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COMMUNICATION FROM THE COMMISSION

on the reviews of Annexes I, IV and V to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

(Text with EEA relevance)

[SEC(2009) 447]

1. INTRODUCTION

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)¹ is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such chemical substances that do not adversely affect human health or the environment.

Registration requires manufacturers and importers of chemicals to obtain relevant information on their substances and to use it to ensure that their substances are managed safely. For substances manufactured or imported in quantities of 10 tonnes or more per year and per legal entity, a chemical safety assessment (CSA) must be carried out and recorded in a chemical safety report (CSR).

Annex I to REACH sets out how to carry out a CSA and to document it in a CSR. This Annex is supplemented by the Technical Guidance Document on information requirements and chemical safety assessment (TGD IR/CSA²).

Annexes IV and V list substances and groups of substances that are exempted from the REACH obligations on registration, as well as downstream users and evaluation provisions of REACH.

Article 138(4) of the REACH Regulation gave the Commission a mandate to carry out a review of Annexes I, IV and V by 1 June 2008, with a view to proposing amendments to them, if appropriate, in accordance with the procedure referred to in Article 131 (comitology, regulatory procedure with scrutiny).

This review was carried out between June 2007 and June 2008. Member States and stakeholders were consulted in the REACH Competent Authorities Subgroup (CASG(Annexes)). Regular progress reports on the review of Annexes I, IV and V were also made to meetings of the REACH Competent Authorities (CAs).

2. REVIEW OF ANNEX I

2.1. Introduction

REACH is based on the principle that manufacturers, importers and downstream users shall ensure that the manufacture, placing on the market and use of substances shall not adversely affect human health or the environment.

For substances manufactured or imported at or above 10 tonnes per year and per legal entity, a chemical safety assessment (CSA) must be carried out and recorded in a chemical safety report (CSR) in accordance with Article 14 of REACH. The CSA consists of a hazard assessment covering human health, physicochemical properties and environmental effects, together with a persistent, bioaccumulative and toxic (PBT)/very persistent and very bioaccumulative (vPvB) assessment. If the assessment concludes that a substance meets the

¹ OJ L 396, 30.12.2006, p. 1, as corrected by OJ L 136, 29.5.2007, p. 3.

² http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm

criteria for classification as dangerous for at least one property or is a PBT/vPvB substance, then an exposure assessment, including the generation of one or more exposure scenarios and a risk characterisation, is required to demonstrate either that the substance is adequately controlled or that exposures to it are minimised. Article 14(6) of REACH requires that the risks from manufacture and all identified uses of a substance must be adequately controlled.

Annex I to REACH sets out details of how to carry out a CSA and to document it in a CSR. This Annex is supplemented by the Technical Guidance Document on information requirements and chemical safety assessment (TGD IR/CSA) developed under REACH Implementation Projects (RIP) 3.2 and 3.3.

2.2. Issues considered in the review of Annex I

The Commission carried out its review of Annex I between 1 June 2007 and 30 May 2008. Based on its own analysis, feedback from Member States and other stakeholders, in particular through the development of the TGD IR/CSA, and specific comments solicited for the review of Annex I, the Commission identified a number of issues for further assessment.

These were:

- Is an operational definition of “adequate control of risks” needed and the relationship with registration requirements;
- The relationship between assessments carried out under Community legislation and the CSA under REACH;
- The procedure to follow if a Derived No Effect Level (DNEL) cannot be derived due to non-threshold effects;
- The procedure to follow if a Predicted No Effect Concentration (PNEC) cannot be derived;
- Clarify the relationship between the Annex XIII criteria and the screening criteria for PBT and vPvB substances;
- Clarify how to conduct a “qualitative” risk assessment if no DNEL or PNEC can be derived.

2.2.1. Operational definition of “adequate control” for the purposes of registration

Article 14(6) of REACH requires that the CSA for a substance must demonstrate that any risks identified are adequately controlled. The concept of “adequate control of risks” is set out in Annex I, Section 6.4, taking account of the appropriate DNEL or PNEC. Furthermore, for those human effects and environmental spheres for which it is not possible to determine a DNEL or a PNEC, Annex I, Section 6.5 applies and a qualitative assessment of the likelihood that effects are avoided must be carried out. However, because of the lack of a clear reference to Annex I, Section 6.5 for the purposes of Article 14(6), the legal clarity of this provision was questioned.

The Commission Legal Service recommended that, to address this issue workably, registrants should be informed (in the TGD IR/CSA) that, for the purposes of registration, measures taken under Sections 6.4 or 6.5 of Annex I are relevant. The TGD IR/CSA now uses the term “control of risks” instead of “adequate control of risks” to describe the objective of the CSA

to be conducted as part of the registration dossier, when relevant. The term “control of risks” refers to both Sections 6.4 and 6.5 of Annex I.

Introduction of this new concept of “control of risks” also aims to avoid any confusion with the definition of “adequate control” under authorisation in Article 60(2), which clearly refers to Section 6.4 of Annex I only.

The Commission considers that, at this stage, incorporation of the concept of “control of risks” in the CSA guidance is satisfactory to address any possible legal uncertainty related to implementation of the obligations imposed by Article 14(6). However, in any subsequent amendment of REACH, an amendment to Article 14(6) may be considered.

2.2.2. Existing Community assessments

Annex I to REACH requires that assessments carried out under non-REACH Community legislation should be taken into account when developing the CSA under REACH, and any deviations justified.

The following types of Community assessments could be relevant for the purposes of REACH Annex I, Section 0.5:

- risk assessment reports (RAR) and risk reduction strategies under Council Regulation (EEC) No 793/93³;
- risk assessment reports for notified substances under Directive 67/548/EEC⁴;
- risk assessment reports for biocidal products and plant protection products; and
- Scientific Committee on Occupational Exposure Limits (SCOEL) assessments for indicative occupational exposure limits (IOEL).

The TGD IR/CSA does not explicitly cover how the assessments should be used, with the exception of the relationship between occupational exposure limits (OEL) under worker protection legislation and DNELs under REACH.

The Commission considers that in all these cases further clarification in the TGD IR/CSA will be sufficient to address these issues satisfactorily. Consequently, the Commission considers that, at this stage, there is no need for changes to the wording in Annex I.

2.2.3. Clarify what to do if there is no Derived No Effect Level (DNEL)

Annex I, Section 1.0.3. of REACH requires DNEL(s) to be established for every substance for which a CSA is required, but acknowledges that this is not always possible. This applies, in particular, to substances for which it is not possible to set an exposure threshold below which there are no effects (non-threshold substances). The procedure to follow if no DNEL can be identified was discussed during the drafting of the TGD IR/CSA.

³ Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances, OJ L 84, 5.4.1993, p. 1.

⁴ Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, OJ 196, 16.8.1967, p. 1.

During the co-decision process the Commission suggested a methodology to deal with such situations – the Derived Minimum Effect Level (DMEL). The co-legislators considered this concept and decided not to include it in Annex I. However, recital 71 was inserted, suggesting that methodologies to establish thresholds for carcinogenic and mutagenic substances may be developed while still ensuring a high level of protection of human health and the environment.

Parts B.6 (Endpoint specific guidance) and B.7 (Deriving threshold and non-threshold effects) of the TGD IR/CSA set out that where no DNEL(s) can be derived, REACH requires a qualitative assessment to be performed. However, for the non-threshold endpoints (e.g. non-threshold carcinogenicity), development of a (semi-)quantitative reference value or DMEL may be useful if data allow.

A DMEL represents a reference risk level which is considered to be of very low concern for a certain exposure scenario and should be used to target risk management measures better. It should be seen as a tolerable level of effects. Nevertheless, a DMEL is not a level at which no potential effects can be foreseen, but rather an exposure level corresponding to a low, possibly theoretical, risk. It should also be remembered that, in the cases of carcinogens and mutagens, Directive 2004/37/EC⁵ requires that workplace exposure must be avoided/minimised as far as technically feasible. As REACH does not overrule Directive 2004/37/EC, the approach to controlling workplace exposure should therefore comply with this minimisation requirement. The DMEL approach is useful for preparing a chemical safety assessment to judge the remaining/residual likelihood of risks. Based on such judgments, the registrant may need to refine the way he uses the substance or recommends to use the substance, by revising the relevant tentative exposure scenario(s).

The Commission considers that the current state of development and applicability of the DMEL concept is adequately addressed in the TGD IR/CSA. The many complex questions related to its applicability and methodology currently do not allow more concrete conclusions on its appropriateness within REACH. Consequently, the Commission considers that, at this stage, there is no need for changes to the wording in Annex I.

2.2.4. Clarify what to do if there is no Predicted No Effect Concentration (PNEC)

Annex I, Section 3.0.4. requires the derivation of a PNEC for all substances. However, the procedure to follow if no PNEC can be identified needs to be established.

Although at least short-term toxicity data are normally available, from which a PNEC could be derived, there might be situations where this is not the case. For example, there are some substances that are highly insoluble in water and unlikely to cross biological membranes and for which no long-term testing is considered necessary, such as where:

- no acute aquatic toxicity is found at the solubility limit in short-term (acute) toxicity tests and no long-term testing is considered necessary; or
- no acute and chronic aquatic toxicity is found at the solubility limit in either short-term or long-term tests.

⁵ Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, OJ L 158, 30.4.2004, p. 50.

Another possibility is that environmental (aquatic, sediment and soil) toxicity testing cannot be conducted due to the physicochemical properties of the substance.

The Commission considers that the issue should be clarified in the TGD IR/CSA, as this is a more flexible option given the technical nature of the issue. Therefore no changes to Annex I are considered necessary at this stage.

2.2.5. Clarify the relationship between the Annex XIII criteria and the PBT/vPvB screening criteria

Annex XIII sets out the criteria for identification of PBT and vPvB substances. Annex I, Section 4 requires a PBT/vPvB assessment of all substances for which a CSA is required. This is to identify substances with PBT or vPvB properties and substances that are likely to have such properties and need further investigation. The PBT/vPvB assessment in Annex I refers not only to the criteria in Annex XIII but also to screening criteria 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 (paragraph 4.1). Currently, the screening criteria and the procedure to follow are not specified in the Annexes to REACH but are set out in the TGD IR/CSA. This raised the question whether these screening criteria should be incorporated into Annex I or Annex XIII.

The TGD IR/CSA applies the methodology currently used for identification of substances with PBT/vPvB properties. This methodology has been agreed by the Commission, Member States and stakeholders. The properties of the substance should be assessed against the criteria and all relevant and available information should be considered. In principle, substances are considered as PBT or vPvB only when they fulfil the criteria for all three inherent properties P, B and T or the two inherent properties vP and vB, respectively. However, in this context it is important to note that even if a criterion is not fulfilled by a small margin, the overall evidence can be sufficient to justify the conclusion that a substance fulfils the Annex XIII criteria. Furthermore, for many substances the available data may not allow a definitive assessment against the criteria in Annex XIII. In such cases, the screening criteria may be used to decide whether a substance may potentially fulfil the PBT or vPvB criteria.

The Commission considers that this issue should be clarified in the ongoing review of Annex XIII and/or in the TGD IR/CSA. Therefore no changes to Annex I are considered necessary at this stage.

2.2.6. Clarify how to conduct a “qualitative” risk assessment

Annex I requires that a “qualitative assessment of the likelihood that effects are avoided” should be carried out when a DNEL or PNEC cannot be derived. However, it is not clear from Annex I what this constitutes and what level of justification and documentation is required.

The TGD IR/CSA suggests that for non-threshold effects (e.g. non-threshold carcinogens) it could be useful to include a semi-quantitative element in the qualitative assessment in order to assess the likelihood that effects are avoided. In such cases, it suggests that the registrant develop a DMEL.

The Commission considers that this issue is adequately addressed in the TGD IR/CSA. At this stage, it would not be appropriate to incorporate the methodology for how to carry out the

qualitative assessment, including any DMEL, into the Annex due to its complexity and applicability.

2.3. Consultation

At the first meeting of CASG(Annexes), on 3 September 2007, the Commission requested Member States and stakeholders to submit comments on Annex I. Several Member States raised issues for consideration. At the fifth CASG(Annexes) meeting, on 23 May 2008, the Commission requested stakeholders to submit comments on a review document on Annex I. Overall, these comments supported the conclusion set out below.

2.4. Conclusion

Taking into account the results of the consultation, the Commission has concluded that no amendment to Annex I is necessary at present, as all issues have been and/or can be dealt with satisfactorily in the TGD IR/CSA.

In any subsequent amendment of REACH, amendment of Article 14(6) should be considered.

3. REVIEW OF ANNEX IV

3.1. Criteria for inclusion in Annex IV

Article 2(7)(a) stipulates that substances covered by Annex IV are exempted from the registration, evaluation and downstream user provisions of REACH on the basis that *“sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties.”*

To make it possible to consider whether further substances should be added to Annex IV and whether substances currently in the Annex should remain there, the Commission, in cooperation with CASG(Annexes), operationalised the core concepts of minimum risk and sufficient information into criteria. These criteria were endorsed by the REACH Competent Authorities on 19 October 2007⁶. Further analysis of the criteria and a more detailed description of the reasons for the approach taken in the review of Annex IV will be made available in the form of a staff working paper on the Commission website⁷.

Following the concerns expressed about exempting substances with nanoforms in Annex IV, agreement was reached that, in order to demonstrate that a substance poses minimum risk because of its intrinsic properties, the minimum risk requirement must be met by all forms of the substance, including its nanoforms.

⁶ Criteria for inclusion of substances in Annex IV of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH):
http://ec.europa.eu/enterprise/reach/com_reviews_en.htm#4
and http://ec.europa.eu/environment/chemicals/reach/reviews_en.htm.

⁷ http://ec.europa.eu/enterprise/reach/com_reviews_en.htm#4
and http://ec.europa.eu/environment/chemicals/reach/reviews_en.htm#annex4.

3.2. Consultation

Proposals for inclusion in or deletion from Annex IV were made to the Member States Competent Authorities (MSCA) and a number of industrial associations (IA). The MSCAs and IAs conducted an initial screening of the proposals and submitted them to the Commission for further analysis of whether or not the dossiers complied with the agreed criteria. A total of 292 submissions for addition of substances to Annex IV and two submissions for deletion of substances already in Annex IV were sent to the Commission and further analysed. All the proposals for inclusion of new substances failed to meet the criteria. The two proposals for deletion (carbon and graphite) were accepted, as the substances did not meet the criteria, primarily in relation to their nanoforms.

3.3. Conclusions

The Commission therefore proposed the following additions to and deletions from Annex IV:

- Four noble gases should be added because they clearly meet the criteria for inclusion in Annex IV and therefore fit better in Annex IV than in Annex V, where they are currently listed. Consequently, helium, neon and xenon should be moved from Annex V and, together with krypton, should be added to Annex IV.
- The sugars fructose, galactose and lactose should be added because, from the information available, it was possible to conclude that they meet the criteria for inclusion in Annex IV.
- Vitamin A should be deleted because it does not meet the criteria for inclusion in Annex IV, mainly because of its potential negative effects on reproduction .
- Carbon and graphite should be deleted, as their nanoforms do not meet the criteria for inclusion in Annex IV. The proposed deletion concerns all forms of carbon and graphite, because Annex IV exempts substances irrespective of their form and because it is currently impossible to clearly define the nanoforms which should not be exempted. However, the Commission committed to review, before the end of 2008, possible ways to exempt the bulk forms of carbon and graphite from registration, the downstream user obligations and evaluation on the basis of further discussion in the REACH Competent Authorities Sub-group on Nanomaterials⁸.
- Limestone should be deleted, as it is considered to be covered already by the Annex V entry for minerals and ores.
- Vegetable and animal oils, fats and waxes, and fatty acids currently listed in Annex IV are to be deleted and transferred to Annex V because some of the substances concerned do not fulfil the criteria for inclusion in Annex IV and the current distinction between substances of different origin was found to be of limited relevance to their hazard profile and to the criteria for Annexes IV and V. Therefore, a generic entry in Annex V, limited to substances with a relatively low hazard profile, was found to be more appropriate for this group of substances.

⁸ The review has been completed in the meantime and the Commission is considering to prepare a proposal for amendment to Annex V on this issue.

4. REVIEW OF ANNEX V

4.1. Criteria for inclusion in Annex V

Article 2(7)(b) sets out that, for substances covered by Annex V, registration is deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACH.

To make it possible to consider, in a transparent and consistent way, whether further substances or groups of substances should be added to Annex V and whether substances or groups of substances currently in the Annex should remain there, the Commission, in cooperation with CASG(Annexes), further analysed the criteria mentioned in Article 2(7)(b) on the basis of their origin in the EINECS reporting rules and their further development and application in the legislative process for adoption of REACH. This analysis and a more detailed description of the reasons for the approach taken in the review of Annex V will be made available in the form of a staff working paper on the Commission website⁹.

4.2. Consultation

Numerous proposals for inclusion in or deletion from Annex V were received from MSCA and a number of IA throughout the review period until 9 April 2008 (the deadline set by CASG(Annexes)). These proposals, together with an analysis of the criteria in Article 2(7)(b), were discussed at two meetings of CASG(Annexes) on 26 March and 23 May 2008.

4.3. Conclusions

The Commission proposed the following additions to and deletions from Annex V:

- Points 1 to 6 and 8 should be left unchanged, as in the original REACH text.
- Point 7 of the original REACH Regulation referred to “substances which occur in nature, if they are not chemically modified.” Nevertheless, the entry contained some substances which do not occur in nature. The substances concerned should therefore be put into a separate heading which does not refer to substances occurring in nature. In the light of arguments in favour of extending the list of exempted substances and of deleting some of the substances currently listed, the Commission proposes to maintain the overall balance found by Parliament and the Council during the legislative process. Addition of only one substance with a relatively low hazard profile was accepted, i.e. magnesia.
- Certain vegetable oils, fats and waxes, animal oils, fats and waxes, certain fatty acids and their potassium, sodium, calcium and magnesium salts, as well as glycerol should be added in order to ensure more consistent treatment while limiting the new exemption in Annex V to substances with low hazard properties. Only some of these substances were exempted in Annex IV of the original REACH Regulation.
- Certain types of glass and ceramic frits that show a relatively low hazard profile should be added, as exemption thereof is in line with the criteria of Article 2(7)(b).

⁹ http://ec.europa.eu/enterprise/reach/com_reviews_en.htm#5
and http://ec.europa.eu/environment/chemicals/reach/reviews_en.htm#annex5.

- It was considered useful to make it clear that compost and biogas should not be subject to the registration, downstream user and evaluation obligations laid down in REACH, as, in line with Article 2(7)(b), registration of these substances is inappropriate and unnecessary.
- Wherever appropriate, the exemptions in Annex V from registration, the downstream user obligations and evaluation should not be granted to substances meeting the criteria for classification as dangerous in accordance with Directive 67/548/EEC nor to substances that are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII and to substances that were identified, in accordance with Article 59(1), at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).
- The substances duplicated in both Annexes IV and V (i.e. argon and nitrogen) should be deleted from point 9 of Annex V and the three noble gases helium, neon and xenon should be added to Annex IV.

5. FOLLOW-UP

The review of Annex I is considered finalised and the Commission will recommend that the ECHA update the TGD IR/CSA as appropriate in line with the conclusions set out above. If, in future, new knowledge and experience were to raise points which would justify amendment of Annex I, the Commission may decide to conduct another review.

Concerning Annexes IV and V, a proposal for a Commission Regulation implementing the conclusions set out above was submitted to the REACH Committee which gave a positive opinion on 5 June 2008. Subsequently, the proposal was submitted for scrutiny by the European Parliament and the Council. Neither the European Parliament nor the Council opposed the draft measure and the Commission Regulation was finally adopted on 8 October 2008 and published on 9 October 2008 (Commission Regulation (EC) No 987/2008, OJ L 268, 9.10.2008, p. 14). In addition, the Commission has drafted a recommendation for guidance on interpretation of Annex V. The Commission has transmitted this guidance to the ECHA for finalisation and inclusion in the technical guidance document on registration.