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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	31 March 2015
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2015) 2067 final
Subject:	Commission Delegated Directive ../…/EU of 31.3.2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

Delegations will find attached document C(2015) 2067 final.

Encl.: C(2015) 2067 final

EUROPEAN
COMMISSION

Brussels, 31.3.2015
C(2015) 2067 final

COMMISSION DELEGATED DIRECTIVE ../…/EU

of 31.3.2015

amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Subject: Commission Delegated Directive amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS 2) entered into force on 21 July 2011. RoHS 2 restricts the use of certain hazardous substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers) in electrical and electronic equipment (EEE). The restricted substances are listed in Annex II to RoHS 2.

Article 6(1) of RoHS 2 establishes a procedure for a periodic review of Annex II and sets the date for the first review: *"With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and amendment of the list of restricted substances in Annex II shall be considered by the Commission* ***before 22 July 2014, and periodically thereafter*** *[…]."*

Pursuant to Article 6(3) of RoHS 2, the *"measures referred to in this Article shall be adopted by the Commission by means of* ***delegated acts****."*

In order to avoid inconsistencies with REACH, the classification of substances and any available substance-specific information under REACH, including the regulatory processes of authorisation and restriction, shall be considered: *"The review and amendment of the list of restricted substances in Annex II shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006, and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review shall use publicly available knowledge obtained from the application of such legislation."*

Recital 16 of RoHS 2 states that the review and amendment of the list of restricted substances in Annex II should also *"reflect the complementary nature of the work carried out under other Union legislation, and in particular under Regulation (EC) No 1907/2006 while ensuring the mutually independent operation of this Directive and that Regulation."*

The position of the Commission is that the REACH reference in RoHS 2 does not indicate that the procedure should be fully aligned or the criteria for a restriction under RoHS 2 are necessarily the same as under REACH. It is however important to avoid double regulation or conflict between the two legislative instruments. Under RoHS 2, *"in order to review and amend Annex II, the Commission shall take special account of whether a substance […] or a group of similar substances:*

(a) could have a negative ***impact during EEE waste management operations****, including on the possibilities for preparing for the reuse of waste EEE or for recycling of materials from waste EEE;*

(b) could give rise, given its uses, to uncontrolled or diffuse ***release*** *into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products* ***through*** *the preparation for reuse, recycling or other* ***treatment of materials from waste EEE*** *under current operational conditions;*

(c) could lead to unacceptable ***exposure of workers involved in the waste EEE*** *collection or* ***treatment*** *processes;*

(d) could be replaced by substitutes or alternative technologies which have less negative impacts."

In its Common Understanding Paper on REACH and RoHS of 9 July 2014[1], the Commission clarified that RoHS 2 is the preferred legal instrument for tackling substance-related issues in electrical and electronic products. In order to ensure coherence between REACH and RoHS 2, the Paper sets out agreed approaches to certain scenarios, in particular for substances already subject to authorisation or restriction under REACH. It is also important to note that although the inclusion of a substance in Annex XIV to REACH (authorisation list) only affects manufacturing and does not prevent finished products containing this substance being imported into the EU, Article 69(2) of REACH requires the European Chemicals Agency (ECHA) to consider whether the use of the substance in articles poses a risk to human health or the environment. If it does, a restriction may be imposed which can address imports.

As regards the first RoHS 2 substance review, Recital 10 names the **highest priority substances**: *"In particular, the risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered as a priority. With a view to further restrictions of substances, the Commission should re-investigate the substances that were subject to previous assessments […]."*

Pursuant to Article 6(1) of RoHS 2, the first review of Annex II was due July 2014. The Commission published an open call and launched a preparatory study in November 2012. The consultants (Environmental Agency Vienna, UBA) developed a methodology for the identification, pre-assessment and assessment of substances that is EEE-specific and does not contradict REACH knowledge and provisions. The aim was to produce a sound basis for future reviews that can also be applied to future Member State submissions as suggested by Article 6 of RoHS 2. They also applied this methodology to the above mentioned priority substances **DEHP, BBP, DBP** (three common phthalate plasticisers) and **HBCDD** (a brominated flame retardant) and, based on this assessment, recommended a restriction of all four. An additional result of the pre-assessment was a list of 24 priority substances for future reviews. Final versions of all documents are available since end of January 2014.[2]

As a follow-up, in order to avoid detrimental substitution effects from one problematic halogenated plasticiser to another, the Commission mandated RoHS consultants Oeko-Institut ("Oeko") under an existing framework contract in November 2013 with the assessment of

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[1] http://ec.europa.eu/geninfo/query/resultaction.jsp?QueryText=rohs+and+reach&query_source=ENTERPRISE&swlang=en#queryText=rohs+and+reach&tab=restricted&customsort=date&filterNum=0&summary=summary.

[2] Direct links to substance evaluations and recommendations:
http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex5_RoHS_AnnexII_Dossier_HBCDD.pdf [HBCDD];
http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex6_RoHS_AnnexII_Dossier_DEHP.pdf [DEHP];
http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex7_RoHS_AnnexII_Dossier_BBP.pdf [BBP];
http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex8_RoHS_AnnexII_Dossier_DBP.pdf [DBP].

DIBP (diisobutyl phthalate) according to the newly developed methodology. DIBP had come up as a top priority substance in UBA's above mentioned prioritisation exercise. Oeko's recommendation published in June 2014 was to give **DIBP** the same treatment as the other three phthalates above.[3]

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Pursuant to Article 6(1) of RoHS 2, any review of the list of restricted substances in Annex II requires the consultation of *"interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations."*

In line with the provisions for the review of Annex II, the Commission launched the above mentioned two studies and carried out the requisite technical and scientific assessment including five official stakeholder consultations and three official stakeholder meetings.[4] The two final reports are available on the consultants' webpages; stakeholders and Member States were notified thereof. The project page is accessible via the DG Environment webpage.[5]

Subsequently, the Commission consulted the official expert group for delegated acts under RoHS 2. A meeting with consultants and experts was held on 25 June 2014, a consolidated recommendation with all necessary background information was sent out on 1 July 2014 and experts were invited to comment on the draft by 25 August 2014. The expert group unanimously supported the draft. All necessary steps pursuant to Article 6 of RoHS 2 have been performed. The Council and the Parliament were notified of all activities of the delegated acts expert group via their official functional mailboxes.

Technical background information (for further information see footnotes 2 and 3):

HBCDD is a brominated flame retardant. It is a substance of very high concern (SVHC)[6]; it is persistent and undergoes long range transport; it accumulates in the food chain, is reprotoxic and accumulates in human breast milk. Although the consultants recommended the restriction of HBCDD, the Commission considered a ban disproportionate and refrained from it for the following reasons: On 22 May 2013 the Stockholm Convention on Persistent Organic Pollutants (POPs) decided to include HBCDD in the Convention's Annex A for elimination, with specific exemptions only for expanded (EPS) and extruded polystyrene (XPS) in buildings. Japan was the first country to implement a ban on the import and production of HBCDD effective since May 2014. A complete phase-out of HBCDD in electronics, whether imported or produced in Europe, will only be a matter of years. In relation to the REACH authorisation process for HBCDD, ECHA did not receive an application for authorisation for any specific use in EEE. This confirms that in Europe HBCDD is not used in EEE.

DEHP, BBP, DBP, DIBP:

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3 http://rohs.exemptions.oeko.info/fileadmin/user_upload/reports/20140520_DIBP_AnnexII_Dossier_final.pdf [DIBP].

4 The consultation list is regularly updated and maintained by the consultants in cooperation with the Commission, and includes electronics related industry organisations, manufacturers and suppliers, recyclers, consumer associations, NGOs, academia, Member States' representatives, etc. DG Enterprise was actively involved in all activities.

5 http://ec.europa.eu/environment/waste/rohs_eee/review/index_en.htm.

6 ECHA Decision ED/67/2008; http://echa.europa.eu/documents/10162/2bbe3f6b-4ef6-4586-b4bc-66f9a6c7a894.

DEHP is the most common plasticiser used in PVC. It is a substance of very high concern.[7] DEHP is a widespread environmental pollutant, found in the food chain and in the human diet.

The majority of environmental releases of DEHP from relevant WEEE treatment processes are releases to air. The total annual releases are estimated to be 0.9 to 6.8 tonnes. In addition, releases of DEHP are also expected from landfills, incineration plants and uncontrolled treatment of WEEE. Estimates of the number workers exposed to DEHP releases range between 2,250 and 6,750. The European risk assessment report on DEHP[8] concludes that there is a need to limit the risks from use of DEHP at workplaces.

Taking into account the regulations pertaining to the use of DEHP (e.g. under REACH) it is expected that the recycling possibilities for PVC will be reduced due to the presence of DEHP in WEEE plastics. Currently recycled PVC is used for the production of low value articles. Thus it is not expected that DEHP will stay in the recycling loop for long. Waste with a DEHP content of 0.5% is considered hazardous. Assuming a separating and shredding rate of 80% for all WEEE cables, the estimated amount of hazardous waste generated per year is 110,000 tonnes.

Detailed assessments on possible alternatives were carried out recently on behalf of the European Chemicals Agency and the Danish Ministry of Environment.[9] Besides the hazard profiles of such substitutes, their use and technical feasibility were assessed.[10] The results of these assessments show that the substitution of DEHP by less harmful substances is possible and already being done. Possible alternatives are DINP (Di-isononyl phthalate, DIDP (Di-isodecyl phthalate), DINCH (Di-isononyl cyclohexane-1,2-dicarboxylate) and ASE (Alkylsulfonic phenyl ester). In general, the use of DEHP in EEE is not considered to be essential, although there are still uncertainties about the safety of possible alternatives in particular in the medical sector.

In total, a ban on DEHP in EEE would create very limited additional costs while creating substantial additional benefits for health, environment and the economy. The overall impact on jobs/employment is expected to be small. With respect to the benefits, however, the impact of a DEHP ban is expected to be substantial:

- Increase in the competitive position of an environmentally friendly industry;
- Global reduction of environmental and health impacts from DEHP and plastics production;
- Reduction of the environmental and health impact from the use of DEHP containing EEE and especially of impacts arising during the waste and recycling phase.

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7 http://echa.europa.eu/documents/10162/2bbe3f6b-4ef6-4586-b4bc-66f9a6c7a894.

8 http://echa.europa.eu/documents/10162/060d4981-4dfb-4e40-8c69-6320c9debb01.

9 COWI 2009, Data on manufacture, import, export, uses and releases of Bis(2-ethylhexyl) phthalate (DEHP) as well as information on potential alternatives to its use; and Danish Environmental Protection Agency 2011, Annex XV Restriction Report. Proposal for a restriction. Substance name: Bis(2-Ethylhexyl) phthalate (DEHP); Benzyl butyl phthalate (BBP); Dibutyl phthalate (DBP); Diisobutyl phthalate (DIBP).

10 Summary and further references: http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex6_RoHS_AnnexII_Dossier_DEHP.pdf, p. 55.

DEHP should therefore be included in Annex II to the RoHS 2 Directive. A restriction of DEHP under RoHS 2 is considered to be an appropriate measure to reduce any negative impacts from or on WEEE management because:

- A risk for the environment (secondary poisoning of mammalians and birds) must be expected from the relevant WEEE treatment processes (i.e. the handling of materials at shredder sites, shredding of cables and recycling of PVC derived from WEEE). Occupational exposure estimates for workers in WEEE treatment plants indicate that it is possible that exposure exceeds the safe exposure levels derived by the risk assessment committee of the European Chemicals Agency. Therefore, a risk for workers cannot be excluded;

- DEHP releases from sites for the mechanical treatment of WEEE and cables and from PVC recycling are relevant contributors to the overall releases to air from treatment of DEHP-containing wastes in a scenario where measures for preventing dust emissions are insufficient;

- There are considerable negative impacts on waste management (reduced recycling possibilities due to regulations for DEHP, generation of considerable amounts of hazardous waste);

- Alternatives with less negative properties are available and technically and economically feasible;

- The socio-economic impact analysis indicates that a restriction of DEHP would have several benefits, including reduced risks and a less negative impact on waste management. Additional costs would be incurred in some sectors, i.e. by producers of chemicals and in the production of EEE.

A restriction of DEHP in EEE would therefore be fully in line with the requirements and criteria of Article 6(1) of RoHS 2. The proposed maximum concentration value of DEHP to be tolerated in EEE is 0.1 weight % per homogeneous material. Given the level of risk estimated by the Commission's consultants when assuming a DEHP concentration in PVC of a few %, it can be expected that a maximum concentration of 0.1 weight %, which is the limit value for all other restricted substances under RoHS except cadmium, will already lead to significantly reduced risks.

The situation regarding **BBP and DBP** is similar. Both substances are SVHC and classified as toxic to reproduction.[11] A risk for workers was identified for DBP for industrial processes in Europe in 2003, with concerns for general systemic toxicity as a consequence of repeated dermal exposure arising from aerosol forming activities, as well as concerns for adverse local effects in the respiratory tract as a consequence of repeated inhalation exposure. The majority of environmental releases of BBP and DBP from relevant WEEE treatment processes are releases to air.

Alternatives are available. In addition to the alternatives mentioned under DEHP, potential substitutes are DGD (Dipropylene glycol di-benzoate) and GTA (Glycerol triacetate).[12] BBP

[11] http://echa.europa.eu/documents/10162/2bbe3f6b-4ef6-4586-b4bc-66f9a6c7a894.

[12] http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex7_RoHS_AnnexII_Dossier_BBP.pdf, p. 38; and

and DBP are not as widely used in EEE as DEHP and industry was reluctant to provide accurate data in the course of the various stakeholder consultations, although specific applications such as capacitors could be identified. Even on the basis of a worst case scenario regarding the amounts of BBP and DBP potentially used in electronics, the overall socio-economic impact of a restriction under RoHS 2 is expected to be very small. This impact assessment covers both substitution and compliance documentation costs. With respect to the benefits, however, the impact of a ban is expected to be substantial. **BBP and DBP should therefore be included in Annex II to the RoHS 2 Directive. The proposed maximum concentration value per substance to be tolerated in EEE is 0.1 weight % per homogeneous material.** For BBP listed in Annex XIV to REACH, no application for authorisation for use in EEE has been received so far; therefore after the sunset date of February 2015, the use of BBP in the production of EEE in Europe will be banned.

Regarding **DIBP**, which is also a substance of very high concern because of its reproductive toxicity[13], the situation is slightly different. Available data collected by the Commission's consultants suggests that DIBP is currently not used in traditional EEE. It is however used as a plasticiser in glues and inks for paper and food packaging, and in toys, childcare articles and a wide range of consumer products, some of which indeed might be in the scope of RoHS 2. Moreover, DIBP has similar properties as DBP and can be used as a substitute for it. In a scenario where DIBP instead of DBP would be used in EEE, the assessment would be the same as for DBP, and a restriction would become necessary in any case. Consultants therefore recommend that measures against DIBP in EEE under RoHS 2 should be tied to the restriction of the other three phthalates in order to avoid "regrettable substitution". The same logic was applied when DIBP was added to Annex XIV to REACH. **DIBP should therefore be included in Annex II to the RoHS 2 Directive. The proposed maximum concentration value per substance to be tolerated in EEE is 0.1 weight % per homogeneous material.** As no application for authorisation for use in EEE has been received so far, after the sunset date of February 2015, the use of DIBP in the production of EEE in Europe will be banned.

The decision to restrict DEHP, BBP, DBP and DIBP under RoHS is coherent with and complementary to REACH. The consultants' assessment is consistent with available REACH data, which were used in the evaluation, and the substance classification under REACH. The restriction is also fully in line with the Commission's Common Understanding Paper on REACH and RoHS of 9 July 2014 (see above).

DEHP, BBP and DBP have been restricted in toys for nearly a decade through entry 51 of Annex XVII to REACH. Toys containing these phthalates in a concentration greater than 0.1% (calculated for the three phthalates cumulatively) by weight of the plasticised material cannot be placed on the EU market. Avoidance of double regulation of EEE toys by RoHS 2 will be ensured by stipulating that the long-standing, stricter restriction in entry 51 of Annex XVII to REACH will continue to be the only restriction applicable to DEHP, BBP and DBP in EEE toys. This preserves the established concentration calculation for toys of 0.1% for the three phthalates in combination and avoids any relaxation of the restriction (by calculating concentration on the basis of 0.1% per phthalate).

With regard to authorisations under REACH, there will be a need to ensure coherent administration of any adaptation to technical progress of Annex III or IV of RoHS 2 to

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http://www.umweltbundesamt.at/fileadmin/site/umweltthemen/abfall/ROHS/finalresults/Annex8_RoHS_AnnexII_Dossier_DBP.pdf, p. 37. Cf. also footnote 10.

[13] ECHA Decision ED/68/2009; http://echa.europa.eu/documents/10162/3b3b4e1d-f47b-43d1-9726-e25f959bd110.

exempt certain applications of DEHP and DBP and any authorisation granted under REACH. Applications for authorisation have been received for these two phthalates including uses in EEE.

In order to allow a smooth transition and to mitigate possible minor socioeconomic impacts, an appropriate transition period should be granted. Extensive discussions with sectoral stakeholders showed that **22 July 2019 is a realistic compliance date for the majority of EEE, while 22 July 2021 should be sufficient for RoHS 2 Annex I categories 8 and 9, i.e. medical devices including in vitro medical devices and monitoring and control instruments including industrial monitoring and control instruments.** This gradual approach is coherent with the gradual extension of RoHS restrictions in Article 4(3) of RoHS 2 and respects the higher reliability requirements and longer innovation cycles of product categories 8 and 9. It will also help ensure legal certainty and allow all economic operators to identify problem areas and submit application specific exemption requests for the newly banned substances well ahead of the deadline.[14] This timetable will also give the Commission enough time to deal with these requests and grant an exemption where the substitution is indeed inappropriate pursuant to the criteria of Article 5(1) of RoHS 2 and the use of a restricted substance should be tolerated beyond the respective compliance date. The exact date is aligned with the compliance date in Article 2(2) of RoHS 2 for products newly included in the scope and will therefore facilitate procedural efforts (documentation etc.) for economic operators.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The act adds the four phthalates DEHP, BBP, DBP and DIBP to the list of restricted substances in Annex II to Directive 2011/65/EU (RoHS 2).

The instrument is a delegated directive.

The delegated directive implements Directive 2011/65/EU, and in particular Article 6(3) thereof.

The objective of the act is to ensure legal certainty and sustainable market conditions for electronic manufacturers, to establish a level playing field for EU and non-EU manufacturers and to facilitate EEE recycling by phasing out problematic substances, while granting an appropriate transition period in order to allow economic operators to apply for the exemption of specific applications of these substances in line with the provisions of RoHS 2 and the procedure established in Article 5 of RoHS 2 for the adaptation of Annexes III and IV to scientific and technical progress.

In accordance with the principle of proportionality, the measure does not go beyond what is necessary to achieve its objective.

The act has no implications for the EU budget.

[14] The medical sector already submitted a draft list and phase-out timetable for DEHP, DBP and BBP on 23 October 2014.

COMMISSION DELEGATED DIRECTIVE ../…/EU

of 31.3.2015

amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment,[15] and in particular Article 6(3) thereof,

Whereas:

(1) Directive 2011/65/EU lays down rules on the restriction of the use of hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE.

(2) Directive 2011/65/EU prohibits the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in electrical and electronic equipment placed on the Union market. Annex II to that Directive lists those restricted substances.

(3) The risks to human health and the environment arising from the use of Hexabromocyclododecane (HBCDD), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP) and Dibutyl phthalate (DBP) should be considered a priority in the periodic review of the list of restricted substances in Annex II. With a view to further restrictions, the substances that were subject to previous assessments should be re-investigated.

(4) In accordance with Article 6(1) of Directive 2011/65/EU, interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations, have been consulted and a thorough assessment has been performed.

(5) Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) are substances of very high concern (SVHC). DIBP is a substance that can be used as a substitute for DBP and was subject to

[15] OJ L 174, 1.7.2011, p. 88.

previous assessments performed by the Commission. The available evidence indicates that those four substances, when used in EEE, can have a negative impact on recycling and on human health and the environment during EEE waste management operations.

(6) Substitutes that have less negative impacts are available for DEHP, BBP, DBP and DIBP in most EEE. The use of those substances in EEE should therefore be restricted. DEHP, BBP and DBP are already restricted through entry 51 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council,[16] so that toys containing DEHP, BBP or DBP in a concentration greater than 0,1 % by weight of the plasticised material, calculated for the three phthalates cumulatively, cannot be placed on the EU market. In order to avoid double regulation, the restriction through entry 51 of Annex XVII to that Regulation shall therefore continue to be the only restriction applicable to DEHP, BBP and DBP in toys.

(7) In order to facilitate transition and to mitigate possible socioeconomic impacts, an appropriate transition period should be granted, which will allow economic operators to apply for exemptions from the substance restrictions in accordance with Article 5 of Directive 2011/65/EU. The longer innovation cycles for medical devices and monitoring and control instruments should be taken into account while determining the transitional period. The restriction of the use of DEHP, BBP, DBP and DIBP should therefore apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.

(8) Any adaptation of Annexes III or IV to Directive 2011/65/EU to exempt applications in relation to DEHP or DBP should take place in a manner which, in order to avoid double regulation and unnecessary burden, ensures coherence with the administration of any authorisation granted under Regulation (EC) No 1907/2006 in relation to the incorporation of those substances in EEE. Operators considering whether to apply for exemptions under Directive 2011/65/EU should be aware that such exemptions may cover the entire life cycle of the EEE, including the manufacturing phase.

(9) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex II to Directive 2011/65/EU is replaced by the text in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 31 December 2016 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

[16] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

They shall apply those provisions from 22 July 2019.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 31.3.2015

For the Commission
The President
Jean-Claude JUNCKER