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Inter-linkages between the REACH Regulation and the Biocides Directive (98/8/EC)

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REACH Regulation (EC) No 1907/2006 (hereafter "REACH Regulation") does not exclude biocidal active substances (hereafter "active substances") from its scope. In fact, many provisions of the REACH Regulation apply to biocidal active substances and thus it is important that Competent Authorities for the implementation of the Biocides Directive and companies involved are aware of the inter-linkages between the REACH Regulation and the Biocides Directive. This information document aims to give an overview of the main links.

1. Scope

It should be noted that the REACH Regulation applies to biocidal active substances and biocidal products. The Regulation is concerned with substances, whether on their own or in one or more preparation(s) or article(s).

Active substances used in biocidal products are considered substances for the purposes of the REACH Regulation.

Active substances can be used for biocidal and/or non-biocidal purposes. The REACH Regulation applies without exemptions to the quantities of active substances intended for non-biocidal uses and all non-active components of the product formulation (co-formulants). The quantities of active substances intended for biocidal uses only are subject to specific provisions of the REACH Regulation in relation to the obligation to

register. Additionally, uses of all substances (active or non-active) in biocidal products only are exempted from the authorisation requirements under REACH.

The rest of this note deals only with active substances intended for biocidal uses.

2. Registration (Title II of the REACH Regulation)

Article 15 of the REACH Regulation stipulates that certain substances or uses of substances **are regarded as being registered**, and thus no registration will be required for these substances or these uses. This applies to:

- active substances and co-formulants for use in plant protection products only (Article 15 (1)), and
- active substances for use in biocidal products only as described below (Article 15 (2)).

More concretely, active substances used in biocidal products are under certain conditions exempted from Chapters 1 and 5 of Title II of the REACH Regulation (registration and pre-registration). The reasoning for this exemption is that sufficient information has already been obtained on active substances for use in biocidal products allowing them to be adequately controlled within the framework of the Biocides Directive.

Article 15 (2) of the REACH Regulation stipulates that 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 or in Commission Regulation (EC) No 2032/2003¹, 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 registered and therefore as fulfilling the requirements of Chapters 1 and 5 of Title II. So in order to benefit from the exemption, several conditions have to be fulfilled:

- a) the substance must be an active substance for use in biocidal products.
- b) the substance must be included in at least one of the following:
 - i. Annex I to the Biocides Directive – this is the list of active substances approved for use in biocidal products; it is regularly updated and manufacturers and importers are advised to check the latest version.
 - ii. Annex IA to the Biocides Directive – this is the list of active substances approved for use in low-risk biocidal products; it is regularly updated and manufacturers and importers are advised to check the latest version.
 - iii. Annex IB to the Biocides Directive – this is the list of basic substances for which requirements are agreed at Community level. In accordance with the definition in Article 2(1) (c) of Directive 98/8/EC, a basic substance is a substance listed in Annex IB whose major use is non pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluent which itself is not a substance of concern and which is not directly marketed for that biocidal use.

¹ As of 21 December 2007, Regulation (EC) No. 2032/2003 was repealed and replaced by Regulation (EC) No. 1451/2007.

- iv. Regulation (EC) No 2032/2003² – Annex II of this Regulation lists existing active substances (i.e. substances which were already on the market on 14 May 2000) for which information was submitted with a view to examine them in the framework of the Directive's review programme of existing active substances for use in biocidal products. Once a decision is taken for an existing active substance in Annex II of Regulation (EC) No 2032/2003 not to include it into Annex I, IA or IB of the Biocides Directive, the active substance no longer benefits from the exemption. Read in conjunction with Article 4(2) of Regulation (EC) No 2032/2003, the registration obligation under REACH will not apply before one year after the date of such non-inclusion decision entering into force. After this period, the producer or importer of such existing active substance must comply with his obligations under Chapters 1 and 5 of Title II of the REACH Regulation.

Under the above-mentioned conditions, active substances will be regarded as registered and the registration as completed for manufacture or import of a substance for use in a biocidal product.

Concerning non-active components of product formulations (also known as co-formulants), it should be noted that Article 15(2) of the REACH Regulation does not mention co-formulants. This means that co-formulants cannot benefit from the exemption from pre-registration and registration. The situation of co-formulants in biocidal products thus differs from the situation of co-formulants in plant protection products which are formally covered by Article 15(1) of the REACH Regulation and can benefit from the pre-registration and registration requirements³.

Only the quantities of the active substance used in biocidal products are exempted from the registration obligation. The quantities used for other purposes (including plant protection products unless exempted on the basis of Article 15(1) of the REACH Regulation) are not exempted and must be registered.

This can be illustrated by the example of a company, manufacturing 100 tonnes of quaternary ammonium compounds in year X, of which 50 tonnes are used as active substances in biocides (e.g. wood preservatives) and the other 50 tonnes as surfactants in cleaning products. This company must register the latter use, which is within the scope of the REACH Regulation. A full registration dossier must then be prepared, with all relevant information including the Chemical Safety Report (CSR) and using the information submitted within the framework of the Biocides Directive as provided for in point 0.5 of Annex I to the REACH Regulation.

2.1 New active substances in provisionally authorised or unauthorised biocidal products (Article 15 of the Biocides Directive)

² As of 21 December 2007, Regulation (EC) No. 2032/2003 was repealed and replaced by Regulation (EC) No. 1451/2007. References to Regulation 2032/2003 will, however, be construed as references to Regulation (EC) No. 1451/2007 and thus the status of the active substances included in the review programme remains the same.

³ However, according to RIP 3.1 Guidance on Registration, only active substances can qualify for the exemption under Article 15(1) of the REACH Regulation. Co-formulants in plant protection products cannot benefit from the exemption and thus are subject to pre-registration and registration requirements.

New active substances in biocidal products that have been given provisional authorisation or exceptional 120 days authorisation (Article 15 of the Biocides Directive) do not fulfil the above requirements. This means that such active substances cannot benefit from the exemption from the pre-registration⁴ and registration requirements under Article 15(2) of the REACH Regulation. REACH registration provisions apply in those cases where the tonnage trigger (1 tonne of the substance per year per manufacturer/importer) is exceeded. The time frames foreseen for pre-registration and registration in the REACH Regulation must be complied with.

2.2 Active substances in biocidal products with an essential use derogation

Article 5 of Regulation (EC) No. 1451/2007⁵ allows Member States to derogate from Article 4(1) where they consider that an active substance is essential for them for reasons of health, safety or protection of cultural heritage or is critical for the functioning of society, and where there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health. Member States are thus allowed to grant authorisation to biocidal products containing active substances which are not included in the review program. These active substances do not qualify for the exemption from pre-registration and registration requirements in Article 15(2) of the REACH Regulation because they do not fulfil the above requirements (i.e. they are not listed in Annex I, IA or IB of the Biocides Directive, or Regulation (EC) No. 1451/2007). Thus, the producers and importers of these active substances will have to comply with their pre-registration and registration requirements under the REACH Regulation.

2.3 Active substances or biocidal products intended for research and development

The Member States can under conditions outlined in Article 17 of the Biocides Directive authorise any experiment or test for the purposes of research or development involving the placing on the market of an unauthorized biocidal product or an active substance intended exclusively for use in a biocidal product. According to Article 2(2)(c) of the Biocides Directive, scientific research and development and process-orientated research and development are defined in Article 2 of Directive 67/548/EEC, as amended.

Active substances used in biocidal products for the purposes of research and development will in most cases not fulfil the conditions for an exemption from registration under the REACH Regulation (i.e. they will not be included in Annexes I, IA or IB to the Biocides Directive or the review program). These substances will therefore be subject to the registration requirements unless they benefit from the exemption for product and process orientated research and development outlined in Article 9 of the REACH Regulation. In addition, there is no obligation to register if the quantities used for product and process-oriented research and development purposes are below 1 tonne per year.

⁴ It should be noted that the period for pre-registration is between 1 June and 1 December 2008.

⁵ Article 5 of Regulation (EC) No. 1451/2007 was formerly Article 4a of Regulation (EC) No. 2032/2003.

It should be noted that as of 1 June 2008 paragraph 1, points (c), (d), (f) and (g) of Article 2 in Directive 67/548/EEC will be deleted by means of Directive 2006/121/EC and replaced by a new definition in the REACH Regulation. This defines scientific research and development as any scientific experimentation, analysis or chemical research carried out under controlled conditions *in a volume less than one tonne per year*. Consequently, the manufacture and use of active substances in biocidal products for scientific research and development is exempt from the provisions of the REACH Regulation on pre-registration and registration if the quantities do not exceed one tonne per year per manufacturer/importer.

2.4 Active substances in articles

It should be noted that Article 7 of the REACH Regulation (substances in articles) can apply to articles treated with active substances and imported from 3rd countries (e.g. timber treated with wood preservatives). A registration will have to be submitted for substances in articles that are present in quantities totalling over one tonne per producer or importer per year and are intended to be released under normal or reasonably foreseeable conditions of use. If these conditions are not met, the producer or importer may still be subject to an obligation to notify the European Chemicals Agency which may decide that the producer or importer of articles has to submit a registration (Article 7(2) and following of the REACH Regulation).

Treated articles, where the biocidal substance is intended to protect the article itself without an external biocidal effect, are outside the scope of the Biocides Directive. It should be further noted that treated articles are currently not defined in the Biocides Directive.

2.5 Submission of information to the European Chemicals Agency

According to Article 16 of the REACH Regulation, the Commission has to make information equivalent to that required by Article 10 available to the Agency for active substances. The equivalent information submitted under the Biocides Directive is the dossier submitted by the applicant including a IUCLID dossier. The Agency shall include this information or a reference to it in its databases and notify the REACH competent authorities accordingly by 1 December 2008. This is to ensure that these data can be used where appropriate such as in REACH processes aiming at not duplicating vertebrate studies (see section 3 below).

The discussion on how to proceed in case of files which are not in IUCLID form is still ongoing. When IUCLID files have been provided to the European Chemicals Bureau, transfer of that information to the Agency should be possible.

2.6 Further details on the application of Title II of the REACH Regulation

The following Articles of Title II (Registration) of the REACH Regulation **do not** apply to active substances for use in biocidal products only: Article 21 (as of when can substances be manufactured and imported), Article 22 (further duties of registrants including the update of the submitted information); Article 25 (data sharing – objectives and general rules); Article 26 (duty to inquire prior to registration); Article 27 (sharing of existing data in the case of registered substances) and Article 28 (pre-registration for phase-in substances). However, other articles such as Article 29 on Substance Information Exchange Fora (SIEF), and thus also part of the data-sharing obligations apply also to active substances used in biocidal products. This is in particular relevant for

data holders on biocidal active substances who are by virtue of Article 29(1) of REACH participants in SIEFs. In the case of active substances, the "registrant" under REACH is the applicant under the Biocides Directive, Article 11.

It should be noted that Article 12 of the Biocides Directive continues to provide protection of data on active substances and biocidal products which are within its scope.

3. Data sharing and avoidance of unnecessary testing (Title III)

According to Article 16(2) of the REACH Regulation, Articles 25 to 28 do not apply to uses of substances regarded as registered according to Article 15. Articles 25 to 28 concern the following:

- objectives and general rules (including the 12-year rule after which any study summaries or robust study summaries submitted in the framework of a registration at least 12 years previously can be used for the purposes of the registration by another manufacturer or importer)
- inquiry process
- sharing of existing data in the case of registered substances
- pre-registration of phase-in substances.

Article 29 and 30 of the REACH Regulation apply without exemptions to applicants under the Biocides Directive. It should be, however, noted that the data sharing provisions are restricted to the purposes of registration under REACH.

Article 29 of the REACH Regulation specifies that third parties whose information is held by the Agency in accordance with Article 15 will, for the same phase-in substance, be participants in a substance information exchange forum (SIEF). SIEF participants have to provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies for the purposes of registration and arrange for such studies to be carried out.

Article 30 of the REACH Regulation further describes the rules for sharing data involving tests. Before testing is carried out in order to meet the registration requirements, a SIEF participant has to inquire whether a relevant study is available within the SIEF. If so, he has to request that study involving tests on vertebrate animals (and may request a study not involving tests on vertebrate animals). Data sharing is mandatory for data involving tests on vertebrate animals and voluntary for data not involving such tests. The owner of the study has to provide the SIEF participant with the data. The owner of the study and the person requesting it have to reach an agreement on compensation.

The RIP 3.4 Guidance on data sharing emphasises that the SIEF participants are free to choose any costs allocation mechanisms that suit them as long as the compensation is determined in a fair, transparent and non-discriminatory manner. However, if they cannot reach an agreement on the cost sharing, the cost of the study shall be shared equally (based on the number of participants). Other possible mechanisms are:

- proportionality, based on production or sales volume or otherwise, or

- alternative mechanisms using part of the two above-mentioned systems (proportionality and equal cost sharing) in different mode.

The RIP 3.4 Guidance on data sharing specifies that as holders of data under the Biocides Directive are not expected to register the substance under REACH, they are not involved in the preparation of the joint registration dossier. Likewise, they are not required to pay any cost linked to the preparation of the dossier for the purposes of the registration under REACH or related to the organisation of the data-sharing among SIEF members.

4. Information in the supply chain (Title IV)

The provisions of Title IV apply to all substances used in biocidal products, without exception. This Title addresses requirements on the Safety Data Sheets, 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, a duty to communicate information on substances in articles and, a duty to communicate information on substances and preparations up the supply chain. It also includes provisions on the access to information for workers and the obligation to keep information on how the manufacturers, importers, downstream users and distributors carry out the obligations resulting from the REACH Regulation for a period of at least 10 years after the substance was last manufactured, imported, supplied or used.

In particular, the Safety Data Sheets for professional, industrial and, as appropriate, other users of biocidal products must be prepared in compliance with the provisions of Title IV. A safety data sheet may also need to be prepared for biocidal active substances in accordance with the provisions of REACH Title IV.

5. Downstream users (Title V)

The REACH Regulation introduced downstream user requirements in order to enhance the communication flow within the supply chain.

Title V describes the requirements concerning downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures. It further outlines provisions on the obligation of downstream users to report certain information to the European Chemicals Agency. Finally, the Title specifies as of when the downstream user requirements must be complied with.

A chemical safety report is not required for active substances covered by Article 15(2) of REACH and co-formulants in quantity below 1 tonne per year. However, whenever an exposure scenario is needed (for example for the manufacturing and use of active substances prior to their inclusion and use in a biocidal product, and for non-biocidal uses), then Article 31 of REACH would require that these exposure scenarios be attached to the safety data sheet.

6. Evaluation (Title VI)

Active substances used in biocidal products are not expressly exempted from the provisions of this Title.

However, Chapter 1 on *Dossier evaluation* does not apply substances that are regarded as registered (e.g. active substances covered by Article 15(2) of REACH or co-formulants in quantity below 1 tonne per year).

Chapter 2 on *Substance evaluation* can apply to these substances, if they have been prioritised and placed on the Community Rolling Action Plan (CRAP). This might be relevant for biocidal substances with additional non-biocidal uses, where the overall cumulative exposure and effect cannot be dealt with properly under the scope of the Biocides Directive (cf. Article 10(1) of Directive 98/8/EC).

7. Authorisation (Title VII)

This Title, with the exception of Articles 57 to 59, does not apply to the uses of all substances (active and non-active) in biocidal products as stated in Article 56(4).

In principle, active substances used in biocidal products could be included in Annex XIV if they fulfil the criteria of Article 57 (e.g. CMR, PBT, vPvB, endocrine disrupters) and are further prioritised in accordance with Article 58. Annex XIV of the REACH Regulation is currently empty. However, the uses in biocidal products of substances included in Annex XIV are, in any case, exempted from the authorisation requirements. The Commission and the European Chemicals Agency are already working on the first list of candidate substances. Article 57 of REACH lists the criteria the compliance with which may result in the inclusion in Annex XIV. Article 58 of REACH describes the process of the inclusion. It also specifies that substances with PBT or vPvB properties, wide dispersive use or high volumes will be prioritised for the inclusion.

8. PBT/vPvB Assessment for active substances used in biocidal products

Under the current system request for a PBT/vPvB assessment are forwarded to the TC NES (Technical Committee for New and Existing Substances) subgroup for the identification of PBT and vPvB substances (PBT Working Group or PBT WG). The activities of the PBT WG will be moved from the European Commission Joint Research Centre in Ispra to the Agency, under the auspices of the Member State Committee (MSC). The procedure for the identification of PBT/vPvB substances (being one of the classes of substances of very high concern that may be included in Annex XIV) is described in Article 59, which consists of three steps:

1. Submission of an Annex XV dossier by the Member State (or preparation of the dossier by the Agency following a Commission's request).
2. Public consultation of a dossier via the website of the Agency.
3. If comments are received within a 60 days period the Agency refers the dossier to the MSC. In case of disagreement within the MSC the Commission will take a decision. If no comments are made the substance is added to the candidate list (Article 58).

Regarding the format of the dossier to be submitted for the identification of a PBT/vPvB active substances used as biocides, the dossier shall be prepared according to Annex XV report format.

9. Restrictions (Title VIII)

This Title applies also to substances used in biocidal products.

As Directive 76/769/EEC is repealed and replaced by Title VIII and Annex XVII of the REACH Regulation as of 1 June 2009, restrictions on active substances in accordance

with Article 16(4) of the Biocides Directive will be dealt with in future under the REACH Regulation.

10. Fees and charges (Title IX)

Title IX of the REACH Regulation does not apply to active substances which comply with the requirements of Article 15 (2) as these are exempted from the processes of pre-registration and registration. However, it may apply to active substances for which a non-inclusion decision under the Biocides Directive has been taken and which are thus subject to registration under the REACH Regulation (i.e. all REACH provisions apply to these substances).

It is envisaged that the registration fees for substances/preparations which are subject to the registration obligation will be adopted in form of a Commission Regulation by 1 June 2008 at the latest.

11. Agency (Title X)

The European Chemicals Agency in Helsinki will be responsible for the management and carrying out of technical, scientific and administrative aspects of the REACH Regulation. The Commission will provide the Agency with specified information as described above (Article 16 of the REACH Regulation).

In principle, the provisions on the European Chemicals Agency apply also to active substances for the use in biocidal products.⁶

12. Classification and labelling inventory (Title XI)

Title XI applies also to active substances used in biocidal products. However, as the registration for active substances for use in biocidal products is regarded as being completed when fulfilling the requirements of Article 15(2) of REACH Regulation, this also means that the classification and labelling information has been provided, which further means that for those active substances, no classification and labelling notification has to be submitted to the European Chemicals Agency.

It is important to note that, according to the REACH Regulation, systematic harmonisation of classification and labelling will be limited to substances having CMR or respiratory sensitising effects. Harmonisation of classification and labelling of other endpoints will only take place on a case-by case basis, when there is a need for action at Community level.

The activities of the Technical Committee for Classification and Labelling will also be moved from the European Commission Joint Research Centre in Ispra to the Agency, in the framework of the Risk Assessment Committee (RAC).

12.1 Process and competences concerning the harmonised classification for biocidal products

⁶ The practical implications seem minor at the moment as the Agency is not yet involved in the evaluation process of active substances or biocidal products. However, the impact may increase in the near future because the Agency will likely be instrumental in ensuring harmonised classification. In addition, it will gather useful experience as the arbitrator in disputes concerning data sharing.

As Article 115 of the REACH Regulation refers to a case-by-case approach and to the need for action at Community level, the process to harmonise the classification and labelling of the other effects than CMR and respiratory sensitisation, needs to be clarified, in particular for biocidal products and plant protection products.

It will be up to the Rapporteur Member State (RMS) to decide to trigger the process of complete harmonisation and consequently to then develop a dossier complying with the requirements of Annex XV of the REACH Regulation.

However, in its proposal for a complete harmonisation going beyond the harmonised classification, the RMS should provide a justification why there is a need for such harmonisation at Community level. The RAC will then decide whether there is sufficient justification.

A sufficient justification for complete harmonisation could lay in stating that it will facilitate a harmonised implementation of the Biocides Directive at the stage of national product authorisation, which include mandatory label approvals.

In addition, as the Biocides Directive offers the possibility of authorising biocidal products via mutual recognition of existing authorisations, it seems reasonable to harmonise labelling requirements to the extent possible to facilitate mutual recognition.

It should also be noted that Title XI of the REACH Regulation will be moved to Title V of the European Commission proposal (COM(2007) 355 final) for a Regulation of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, and amending Directive 67/548/EEC and Regulation (EC) No 1907/2006.

12.2 Format of the harmonised classification dossier

Regarding the format of the dossier to be submitted for the harmonisation of classification and labelling of active substances used as biocides, it remains to be clarified whether the CA reports prepared under the Biocides Directive would be accepted or if they have to be re-formatted as per the Annex XV report format.

In principle, the format specified in the RIP 4.4 Guidance for the preparation of an Annex XV dossier for harmonised classification and labelling (available from the ECHA web-site) should be used. However, again it would be up to the RAC to decide whether other types of formats, such as the CA reports of the Biocides Directive, could be accepted.

13. Information (Title XII)

Title XII of the REACH Regulation deals with the reporting obligations of the Member States, the European Chemicals Agency and the Commission. It further contains provisions on the access to information and the cooperation with third countries and international organisations.

There is no specific exclusion for substances for use in biocidal products from this Title.

ANNEX

Extract of the relevant Articles of the REACH Regulation

Article 15

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 Directive 91/414/EEC or in Regulation (EEC) No 3600/92, Regulation (EC) No 703/2001, Regulation (EC) No 1490/2002, Decision 2003/565/EC 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 1 and 5 of this Title.
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 of 16 February 1998 concerning the placing of biocidal products on the market or in Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, 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 1 and 5 of this Title.

Article 16

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 10 available to the Agency for substances regarded as registered according to Article 15. The Agency shall include this information or a reference thereto in its databases and notify the competent authorities thereof by 1 December 2008.
2. Articles 21, 22 and 25 to 28 shall not apply to uses of substances regarded as registered according to Article 15.