safety data sheet heading 7)

5.5. Transport information (safety data sheet heading 14)

Where a chemical safety report is not required, the following additional information is required:

5.6. Exposure Controls/Personal Protection (safety data sheet heading 8)

5.7. Stability and Reactivity (safety data sheet heading 10)

5.8. Disposal considerations

5.8.1. Disposal considerations (safety data sheet heading 13)

5.8.2. Information on recycling and methods of disposal for industry

5.8.3 Information on recycling and methods of disposal for the public

6. INFORMATION ON EXPOSURE FOR SUBSTANCES REGISTERED IN QUANTITIES BETWEEN 1 AND 10 TONNES PER YEAR PER MANUFATCURER OR IMPORTER

6.1. Main use category:

6.1.1. *(a) industrial use and/or*

(b) professional use and/or

(c) consumer use

6.1.2 Specification for industrial and professional use:

(a) used in closed system and/or

(b) use resulting in inclusion into or onto matrix and/or

(c) non-dispersive use and/or

(d) dispersive use

6.2. Significant route(s) of exposure:

6.2.1 Human exposure:

(a) oral and/or

(b) dermal and/or

(c) inhalatory

6.2.2 Environmental exposure

(a) water and/or

(b) air and/or

(c) solid waste and/or

(d) soil

6.3. Pattern of exposure:

(a) accidental/infrequent and/or

(b) occasional and/or

(c) continuous /frequent

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ANNEX V

STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1 TONNE OR MORE

Column 1 of this Annex establishes the standard information required for:

(a) non-phase-in substances manufactured or imported in quantities of 1 to 10 tonnes;

(b) phase-in substances manufactured or imported in quantities of 1 to 10 tonnes and meeting the criteria in Annex Ic in accordance with Article 11 (1) (a) and (abis); and

(c) substances manufactured or imported in quantities of 10 tonnes or more.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided.

Column 2 of this Annex lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way. If the conditions are met under which column 2 of this Annex allows adaptations, the registrant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex IX with the exception of section 3 on substance-tailored exposure waiving. In this case as well, he shall clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annexes IX or X[55].

[55] Note: conditions for not requiring a specific test that are set out in the appropriate test methods in Annex X itself that are not repeated in column 2, also apply

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex IX, this fact and the reasons shall also be clearly stated.

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5. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
5.1. State of the substance at 20° C and 101,3 kPa	
5.2. Melting/freezing point	5.2. The study does not need to be conducted below a lower limit of -20 °C.
5.3. Boiling point	5.3. The study does not need to be conducted: – for gases; or – for solids which either melt above 300 °C or decompose before boiling. In such cases the boiling point under reduced pressure may be estimated or measured; or – for substances which decompose before boiling (e.g. auto-oxidation, rearrangement, degradation, decomposition, etc.).
5.4. Relative density	5.4. The study does not need to be conducted if: – the substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density is sufficient; or – the substance is a gas. In this case, an estimation based on calculation shall be made from its molecular weight and the Ideal Gas Laws.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
5.5. Vapour pressure	5.5. The study does not need to be conducted if the melting point is above 300 °C. If the melting point is between 200 °C and 300 °C, a limit value based on measurement or a recognised calculation method is sufficient.
5.6. Surface tension	5.6. The study need only be conducted if: – based on structure, surface activity is expected or can be predicted; or – surface activity is a desired property of the material. If the water solubility is below 1 mg/l at 20 °C the test does not need to be conducted.
5.7. Water solubility	5.7. The study does not need to be conducted if: – the substance is hydrolytically unstable at pH 4, 7 and 9 (half-life less than 12 hours); or – the substance is readily oxidisable in water. If the substance appears "insoluble" in water, a limit test up to the detection limit of the analytical method shall be performed.
5.8. Partition coefficient n-octanol/water	5.8. The study does not need to be conducted if the substance is inorganic. If the test cannot be performed (e.g. the substance decomposes, has a high surface activity, reacts violently during the performance of the test or does not dissolve in water or in octanol, or it is not possible to obtain a sufficiently pure substance), a calculated value for log P as well as details of the calculation method shall be provided.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
5.9. Flash-point	5.9. The study does not need to be conducted if: – the substance is inorganic; or – the substance only contains volatile organic components with flash-points above 100 °C for aqueous solutions; or – the estimated flash-point is above 200 °C; or – the flash-point can be accurately predicted by interpolation from existing characterised materials.
5.10. Flammability	5.10. The study does not need to be conducted: – if the substance is a solid which possesses explosive or pyrophoric properties. These properties should always be considered before considering flammability; or – for gases, if the concentration of the flammable gas in a mixture with inert gases is so low that, when mixed with air, the concentration is all time below the lower limit; or – for substances which spontaneously ignite when in contact with air.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
5.11. Explosive properties	5.11. The study does not need to be conducted if: – there are no chemical groups associated with explosive properties present in the molecule; or – the substance contains chemical groups associated with explosive properties which include oxygen and the calculated oxygen balance is less than –200; or – the organic substance or a homogenous mixture of organic substances contains chemical groups associated with explosive properties, but the exothermic decomposition energy is less than 500 J/g and the onset of exothermic decomposition is below 500 ºC; or – for mixtures of inorganic oxidising substances (UN Division 5.1) with organic materials, the concentration of the inorganic oxidising substance is: – less than 15 %, by mass, if assigned to UN Packaging Group I (high hazard) or II (medium hazard) – less than 30 %, by mass, if assigned to UN Packaging Group III (low hazard). *Note*: Neither a test for propagation of detonation nor a test for sensitivity to detonative shock is required if the exothermic decomposition energy of organic materials is less than 800 J/g.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
5.12. Self-ignition temperature	5.12. The study does not need to be conducted: – if the substance is explosive or ignites spontaneously with air at room temperature; or – for liquids non flammable in air, e.g. no flash point up to 200 °C; or – for gases having no flammable range; or – for solids, if the substance has a melting point < 160 °C, or if preliminary results exclude self-heating of the substance up to 400 °C.
5.13. Oxidising properties	5.13. The study does not need to be conducted if: – the substance is explosive; or – the substance is highly flammable; or – the substance is an organic peroxide; or – the substance is incapable of reacting exothermically with combustible materials, for example on the basis of the chemical structure (e.g. organic substances not containing oxygen or halogen atoms and these elements are not chemically bonded to nitrogen or oxygen, or inorganic substances not containing oxygen or halogen atoms).

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	The full test does not need to be conducted for solids if the preliminary test clearly indicates that the test substance has oxidising properties. Note that as there is no test method to determine the oxidising properties of gaseous mixtures, the evaluation of these properties must be realised by an estimation method based on the comparison of the oxidising potential of gases in a mixture with that of the oxidising potential of oxygen in air.
5.14. Granulometry	5.14. The study does not need to be conducted if the substance is marketed or used in a non solid or granular form.

6. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.1. Skin irritation or skin corrosion The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human and animal data, (2) an assessment of the acid or alkaline reserve, (3) *in vitro* study for skin corrosion, (4) *in vitro* study for skin irritation.	6.1. Steps 3 and 4 do not need to be conducted if: – the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes; or – the substance is flammable in air at room temperature; or – the substance is classified as very toxic in contact with skin; or – an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2000 mg/kg body weight).
6.2. Eye irritation The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human and animal data, (2) an assessment of the acid or alkaline reserve, (3) *in vitro* study for eye irritation.	6.2. Step 3 does not need to be conducted if: – the available information indicates that the criteria are met for classification as corrosive to the skin or irritating to eyes; or – the substance is flammable in air at room temperature; or

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.3. Skin sensitisation The assessment of this endpoint shall comprise the following consecutive steps: (1) an assessment of the available human, animal and alternative data, (2) *In vivo* testing .	6.3. Step 2 does not need to be conducted if: – the available information indicates that the substance should be classified for skin sensitisation or corrosivity; or – the substance is a strong acid (pH < 2.0) or base (pH > 11.5); or – the substance is flammable in air at room temperature. The Murine Local Lymph Node Assay (LLNA) is the first-choice method for *in vivo* testing. Only in exceptional circumstances should another test be used. Justification for the use of another test shall be provided.
6.4. Mutagenicity **6.4.1. *In vitro* gene mutation study in bacteria**	6.4. Further mutagenicity studies shall be considered in case of a positive result.
6.5. Acute toxicity **6.5.1. By oral route**	6.5. The study/ies do(es) not generally need to be conducted if: – the substance is classified as corrosive to the skin. The study need not be conducted if a study on acute toxicity by the inhalation route (6.5.2) is available.

7. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.1. Aquatic toxicity	
7.1.1. Short-term toxicity testing on invertebrates (preferred species ***Daphnia)*** The registrant may consider long-term toxicity testing instead of short-term.	7.1.1. The study does not need to be conducted if: there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes; or – a long-term aquatic toxicity study on invertebrates is available; or – adequate information for environmental classification and labelling is available. **The long-term aquatic toxicity study on *Daphnia*** (Annex VII, 7.1.5) shall be considered if the substance is poorly water soluble.
7.1.2. Growth inhibition study aquatic plants (algae preferred)	7.1.2. The study does not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.2. Degradation	
7.2.1. Biotic	
7.2.1.1. Ready biodegradability	7.2.1.1 The study does not need to be conducted if the substance is inorganic.

Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided.

ANNEX VI

ADDITIONAL STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 10 TONNES OR MORE

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 10 tonnes or more in accordance with Article 11 (1) (b). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annex V. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the required standard information may be omitted, replaced by other information, provided at a different stage or adapted in another way. If the conditions are met under which column 2 of this Annex allows adaptations, the registrant shall clearly state this fact and the reasons for each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex IX. In this case as well, he shall clearly state the reasons for any decision to adapt the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annexes IX or X[56].

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

When, for certain endpoints, information is not provided for other reasons than those mentioned in column 2 of this Annex or in Annex IX, this fact and the reasons shall also be clearly stated.

[56] Note: conditions for not requiring a specific test that are set out in the appropriate test methods in Annex X itself that are not repeated in column 2, also apply.

6. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.1. Skin irritation **6.1.1. *In vivo* skin irritation**	6.1.1. The study does not need to be conducted if: – the substance is classified as corrosive to the skin or as a skin irritant; or – the substance is a strong acid (pH < 2.0) or base (pH > 11.5); or – the substance is flammable in air at room temperature; or – the substance is classified as very toxic in contact with skin; or – an acute toxicity study by the dermal route does not indicate skin irritation up to the limit dose level (2000 mg/kg body weight); or
6.2. Eye irritation **6.2.1. *In vivo* eye irritation**	6.2.1. The study does not need to be conducted if: – the substance is classified as irritating to eyes with risk of serious damage to eyes; or – the substance is classified as corrosive to the skin and provided that the registrant classified the substance as eye irritant; or – the substance is a strong acid (pH < 2.0) or base (pH > 11.5); or – the substance is flammable in air at room temperature; or

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.4. Mutagenicity	
6.4.2. *In vitro* cytogenicity study in mammalian cells	6.4.2. The study does not usually need to be conducted – if adequate data from an *in vivo* cytogenicity test are available or – the substance is known to be carcinogenic category 1 or 2 or mutagenic category 1, 2 or 3.
6.4.3. *In vitro* gene mutation study in mammalian cells, if a negative result in Annex V, 6.4.1. and Annex VI, 6.4.2.	6.4.3. The study does not usually need to be conducted if adequate data from a reliable *in vivo* mammalian gene mutation test are available. 6.4. Appropriate *in vivo* **mutagenicity** studies shall be considered in case of a positive result in any of the genotoxicity studies in Annex V or VI.
6.5. Acute toxicity	6.5. The study/ies do(es) not generally need to be conducted if: – the substance is classified as corrosive to the skin. In addition to the oral route (6.5.1), for substances other than gases, the information mentioned under 6.5.2. to 6.5.3. shall be provided for at least one other route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route need be provided.
6.5.2. By inhalation	*6.5.2.* Testing by the inhalation route is appropriate if exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.5.3. By dermal route	*6.5.3.* Testing by the dermal route is appropriate if: (1) inhalation of the substance is unlikely; and (2) skin contact in production and/or use is likely; and (3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin.
6.6. Repeated dose toxicity **6.6.1. Short-term repeated dose toxicity study (28 days)**, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure.	6.6.1. The **short-term toxicity study** (28 days) does not need to be conducted if: – a reliable sub-chronic (90 days) or chronic toxicity study is available, provided that an appropriate species, dosage, solvent and route of administration were used; or – where a substance undergoes immediate disintegration and there are sufficient data on the cleavage products; or – relevant human exposure can be excluded in accordance with Annex IX(3). The appropriate route shall be chosen on the following basis: *Testing by the dermal route is appropriate if:* (1) inhalation of the substance is unlikely; and (2) skin contact in production and/or use is likely; and (3) the physicochemical and toxicological properties suggest potential for a significant rate of absorption through the skin. *Testing by the inhalation route is appropriate if* exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	The **sub-chronic toxicity study** (90 days) (Annex VII, 6.6.2) shall be proposed by the registrant if: – the frequency and duration of human exposure indicates that a longer term study is appropriate; and one of the following conditions is met: – other available data indicate that the substance may have a dangerous property that cannot be detected in a short-term toxicity study; or – appropriately designed toxicokinetic studies reveal accumulation of the substance or its metabolites in certain tissues or organs which would possibly remain undetected in a short-term toxicity study but which are liable to result in adverse effects after prolonged exposure.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Article 39 or 40 in case of: – failure to identify a NOAEL in the 28 or the 90 days study, unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects; or – toxicity of particular concern (e.g., serious/severe effects); or – indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation; In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g., immunotoxicity, neurotoxicity); or
	– the route of exposure used in the initial repeated dose study was inappropriate in relation to the expected route of human exposure and route-to-route extrapolation cannot be made; or – particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity to humans may be expected); or – effects shown in substances with a clear relationship in molecular structure with the substance being studied, were not detected in the 28 or the 90 days study.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.7. Reproductive toxicity	6.7.1 This study does not need to be conducted if: the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or – the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or – relevant human exposure can be excluded in accordance with Annex IX(3); or – a pre-natal developmental toxicity study (6.7.2.) or a two-generation reproductive toxicity study (6.7.3.) is available. If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1 or 2: R60, and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered. If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1 or 2: R61, and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.7.1. Screening for reproductive/developmental toxicity, one species (OECD 421 or 422), if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant.	In cases where there are serious concerns about the potential for adverse effects on fertility or development, either a pre-natal developmental toxicity study (Annex VII, 6.7.2.) or a two-generation reproductive toxicity study (Annex VII, 6.7.3.) may be proposed by the registrant instead of the screening study (6.7.1.).
6.8 Toxicokinetics **6.8.1. Assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information**	

7. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.1.3. Short-term toxicity testing on fish: The registrant may consider long-term toxicity testing instead of short-term.	7.1.3. The study does not need to be conducted if: – there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or – the substance is unlikely to cross biological membranes; or – a long-term aquatic toxicity study on fish is available. Long-term aquatic toxicity testing as described in Annex VII shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further effects on aquatic organisms. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment. **The long-term aquatic toxicity study on fish** (Annex VII, 7.1.6) shall be considered if the substance is poorly water soluble.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.1.4. Activated sludge respiration inhibition testing	7.1.4. The study does not need to be conducted if: – there is no emission to a sewage treatment plant; or – there are mitigating factors indicating that microbial toxicity is unlikely to occur, for instance the substance is highly insoluble in water; or – the substance is found to be readily biodegradable and the applied test concentrations are in the range of concentrations that can be expected in the influent of a sewage treatment plant. The study may be replaced by a nitrification inhibition test if available data show that the substance is likely to be an inhibitor of microbial growth or function, in particular nitrifying bacteria.
7.2. Degradation **7.2.2. Abiotic** 7.2.2.1. Hydrolysis as a function of pH.	7.2. Further degradation testing shall be considered if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance. The choice of the appropriate test(s) will depend on the results of the chemical safety assessment. 7.2.2.1. The study does not need to be conducted if: – the substance is readily biodegradable; or – the substance is highly insoluble in water.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.3. Fate and behaviour in the environment	
7.3.1. Adsorption/desorption screening	7.3.1. The study does not need to be conducted if: – based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or – the substance and its relevant degradation products decompose rapidly.

ANNEX VII

ADDITIONAL STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 100 TONNES OR MORE

At the level of this Annex, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 11 (1) (c).

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 100 tonnes or more in accordance with Article 11 (1) (c). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes V and VI. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may propose to adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex IX. In this case as well, he shall clearly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annexes IX or X[57].

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

[57] Note: conditions for not requiring a specific test that are set out in the appropriate test methods in Annex X itself that are not repeated in column 2, also apply.

When, for certain endpoints, it is proposed not to provide information for other reasons than those mentioned in column 2 of this Annex or in Annex IX, this fact and the reasons shall also be clearly stated.

5. INFORMATION ON THE PHYSICOCHEMICAL PROPERTIES OF THE SUBSTANCE

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
5.15. Stability in organic solvents and identity of relevant degradation products Only required if stability of the substance is considered to be critical.	5.15. The study does not need to be conducted if the substance is inorganic.
5.16. Dissociation constant	5.16. The study does not need to be conducted if: – the substance is hydrolytically unstable (half-life less than 12 hours) or is readily oxidisable in water; or – it is scientifically not possible to perform the test for instance if the analytical method is not sensitive enough.
5.17. Viscosity	

6. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	6.4. If there is a positive result in any of the *in vitro* **genotoxicity** studies in Annex V or VI and there are no results available from an *in vivo* study already, an appropriate *in vivo* somatic cell genotoxicity study shall be proposed by the registrant. If there is a positive result from in an *in vivo* somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered..
6.6. Repeated dose toxicity **6.6.1. Short-term repeated dose toxicity study (28 days)**, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex VI requirements or if tests according to 6.6.2 is proposed. In this case, Section 3 of Annex IX shall not apply.	

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.6.2. Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.	6.6.2. The sub-chronic toxicity study (90 days) does not need to be conducted if: – a reliable short-term toxicity study (28 days) is available showing severe toxicity effects according to the criteria for classifying the substance as R48, for which the observed NOAEL-28 days, with the application of an appropriate uncertainty factor, allows the extrapolation towards the NOAEL-90 days for the same route of exposure; or – a reliable chronic toxicity study is available, provided that an appropriate species and route of administration were used; or – a substance undergoes immediate disintegration and there are sufficient data on the cleavage products (both for systemic effects and effects at the site of uptake); or – the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day "limit test", particularly if such a pattern is coupled with limited human exposure. The appropriate route shall be chosen on the following basis: *Testing by the dermal route is appropriate if:* (1) skin contact in production and/or use is likely; and (2) the physicochemical properties suggest a significant rate of absorption through the skin; and

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	(3) one of the following conditions is met: – toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test; or – systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies; or – *in vitro* tests indicate significant dermal absorption; or – significant dermal toxicity or dermal penetration is recognised for structurally-related substances. *Testing by the dermal route is inappropriate if:* – inhalation of the substance is unlikely; and – skin contact in production and/or use is likely; and – the physicochemical and toxicological properties suggest potential for significant absorption through the skin. *Testing by the inhalation route is appropriate if:* – exposure of humans via inhalation is likely taking into account the vapour pressure of the substance and/or the possibility of exposure to aerosols, particles or droplets of an inhalable size.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	Further studies shall be proposed by the registrant or may be required by the Agency in accordance with Articles 39 or 40: – failure to identify a NOAEL in the 90 days study unless the reason for the failure to identify a NOAEL is absence of adverse toxic effects; or – toxicity of particular concern (e.g. serious/severe effects); or – indications of an effect for which the available evidence is inadequate for toxicological and/or risk characterisation; In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or – particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are high relative to the dose levels at which toxicity to humans may be expected).
6.7. Reproductive toxicity	6.7. The studies do not need to be conducted if: – the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or – the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	– the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure. If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1 or 2: R60, and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered. If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1 or 2: R61, and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.
6.7.2. Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (Annex X B.31 or OECD 414).	6.7.2. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available data.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.7.3. Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, if the 28-day or 90-day study indicates adverse effects on reproductive organs or tissues.	6.7.3. The study shall be initially performed on one species. A decision on the need to perform a study at this tonnage level or the next on a second species should be based on the outcome of the first test and all other relevant available date.

7. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.1. Aquatic toxicity **7.1.5. Long-term toxicity testing on invertebrates** (preferred species ***Daphnia)***, (unless already provided as part of Annex V requirements) **7.1.6. Long-term toxicity testing on fish**, (unless already provided as part of Annex VI requirements) The information shall be provided for one of the following 7.1.6.1, 7.1.6.2 or 7.1.6.3.	7.1. Long-term toxicity testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the effects on aquatic organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.
7.1.6.1 Fish early-life stage (FELS) toxicity test **7.1.6.2 Fish short-term toxicity test on embryo and sac-fry stages** **7.1.6.3 Fish, juvenile growth test**	

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.2. Degradation	7.2. Further biotic degradation testing shall be proposed by the registrant if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).
7.2.1. Biotic	
7.2.1.2. Simulation testing on ultimate degradation in surface water	7.2.1.2. The study need not be conducted if: – the substances is highly insoluble in water ; – the substance is readily biodegradable.
7.2.1.3. Soil simulation testing (for substances with a high potential for adsorption to soil)	7.2.1.3. The study need not be conducted: – if the substance is readily biodegradable; or – if direct and indirect exposure of soil is unlikely.
7.2.1.4. Sediment simulation testing (for substances with a high potential for adsorption to sediment)	7.2.1.4. The study need not be conducted: – if the substance is readily biodegradable; or – if direct and indirect exposure of sediment is unlikely.
7.2.3. Identification of degradation products	7.2.3. Unless the substance is readily biodegradable

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.3. Fate and behaviour in the environment	
7.3.2. Bioaccumulation in aquatic species, preferably fish	7.3.2. The study need not be conducted if: – the substance has a low potential for bioaccumulation (for instance a log Kow < 3) and/or a low potential to cross biological membranes; or – direct and indirect exposure of the aquatic compartment is unlikely.
7.3.3. Further information on adsorption/desorption depending on the results of the study required in Annex VI	7.3.3. The study need not be conducted if: – based on the physicochemical properties the substance can be expected to have a low potential for adsorption (e.g. the substance has a low octanol water partition coefficient); or – the substance and its degradation products decompose rapidly.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.4. Effects on terrestrial organisms	7.4. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the exposure to soil organisms. The choice of the appropriate tests depends on the outcome of the chemical safety assessment. In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall consider long-term toxicity testing instead of short-term.
7.4.1. Short-term toxicity to invertebrates	
7.4.2. Effects on soil micro-organisms	
7.4.3. Short-term toxicity to plants	

9. METHODS OF DETECTION AND ANALYSIS

Description of the analytical methods shall be provided on request, for the relevant compartments for which studies were performed using the analytical method concerned. If the analytical methods are not available this shall be justified.

ANNEX VIII

ADDITIONAL STANDARD INFORMATION REQUIREMENTS FOR SUBSTANCES MANUFACTURED OR IMPORTED IN QUANTITIES OF 1000 TONNES OR MORE

At the level of this Annex, the registrant must submit a proposal and a time schedule for fulfilling the information requirements of this Annex in accordance with Article 11(1)(d).

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 1000 tonnes or more in accordance with Article 11(1)(d). Accordingly, the information required in column 1 of this Annex is additional to that required in column 1 of Annexes V, VI and VII. Any other relevant physicochemical, toxicological and ecotoxicological information that is available shall be provided. Column 2 of this Annex lists specific rules according to which the registrant may propose to omit the required standard information, replace it by other information, provide it at a later stage or adapt it in another way. If the conditions are met under which column 2 of this Annex allows an adaptation to be proposed, the registrant shall clearly state this fact and the reasons for proposing each adaptation under the appropriate headings in the registration dossier.

In addition to these specific rules, a registrant may propose to adapt the required standard information set out in column 1 of this Annex according to the general rules contained in Annex IX. In this case as well, he shall clearly state the reasons for any decision to propose adaptations to the standard information under the appropriate headings in the registration dossier referring to the appropriate specific rule(s) in column 2 or in Annexes IX or X[58].

Before new tests are carried out to determine the properties listed in this Annex, all available *in vitro* data, *in vivo* data, historical human data, data from valid (Q)SARs and data from structurally related substances (read-across approach) shall be assessed first. *In vivo* testing with corrosive substances at concentration/dose levels causing corrosivity shall be avoided. Prior to testing, further guidance on testing strategies should be consulted in addition to this Annex.

[58] Note: conditions for not requiring a specific test that are set out in the appropriate test methods in Annex X itself that are not repeated in column 2, also apply.

When, for certain endpoints, it is proposed not to provide information for other reasons than those mentioned in column 2 of this Annex or in Annex IX, this fact and the reasons shall also be clearly stated.

6. TOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	6.4. If there is a positive result in any of the in vitro genotoxicity studies in Annex V or VI, a second in vivo somatic cell test may be necessary, depending on the quality and relevance of all the available data. If there is a positive result from in an *in vivo* somatic cell study available, the potential for germ cell mutagenicity should be considered on the basis of all available data, including toxicokinetic evidence. If no clear conclusions about germ cell mutagenicity can be made, additional investigations shall be considered 6.6.3. **A long-term repeated toxicity study** (≥ 12 months) may be proposed by the registrant or required by the Agency in accordance with Articles 39 or 40 if the frequency and duration of human exposure indicates that a longer term study is appropriate and one of the following conditions is met: – serious or severe toxicity effects of particular concern were observed in the 28 days or 90 days study for which the available evidence is inadequate for toxicological evaluation or risk characterisation; or – effects shown in substances with a clear relationship in molecular structure with the substance being studied were not detected in the 28 days or 90 days study; or – the substance may have a dangerous property that cannot be detected in a 90 days study.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
	6.6.4 **Further studies** shall be proposed by the registrant or may be required by the Agency in accordance with Articles 39 or 40in case of: – toxicity of particular concern (e.g. serious/severe effects); or – indications of an effect for which the available evidence is inadequate for toxicological evaluation and/or risk characterisation; In such cases it may also be more appropriate to perform specific toxicological studies that are designed to investigate these effects (e.g. immunotoxicity, neurotoxicity); or – particular concern regarding exposure (e.g. use in consumer products leading to exposure levels which are close to the dose levels at which toxicity is observed).
6.7 Reproductive toxicity	6.7 The studies need not be conducted if: – the substance is known to be a genotoxic carcinogen and appropriate risk management measures are implemented; or – the substance is known to be a germ cell mutagen and appropriate risk management measures are implemented; or – the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure (e.g. plasma/blood concentrations below detection limit using a sensitive method and absence of the substance and of metabolites of the substance in urine, bile or exhaled air) and there is no or no significant human exposure.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.7.2. Developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (Annex X B.31 or OECD 414).	If a substance is known to have an adverse effect on fertility, meeting the criteria for classification as Repr Cat 1 or 2: R60, and the available data are adequate to support a robust risk assessment, then no further testing for fertility will be necessary. However, testing for development toxicity must be considered. If a substance is known to cause developmental toxicity, meeting the criteria for classification as Repr Cat 1 or 2: R61, and the available data are adequate to support a robust risk assessment, then no further testing for developmental toxicity will be necessary. However, testing for effects on fertility must be considered.
6.7.3. Two-generation reproductive toxicity study, one species, male and female, most appropriate route of administration, having regard to the likely route of human exposure, unless already provided as part of Annex VII requirements	

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
6.9.1 Carcinogenicity study	6.9.1 **A carcinogenicity study** may be proposed by the registrant or may be required by the Agency in accordance with Articles 39 or 40if: – the substance has a widespread dispersive use or there is evidence of frequent or long-term human exposure; and – the substance is classified as mutagen category 3 or there is evidence from the repeated dose study(ies) that the substance is able to induce hyperplasia and/or pre-neoplastic lesions. If the substances is classified as mutagen category 1 or 2, the default presumption would be that a genotoxic mechanism for carcinogenicity is likely. In these cases, a carcinogenicity test will normally not be required.

7. ECOTOXICOLOGICAL INFORMATION

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.2. Degradation **7.2.1. Biotic**	7.2. Further biotic degradation testing shall be proposed if the chemical safety assessment according to Annex I indicates the need to investigate further the degradation of the substance and its degradation products. The choice of the appropriate test(s) depends on the results of the chemical safety assessment and may include simulation testing in appropriate media (e.g. water, sediment or soil).
7.3. Fate and behaviour in the environment **7.3.4. Further information on the environmental fate and behaviour of the substance and/ore degradation products**	7.3.4 Further testing shall be proposed by the registrant or may be required by the Agency in accordance with Article 39 or 40 if the chemical safety assessment according to Annex I indicates the need to investigate further the fate and behaviour of the substance. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.

COLUMN 1 STANDARD INFORMATION REQUIRED	COLUMN 2 SPECIFIC RULES FOR ADAPTATION FROM COLUMN 1
7.4. Effects on terrestrial organisms	7.4. Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment according to Annex I indicates the need to investigate further the effects of the substance and/or degradation products on terrestrial organisms. The choice of the appropriate test(s) depends on the outcome of the chemical safety assessment. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.
7.4.4. Long-term toxicity testing on invertebrates , unless already provided as part of Annex VII requirements. **7.4.6. Long-term toxicity testing on plants**, unless already provided as part of Annex VII requirements.	
7.5.1. Long-term toxicity to sediment organisms	7.5.1. Long-term toxicity testing shall be proposed by the registrant if the results of the chemical safety assessment indicates the need to investigate further the effects of the substance and/or relevant degradation products on sediment organisms. The choice of the appropriate test(s) depends on the results of the chemical safety assessment.
7.6.1. Long-term or reproductive toxicity to birds	7.6.1. Any need for testing should be carefully considered taking into account the large mammalian dataset that is usually available at this tonnage level.

9. METHODS OF DETECTION AND ANALYSIS

Description of the analytical methods shall be provided on request, for the relevant compartments for which studies were performed using the analytical method concerned. If the analytical methods are not available this shall be justified.

ANNEX IX

GENERAL RULES FOR ADAPTATION OF THE STANDARD TESTING REGIME SET OUT IN ANNEXES V TO VIII

Annexes V to VIII set out the information requirements for all substances manufactured or imported in quantities of:

– 1 tonne or more in accordance with Article 11 (1) (a),
– 10 tonnes or more in accordance with Article 11 (1) (b),
– 100 tonnes or more in accordance with Article 11 (1) (c), and
– 1000 tonnes or more in accordance with Article 11 (1) (d).

In addition to the specific rules set out in Column 2 of Annexes V to VIII, a registrant may adapt the standard testing regime in accordance with the general rules set out in Section 1 of this Annex. Under evaluation competent authorities of evaluating Member States may assess these adaptations to the standard testing regime.

1. TESTING DOES NOT APPEAR SCIENTIFICALLY NECESSARY

1.1. Use of existing data

1.1.1. Data on physical-chemical properties from experiments not carried out according to GLP or the test methods referred to in Article 12(2)

Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 12(2)if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and/or risk assessment,
(2) sufficient documentation is provided to assess the adequacy of the study and
(3) the data are valid for the endpoint being investigated and the study is performed using an acceptable level of quality assurance.

1.1.2. Data on human health and environmental properties from experiments not carried out according to GLP or the test methods referred to in Article 12(2)

Data shall be considered to be equivalent to data generated by the corresponding test methods referred to in Article 12(2) if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and/or risk assessment,

(2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 12(2),

(3) exposure duration comparable to or longer than the corresponding test methods referred to in Article 12(2) if exposure duration is a relevant parameter, and

(4) adequate and reliable documentation of the study is provided

1.1.3. Historical human data

Historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data and clinical studies, shall be considered.

The strength of the data for a specific health effect depends, among other things, on the type of analysis and on the parameters covered and on the magnitude and specificity of the response and consequently the predictability of the effect. Criteria for assessing the adequacy of the data include:

(1) the proper selection and characterisation of the exposed and control groups,

(2) adequate characterisation of exposure,

(3) sufficient length of follow-up for disease occurrence,

(4) valid method for observing an effect,

(5) proper consideration of bias and confounding factors, and

(6) a reasonable statistical reliability to justify the conclusion.

In all cases adequate and reliable documentation shall be provided.

1.2. Weight of evidence

There may be sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, while the information from each single source alone is regarded insufficient to support this notion.

There may be sufficient weight of evidence from the use of newly developed test methods, not yet included in the test methods referred to in Article 12(2) or from an international test method recognised by the Commission or the Agency as being equivalent, leading to the conclusion that a substance has or has not a particular dangerous property.

Where sufficient weight of evidence for the presence or absence of a particular dangerous property is available:

– further testing on vertebrate animals for that property shall be omitted,
– further testing not involving vertebrate animals may be omitted.

In all cases adequate and reliable documentation shall be provided.

1.3. Structure-activity relationship (SAR)

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence or absence of a certain dangerous property. Results of (Q)SARs may be used instead of testing when the following conditions are met:

– results are derived from a (Q)SAR model whose scientific validity has been established,
– the substance falls within the applicability domain of the (Q)SAR model,
– results are adequate for the purpose of classification and labelling and/or risk assessment, and
– adequate and reliable documentation of the applied method is provided.

The Agency in collaboration with the Commission, Member States and interested parties shall develop and provide guidance in assessing which (Q)SARs will meet these conditions and provide examples.

1.4. In vitro methods

Results obtained from suitable *in vitro* methods may indicate the presence of a certain dangerous property or may be important in relation to a mechanistic understanding, which may be important for the assessment. In this context, "suitable" means sufficiently well developed according to internationally agreed test development criteria (e.g. the ECVAM criteria for the entry of a test into the prevalidation process). Depending on the potential risk, immediate confirmation requiring testing beyond the information foreseen in Annex V or VI or proposed confirmation requiring testing beyond the information foreseen in Annex VII or VIII for the respective tonnage level may be necessary.

If the results obtained from the use of such *in vitro* methods do not indicate a certain dangerous property, the relevant test shall nevertheless be carried out at the appropriate tonnage level to confirm the negative result, unless testing is not required in accordance with Annexes V to VIII or the other rules in Annex IX.

Such confirmation may be waived, if the following conditions are met:

(1) results are derived from an in vitro method whose scientific validity has been established by a validation study, according to internationally agreed validation principles,
(2) results are adequate for the purpose of classification and labelling and/or risk assessment, and
(3) adequate and reliable documentation of the applied method is provided.

1.5. Grouping of substances and read-across approach

Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or "category" of substances. Application of the group concept requires that physicochemical properties, human health effects and environmental effects or environmental fate may be predicted from data for a reference substance within the group by interpolation to other substances in the group (read-across approach). This avoids the need to test every substance for every endpoint.

The similarities may be based on:

(1) a common functional group,
(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals, or
(3) a constant pattern in the changing of the potency of the properties across the category.

If the group concept is applied, substances shall be classified and labelled on this basis.
In all cases results should:

– be adequate for the purpose of classification and labelling and/or risk assessment,
– have adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 12(2)
– cover an exposure duration comparable to or longer than the corresponding test method referred to in Article 12(2) if exposure duration is a relevant parameter, and
– adequate and reliable documentation of the applied method shall be provided.

2. TESTING IS TECHNICALLY NOT POSSIBLE

Testing for a specific endpoint may be omitted, if it is technically not possible to conduct the study as a consequence of the properties of the substance: e.g. very volatile, highly reactive or unstable substances cannot be used, mixing of the substance with water may cause danger of fire or explosion or the radio-labelling of the substance required in certain studies may not be possible. The guidance given in the test methods referred to in Article 12(2), more specifically on the technical limitations of a specific method, shall always be respected.

3. SUBSTANCE-TAILORED EXPOSURE-DRIVEN TESTING

3.1 Testing in accordance with Annex VI, section 6.6 and 6.7, Annexes VII and VIII may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.

3.2 In all cases, adequate justification and documentation shall be provided. The justification shall be based on an exposure assessment in accordance with Annex I, section 5, and be consistent with the criteria adopted pursuant to paragraph 3.2bis, and the specific conditions of use must be communicated through the chemical supply chain in accordance with Articles 29 or 30.

3.2bis. The Commission shall adopt criteria defining what constitutes adequate justification under Section 2 in accordance with Article 130(3) within 18 months of entry into force of this Regulation.

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ANNEX X

TEST METHODS

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ANNEX XI

GENERAL PROVISIONS FOR DOWNSTREAM USERS TO ASSESS SUBSTANCES AND PREPARE CHEMICAL SAFETY REPORTS

Introduction

The purpose of this Annex is to set out how downstream users are to assess and document that the risks arising from the substance(s) they use are adequately controlled during their use for a use not covered by the safety data sheet supplied to them and that other users further down the supply chain can adequately control the risks. The assessment shall cover the life-cycle of the substance, from its receipt by the downstream user, for his own uses and for his identified uses further down the supply chain. The assessment shall consider the use of the substance on its own, in a preparation or in an article.

In carrying out the chemical safety assessment and producing the Chemical Safety Report, the downstream user shall take account of information received from the supplier of the chemical in accordance with Article 29 and 30 of this Regulation. Where available and appropriate, an assessment carried out under Community legislation, (e.g. risk assessments completed under Regulation 793/93) shall be taken into account in the chemical safety assessment and be reflected in the Chemical Safety Report. Deviations from such assessments shall be justified. Assessments carried out under other international and national programmes may also be taken into account.

The process which the downstream user goes through in carrying out the chemical safety assessment and in producing his Chemical Safety Report, involves three steps:

Step 1: Development of exposure scenario(s)

The downstream user shall develop exposure scenarios for uses not covered in a safety data sheet supplied to him in accordance with Section 5 of Annex I.

Step 2: If necessary, a refinement of the hazard assessment by the supplier;

If the downstream user considers the hazard and PBT assessments reported in the Safety Data Sheet supplied to him to be appropriate, then no further hazard assessment or PBT and vPvB assessment is necessary. In this case he shall use the relevant information reported by the supplier for the risk characterisation. This shall be stated in the chemical safety report.

If the downstream user considers the assessments reported in the Safety Data Sheet supplied to him to be inappropriate, then he shall carry out the relevant assessments in accordance with Annex I, sections 1 through 4 as appropriate to him.

In those cases where the downstream user considers that information in addition to that provided by the supplier is necessary for producing his Chemical Safety Report the downstream user shall gather this information. Where this information can only be obtained by testing on vertebrate animals, he shall submit a proposal for a testing strategy to the Agency in accordance with Article 35. He shall explain why he considers that additional information is necessary. While waiting for results of further testing, he shall record in his chemical safety report the risk management measures intended to manage the risks being explored that he has put in place.

On completion of any additional testing, the downstream user shall revise the Chemical Safety Report, and his Safety Data Sheet if he is required to prepare one, as appropriate.

Step 3: Risk characterisation.

A risk characterisation shall be carried out for each new exposure scenario as prescribed in section 6 of Annex I. The risk characterisation shall be presented under the relevant heading of the Chemical Safety Report and summarised in the Safety Data Sheet under the relevant heading(s).

When generating an exposure scenario it will be necessary to make initial assumptions about the operating conditions and risk managements measures. If the initial assumptions lead to a risk characterisation indicating inadequate protection of human health and the environment, then it shall be necessary to carry out an iterative process with amendment of one or a number of factors until adequate control can be demonstrated. This may require the generation of additional hazard or exposure information or appropriate alteration of the process, operating conditions or risk management measures. Therefore, iterations may be made between on the one hand developing and revising an (initial) exposure scenario, which includes developing and implementing risk management measures, and on the other hand generating further information to produce the definitive exposure scenario. The purpose of generating further information is to establish a more precise risk characterisation, based on a refined hazard assessment and/or exposure assessment.

The downstream user shall produce a Chemical Safety Report detailing his chemical safety assessment using part C, sections 5 and 6, of the format set out in Section 7 of Annex I and the other sections of this format, if appropriate.

Part A of the Chemical Safety Report shall include a declaration that the risk management measures outlined in the relevant exposure scenarios are implemented by the downstream user for his own uses and that the risk management measures outlined in the exposure scenarios for the identified uses are communicated down the supply chain.

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ANNEX XII

CRITERIA FOR THE IDENTIFICATION OF PERSISTENT, BIOACCUMULATIVE AND TOXIC SUBSTANCES, AND VERY PERSISTENT AND VERY BIOACCUMULATIVE SUBSTANCES

This Annex lays down the criteria for the identification of:

i) persistent, bioaccumulative and toxic substances (PBT-substances), and

ii) very persistent and very bioaccumulative substances (vPvB-substances).

A substance is identified as a PBT substance if it fulfils the criteria in Sections 1.1, 1.2 and 1.3. A substance is identified as a vPvB substance if it fulfils the criteria in Sections 2.1 and 2.2. This annex shall not apply to inorganic substances, but shall apply to organo-metals.

1. PBT-SUBSTANCES

A substance that fulfils all three of the criteria of the sections below is a PBT substance.

1.1. Persistence

A substance *fulfils* the persistence criterion (P-) when:

– the half-life in marine water is higher than 60 days, or

– the half-life in fresh- or estuarine water is higher than 40 days, or

– the half-life in marine sediment is higher than 180 days, or

– the half-life in fresh- or estuarine water sediment is higher than 120 days, or

– the half-life in soil is higher than 120 days.

The assessment of the persistency in the environment shall be based on available half-life data collected under the adequate conditions, which shall be described by the registrant.

1.2. Bioaccumulation

A substance *fulfils* the bioaccumulation criterion (B-) when:

– the bioconcentration factor (BCF) is higher than 2000.

The assessment of bioaccumulation shall be based on measured data on bioconcentration in aquatic species. Data from freshwater as well as marine water species can be used.

1.3. Toxicity

A substance *fulfils* the toxicity criterion (T-) when:

– the long-term no-observed effect concentration (NOEC) for marine or freshwater organisms is less than 0.01 mg/l, or

– the substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or

– there is other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC.

2. vPvB – SUBSTANCES

A substance that fulfils the criteria of the sections below is a vPvB substance.

2.1. Persistence

A substance *fulfils* the very persistence criterion (vP-) when:

– the half-life in marine, fresh- or estuarine water is higher than 60 days, or

– the half-life in marine, fresh- or estuarine water sediment is higher than 180 days, or

– the half-life in soil is higher than 180.

2.2. Bioaccumulation

A substance *fulfils* the very bioaccumulative criterion (vB-) when:

– the bioconcentration factor is greater than 5000.

ANNEX XIII

LIST OF SUBSTANCES SUBJECT TO AUTHORISATION

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ANNEX XIV

DOSSIERS

I. INTRODUCTION AND GENERAL PROVISIONS

This Annex lays down general principles for preparing dossiers to propose and justify:

– harmonised classification and labelling of CMRs and respiratory sensitisers;
– the identification of PBTs, vPvBs, or a substance of equivalent concern;
– restrictions of the manufacture, placing on the market or use of a substance within the Community.

The relevant parts of Annex I shall be used for the methodology and format of any dossier according to this Annex.

For all dossiers any relevant information from registration dossiers shall be considered and other available information may be used. For hazard information which has not been previously submitted to the Agency, a robust study summary shall be included in the dossier.

II. CONTENT OF DOSSIERS

1. Dossier for harmonised classification and labelling for CMRs and respiratory sensitisers

Proposal

The proposal shall include the identity of the substance(s) concerned and the harmonised classification and labelling proposed.

Justification

A comparison of the available information with the criteria in Directive 67/548/EEC for CMRs and respiratory sensitizers according to the relevant parts of Section 1 of Annex I shall be completed and documented in the format set out in Part B and C of the Chemical Safety Report in Annex I.

2. Dossier for the identification of a substance as a PBT, vPvB or a substance of equivalent concern

Proposal

The proposal shall include the identity of substance(s) concerned and whether it is proposed to be identified as a PBT according to Article 54(d), a vPvB according to Article 54(e), or a substance of equivalent concern according to Article 54(f).

Justification

A comparison of the available information with the criteria in Annex XII for PBT according to Article 54(d), and vPvBs according to Article 54(e), or an assessment of the hazards and a comparison with Article 54(f), according to the relevant parts of Section 1 to 4 of Annex I shall be completed. This shall be documented in the format set out in Part B and C of the Chemical Safety Report in Annex I.

Information on exposures, alternative substances and risks

The available use and exposure information and information on alternative substances and techniques shall be provided.

3. Dossiers for restrictions proposal

Proposal

The proposal shall include the identity of the substance and the restriction(s) proposed for the manufacture, placing on the market or use(s) and a summary of the justification.

Information on hazard and risk

The risks to be addressed with the restriction shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I and shall be documented in the format set out in Part B and C of that Annex for the Chemical Safety Report.

Evidence shall be provided that implemented risk management measures (including those identified in registrations under Articles 9 to 13) are not sufficient.

Information on alternatives

Available information on alternative substances and techniques shall be provided, including:

– information on the risks to human health and the environment related to the manufacture or use of the alternatives;
– availability, including the time scale;
– technical and economical feasibility.

Justification for Restrictions at Community Level

Justification shall be provided that:

– action is required on a Community-wide basis
– a restriction is the most appropriate Community wide measure which shall be assessed using the following criteria:
  (i) **effectiveness**: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk;
  (ii) **practicality**: the restriction must be implementable, enforceable and manageable.
  (iii) **monitorability**: the ability to monitor the result of the implementation of the proposed restriction

Socio-economic assessment

The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XV. To this end, the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

Information on stakeholder consultation

Information on any consultation of stakeholders and how their views have been taken into account shall be included in the dossier.

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ANNEX XV

SOCIO-ECONOMIC ANALYSIS

This Annex outlines the information that may be addressed by those submitting a socio-economic analysis (SEA) with an application for authorisation, as specified in Article 59 (5) (a), or in connection with a proposed restriction, as specified in Article 66(3)(b).

The Agency shall prepare guidance for the preparation of SEAs. SEAs, or contributions to them, shall be submitted in the format specified by the Agency in accordance with Article 108.

However, the level of detail and scope of the SEA, or contributions to them, shall be the responsibility of the applicant for authorisation, or, in the case of a proposed restriction, the interested party. The information provided can address the socio-economic impacts at any level.

An SEA may include the following elements:

– Impact of a granted or refused authorisation on the applicant(s), or, in the case of a proposed restriction, the impact on industry (e.g. manufacturers and importers). The impact on all other actors in the supply chain, downstream users and associated businesses in terms of commercial consequences such as impact on investment, research and development, innovation, one-off and operating costs (e.g. compliance; transitional arrangements; changes to existing processes, reporting and monitoring systems; installation of new technology etc.) taking into account general trends in the market and technology.

– Impacts of a granted or refused authorisation, or a proposed restriction, on consumers. For example, product prices, changes in composition or quality or performance of products, availability of products, consumer choice, as well as effects on health and the environment to the extent that these affect consumers.

– Social implications of a granted or refused authorisation, or a proposed restriction. For example job security and employment.

– Availability, suitability, and technical feasibility of alternative substances and/or technologies, and economic consequences thereof, and information on the rates of, and potential for, technological change in the sector(s) concerned. In the case of an application for authorisation, the social and/or economic impacts of using any available alternatives identified in Article 59(5)(b).

– Wider implications on trade, competition and economic development (in particular for SMEs and in relation to third countries) of a granted or refused authorisation, or a proposed restriction. This may include consideration of local, regional, national or international aspects.

– In the case of a proposed restriction, proposals for other regulatory or non-regulatory measures that could meet the aim of the proposed restriction (this shall take account of existing legislation). This should include an assessment of the effectiveness and the costs linked to alternative risk management measures.

– In the case of a proposed restriction or refused authorisation, the benefits for health and the environment as well as the social and economic benefits of the proposed restriction. For example, worker health, environmental performance and the distribution of these benefits, for example, geographically, population groups.

– An SEA may also address any other issue that is considered to be relevant by the applicant(s) or interested party.

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ANNEX XVI

RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES

[This annex is set out in document 15921/1/05 REV 1 ADD 1]

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ANNEX XVII

PERSISTENT ORGANIC POLLUTANTS (POPS)

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