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ADDENDUM to REVISED NOTE

from:	General Secretariat
to:	Delegations
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Subject:	Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products

The Annex to this addendum contains Presidency suggestions for Annex IV to the proposed Regulation.

ANNEX IV

GENERAL RULES FOR THE ADAPTATION OF THE DATA REQUIREMENTS

This annex gives guidance to be followed when the applicant proposes to adapt the data requirements set out in Annexes II and III according to article 6, 2 and 3 or to article 19, 1 and 2. The reasons for such adaptations to the data requirements must be clearly stated under the appropriate heading of the dossier referring to the specific rule(s) of this Annex.

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 relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and risk assessment;

(2) sufficient adequate and reliable documentation is provided to assess the equivalency 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 relevant test methods.

Data shall be considered to be equivalent to data generated by the corresponding test methods if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and risk assessment;

(2) adequate and reliable coverage of the key parameters/end-points foreseen to be investigated in the corresponding test methods;

(3) exposure duration comparable to or longer than the corresponding test methods if exposure duration is a relevant parameter; and

(4) adequate and reliable documentation of the study is provided.

1.1.3. Historical human data

As a general rule, new human data should not be generated with the purpose of this regulation.

However, existing historical human data, such as epidemiological studies on exposed populations, accidental or occupational exposure data, biomonitoring studies, clinical studies and human volunteer studies performed in accordance with internationally accepted ethical standards shall be considered. The strength of the data for a specific human 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 positive results of newly developed test methods, not yet included in the relevant test methods or from an international test method recognised by the Commission as being equivalent, leading to the conclusion that a substance has a particular dangerous property. However if the newly developed test method has been approved by the Commission but not yet been published, its results may be taken into account even if leading to the conclusion that a substance has not a particular dangerous property.

Where consideration of all the available data provides sufficient weight of evidence for the presence or absence of a particular dangerous property […] :

– 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. Qualitative or Quantitative structure-activity relationship ((Q)SAR)

Results obtained from valid qualitative or quantitative structure-activity relationship models ((Q)SARs) may indicate the presence but not the 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 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 on the use of (Q)SARs.

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.
Where such in vitro tests are positive, it is necessary to confirm this toxic property by adequate in vivo tests. However, 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 risk assessment; and
(3) adequate and reliable documentation of the applied method is provided.

In case of negative results, these exemptions do not apply.

1.5. Grouping of substances and read-across approach

Substances whose physicochemical, toxicological and ecotoxicological properties are […] 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 reference substance(s) 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 indicating the presence of dangerous properties;

(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals and indicates the presence of dangerous properties; 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 risk assessment,
– have adequate and reliable coverage of the key parameters addressed in the corresponding test method,
– cover an exposure duration comparable to or longer than the corresponding test method if exposure duration is a relevant parameter, and
– adequate and reliable documentation of the applied method shall be provided.

The Agency in collaboration with the Commission, Member States and interested parties shall develop and provide guidance on technically and scientifically justified methodology for the grouping of substances.

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 relevant test methods, more specifically on the technical limitations of a specific method, shall always be respected.

3. PRODUCT-TAILORED EXPOSURE-DRIVEN TESTING

3.1. Testing in accordance with some end-points in sections {6 and 7} of Annexes II and III may be omitted based on exposure considerations, in case exposure data are available.
In this case, the following conditions must be met:

- An exposure assessment must be performed, covering primary and secondary exposure under realistic worst case for all intended uses of the biocidal product that contains the active substance for which the Annex I inclusion is applied for, or of the biocidal product for which the authorisation is sought.
- If a new exposure scenario is introduced at a later stage, during the product authorisation process, additional data must be submitted to assess whether the justification for data adaptation still applies.
- The reasons why the outcome of the exposure assessment justifies waiving of data requirements must be clearly and transparently explained.

However, testing cannot be omitted for non-threshold effects. As a consequence certain core data should always be obligatory, e.g. genotoxicity testing.

If relevant, the Agency in collaboration with the Commission, Member States and interested parties shall develop and provide further guidance on the criteria established according to articles 6,4 or article 19,4.

3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on an exposure assessment in accordance with the Technical Notes for Guidance.