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Aggregated Environmental Exposure Assessment and Risk Characterisation of Biocidal Products

Legal Aspects

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Aggregated Environmental Exposure Assessment And Risk Characterisation of Biocidal Products - Legal Aspects

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Kurzbeschreibung

Artikel 19(2) der neuen Biozidproduktverordnung (BiozidVO, 528/2012) führt aus dass die Bewertung [...] die folgenden Faktoren berücksichtigen soll: „[...] (d) kumulative Wirkungen, (e) synergistische Wirkungen". Biozide Wirkstoffe sind häufig in vielen unterschiedlichen Produkten enthalten. Oft werden sie in unterschiedlichen Anwendungen eingesetzt. Dennoch werden in der Regel bei der Expositionsbeurteilung nur einzelne Verwendungen bewertet. Dies kann die tatsächlichen Konzentrationen der Wirkstoffe in der Umwelt unterschätzen.

Wie können kumulative und synergistische Wirkungen bei der Biozidzulassung berücksichtigt werden? Derzeit gibt es nur wenige Hinweise zu dieser Aufgabenstellung in den „Technical Notes for Guidance on Product Evaluation" (TNsG on product evaluation, EU, 2002). Hinzu kommt, dass auch keine Anleitung verfügbar ist, wie bei der umweltbezogenen Risikobewertung von Biozidprodukten gleichzeitige Expositionen der Umwelt durch einen Wirkstoff zu berücksichtigen sind, die aus der Verwendung in verschiedenen Anwendungen und/oder in verschiedenen Produkten entstehen.

Mit der Risikobewertung multipler simultaner Umweltexpositionen sind verschiedene rechtliche Fragen verbunden. Sie sind im Rahmen der vorliegenden rechtlichen Analyse angesprochen worden. Die Ergebnisse dieser Analyse sind anhand von Fallstudien im zweiten Teil des Berichts anschaulich diskutiert.

Abstract

Article 19(2) of the new Biocidal Products Regulation (BPR, 528/2012 EU) states that "the evaluation [...] shall take into account the following factors: [...] (d) cumulative effects, (e) synergistic effects." Biocidal active substances (a.s.) are often contained in many different products. Frequently they are used in various applications. However, in general only the exposure assessment of single uses is assessed. This may underestimate the actual concentration of active substances in the environment.

How can cumulative and synergistic effects be considered during the authorisation of a biocidal product? Up to now, only very limited details on this task are provided in the current "Technical Notes for Guidance on Product Evaluation" (TNsG on product evaluation, EU, 2002). In addition, no specific guidance exists on how the multiple simultaneous exposure of the environment arising from an active substance should be accounted for during the environmental risk assessment of biocidal products, if it is used in various applications and/or different products.

Legal aspects are of importance for the risk assessment of multiple simultaneous environmental exposures. They have been addressed in the following legal analysis on aggregated environmental exposure assessment and risk charactersation of biocidal products. The results of this analysis are documented and case studies are given, to illustrate legal aspects concerning aggregated exposure assessment options.

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List of Abbreviations

Art.	Article
BImSchG	Bundes-Immissionsschutzgesetz (Federal Immission Control Act)
BMU	Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (Federal Ministry for the Environment, Nature Conservation and Nuclear Safety)
BPD	Biocidal Products Directive 98/8/EC
BPR	Biocidal Products Regulation (EU) No 528/2012
CA	Competent Authority
Com, COM	Commission of the European Union
Doc	Document
DBP	Disinfection by-Products
EC	European Community
ECHA	European Chemicals Agency
ECJ	European Court of Justice
EEC	European Economic Community
et al.	and others
EU	European Union
ff.	and following pages
MS	Member State
No	number
OJ	Official Journal
PT	Product type
REACH	EU Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
UBA	Umweltbundesamt (Federal Environment Agency)

1 Introduction

From 1 September 2013, the Regulation (EU) No. 528/2012[1] (thereinafter: BPR) applies to the approval of active substances and product authorisation in the EU. The BPR replaces the previous Biocides Directive 98/8/EC[2]. The BPR states that the (eco)toxicological risk assessment of biocidal active substances as well as of the biocidal product shall take into account cumulative and synergistic effects (cf. Art. 19 (2) BPR). This reflects the fact that biocidal active substances are contained in many different products, and the exposure assessment of single uses may underestimate the actual concentrations found in the environment. To assess cumulative and synergistic effects, the European Chemicals Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide further guidance on the scientific definitions and methodologies (cf. No. 15 of Annex VI BPR).

Against that background it is the aim of this study to describe the legal situation and legal options/instruments available to national competent authorities and the ECHA in order to address risks resulting from aggregated environmental exposure of active substances and biocidal products. To assess the legal options a legal assessment is conducted in Part A of the study followed by case studies in Part B.

It must be pointed out that the scope of this study only covers aggregated environmental exposure assessment i.e. exposure to single substances from multiple products and uses via single or multiple routes (see Chapter 1.1).

1.1 "Cumulative effect" and "aggregated environmental exposure"

With regard to the conditions of authorisations the BPR refers to "cumulative effects" (cf. Art. 19 (2) (d) BPR) without defining the term legally in Art. 3 BPR. A definitive and universally applicable definition, however, does not exist as the use and significance of the term "cumulative" depends on whether it is used in the context of human health or environmental risk assessment and on the regulatory framework in which it is used. Consequently, "cumulative" is used in the context of exposure and effect for both single and multiple chemicals and routes. Therefore a different wording to precisely define the application of the BPR was recommended on the 47th meeting of representatives of the Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market (CA-Meeting) in July 2012. Accordingly, it was proposed to distinguish between the terms "aggregated exposure" and "mixture toxicity":

- "Aggregated exposure" refers to the overall exposure of humans and the environment, to the same substance, by emissions through all life cycle steps

[1] Regulation 2012/528 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, OJ L 167, 27.06.2012, p.1.

[2] Directive 98/8/EC of the European Parliament and of the Council of 16.02.98 concerning the placing of biocidal products on the market, OJ L 123, 24.04.98, p. 1.

relevant under the BPR of different products belonging to the same PT or different PTs. The scope of the BPR does not cover any potential additional exposure from the same substance resulting from non-biocidal uses regulated under other legal frameworks.

- "Mixture toxicity"[3] refers to the combined toxicity and thus risk to human and animal health, and the environment, from all relevant substances in a biocidal product, including their degradation products and regardless of the underlying mechanism(s) of the mixture toxicity (non-interactive or interactive joint action), taking into account the different environmental, occupational and residential mixture(s) which are arsing through all life cycle steps relevant under the BPR.

[3] For Guidance to assess mixture toxicity in the authorisation, see: Final Draft Proposal - Guidance on mixture toxicity assessment within the biocidal products authorisation, German Federal Environment Agency, February 2013.

1.2 Approval of active substances and authorisation of biocidal products

According to the BPR different approval procedures apply for biocidal active substances and biocidal products:

- The approval of biocide active substances at EU level;

  > Art. 3 (1) (c) BPR defines an active substance as
  >
  > "a substance or micro-organism, which has an action on or against harmful organisms."

  For active substances, the BPR provides for a European approval or refusal by the Commission. This decision is based on the recommendation and statements of the ECHA (Art. 9 BPR) which is again based on the assessment of applications by the evaluating competent authority (Art. 8 (1) BPR).

- The authorisation of biocidal products in the Member States and at EU level (Union authorisation).

  > Art. 3 (1) (a) BPR defines a biocidal product as
  >
  > "any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action."
  >
  > Likewise, treated articles which have a primary biocidal function are considered biocidal products (cf. Art. 3 (1) (a) second sentence BPR).

  For the authorisation of biocidal products the BPR foresees the following authorisation procedures applying both at national and European level, granting different rights for the Member States:

  - National authorisation,
  - simplified authorisation,
  - mutual recognition, and
  - Union authorisation.

Part A: Legal Assessment

2 Approval of biocidal active substances

This chapter describes the competent authorities' options to regulate risks from an aggregated environmental exposure in the approval of an active substance before that substance is placed on the market (pre-market control) and after it has been placed on the market (post-market control).

2.1 Pre-market Control

While approving active substances, the authority is able to consider the risk resulting from an aggregated environmental exposure in the evaluation of an active substance and within the time limit of the approval. However, it has not been unequivocally clarified on the basis of which criteria the risk resulting from an aggregated environmental exposure shall be observed by the competent authority. Possible criteria discussed in the context of the authorisation of biocidal products (see Section 3.1.2) apply for the approval of active substances, too.

2.1.1 Aggregated environmental exposure and the evaluation of an active substance

The provisions in Chapter 2 for the approval of active substances contain standards for dealing with the risk from an aggregated environmental exposure in Art. 4 (1) and Art. 8 (3) BPR:

According to Art. 8 (3) BPR, the competent authority evaluating the approval has to document concerns with respect to risks from an aggregated environmental exposure. This means, if there are concerns for human health, animal health or the environment because of cumulative effects resulting from the use of biocidal products containing the same or different active substances, the competent authority has to document these concerns in accordance with the requirements of the relevant parts of Section Part II.3 of Annex XV to Regulation (EC) No. 1907/2006 and to include this as a part of its conclusions. According to the wording of this provision, it appears to be a pure procedural guideline for the authority carrying out the evaluation and not a legal basis which allows the authority to grant or to refuse the approval of an active substance. The reason for the request of documenting concerns is that it provides the approving authority with information relevant to decision-making.

Art. 4 (1) BPR which refers to Art. 19 (1) (b) and Art. 19 (2) BPR, however, is the legal basis for the approval of active substances. By refering to Art. 19 (2) BPR, the provisions for the authorisation of biocidal products - especially for the consideration of cumulative effects - apply to the approval of active substances, too.

Art. 4 (1) BPR states that an active substance shall be approved if at least one biocidal product, which contains this active substance, meets the requirements of Art. 19 BPR. Consequently, a competent authority can refuse the granting of an approval for an active substance only, if the aggregated exposure in every use of an active substance in every product type results in PEC/PNEC ratios > 1, as this indicates an unacceptable risk. This

means the approval can only be refused if not one biocidal product meets the criteria laid down in Art. 19 BPR. This is the case if the ratio of PECaggr to PNEC in an environmental compartment for an active substance in every product is greater than one (PECaggr/PNEC > 1).

However, if the PEC/PNEC ratio is < 1 for only one single use of an active substance the authorisation has to be granted, despite the fact that PEC/PNEC ratio might be > 1 for all uses of that active substance. Because according to Art. 4 (1) BPR it is sufficient to grant an authorisation if "at least one biocidal product" complies with the requirements. In this case a competent authority cannot refuse an approval of an active substance based on the argument that a risk resulting from an aggregated exposure exists.

2.1.2 Time limit of the approval

For the first approval of any active substance the BPR provides a maximum approval period of ten years (Art. 4 (1) BPR). After this period, i.e. not later than ten years after initial authorisation, it is forbidden to place the active substance on the market. However, it is possible for the applicant to request an extension of the approval (see below).

If there are indications that the active substance entails a risk in terms of an aggregated environmental exposure, the competent authority can react to this risk by amending the maximum period for the first approval of the active substance accordingly. For example, the approval of active substances such as anti-coagulants with a known risk - like in the case of bromadiolone - is limited to five years. In the case of active substances with intrinsic hazardous properties, which are candidates for substitution, the approval is limited to seven years (Art. 10 (4) BPR).[4] Although there is no explicit legal regulation in order to limit the approval for active substances which can pose risks associated with an aggregated environmental exposure, it is possible to analogically set a maximum period for approval. A prerequisite is, however, that the risk associated with an aggregated environmental exposure is considered as being as dangerous as risks associated with substitution candidates. In the same manner as a substance which is candidate for substitution under Art. 10 BPR, the aggregated environmental exposure to an active substance can also present a risk for the environment and human health. Furthermore, the authorities have to counteract the risk resulting from an aggregated environmental exposure to an active substance under Art. 4 (1) in conjunction with Art. 19 (2) (d) BPR. Finally, for the purposes of the interpretation of the provisions of the BPR, the precautionary principle, which aims at protecting health and environment, has to be considered. In order to prevent an aggregated environmental exposure, it appears possible - for the above-mentioned reasons - to set a shorter approval time instead of taking full advantage of the legally permitted timeframe of ten years for initial approvals. According to the regulation on the substitution candidates, an approval time of seven years seems to be appropriate, too.

In the end, to define a time limit for the approval, all aspects of the individual case of one specific active substance have to be monitored, bearing in mind that the proportionality

[4] See in the comments of Recital 14 of the BPR.

principle has to be applied. In particular, the competent authority would have to describe the origination of the risk associated with an aggregated environmental exposure.

As a result it should be noted that the competent authority is able to examine the risk from an aggregated environmental exposure by setting a timeframe for the approval.

2.1.3 Conditions of the approval

According to Art. 4 (3) BPR, the competent authority has to specify the conditions for the use of an active substance in the approval. Thereto, it has to assess all relevant points mentioned for conditions in Art. 4 (3) BPR. Beside the conditions for the active substance and the time of the approval at this point, it is also possible to specify conditions for the product-type (Art. 4 (3) (c) BPR) and for the manner and area of use (Art. 4 (3) (d) BPR). In order to address the risk associated with an aggregated environmental exposure, the authority is able to restrict the approved product-types, the manner of use and the area of use for an active substance.

Apart from this legal basis, the competent authority is also able to rely on Art. 4 (3) (g) BPR for imposing particular requirements as a condition. Point g is broadly defined and provides for the description of other particular conditions based on the evaluation of the information related to that active substance. Thus, Art. 4 (3) (g) BPR can effectively serve as a catch-all element in order to minimize the risk resulting from an aggregated environmental exposure. According to that interpretation, the tonnage of an active substance to be put on the market could be restricted based on Art. 4 (3) (g) BPR in case of a risk associated with an aggregated environmental exposure.

2.2 Post-market Control

2.2.1 Review of approval

The BPR allows the Commission to review the approval of an active substance at any time (cf. Art. 15 (1) (1) BPR). A review requires that there are significant indications that the conditions for an approval of an active substance for one or more product-types laid down in Art. 4 (1) in conjunction with Art. 19 BPR are no longer met. Furthermore, the Commission has discretion whether or not to review the approval when a Member State applies the review of an active substance for one or more product-types. Before the Commission takes action, the Member State has to provide evidence that the use of the active substance in biocidal products or treated articles raises significant concerns about the safety of such products or articles.

Since in both cases no evidence is required for starting the review procedure, it will be sufficient if there are indications on the lacking of the approval requirements. Both the term “significant indications” and the term “significant concerns” are indeterminate legal concepts which need to be interpreted or concreted. They may be substantiated by an implementing act according to Art. 16 BPR.

If the Commission or the MS have serious indications or serious concerns, that the requirements for the approval according to Art. 19 (1) in conjunction with Art. 19 (2) BPR

are no longer met, both are able to set up a review on the grounds that a risk from an aggregated environmental exposure leads to unacceptable effects (Art. 19 (1) (b) (iv) BPR).

If the Commission concludes in its review that the requirements for the approval are no longer met, for example because the active substance bears an unacceptable risk from an aggregated environmental exposure, it adopts an implementing regulation amending the conditions of approval or cancelling its approval (Art. 15 (1) BPR). Thereafter, the MS and the Commission have to adjust the authorisation of biocidal products which contain the relevant active substance either by cancelling or amending the authorisation (Art. 48 BPR).

2.2.2 Renewal

The applicant is able to seek a renewal of the approval which is usually granted for 15 years, provided that the requirements are met (cf. Art. 12 (3) BPR). The requirements for the renewal of the approval are regulated in Art. 12 BPR. Accordingly, the requirements for a renewal are that the conditions for an approval under Art. 4 (1) and Art. 5 (2) BPR are met (cf. Art. 12 (1) BPR). Therefore, the Commission has to review the conditions in the light of scientific and technical progress and where appropriate has to amend them as required by Art. 4 (3) BPR (cf. Art. 12 (2) BPR). In this context also the modifications of the risk from an aggregated environmental exposure have to be considered. With his application the applicant has to submit all data, collected since the initial approval or previous renewal (Art. 13 (2) (a) BPR).

According to Art. 14 BPR, the evaluating competent authority decides whether a full evaluation of the application for renewal is necessary or not. If no full evaluation of the application is necessary, according to Art. 13 BPR the evaluating competent authority submits a recommendation on the renewal of the approval to the ECHA. Where the authority decides whether a full evaluation is necessary or not (Art. 14 (2) BPR refers back to Art. 8 BPR). In this case, there is the possibility to consider the risk from an aggregated environmental exposure according to Art. 8 (3) BPR. Therefore, the renewal of an approval offers the option of refusing the authorisation of products in case an active substance would not be approved anymore or would not be approved under the initial conditions.

The Commission can adopt detailed measures to further specify the procedures for the renewal and review of the approval of an active substance by means of implementing acts (cf. Art. 16 BPR). In this context it should be noted that the Member States (competent authorities), represented by their national comitology members, can indirectly influence the proceeding regarding questions on aggregated exposure in the context of the approval (see Section 3.1.10).

2.2.3 Consideration of an active substance as candidate for substitution

One way to assess the risk resulting from an aggregated environmental exposure could be to consider the active substance as a substitution candidate because of its aggregated effects. An active substance is a candidate for substitution if one of the following conditions is fulfilled (cf. Art. 10 (1) BPR):

- It meets at least one of the exclusion criteria stipulated in Art. 5 (1) BPR, but can be approved as an exception according to Art. 5 (2) BPR.

It meets the criteria to be classified as a respiratory sensitiser in accordance with Regulation (EC) No 1272/2008.
- Its acceptable daily intake, the acute reference dose or acceptable operator exposure level is significantly lower than that of the majority of approved active substances.
- It meets two of the criteria for being persistent, bioaccumulative or toxic in accordance with Regulation (EC) No 1907/2006.
- There are reasons for concern that the use is associated with a high-risk potential, e.g. with regard to the groundwater.
- It contains a significant proportion of non-active isomers or impurities.

The list is conclusive, so that other reasons for the classification as candidate for substitution cannot be considered. Nevertheless, the risk resulting from an aggregated environmental exposure has to be considered under the aspect that there are reasons that the use could be associated with a high-risk potential, e.g. with regard to the groundwater or the surface water.

The consequences for the consideration as a candidate for substitution are:

- A special identification of the active substance as candidate for substitution in the relevant Regulation adopted in accordance with Art. 9 Implementing Act. This identification is relevant for the further authorisation of biocidal products but is clearly at variance with a refusal of the approval or authorisation;
- The approval and each renewal shall be granted for a maximum period of seven years (Art. 10 (4) BPR).

2.3 Interim Finding

In order to counter the risk from an aggregated environmental exposure, the authority - during the approval process for active substances as well as after it - can act in different ways.

If there are indications for an existing risk resulting from an aggregated environmental exposure the authority has the possibility to grant the approval for less than ten years. In this case it has to consider all data submitted, taking into account the proportionality principle.

The approval can be granted with conditions for the use of an active substance (Art. 4 (3) BPR). The authority may especially restrict the permissible product-types (Art. 4 (3) (c) BPR), the manner of use and the area of use (Art. 4 (3) (d) BPR) for an active substance.

After the approval, the authority has the possibility to review the decision at all times. The review expects that there are “significant indications”, that the conditions for the approval of an active substance according to Art. 4 (1) in conjunction with Art. 19 BPR are no longer met.

Finally, the competent authority may refuse the approval of an active substance if the requirements according to Art. 4 (1) BPR in conjunction with Art. 19 (1) (b) and Art. 19 (2)

and (5) BPR are not met. Focusing on the risk from an aggregated exposure this is only the case, if the aggregated exposure in every use of an active substance in every product type results in PEC/PNEC ratios > 1, as this indicates an unacceptable risk. This means the approval can only be refused if not one biocidal product meets the criteria laid down in Art. 19 BPR, which is the case, if the ratio of PECaggr to PNEC in an environmental compartment for an active substance in every product is greater than one (PECaggr/PNEC > 1).

Therefore it seems to be more successful to encounter the risk resulting from an aggregated exposure on the authorisation-level of biocidal products rather than on the approval of the active substance.

3 Options for the authorisation of biocidal products

In this chapter, the options of national competent authorities to regulate the risks resulting from an aggregated environmental exposure within the authorisation of biocidal products are examined. Similar to the approval of active substances, a distinction has to be made between pre-market and post-market control. Moreover, in the case of an authorisation of a biocidal product, the BPR, has at its disposal further regulatory options regarding modifications or cancellations of the authorisation.

3.1 Pre-market Control

3.1.1 Conditions for the authorisation of a biocidal product

Biocidal products shall not be made available on the market or used unless authorised in accordance with the BPR (cf. Art. 17 (1) BPR). In order to grant an authorisation for a biocidal product all conditions of Art. 19 (1) BPR must be fulfilled:

At first the active substance for the relevant product-type has to be approved and eventual conditions, which are specified for those active substances, have to be met (cf. Art. 19 (1) (a) BPR).

Moreover the applicant has to prove that a number of further conditions are fulfilled according to Art. 19 (1) (b) BPR. To examine the risk resulting from an aggregated environmental exposure, the following conditions could be relevant:

- "[...]
- (ii) the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
- (iii) the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
- (iv) the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
    - The fate and distribution of the biocidal product in the environment,
    - Contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil taking into account locations distant from its use following long-range environmental transportation,
    - The impact of the biocidal product on non-target organisms,
    - The impact of the biocidal product on biodiversity and the ecosystem;"

While deciding whether the before-mentioned conditions are fulfilled or not, the risk from an aggregated environmental exposure shall be taken into account according to Art. 19 (2) (d) BPR). However, the term „shall take into account cumulative effects" leaves scope for legal interpretation. An analysis of the wording in Art. 19 (1) BPR reveals that the competent authority is legally bound to grant an authorisation for a biocidal product ("shall be authorised") if the conditions in Art. 19 (2) BPR are met. In other words it is not at the

discretion of the competent authority to grant an authorisation. The possible conclusions a competent authority can arrive at when assessing the criteria of Art. 19 (1) (b) BPR for each product-type and each area of use for which an application has been made, are enumerated in Remark 56 of Annex VI BRP:

- the biocidal product complies with the criteria (authorisation must be granted);
- subject to specific conditions/restrictions, the biocidal product can comply with the criteria (authorisation must be granted);
- it is not possible, without additional data, to establish if the biocidal product complies with the criteria;
- the biocidal product does not comply with the criteria (no authorisation can be granted).

However, the conditions outlined in Art. 19 (1) (b) (ii) to (iii) BPR are based on the assessment that a biocidal product has "no unacceptable effects" leaving the competent authority with a reasonable scope for judgment evaluation. To determine the effects and their acceptability, the competent authority has to apply the common principles for the evaluation of dossiers for biocidal products which are laid down in Annex VI BPR (cf. Art. 19 (1) (b) BPR). To that end the competent authority "shall take into account" the risk from an aggregated environmental exposure (cf. Art. 19 (1) b and Art. 19 (2) (d) BPR). From the wording of these provisions it is clear that the competent authority is obliged[5] to assess whether such a risk truly exists according to the dossier information for the specific biocidal product, and against the background of further biocidal products containing the same active substance permitted for inclusion. However, it is less clear how these "factors" in Art. 19 (2) BPR are reflected in the assessment of an "unacceptable effect" according to Art. 19 (1) BPR. For example, the question arises whether a risk from an aggregated environmental exposure will inevitably result in an "unacceptable effect". Following the principles laid down in Annex VI BPR, the competent authority "has to produce an overall assessment for the biocidal product itself based on the results for each area of the risk assessments", taking into account any cumulative or synergistic effects (Remark 53 in Annex VI BPR).

As a result, a risk resulting from an aggregated environmental exposure is an issue that has to be regarded by the authority when reviewing the conditions in Art. 19 (1) BPR. It remains unclarified how possible indications for a risk resulting from an aggregated environmental exposure could look like and what consequences could arise for authorisation. This will be examined in the following sections.

3.1.2 Indications for a risk resulting from an aggregated environmental exposure

Ratio of PEC_{aggr} to PNEC

The existence of a risk resulting from an aggregated environmental exposure may be confirmed if the dossier evaluation according to Art. 19 (1) (b) and Annex VI BPR concludes that there is a certain ratio of PEC_{aggr} to PNEC in an environmental compartment. Annex VI of the BPR stipulates the "Common principles for the evaluation of dossiers for biocidal

[5] See the wording "shall" in Art. 19 (2) (b) BPR.

products". The evaluation carried out according to Annex VI builds the basis to decide whether the conditions set down in Article 19 (1) (b) BPR are met and thus whether a Member State or the Commission will authorise a biocidal product.

The predicted environmental concentration (PEC) has to be assessed for each environmental compartment (air, water, soil). This is done by an exposure assessment which predicts the likely concentration of each active substance or substance of concern in the biocidal product (Remark 42 in Annex VI BPR). To derive the predicted no effect concentration (PNEC), a dose (concentration) — response (effect) assessment is carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur (Remark 39 in Annex VI BPR). The risk characterisation for each environmental compartment shall, as far as possible, entail the comparison of the PEC with the PNEC from which a PEC/PNEC ratio can then be derived.

According to the current practice, an unacceptable risk is assumed if the ratio of PEC_{aggr} to PNEC in an environmental compartment for an active substance is greater than one ($PEC_{aggr}/PNEC > 1$) and risk management measures to minimise the risk are not sufficient. So far, neither the PEC_{aggr} nor the ratio between $PEC_{aggr}/PNEC$ that constitutes a risk from an aggregated environmental exposure is defined in the BPR or respective guidelines. Provisions to define these factors should be introduced in order to achieve procedural reliability and to improve the predictability of the authority decisions for the applicant.

Referring to limits in other regulations

Furthermore, it has to be analysed whether the exceeding of the limits values set forth in (environmental) legislation (e.g. for substances in foodstuffs or the Water Framework Directive, Groundwater and Drinking Water Directive) set binding limit values for the existence of a risk resulting from an aggregated environmental exposure or can be used as an indicator for such a risk.

This reasoning can be illustrated by two case examples:

1. In the case of Maximum Residue Levels (MRLs) for pharmacologically active substances in foodstuffs of animal origin. MRLs are maximum allowable concentrations of residues, for example in food. Since established MLRs virtually represent the consequences of emissions, they are suitable for indicating the threshold that may be applied in case of a risk resulting from an aggregated exposure. As a result, the competent authority could for example restrict the authorisation for a biocidal product with conditions for the spatial or application-specific use if the MLRs are exceeded. With regard to MRLs, however, the BPR only provides for a one-off scheme. Thus, an MRL has been set for biocides in residues of food of animal origin. For active substances used in animal husbandry according to Art. 10 Regulation (EC) 470/2009[6], an MLR set in that Regulation has to be applied

[6] Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and

in the BPR (Art. 19 (8) BPR). If an MLR exists this could be used by the competent authorities to determine a risk resulting from an aggregated exposure under the BPR. As there is no EU-wide harmonised and validated model to estimate the magnitude of residues in food resulting from the use of biocidal products, DG Environment has issued a guidance document containing an approach to be followed for active substances.[7] In the case of residues resulting from livestock exposure to biocides the appropriate body for full food risk assessment and MRL setting is the European Medicines Agency (EMA) as foreseen in Article 10 of Regulation (EC) No 470/2009.

2. With regard to the effects of a biocidal product on the environment the contamination of surface water, groundwater and drinking water has to be assessed, too (cf. Art. 19 (1) (b) (iv) BPR). For the compartment "water" Annex VI of the BPR contains rules under which conditions a biocidal product has unacceptable effects on the environment according to Art. 19(1) (b) (iv) BPR and thus shall not be authorised (cf. remarks 67, 68 and 69). The evaluating body has to conclude an unacceptable effect, if the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products do not to comply with conditions laid down in legislation for the protected goods "water (or its sediments)", "groundwater" and "drinking water". When calculating the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products the evaluating body must not only focus on the biocidal product to be authorised, but has to take into account the risk from an aggregated environmental exposure regarding each of the aforementioned substances (cf. Art. 19 (1) (b) and (2) (d) BPR).

   In terms of the protection of "water (or its sediments)" the biocidal product does not comply with Art. 19 (1) (b) (iv) BPR if the achievements of compliance with standards set in the several laws to protect the surface water[8], e.g. the Water Framework Directive (WFD)[9], are undermined. It is questionable, when the authorisation of a

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amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council, OJ L 152, 16.6.2009, p. 11.

7 EU Commission (2012).

8 Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration, OJ L 372, 27.12.2006, p. 19;
Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council, OJ L 348, 24.12.2008, p. 84;
Directive 2008/56/EC of the European Parliament and of the Council of 17 June 2008 establishing a framework for community action in the field of marine environmental policy (Marine Strategy Framework Directive) (Text with EEA relevance), OJ L 164, 25.6.2008, p. 19; and
International agreements on the protection of river systems or marine waters from pollution.

9 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy, OJ L 327, 22.12.2000, p. 1

biocidal product undermines the compliance with standards, for example according to the WFD standards.

The aim of the WFD is to achieve a good surface and ground water status (cf. Art. 4 (1) (a) and (b) WFD). A good chemical status of the surface water[10] is reached for a water body when it complies with the EQS for all the priority substances and other pollutants listed in Annex I of the Directive 2008/105/EC (cf. Annex V, point 1.4.3 of the WFD and Art. 1 of Directive 2008/105/EC). On the legal basis of Art. 16 (7) WFD environmental quality standards (EQS) have been established for 33 priority substances and 8 other pollutants applicable to water.[11]

Against this background it can be argued, that a biocidal product has unacceptable effects on the environment according to Art. 19(1) (b) (iv) BPR if the foreseeable concentration of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products exceeds one of the EQS for the 33 priority substances or one of the 8 other pollutants applicable to water.

3.1.3 Refusal of an authorisation

If according to the application the conditions in Art. 19 BPR are not fulfilled, the competent authority has to refuse an authorisation for the biocidal product. If the competent authority wants to refuse an authorisation it has to respect the principle of proportionality. That means that the competent authority has to consider whether the conditions in Art. 19 BPR can be met by imposing modifications/restrictions to the authorisation (see Section 3.1.6).

3.1.4 Refusal of the authorisation on grounds of animal welfare

Furthermore, a Member State may refuse to grant an authorisation for product-types 15, 17 and 20 on the grounds of animal welfare (according to Art. 37 (4) BPR). In this case, the Member States are only obliged to inform the other Member States and the Commission of any decisions in this respect and on their justification.

In order to take account of a risk resulting from an aggregated environmental exposure, the appeal to animal welfare reasons, however, is only a vague approach, which is not considered feasible.

3.1.5 Refusal in case of substitution-candidates

Even the authorisation of biocidal products which contain substances that are listed as candidates for substitution, provide for a comparative assessment. If the assessment indicates that other authorised biocidal products, non-chemical or preventive measures have a significantly lower risk, the authorisation or the renewal will be refused. The prerequisite is that the alternatives are sufficiently effective and that they have no

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[10] In order to evaluate whether a “good surface water status” or “good groundwater status” has been achieved the chemical status has to be obeyed, too (cf. Art. 2 No. 18 and 20 WFD).

[11] The substances are listed in: Decision No 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 establishing the list of priority substances in the field of water policy and amending Directive 2000/60/EC, OJ L 331, 15.12.2001, p. 1.

significant economic or practical disadvantages. Moreover, the diversity of available active substances should allow for an effective resistance management (Recital 15 BPR and Art. 23 BPR).

3.1.6 Restricting the authorisation in case of an aggregated environmental exposure

Art. 19 BPR states that a biocidal product shall be authorised if the conditions outlined in Art. 19 (1) and (2) BPR are met. These conditions do not explicitly contain a specific limit for the amount of active substances in authorised products or other criteria for a limitation. Indeed, Art. 19 BPR is a conditional administrative act, meaning that if the conditions of Art. 19 are met, the biocidal product has to be authorised regardless of other (prospective) applications for biocidal products with the same active substance.

Nevertheless, applicants are asked to give an estimate ("likely tonnage") in their application on the quantity of the active substance they place or will place on the EU market per year (i.e. to be produced or imported). Furthermore the applicants should indicate "the quantities for biocidal use and in which product-type(s), and where relevant, for the envisaged major use categories within each product-type. In case of the renewal of approved active substances, tonnage data should cover the last three years. For new substances not previously marketed, production plans covering three years after authorisation should be provided."[12] Based on this data competent authorities can calculate the aggregated exposure of an active substance in an environmental compartment (PECaagr).[13]

However, a tonnage-threshold for active substances could be established "indirectly", if this is necessary in order to fulfil the conditions of the authorisation, i.e., if, for example the biocidal product will otherwise have unacceptable effects (cf. Art. 19 (1) (b) (iv) BPR). In order to prevent risks resulting from an aggregated exposure, a specific application of the biocidal product could be restricted if a specific tonnage threshold for an active substance contained in that product is exceeded.

Regarding possible restrictions the principle of capacity utilisation has to be applied by the competent authority. This means that in case a scarce resource has to be distributed in an administrative procedure, the competent authority has to grant the authorisations (according to the application) until the capacity of the scarce resource will be fully utilized.[14] It must be pointed out that applicants may not demand the extension of the capacity.[15] Thus, the granting of authorisations according to the market share of biocidal products in case of a risk from an aggregated environmental exposure is neither in line with the principle of capacity utilisation nor required by the BPR.

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[12] Cf. No. 7.5 Annex II of BPR on the information requirements for active substances; ECHA (2013), p. 167.

[13] The applicability of the „tonnage approach" is explicitly mentioned in order to determine the exposure from treated articles in an environmental compartment, cf. ECHA (2013), p 60 ff..

[14] Cf. Martini (2008), p. 711; BVerfGE 33, 303.

[15] Cf. OVG Hamburg, GewArch 1987, 303, 305; Ruthig/Storr (2011), Rn. 371.

Finally, it is questionable how the principle of capacity utilisation is applied in the case of a product authorisation according to the BPR. In case of the BPR a product is authorised following the respective application. Thus the capacity is allocated step by step (authorisation by authorisation). It is very unlikely that all applications for products containing the same active substance are requested at the same time. Therefore the utilization of the capacity, until the level of the risk from an aggregated environmental exposure is reached, should follow the principle of priority („first come, first serve“).

Principle of priority

The principle of priority is applied in several European and national legislations and follows the basic idea that limited resources shall be only distributed according to the timing of the requirement registered. Examples for the principle of priority can be found in the emissions trading legislation[16], the limit values for emissions from industrial plants according to the German Technical Guidance “Ambient Air” (TA Luft)[17], the capacity allocation in the gas market[18] or the granting of subsidies and aids.[19] Moreover, the principle of priority is a possible selection criterion in the case of a capacity limitation, for example in the case of the access to public institutions.[20]

Compatibility of restrictions with the free movement of goods

The restriction of a product authorisation is an intervention in the free movement of goods as with regard to the Dassonville-, Keck- and Cassis-de Dijon -judgments the market access is part of the free movement of goods (Art. 34 TFEU).[21] Such an intervention can be justified on grounds of the protection of health and life of humans, animals or plants (Art. 36 TFEU). However, the provisions of the BPR are lex specialis to the regulations in Art. 36 TFEU.[22] An intervention is justified if it pursues legitimate aims, if it is suitable for ensuring the attainment of the legitimate objective pursued, and if it is appropriate to achieve the objectives pursued and does not go beyond what is necessary to achieve the objectives. The legitimate aim to impose restrictions to the authorisation of biocidal products is to protect the health and life of humans, animals or plants (cf. Art. 37 (1) (a) and (c) BPR). The imposition of restrictions to authorisations is not an improper means to achieve these aims,

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16 Cf. “Member States shall notify to the Commission without delay the preliminary total annual amount of emission allowances allocated free of charge. Emission allowances from the new entrants reserve created pursuant to Article 10a(7) of Directive 2003/87/EC shall be allocated on a first come, first served basis with regard to the receipt of this notification.” as stated in Art. 19 Abs. 4 Commission Decision of 27 April 2011 determining transitional Union-wide rules for harmonised free allocation of emission allowances pursuant to Article 10a of Directive 2003/87/EC of the European Parliament and of the Council (notified under document C(2011) 2772), Official Journal L 130 from 17.5.2011, p.1.

17 Roßnagel, in: Koch/Scheuing, BImSchG, § 5, Rn. 292 f.

18 § 9 GasNZV.

19 A recent example for the application of the priority principle was the car-scrap bonus for old vehicles (cf. Nr. 1.2 BAFA-Richtlinie zur Förderung des Absatzes von Personenkraftwagen vom 20. Februar 2009).

20 For example § 8 Abs. 2 Gemeindeordnung NRW; § 70 GewO.

21 Oppermann (2011), § 22, Rn. 3.

22 Cf. especially Art. 37 (1) BPR; for further examples see: Leible/T. Streinz in: Grabitz (2012), TFEU, Art. 34, Rn. 14.

and therefore can be regarded as suitable. Restrictions are an appropriate means to achieve the objectives pursued, provided that no less restrictive alternative measures are available to achieve the aim with the same degree of effectiveness. Imposing restrictions constitutes a less restrictive measure than refusing the authorisation of biocidal products. Apart from the imposition of restrictions to the authorisation, there are no other measures available which are equally effective in terms of achieving environmental protection, but which are less restrictive. Restrictions are therefore an appropriate means. Finally, for example restricting the use of biocidal products does not generally prohibit the placing on the market of these products but only limits their application. These restrictions do not go beyond what is necessary to avoid the risk from an aggregated environmental exposure and in this way achieve the objectives to protect the environment and human health. An infringement of the free movement of goods is justified by Art. 37 (1) BPR.

However, applying the principle of priority to the granting of authorisations in terms of Art. 34 TFEU could be an unjustified discrimination of a "new" applicant for an authorisation with regard to holders of authorisations for products containing the same active substance. Such an unjustified discrimination against an applicant could be the case if the competent authority refuses to grant an "new" authorisation (or grants the authorisation with conditions) based on the facts that there are already products on the market which contain the same active substance and that granting an authorisation for a further product with that substance would cause a risk from an aggregated environmental exposure.

A possible new authorisation and existing authorisations are based on similar situations. In both cases the authorisation is only granted if all conditions in Art. 19 BPR are fulfilled. Moreover, all products on the market and the new product account for the risk of an aggregated environmental exposure. The only difference lies in the fact that products on the market have been granted without limitations regarding the risk from aggregated exposure whereas an authorisation for the new product would be refused or restricted based on the risk form an aggregated exposure.

This unequal treatment could be justified if the principle of priority is an objective reason for differentiation regarding the allocation of authorisations in the case of a risk from an aggregated environmental exposure. Basically, the principle of priority is a recognised and suitable criterion for selection in the context of capacity decisions.[23] However, criticism of the principle is based on the fact that it does not allow an objective comparison between different situations.[24] Though, this criticism is not valid for the authorisation procedure in the BPR as it stands because there are no regulations requiring a simultaneous decision for authorisation of all biocidal products to be put on the market, like a deadline for the authorisation. In fact, it is up to the applicants at which time they want to seek an authorisation and in which procedure. Furthermore, the provisions on the authorisation procedure contain rigid timelines for the competent authority to grant an authorisation

[23] Franz (2012), p. 72; Malaviya (2009), p. 149.

[24] Malaviya (2009), p. 151 ff. Maslaton (2013), who recognizes the applicability of the principle for the formal decision procedure but not for the substantive decision.

regarding the national authorisation, the mutual recognition procedures or the Union authorisation (cf. Art. 29 ff., Art. 32 ff. or Art. 42 ff. BPR). Therefore it is not possible for the competent authorities to await further applications and then grant all authorisations for products with the same active substance simultaneously in the light of a risk from an aggregated environmental exposure. But a possible option of the competent authority could be to synchronise the duration of authorisations in order to pool the renewal of authorisations (cf. Section 6.2.2).

In addition, it is remarkable that actual authorisation procedure in the BPR together with the principle of priority might stimulate a producer to overestimate the expected production volume for his product. If the authorisation is granted for that product without restrictions regarding a possible aggregated environmental exposure other (possibly more innovative) products containing the same active substance could be excluded from the market.[25]

Interim conclusion

The principle of priority is a recognised and suitable criterion for selection in the context of capacity decisions.[26] To impose restrictions on product authorisations is an intervention in the free movement of goods according to Art. 34 TFEU. But in case of a risk from an aggregated environmental exposure these restrictions are justified on grounds of the protection of health and life of humans, animals or plants (Art. 36 TFEU). The refusal of product authorisations or the imposition of restrictions on authorisations is not an unjustified discrimination in terms of Art. 34 TFEU. Against the background of the present regulation of product authorisations in the BPR the principle of priority justifies an unequal treatment of new applications to grant an authorisation versus existing authorisations in the case of a risk from an aggregated environmental exposure.

Imposing ancillary clauses

Ancillary clauses are a legal instrument of the competent authority to impose restrictions to an authorisation. On the one hand these ancillary clauses can be rather general like a reservation to make modifications or a proviso of cancellation in case a risk from an aggregated environmental exposure will occur. If, for example, any further authorisation of a product in a Member State would entail a risk from an aggregated environmental exposure due to the total amount of an active substance contained in the biocidal products already authorised in that Member State, existing authorisations could be modified to allow further authorisations for like products. On the other hand the ancillary clauses can specify in detail which conditions the applicant has to comply with in order to receive an authorisation. Such detailed conditions could cover:

- Restricting the use of a biocidal product on specific uses / specific harmful organisms;
- regulating the user categories (professional/non-professional);

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[25] Cf. Franz (2012), aaO.

[26] Regarding the German law cf. Voßkuhle (1999), p. 38; approving but critical Malaviya (2009), p. 154.

- imposing risk management measures;
- determining the maximum concentration per use; or
- determining the application intervals.

However, as the authorisation is a conditional administrative act and with regard to the principle of priority (see above), it is not possible to impose ancillary conditions which limit the maximum tonnage for biocidal products an applicant is allowed to put on the market, as long as a risk from an aggregated exposure does not exist.

Indeed, in the BPR no provisions are stipulated that empower the competent authority with the reservation to make modifications or the proviso of cancellation. However, as biocidal products are authorised according to an EU regulation (the BPR) which is directly applicable in the Member States the general rules of the European administrative law have to be applied by the Member States. According to European administrative law ancillary clauses are legal.[27] Regarding the admissibility of ancillary clauses, a difference exists between ancillary clauses that are based on an enabling provision and those ancillary clauses which do not contain such a provision. In the case of discretionary decisions, ancillary clauses are generally legal (cf. § 36 para. 2 German administrative law). In the case of conditional decisions they are legal if they are explicitly admitted by an enabling provision or if they ensure that the legal requirements of the administrative act are achieved.[28] In the European law, an equivalent systematisation exists.[29]

Against the background of this systematisation it is questionable whether a reservation to make modifications or a provisio of cancellation can be legally imposed to the authorisation of biocidal products because the authorisation is a conditional decision (cf. the wording in Art. 19 (1) BPR "shall be authorized"). Articles 22 (1) and Art. 37 (1) BPR can be seen as an enabling provisions. According to Art. 22 (1) BPR, the competent authority shall stipulate „terms and conditions" regarding the content of an authorisation. In the case that a competent authority decides to derogate from an authorisation in a mutual recognition procedure the authority concerned can "adjust the terms and conditions of the authorisation" to be granted (Art. 37 (1) BPR). In both cases, the competent authority is entitled to impose "conditions" to the authorisation, but it is not entirely clear if the term "condition" covers the imposition of ancillary clauses, i.e. if they are meant to be enabling provisions. An argument against the presumption of an enabling provision is the fact that the term "condition" rather implies to impose on the applicant a duty to act, to tolerate or omit an action than to condition the granting of the authorisation.[30] It can be argued in favor of the legality to impose ancillary clauses that they secure the legal requirements of the administrative act, i.e. they ensure that the requirements of Art. 19 (1) and (2) BPR are met, including the avoidance of risks from an aggregated environmental exposure.

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27 Cf. Schwarze (2005), p. 981 f.
28 For further information see: Stelkens (2008), §36, Rn. 63 ff.
29 Frenz (2010), Rn. 1328 f.
30 Cf. for medical products for human use see: Kern (2010).

Irrespective of the preliminary discussion the reservation to modification and the provisio of cancellation gives the competent authority the possibility of granting authorisations for biocidal products containing an active substance, high volumes of which are on the market, and where a risk from an aggregated environmental exposure is likely to result. In case of a reservation, the holder of an authorisation cannot rely on a legitimate expectation, because the reservation precludes the emergence of such a legitimate expectation regarding the administrative main act.[31] Indeed, this approach will give the holder of an authorisation less planning reliability.

Moreover, the imposition of ancillary clauses has similar pre-conditions as the cancellation of an authorisation. Therefore reference is made to the remarks on the cancellation of an authorisation in Section 3.2.2.

To sum up, in the case of risks from an aggregated environmental exposure it appears to be a sound legal option to impose a reservation to make modification or a proviso of cancellation to an authorisation in order to ensure that the requirements in Art. 19 BPR are met and to enable further product authorisations in the Member State concerned. However, some uncertainty remains with respect to the question of whether a modification or a proviso of cancellation is a legal instrument, since a codified common European administrative law is missing.[32]

3.1.7 Authorisation through mutual recognition

The mutual recognition procedures (Art. 32 ff. BPR)

The mutual recognition procedures intend to alleviate the authorisation process for those applicants who do not apply for an EU-wide authorisation, but want to place a product on the market in several Member States. The assessment of the authorisation is done by one Member State, the so-called “reference Member State”. The national approval procedure will be executed only in the reference Member State. If a national authorisation is requested in another Member State (so-called “Member State concerned”), this is executed in a mutual recognition process based on the first authorisation. The procedure is regulated in Art. 32 ff. BPR, stating that all Member States have to authorise the biocidal product under the same terms and conditions (cf. Art. 32 (2) BPR). There are two procedural options:

1. The mutual recognition in sequence according to Art. 33 BPR and
2. The mutual recognition in parallel according to Art. 34 BPR.

In both cases, an application for a national authorisation had been submitted to the reference Member State. The conditions for the authorisation are that the Member State which should recognise the substance agrees with the properties of the biocidal product and has no objection to the authorisation and does not make any deviation from the mutual recognition.

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[31] Stelkens (2008), §36, Rn. 22.

[32] Frenz (2010), Band 5, Rn. 1770 ff.

Mutual recognition in sequence

The Member State in which the application for mutual recognition is made, assesses the situation based on the national authorisation of the reference Member State. As a rule, the BPR assumes that the Member States concerned are able to reach an agreement regarding the properties of the biocidal product (cf. Art. 33 (3) BPR). If there is no agreement between the Member States within the period defined under Art. 33 BPR, every affected Member State which consents to the summary of the biocidal product characteristics according to Art. 33 (2) BPR is able to authorise the product accordingly.

As a result, it is possible to authorise individual biocidal products on national level, although not all Member States in which an application for authorisation is made, agree to the characteristics. For further details see case study 1 in Section 6.2.

Mutual recognition in parallel

In the mutual recognition in parallel, the applicant must submit an application for authorisation to the competent authority of the reference Member State pursuant to Art. 20 BPR, and add up a list of those states, for which he wants to obtain another national authorisation. The reference Member State shall assess the application for authorisation. At the same time the applicant has to submit an application for mutual recognition to the competent authorities of each of the Member States concerned. According to Art. 34 (2) BPR, the application(s) contains the name of the reference Member State and a summary of biocidal product characteristics pursuant to Art. 20 (1) (a) (ii) BPR.

Again, the BPR assumes that the Member States concerned are able to reach an agreement regarding the characteristics of the biocidal product (cf. Art. 34 (6) BPR). The precise procedure is regulated in Art. 34 BPR.

Different assessment of biocidal products by the Member States

In order to achieve a consensus in the concerned states, Art. 35 BPR provides for the establishment of a coordination group for the mutual recognition procedure. First, this group will check all the questions that are relevant to the issue of an authorisation. All Member States and the Commission shall be entitled to cooperate in the coordination group.

If a Member State, contrary to the opinion of the reference Member State, comes to the conclusion that the product assessed by the Reference does not fulfil the requirements of Art. 19 BPR, it informs the other concerned Member, the Commission, the applicant and the authorisation holder about the issues on which it has a different opinion and substantiates its position. Within the framework of a coordination group, the stakeholders involved will try to come to an agreement. If such an agreement is reached within 60 days, the Member States concerned will authorise the biocidal product.[33] If there is no agreement, this has to be seen as an objection and must be reported to the Commission

[33] cf. for the proposed proceeding: Art. 35 (3) BPR.

immediately (cf. Art. 36 BPR). The Commission shall adopt, by means of implementing acts[34], a decision (cf. Art. 36 (3) BPR). According to Art. 36 (4) BPR, this decision is binding for the concerned Member States which are obligated to approve the result of the decision within 30 days, and thus to grant or to refuse the authorisation.

Derogation from the mutual recognition

Each Member State may propose a derogation from the mutual recognition by refusing an authorisation or by imposing conditions[35] to an authorisation, if this can be justified by:

- The protection of the environment,
- public policy or public security,
- the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants,
- [...],
- the target organisms not being present in harmful qualities.

Where this is the case, the competent authority must first try to achieve a consensus with the applicant, addressing the divergence of views (cf. see Art. 36 (2) BPR). If no agreement can be reached, or if the applicant does not respond within 60 days, the decision is up to the Commission again. The decision is binding for the Member States. If the Commission does not come to a conclusion, the Member State is allowed to apply the derogation which it has suggested.

Referring to an aggregated environmental exposure in the mutual recognition procedure the conflict of interest described and examined in case study 1 (see Section 6.1) is of importance. In the course of the case study 1 options of the competent authority to solve this conflict are examined.

[34] Probably meant is the test procedure according to the Comitology Regulation.

[35] Conditions for biocides if the concerned biocidal product includes an active substance, for which Art. 5 (2) or Art. 10 (1) BPR apply.

3.1.8 Union authorisation

The Union authorisation (cf. Art. 41 ff. BPR) differs from other authorisation procedures in the BPR, in that it authorises the placing on the market of a biocidal product throughout the EU. Thus, it substitutes national authorisation and authorisation through mutual recognition. This section explores how risks resulting from aggregated environmental exposure are regulated in the union authorisation, and how national competent authorities can participate in the procedure regarding aggregated environmental exposure.

First of all it must be noted, that the Union authorisation will be introduced in three steps (2013, 2017 and 2020) according to product-type (cf. Art. 42 (1) BPR).

Moreover, a Union authorisation is not applicable to active substances having characteristics listed in Art. 5 BPR, nor to the product-types 14, 15, 16, 17 and 21.

The conditions for a union authorisation and a national authorisation are identical apart from the following two additional aspects (cf. Art. 43 (1) BPR):

- A Union authorisation will be granted only to biocidal products with similar conditions of use;
- the applicant must provide a written confirmation of a competent authority of a Member State (evaluating competent authority) which agrees to evaluate the application.

According to Articles 44 (1) and 19 (2) (d) BPR, the risk from an aggregated environmental exposure must be reflected in a Union authorisation as in any other authorisation procedure.

The authorisation procedure starts with the submission of a dossier by a company to ECHA. The evaluating competent authority that has previously been chosen by the applicant evaluates the dossier and forwards the result to ECHA's Biocidal Products Committee to prepare an opinion within 180 days. Finally, the European Commission takes a decision based upon ECHA's opinion.

For more details on the options of Member States to react on the risk from an aggregated environmental exposure in the case of a Union authorisation, see Section 6.3.

3.1.9 Determine the term “cumulative effect” in the comitology procedure

Member States could contribute to the definition of “a risk from an aggregated environmental exposure” in Art. 19 (2) (d) BPR) in the framework of the comitology procedure.

Various provisions in the BPR highlight that a specification of the procedure can be done by implementing acts. An example is the authorisation of identical biocidal products on the same conditions by one or more applicant. By Art. 17 (7) BPR, the legislator authorised the Commission to establish, by means of an implementing act, procedures for the authorisation of biocidal products. Another example is the regulation of cancellation and amendments. Art. 51 BPR provides that the Commission is authorised to adopt detailed rules for the application of Art. 47 to 50 BPR by way of implementing acts, in order to harmonise the procedure.

The authorisations for the adoption of implementing acts are usually directed to the procedure and not explicitly to the specification of terms and their interpretation. Nevertheless, the procedure may indirectly provide that a clarification of the terminology in order to harmonise the procedure is possible. This is possible within narrow limits, if an authorisation to the Commission to clarify the meaning of Art. 291 TFEU is given and if there is no intervention under the scope of Art. 290 TFEU. For example, limits or threshold values for an aggregated environmental exposure could be specified as well as a set of risk management measures to avoid the risk from an aggregated environmental exposure.

3.2 Post-market Control

3.2.1 Renewal

As a legal instrument of the post-market control the competent national authority or, in the case of a Union authorisation, the ECHA can refuse the renewal of a product authorisation in order to avoid the risk from an aggregated environmental exposure. Due to the duration for authorisations (10 years), existing authorisations may be reviewed within a prescribed period of time (see in Section 6.3 for the Union authorisation.

As part of the renewal of the authorisation the ECHA or the national competent authorities notes whether, according to the present scientific knowledge, a comprehensive re-assessment of the application documents is necessary or not. So there may be a re-evaluation of the application, if for example the scientific results with respect to risks resulting from an aggregated exposure have changed.

As a result of the re-evaluation a renewal can be refused by the authorities because of a risk from an aggregated environmental exposure.

3.2.2 Cancellation of authorisations

The conditions for the cancellation and amendment of product authorisations are regulated in Art. 47 ff. BPR.

The competent national authority or the Commission (in case of Union authorisation) may at any time cancel or amend an authorisation they have granted (cf. Art. 48 BPR), if they consider that certain conditions of an authorisation are not met. Regarding the risk from an aggregated environmental exposure, the following reason seems to be of particular interest: the Commission or the competent authority considers that the conditions for obtaining the authorisation are (possibly in the simplified authorisation procedure) not satisfied (Art. 48 (1) (a) BPR).[36]

An authorisation may therefore be cancelled if it turns out, that the conditions of Art. 19 (1) BPR are not effective, e.g. because the risk resulting from an aggregated environmental exposure has been wrongly assessed (cf. Art. 48 (1) (a) BPR referring to the authorisation

[36] Moreover, the following reasons in Art. 48 (1) BPR seem to be of less importance for the examined question:

- The authorisation was granted on the basis of false or misleading information.
- The authorisation-holder does not fulfil his obligations under the authorisation or under the BPR.

requirements in Art. 19 BPR). If the Commission or the competent authority intends to cancel or to amend an authorisation for a biocidal product, it shall inform the authorisation holder, and at the same time give him a specified time limit to comment or to submit further information (cf. Art. 48 (2) BPR). The Commission or the competent authority shall take appropriate account of the information. It must be noted that the competent authority shall grant a period of grace for the disposal, making available on the market and use of existing stocks, except where that would constitute an unacceptable risk to human health, animal health or the environment (cf. Art. 52 BPR).

Harmonisation of the procedure for cancellation and amendment of an authorisation

Following Art. 51 BPR, the Commission shall, in accordance with the comitology procedures[37], draft implementing acts which should harmonise the procedure regarding the cancellation and amendment of the authorisation. The implementing acts, which still have to be issued[38], should regard certain principles for the different types of changes. According to this, for administrative changes a simplified notification procedure should be applied (cf. Art. 51 (1) (a) BPR). For minor changes, a reduced evaluation period shall be established (cf. Art. 51 (1) (b) BPR). If there are significant changes, the evaluation period shall be proportionate to the extent of the proposed change (cf. Art. 51 (1) (c) BPR).

3.3 Interim Finding

Similar to the approval of active substances, the national competent authorities or the Commission have legal options to encounter the risk from an aggregated environmental exposure in the pre-market and post-market control of an authorisation. In the pre-market control, the competent authority can refuse an authorisation if the conditions in Art. 19 BPR are not fulfilled and the principle of proportionality has been taken into account. Before an authorisation is refused, it should be examined whether ancillary clauses could be imposed in the authorisation. General ancillary clauses like a reservation to make modifications or a proviso of cancellation could be used to avoid the risk from an aggregated environmental exposure. Specific restrictions which can be imposed to the authorisation by means of ancillary clauses might contain:

- Restricting the use of a biocidal product on specific uses / specific harmful organisms;
- regulating the user categories (professional/non-professional);
- imposing risk management measures;
- determining the maximum concentration per use;
- determining the application intervals;

[37] The BPR refers to the committee procedure in Art. 82 (3) BPR, which refers to Art. 5 Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

[38] Status quo: April 2012.

However, as the authorisation is a conditional administrative act and with regard to the principle of priority it is not possible to impose restrictions which limit the maximum tonnage for biocidal products as long as a risk from an aggregated environmental exposure does not exist

Other options to restrict the authorisation of a biocidal product are stated in Art. 37 BPR. With regard to Art. 37 (1) BPR a Member State concerned can derogate from the authorisation of the reference Member State if it can justify the derogation with a reason listed in an exhaustive list in Art. 37 (1) (a) to (e) BPR. A legal instrument for the derogation is to impose a condition to the authorisation. Furthermore, a Member State may refuse to grant an authorisation for product-types 15, 17 and 20 on the grounds of animal welfare (according to Art. 37 (4) BPR). In order to take account of a risk resulting from an aggregated environmental exposure, the appeal to animal welfare reasons, however, is only a vague approach, which is not considered feasible (for further details see case study 1 in chapter 6).

In the post-market control, the renewal of an authorisation can be refused if the competent authority concludes in a re-evaluation of the conditions outlined in Art. 19 BPR, that a risk resulting from an aggregated environmental exposure exists. Furthermore the competent national authority or the Commission (in case of Union authorisation) may at any time cancel or amend an authorisation they have granted (cf. Art. 48 (1) (a) BPR), if they consider that certain conditions of an authorisation are not met.

4 Necessary data and deadline to evaluate an environmental risk from an aggregated environmental exposure

In this chapter, it will be examined whether the competent authority is entitled or even obliged to use information received in a former approval procedure for an active substance or in a former authorisation procedure of a biocidal product to assess the risk from an aggregated environmental exposure. To this aim the rules of the BPR regarding the protection and sharing of data will be analysed in section 4.1. Moreover, the extent to which an applicant must provide information about his biocidal product or his active substance is discussed in section 4.2 in order to assess a risk resulting from an aggregated environmental exposure. Finally a deadline is proposed in section 4.3 for the applicant to provide information on the biocidal product or the active substance to the competent authority, in order to assess an environmental risk from an aggregated environmental exposure. Legal aspects of data protection and data sharing in the authorisation process are examined in case study 2 in part B of this report, too.

4.1 Data protection and data-sharing

First of all it will be analysed which rules regarding data protection and data sharing the competent authority has to obey in an approval or authorisation procedure. On this basis it can be determined which information is available for a subsequent applicant. This is of significance for the subsequent applicant in order to appraise, whether he will face problems with a risk from an aggregated environmental exposure or whether he will have to produce data for his application on his own or can use the data from a prior application.

According to Art. 66 (2) BPR, ECHA and the competent authority shall not disclose information where disclosure would undermine the protection of the commercial interest or the privacy and safety of the persons concerned. Art. 66 (2) sentence 2 BPR contains a list of information which by definition of the law normally undermines the commercial interest or the privacy and safety of the persons concerned:

- details of the full composition of a biocidal product;
- the precise tonnage of the active substance or biocidal product manufactured or made available on the market;
- links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;
- names and addresses of persons involved in testing on vertebrates.

These data have to be treated confidential by all competent authorities in general, unless the exception under Art. 66 (2) (3) BPR is applicable. Thereafter, the competent authorities may disclose information if urgent action is necessary, for example to protect the environment or public health.

Beside the aforementioned list of data, which generally may not be disclosed, Art. 66 (3) BPR contains a positive list of data for which access shall not be refused after the authorisation has been granted:

- The name and address of the authorisation holder,
- the name and address of the biocidal product manufacturer,
- the name and address of the active substance manufacturer,
- the content of the active substance or substances in the biocidal product and the name of the biocidal product,
- physical and chemical data concerning the biocidal product,
- any methods for rendering the active substance or biocidal product harmless,
- a summary of the results of the tests required pursuant to Art. 20 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance,
- recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards,
- safety data sheets, and
- methods of analysis referred to in Art. 19(1)(c).

Upon reversion it cannot be concluded that other information than outlined in the list of Art. 66 (3) BPR does not undermine the commercial interests and therefore shall be disclosed.

In order to assess the sensitivity of the data, it has to be distinguished between different data sources and the receivers of the data, i.e. whether the information is from other applicants or from another competent authority.

4.1.1 Confidentiality of data from third parties

In accordance with the wording "may agree" in Art. 64 (1) and (2) BPR it is left to the discretion of the competent authority or the ECHA, whether it allows a subsequent applicant to refer to the test reports of a previous applicant in the approval of an active substance or in the authorisation of a biocidal product. In the consecutive authorisation of biocidal products or approval of biocidal active substances the national competent authority or the ECHA therefore is granted the right to make available data, which it received during the initial authorisation procedure of a biocidal product, to other applicants.

In both cases (active substance and biocidal product), the authority can exercise its discretion only when the following two conditions are met:

- The relevant data protection period according to Art. 60 BPR has expired and
- the first applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities (Art. 64 (1) BPR). For biocidal products, the foregoing applies accordingly to the substance(s) contained in the biocidal product. In addition, the second applicant must provide evidence that the biocidal product is identical with the previously authorised biocidal product or that the differences between them are not significant in relation to risk assessment (Art. 64 (1) BPR).

The data protection period for the documents submitted for active substances and biocidal products do prevent the data from being freely accessed by other applicants and thus

ensure that products will not be authorised to the detriment of the first applicant. According to Art. 60 BPR, the authority shall comply with the following data protection periods for active substances or for biocidal products:

Table 1: Data protection periods for active substances and biocidal products according to Art. 60 BPR.

Source	End of the protection period	Example
Active substances		
Approval of an existing active substance (Art. 60 (2) sentence 1 BPR)	10 years from the first day of the month following the date of adoption of a decision in accordance with Art. 9 of the approval of the relevant active substance for the particular product-type.	If the existing active substance for the product-type was approved on 15 June 2012, the protection period ends on 1 July 2022 at midnight.
Approval of a new active substance (Art. 60 (2) sentence 2 BPR)	15 years from the first day of the month following the date of adoption of a decision in accordance with Art. 9 of the approval of the relevant active substance for the particular product-type.	If the new active substance for the product-type was approved on 15 June 2012, the protection period ends on 1 July 2027 at midnight.
New data submitted with a view to the renewal or review of the approval of an active substance (Art. 60 (2) sent. 3 BPR)	5 years from the first day of the month following the date of adoption of a decision in accordance with Art. 14 (4) concerning the renewal or the review.	If the decision about the renewal or review was made on 15 June 2012, the protection period ends on 7 January 2017 at midnight.
Biocidal products		
Authorisation of a biocidal product containing only existing active substances (Art. 60 (3) sentence 1 BPR)	10 years from the first day of the month following the date of a decision concerning the authorisation the product taken in accordance with Art. 30 (4), Art. 34 (6) or Art. 44 (4).	If the first decision concerning the authorisation of the biocidal product was made on 15 June 2000, the protection period ends on 1 June 2010 at midnight.
Authorisation of a biocidal product containing new active substances (Art. 60 (3) sentence 2 BPR)	15 years from the first day of the month following the date of a decision concerning the authorisation the product taken in accordance with Art. 30 (4), Art. 34 (6) or Art. 44 (4).	If the first decision concerning the authorisation of the biocidal product was made on 15 June 2010, the protection period ends on 1 July 2025 at midnight.
New data submitted with a view to the renewal or amendment of the authorisation of a biocidal product (Art. 60 (3) sentence 3)	5 years from the first day of the month following the decision concerning the renewal or amendment.	If the decision about the renewal or amendment was made on 6 June 2012, the protection period ends on 1 July 2017 at midnight.

It is important that the data protection periods start with first submission of the data and that it does not matter whether the data was submitted under Directive 98/8/EC or the BPR (cf. Art. 60 (1) BPR). Furthermore, the protection period cannot be extended or renewed (Art. 60 (1) sentence 2 BPR). This means that in accordance with Art. 60 BPR, data for which the protection period has expired will not be protected again and can be used by the authority in an approval or authorisation process. However, it must be stressed that there are shorter data protection periods for "new data" submitted to the authority in the context of a renewal or amendment process (for an existing authorisation of a biocidal product cf. Art. 60 (3) sentence 3 BPR, and for the approval of an active substance cf. Art. 60 (2) sentence 3 BPR).

If a subsequent applicant wants to use data of the first applicant, before the data protection period ends, he must obtain a letter of access that contains the information stated in Art. 61 BPR. The BPR prohibits the repeated conduct of tests on vertebrates for the objectives of the regulation. In the case of data involving tests on vertebrates, the applicant must therefore submit a request to the ECHA (Art. 62 (2) (a) BPR). In case ECHA possesses the requested data, it communicates the name and contact details of the data submitter and data owner to the prospective applicant. Art. 63 BPR regulates procedures for granting compensation for the sharing of data. For data which are not connected with tests on vertebrate animals, the applicant may also submit an application (Art. 62 (2) (b) BPR).

4.1.2 Confidential classification by third parties

The competent authority has to treat information as confidential if it was classified as confidential by third parties (for example the receiving competent authority, Member States and the Commission), cf. Art. 19 (2) sentence 2 Regulation BPD.[39] A similar provision is not explicitly stated in the BPR. However, the purpose and intention of the provisions in Art. 66 BPR regarding the protection of commercial interests or the privacy or safety of the persons concerned together with the rules on public access to documents (cf. Art. 66 (1) BPR) ensure the equal treatment throughout the Community.

In that context attention should be drawn to Art. 66 (4) BPR which gives every person submitting information on an active substance or a biocidal product the right to declare types of information listed in Art. 66 (3) BPR as confidential. The request must include a justification as to why the disclosure of information could be harmful for the commercial interests of the person or to any other party.

4.2 Available information to determine an aggregated environmental exposures

According to Art. 66 (2) BPR, a competent authority may not, in assessing the aggregated environmental exposure of biocidal products or biocidal active substances, share particulars relating to the full composition of a biocidal product (recipe), or the precise tonnage of the

[39] This information shall only be communicated in administrative or penal procedures which had been commenced in order to contain the substances which have been made available on the market and only to people directly involved.

active substance or a biocidal product being manufactured or made available on the market, with a third party (i.e. other applicants). Conversely, information regarding the approval of an active substance can be passed on, provided that this data does not allow any useful conclusions to be drawn on the part of individual applicants. For example the competent authority might inform the subsequent applicant that due to a prior application a risk from an aggregated environmental exposure is likely to affect his authorisation. However, before an authorisation is granted to a prior applicant the competent authority is not allowed to share data outlined in Art. 66 (3) BPR with the subsequent applicant, e.g. the name and address of that applicant.

After the authorisation has been granted, the competent authority is allowed to pass on for example the content of the active substance or substances in the biocidal product and the name of the biocidal product to third parties (cf. Art. 66 (3) (d) BPR). This information could be important for a subsequent applicant, for example in order to check whether it is possible that with his application an unacceptable risk from an aggregated environmental exposure can be expected.

In order to assess the risk resulting from an aggregated environmental exposure the following results of the submitted tests according to Art. 20 BPR demonstrate the efficacy of the product as well as the effects on humans, animals and the environment. Where applicable, its ability to promote resistance is also important. According to Art. 66 (3) (g) BPR, the authority may disclose the summary of these results to third parties, if the data is not qualified as company and business secrets. In the approval process for an active substance, the applicant must submit a dossier for the active substance, which is divided into the following 4 levels:

- Document IV is equal to the original test reports (studies), separated by active substance (Part A) and product (Part B).
- Document III contains summaries (style sheet and examples on adsorption / desorption and acute fish toxicity can be found below), separated by active substance (Part A) and product (Part B).
- Document II in Part A, contains the effect and exposure assessment for the active substance, in Part B it contains the effect and exposure assessment for the product and in Part C the risk characterisation.
- Document I contains the summary and the vote, as well as the list of endpoints.

According to Art. 66 (3) (g) BPR, the test results and the summaries of the data about the effectiveness and potential development of resistance promotion in the documents I to IV do not have to be regarded as company and business secrets and shall not be treated confidential after an authorisation has been granted. Because the “Doc. I”-Level is published in the Assessment Report, after the active substance was included in Annex I of Directive 98/8/EC, the data contained therein are public and an interest to treat it confidential does not exist anymore. Particularly individual data at the level of Doc II, III and IV are operating and business secrets that must be kept confidential. On the basis of a case-by-case assessment, it has to be determined, whether it is possible to conclude from the particular individual specification to operational know-how, which disclosure may result in an operating loss.

4.3 Deadline and scope of the data to be submitted

The aim of this section is to examine which data is necessary for the competent authority to assess the risk resulting from an aggregated environmental exposure in the case of the approval of an active substance and in case of an authorisation of a biocidal product.

To determine the risk resulting from an aggregated environmental exposure, the competent authority of the relevant Member State needs information about the total tonnage of the active substance in all applications which are on the market in a Member State. In addition, the authority needs to be able to calculate the relevant PEC for the active substance and the corresponding PNECs regarding the environmental compartment.

According to Art. 20 (1) (a) (iii) BPR an applicant has to submit together with its application a dossier or a letter of access that for each active substance in its biocidal product the information requirements according to Annex II of the BPR are fulfilled; for the approval of active substances this duty results from Art. 6 (1) (a) BPR. In the core data set and the additional data set of Annex II of the BPR applicants are asked to give an estimate ("likely tonnage") on the quantity of the active substance they place or will place on the market per year (i.e. to be produced or imported), see No. 7.5 of Annex II of the BPR. Furthermore the applicants should indicate "the quantities for biocidal use and in which product-type(s), and where relevant, for the envisaged major use categories within each product-type."[40] The competent authority can determine the PEC for an active substance either on the basis of the quantities for use of a biocidal product in a product-type (use-based approach), or on the basis of the tonnage of the active substance to be placed on the market (tonnage approach). In either of these cases the competent authority needs information specific to the Member State´s territory (the tonnage to be placed on the market of the specific Member State or the product-types to be marketed in the specific Member State) in order to calculate the PEC. According to No. 7.5 of Annex II of the BPR the applicant must submit information on the likely tonnage to be placed "on the market". It is not defined whether the information on the tonnage refers to the "EU-market" and a split of the tonnages to be put on national markets is not explicitly required. According to the Guidance on information requirements of ECHA the applicant has to submit information on the likely tonnage for the "EU-market".[41]

Therefore the question is how a national competent authority can assess the risk from an aggregated environmental exposure for its territory. In case of an authorisation through mutual recognition the competent authority of the Member State concerned needs information about the quantity of the active substance to be placed on his market in order to assess the risk from an aggregated environmental exposure for its territory. It is questionable whether the applicant has submitted such information to the competent authority in the reference Member State and whether such information would be exchanged between the authorities:

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[40] Cf. ECHA (2013), p. 167.
[41] Cf. ECHA (2013), p. 167.

- In case of a mutual recognition in sequence the applicant has to submit an application to each of the competent authorities of the Member States concerned containing a translation of the national authorisation granted by the reference Member State (cf. Art. 33 (1) BPR). Thus the competent authority of the Member State concerned may require information from the applicant on the quantities of the active substance he wants to put on the market in the Member State concerned in order to assess the risk from an aggregated environmental exposure.
- In case of a mutual recognition in parallel the applicant has to submit information according to Art. 20 BPR only to the competent authority of the Member State of its choice (reference Member State) which is responsible for the evaluation of the application (cf. Art. 34 (1) BPR). The Member States concerned only receive the summary of the biocidal product characteristics referred to in Art. 20 (1) (a) (ii) BPR (cf. Art. 34 (2) BPR). As this summary does not cover information on the quantity of the active substance to be put on the market in the Member State concerned, the competent authority is not able to assess the risk from an aggregated environmental exposure.

The problem discussed before occurs in a Union authorisation, too, if the applicant only specifies the tonnage of the active substance he applies EU-wide, without differentiating between this volume and the tonnage he wants to make available on the market in relevant Member States. It is therefore questionable how a Member State can detect a risk from an aggregated environmental exposure for his territory in case of a Union authorisation (cf. the alternatives of a Member State to react in Section 6.3).

Finally, the deadline for the submission of data (inter alia the tonnage amount) depends on the authorisation procedure applicable:

- In the premarket control the data shall be submitted not later than the deadline for the application of the authorisation;
- In the case of a renewal data shall be submitted not later than the deadline to apply for the renewal.

5 Stricter national requirements

In this chapter it is assessed whether Member States can establish a higher level of protection regarding the risk from an aggregated environmental exposure than that established in the BPR.

At first it should be pointed out that Member State can establish a higher level of protection if that is regulated in a secondary Community law, like the BPR, and in any other case Member States may introduce more stringent protective measures on the grounds of the primary Community law according to Art. 193 TFEU.

Art. 88 BPR (called "safeguard clause") empowers Member States to take "appropriate provisional measures" to protect the health of humans and the environment with regard to the authorisation of biocidal products. This safeguard clause gives the Member States the power to act by derogation from the rules established in the BPR to grant, cancel, amend or renew authorisation for biocidal products. Art. 88 BPR therefore constitutes a lex specials in the secondary Community legislation in relation to the primary Community law and thus has precedence over it. On two conditions Member States are entitled to take provisional measures (cf. Art. 88 BPR): Firstly a biocidal product that is authorised according to the regulations in the BPR must pose "a serious immediate or long-term risk to the health of humans, particularly of vulnerable groups or animals or to the environment". Secondly the Member State has to reach this conclusion on the basis of "new evidence". The condition, that measures according to Art. 88 BPR muss be based on "new evidence", excludes actions by Member States due to any information that was used in the authorisation procedure of a biocidal product. If a Member State, for example, does not agree with the conditions of an authorisation for a biocidal product it cannot derogate from that authorisation based on Art. 88 BPR. With regard to the risk from an aggregated environmental exposure new scientific evidence on the effect that an active substance has on the human health could constitute "new evidence".

If Member States want to introduce more stringent measures regarding the use of biocidal products which do not fall within the scope of Art. 88 BPR, these measures have to comply with primary Community law. Art. 193 TFEU allows Member States to introduce more stringent protective measures. But, Art. 193 TFEU is only applicable if it regards legislation that is based on Art. 192 TFEU.[42] Whereas product related environmental legislation is, normally, based on Art. 114 TFEU[43], Union policy aiming to protect human health and the environment is based on Art. 192 TFEU.[44] According to Art. 1 BPR the scope of the BPR is to improve the functioning of the internal market and the protection of the human health and the environment, similarly. The legal basis of the regulation shall be decided on the main focus of the regulation.[45] In case of the BPR the main focus lies on the protection of

[42] Streinz (2012), Rn. 1173. Krämer/Winter (2010), Rn. 11ff.
[43] Krämer/Winter (2010), Rn. 13.
[44] Streinz (2012), Rn. 1172.
[45] Krämer/Winter (2010), Rn. 12.

the human health and the environment associated with the placing on the market and use of biocidal products.

However, the Member States are not empowered to impose more stringent measures according to Art. 193 TFEU if the provisions in a regulation or directive are exhaustive and have the aim to fully harmonise a regulatory area.[46] To determine the degree of harmonization either the safeguard clauses in the secondary Community law or the wording, purpose, content and context of the provisions in that law have to be interpreted.[47] The provisions in the BPR regulate in a two-stage procedure the approval of active substances (Chapter II ff.) and the granting of authorisation for biocidal products (Chapter IV ff.) regarding their placing on the market and the use. In very detailed provisions the conditions for an authorisation as well as the cancellation, review, amendment and renewal of the authorisation are described. Moreover the Commission is entitled to adopt delegated acts which aim to harmonise the administrative procedure. Finally, the BPR contains provisions that give Member States the right to derogate from authorisations in order to take national specifics into consideration (e.g. in the Art. 37 BPR for mutual recognition). In the light of this assessment the placing on the market and use of biocidal products is fully harmonised by the BPR and Member States are not empowered to impose stricter regulations according to Art. 193 TFEU.

It can be concluded that stricter national rules, for example, to cope with the risk of an aggregated environmental exposure are only legal if a Member State has new evidence that an authorised biocidal product constitutes a serious immediate or long-term risk to the health of humans or animals or to the environment (cf. Art. 88 BPR).

[46] Krämer/Winter, (2010), Rn. 15.
[47] Müller-Graff (2003), Rn. 67.

Part B: Case studies

In this chapter, based on the statements in the preceding chapters three case studies are examined. In each of the three case studies the following legal options of the competent authorities at hand are analysed:

- To deny or set conditions for the approval of an active substance in biocidal products and their application,
- the scope and form of possible risk reduction measures to be introduced in an authorisation, and
- subsequent amendments or cancellation of national product authorisations.

In all three case studies, it is assumed that an active substance "xy" is included in Annex I of the BPR, and that the same active substance is included in the biocidal products "A" and "B".

6 Case study 1

The constellation of the first case study is:

A product A is authorised in a Member State *with a lower tonnage and should be authorised on mutual recognition in another* Member State *where numerous products with high tonnage had already been authorised.*

It is assumed in this case study that with the placing on the market of product A containing the active substance “xy” the risk from an aggregated environmental exposure is to be expected in the Member State concerned. The focus of this case study is to examine the legal alternatives a Member State concerned has in order to avoid the risk from an aggregated environmental exposure, e.g. regarding the granting of an authorisation for product A (see Section 6.1) or regarding the existing product authorisations in the Member State concerned (see Section 6.2). Therefore, it is necessary to examine the reasons a Member State concerned can state in order to modify or to refuse the authorisation for product A from the reference Member State.

6.1 Options regarding the authorisation of product A

The competent authority in the Member State concerned has two options if the risk of an aggregated environmental exposure is ascertained in the course of a mutual recognition for the authorisation of product A:

1. To impose specific conditions to the authorisation (see Section 6.1.1) or
2. To refuse the authorisation in the course of a mutual recognition (see Section 6.1.2).

6.1.1 Conditions for an authorisation

The term „condition“ in the context of the BPR – being equivalent to the term „incidental provision“ – is used in the meaning of a restriction to the authorisation, i.e. the condition requires from the applicant an action, tolerance or omission of an action in connection

with the placing on the market of his biocidal product.[48] Basically, the authorisation through mutual recognition is subject to the same terms and conditions that are applicable to the authorisation in the reference Member State (cf. Art. 32 (2) BPR). With regard to Art. 37 (1) BPR a Member State concerned can derogate from the authorisation of the reference Member State if it can justify the derogation with a reason listed in an exhaustive list in Art. 37 (1) (a) to (e) BPR. A legal instrument for the derogation is to impose a condition to the authorisation of the Member State concerned. Thereby the competent authority has to comply with the principle of proportionality. The basic steps for assessing whether the restrictions comply with the principle of proportionality are: The restriction is justified if it pursues legitimate aims, is suitable to attain legitimate objective (i.e. securing the reasons of Art. 37 (1) BPR), is appropriate to achieve the objectives pursued and does not go beyond what is necessary to achieve the objectives.

With respect to the case study 1 the Member State concerned can base its derogation on the grounds of the protection of the environment (Art. 37 (1) lit. a BPR). As numerous products containing the active substance "xy" with a high tonnage had already been authorised in the Member State concerned the PEC for substance xy in the Member state concerned is already higher than in the reference Member State. Assumed that the PNEC in both States is similar the authorisation of product A in the Member State concerned would lead to a ratio of PEC/PNEC that is higher than 1 resulting in a risk from an aggregated environmental exposure. In such a case the Member State concerned can derogate from the authorisation in the reference Member State on the basis of Art. 37 (1) lit. a BPR.

Further examples for legal derogation according to Art. 37 BPR are different environmental conditions in the Member State concerned and the reference Member States or the fact that target organisms are not being present in harmful quantities are inter alia reasons for a derogation according to Art. 37 (1) BPR. In case the Member State concerned has a biota (flora and fauna) that is very sensible to the exposition of an active substance contained in product A (e.g. the use of anti-fouling products in the Baltic Sea) or the intended use is not relevant in that Members State (e.g. wood preservatives against termites in the Northern Member States) the competent authority of that Member State has the right to impose conditions to the authorization of product A on the legal ground of Art. 37 (1) BPR.[49]

The Member State concerned has to inform the applicant of product A about the proposed derogation together with a detailed statement and shall seek an agreement with the applicant on the derogation within 60 days (cf. Art. 37 (2) BPR). If no agreement is reached within 60 days the Member State shall inform the Commission which than can adopt a

[48] See for medicinal products for human use: Kern (2010), S. 98 f.

[49] If a Member State concerned has doubts whether other conditions than listed in Art. 37 BPR are fulfilled, a coordination group according to Art. 35 BPR is responsible to resolve that. These are cases relating to the granting of an authorisation according to Art. 19, e.g. whether the biocidal product is sufficiently effective (cf. Art. 19 (1) (b) (i) BPR).

decision on the proposed derogation. The Member State shall comply with the Commission´s decision within 30 days of its notification.

Possible restrictions that could be imposed to the authorisation of product A by means of ancillary clauses cover:

- Restricting the use of a biocidal product on specific uses / specific harmful organisms,
- regulating the user categories (professional/non-professional),
- imposing risk management measures,
- determining the maximum concentration per use or
- determining the application intervals.

However, if there is a risk from an aggregated environmental exposure in a specific compartment it is also possible to set a limit for the maximum tonnage of the active substance "xy" contained in product A in uses that will end up in that compartment.

6.1.2 Refusal of an authorisation

According to Art. 37 (1) 1st alternative BPR it is within the discretion of the Member State concerned to refuse an authorisation for product A provided the Member State can justify it on the reasons listed in Art. 37 (1) (a) to (e) BPR.[50] In case a risk from an aggregated environmental exposure is to be expected if product A is authorised the competent authority may justify its refusal on the grounds of the "protection of the environment" and/or "the protection of health and life of humans" (cf. Art. 37 (1) (a) and (c) BPR). In case of a refusal the competent authority has to respect the principle of proportionality. Thus a refusal is not legal if conditions (see Section 6.1.1) are sufficient to secure the protect goods in Art. 37 (1) and (c) BPR.

Moreover, Art. 37 (4) BPR provides the competent authority with a discretionary decision[51] to refuse the granting of an authorisation for the product-types 15, 17 and 20 on the grounds of animal welfare. The principle of proportionality must be obeyed in that case, too. The procedure in Art. 37 (4) BPR deviates from the procedure in Art. 37 (2) and (3) BPR as the Member State only has to inform without delay other Member States and the Commission about the decision and the reasoning for that decision.

Thus in case the product A belongs to the product-types 15, 17 or 20 the Member State concerned can refuse to grant an authorisation based on animal welfare choosing a simplified procedure compared with Art. 37 (2) and (3) BPR.

6.2 Options regarding already granted authorisations in the MS concerned

This chapter contains an assessment whether the competent authority in the Member State concerned is entitled to review authorisations which it has already granted in order avoid the risk from an aggregated environmental exposure. The following legal alternatives of

[50] Cf. Art. 37 (1) BPR states "...any of the Member States concerned may propose to refuse to grant an authorisation..."

[51] Cf. Art. 37 (4) BPR states „...a Member State may refuse to grant authorisations ..."

the competent authority to consider the risk from an aggregated environmental exposure are analysed:

- In the procedure regarding the renewal of already granted authorisations;
- synchronize the authorisation period in order to pool the renewal of authorisations;
- provide for a tonnage in reserve;
- cancelling or amending authorisations; and
- authorise with the reservation to make modifications or the proviso of cancellation.

6.2.1 In the renewal procedure of granted authorisations

If the authorisation of product A for the territory of the Member State concerned would cause a risk from an aggregated environmental exposure, the competent authority of the Member State concerned cannot cancel or amend the existing authorisations according to Art. 48 BPR. Because regarding the existing authorisations the conditions for a cancellation outlined in Art. 48 (1) BPR are not fulfilled, particularly a risk from an aggregated environmental exposure does not exist as long as an authorisation for product A is not granted (see Section 6.2.4). Therefore the competent authority in the Member State concerned only has the alternative to wait until existing authorisations expire (in general 10 years according to Art. 17 (4) BPR) and then consider the risk from an aggregated environmental exposure in the case of a renewal of the existing authorisations according to Art. 31 BPR.

However, the producer A would have to submit a new application at the time at which an existing authorisation expires as the competent authority cannot delay a decision on his application being bound to rigid deadlines. According to Art. 32 in conjunction with 33 BPR the competent authorities have 30 days to accept the application, 90 days to validate it, and within another 30 days of reaching agreement the Member State concerned shall authorise the biocidal product These deadlines in the mutual recognition procedure impede a synchronization of the granting of authorisations of product A with the renewal of existing authorisations.

6.2.2 Synchronize the duration of authorisations in order to pool their renewal

Another alternative for competent authorities is to limit the duration of authorisations to a shorter period than the maximum period of 10 years (cf. Art. 17 (4) BPR) in case a risk from an aggregated environmental exposure is to be expected. Due to shorter duration periods of authorisations the competent authority can take the risk from an aggregated environmental exposure into consideration in the review process for authorisations at shorter intervals. Nevertheless, a synchronization of authorisations in order to pool their renewal at the same time seems to be rather not feasible due to the rigid deadlines for the authorisation procedure (see Section 6.2.1). Therefore in the end this alternative appears to be unsuitable to solve the problem.

6.2.3 Provide for a tonnage of an active substance in reserve

A further option of the competent authority is to provide for a certain tonnage of an active substance in reserve when granting the first authorisation or when renewing

authorisations. This would mean that the competent authority calculates the total tonnage level of an active substance for which a risk from an aggregated environmental exposure is to be expected. Based on that the competent authority would impose a condition in each authorisation that limits the tonnage of an active substance to be placed on the market in products and which provides for a tonnage in reserve. Thus subsequent authorisations could be granted. Whenever an authorisation is renewed the permitted tonnage would have to be adapted in order to keep a tonnage of an active substance in reserve.

Yet, this option violates the principle of capacity utilization. According to that principle the State is obliged to utilize the existing capacities of a scarce resource to its full capacity.[52] Furthermore the competent authority cannot argue with environmental protection aspects to provide for a tonnage of an active substance in reserve because the risk from an aggregated environmental exposure in an environmental compartment is only to be expected if a certain tonnage threshold is exceeded. Against that background this option is not legal and is not recommended.

6.2.4 Cancellation or amendment of existing authorisation(s)

On the assumption that the granting of an authorisation for product A will lead to a risk from an aggregated environmental exposure it is the question whether the competent authority can cancel or amend existing authorisations in the Member State concerned to enable such an authorisation.

According to Art. 48 BPR a competent authority or the Commission (in case of a Union authorisation) "shall at any time ... cancel or amend" an authorisation if the conditions in Art. 19 BPR are not met. As stated in Section 3.1.1 the conditions in Art. 19 BPR (1) (b) (iv) BPR encompasses the risk from an aggregated environmental exposure. However, the competent authority would not be entitled to cancel or amend authorisations in order to grant an authorisation for product A. As in case study 1 it would be the competent authority itself which would cause the risk from an aggregated exposure by granting an authorisation for product A. Such an act would contradict with the principle of priority and the legal notion of Art. 48 BPR. If the competent authority can grant new authorisations for products which in return give the authority the possibility to cancel already granted authorisations due to the risk of an aggregated environmental exposure the principle of priority would run dry. Again, the notion of Art. 48 BPR is to empower the competent authority to react if the conditions for an authorisation according to Art. 19 BPR are not fulfilled. As Art. 19 (1) (a) to (c) BPR show the reason for a cancellation or amendment lie not within the sphere of the competent authority but in the sphere of the authorisation holder (false or misleading information or misconduct) or are due to an inappropriate authorisation (conditions of Art. 19 BPR are not satisfied). If the competent authority would cause the conditions in Art. 19 (1) (a) to (c) BPR by granting an authorisation to product A this would be an abuse of its rights.

The argumentation mentioned before has the following consequences for case study 1:

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[52] Cf. Martini (2008), p. 711.

As several products containing the active substance „xy“ have been authorised already in the Member State concerned the competent authority either cannot authorise product A or only authorise it with restrictions if that would lead to a risk from an aggregated environmental exposure. As the other holders of authorisations in the Member State concerned have utilized (almost) the full capacity regarding the active substance “xy” an authorisation for product A can be only granted if a risk from an aggregated environmental exposure can be excluded (e.g. a tonnage capacity is available). Following the principle of priority an authorisation for product A can be granted when existing authorisations have to be renewed.

6.2.5 Authorisation with the reservation to make modifications or the proviso of cancellation

The competent authority in the Member State concerned could impose a reservation to make a modification or a proviso of cancellation to authorisations in order to provide that the requirements in Art. 19 BPR are met and to enable further product authorisations. However, some uncertainty remains to whether a modification or a proviso of cancellation is legal. For more details on the argumentation see Section 3.1.6 “Imposing ancillary clauses”.

Yet, in the situation of this case study based on the assumption that the existing authorisations in the Member State concerned do not contain such ancillary clauses they cannot be modified or cancelled in order to grant an authorisation to product A.

6.3 Interim finding

The legal options of the competent authority are to impose restrictions to the authorisation of product A which effectively prevent a risk from an aggregated environmental exposure (see Section 6.1.1). The following restrictions for product A should be taken into account:

- Restricting the use of a biocidal product on specific uses / specific harmful organisms,
- regulating the user categories (professional/non-professional),
- imposing risk management measures,
- determining the maximum concentration per use or
- determining the application intervals.

However, if a risk from an aggregated environmental exposure in a specific compartment exists it is also possible to set a limit for the maximum tonnage of product A to be applied in that compartment.

If imposing restrictions to the authorisation of product A is not sufficient to avoid the risk from an aggregated environmental exposure the competent authority has to refuse to grant an authorisation based on the reasons stated in Art. 37 (1) (a) and (c) BPR.

Looking at existing authorisations in the Member State concerned the competent authority has no immediate options to cancel or amend those existing authorisations in case study 1. A possible way to enable further product authorisations in the future while avoiding the risk from an aggregated environmental exposure lies in an ex ante strategy for the

authorisation procedure. If ancillary clauses (like reservations to make modifications or the proviso of cancellation) are imposed to authorisations granted or renewed the authorisation holder could not rely on the legitimate expectation that he can place his products on the market without restrictions in the future. In those cases the competent authority might amend or cancel existing authorisations to grant an authorisation for product A. However, some uncertainty remains to whether a modification or a proviso of cancellation is legal.

6.4 Options in case of a Union authorisation

Although not addressed in the case study the legal options of the competent authority in case of a Union authorisation shall be analysed. Two alternatives are possible: alternatives regarding the granting of a Union authorisation for product A (see section 6.3.1) alternative) and options regarding the already granted Union authorisations for products containing the active substance "xy" (see section 6.3.2).

6.4.1 Granting a Union authorisation for product A

A Member State has the following options to avoid the risk of an aggregated environmental exposure for his territory in case of an application for a Union authorisation according to Art. 41 BPR for product A:

The Commission can decide according to Art. 44 (5) BPR either to adjust the conditions of a Union authorisation or to not apply the Union authorisation in the territory of the Member State that requests it based on one or more reasons stated in Art. 37 (1) BPR.

To impose conditions to a Union authorisation for product A or to refuse a Union authorisation regarding the territory of the Member State is therefore possible within the pre-conditions mentioned in section 6.1. It must be highlighted that the Member State has to state his objections in the comitology procedure at the latest (Art. 44 (5) BPR).[53]

6.4.2 Already granted Union authorisation for products containing the active substance „xy"

Regarding biocidal products containing the active substance „xy", which have been already authorised on the grounds of a Union authorisation the foregoing explanations apply. For the product A the legal alternatives according to section 6.2 are available. It is possible to amend or cancel the Union authorisation for the other products according to Art. 48 (1) (a) BPR, but the same objections as mentioned in section 6.2.4 apply. Against that background the following two alternatives appear to be more successful with regard to this case study:

1. To amend the existing authorisation(s) in case of their renewal.
2. In case a reservation to make modification or a provisio of cancellation was imposed to the existing Union authorisation(s) an amendment of the authorisation(s) is possible.

[53] Cf. for the comitology procedure: Section 3.1.9.

The first alternative "to amend existing authorisations in their renewal" is most promising for the competent authority (based on the assumption that existing authorisations do not contain ancillary clauses mentioned in the second alternative). The renewal of the Union authorisation is regulated in Art 45 f. BPR. In general the Commission shall renew a Union authorisation provided that the conditions in Art. 19 BPR are still satisfied (cf. Art. 46 (4) BPR). It is questionable whether a Member State can claim special conditions for his territory in the renewal of a Union authorisation for the first time (cf. Art. 44 (5) BPR). Neither the text in Art. 45 and 46 BPR contains a reference to Art. 44 (5) BPR nor does the system of the regulations on renewal in Art. 41 ff. BPR provide a clear answer. However, if a risk from an aggregated environmental exposure exists in one Member State it is a proportionate means to amend the existing Union authorisation in case of their renewal instead of refusing the renewal for the territory of the whole EU. Therefore the Commission can amend the existing authorisations for products containing the active substances "xy" in the renewal procedure in order to avoid the risk from an aggregated environmental exposure.

7 Case study 2

The constellation of the second case study is:

The dossiers on the products A and B are submitted by different applicants at the same time. Another comparative product wasn't authorised yet.

In this case in particular the transfer and the handling of confidential data from the dossiers in the relationship of authority, applicant A and applicant B is considered. One aspect is the question of equal treatment, so how can be ensured that applicants A and B have to pay the same "application loads" or how a balance between A and B can be arranged.

7.1 Confidential and non-confidential data in the authorisation procedure

First of all, a "simultaneous submission of dossiers" by different applicants should be assessed from a legal point of view. To this aim the different steps of a national authorisation procedure according to administrative law can be described as following:

- Submission of an application,
- acceptance of the application,
- evaluation of the application, and
- granting of an authorisation.

Following the principle of priority (cf. details on the principle in Section 3.1.6) it is not possible according to administrative law that producers A and B simultaneously apply for the granting of an authorisation for their products A and B. Accordingly, the competent authorities receiving applications will have to design the procedures for receiving and deciding upon applications (generally a receipt stamp with date and time). Subject to these conditions it is possible that dossiers on the products A and B are submitted at the same time. However, the dossiers belong to different administrative acts and with respect to the confidentiality of the dossiers´ content it is of importance whether application A or B is given priority – and which application will be classified as a subsequent application. For the purpose of this case study the authorisation of product A takes precedence over that of product B.

In this light, the alternatives of the competent authority to disclose information from one of the two application procedures to the applicant A or B will be assessed in the following.

Basically, the competent authorities or ECHA shall not use data submitted for the purpose of the BPD or the BPR for the benefit of a subsequent applicant (cf. Art. 59 (1) BPR).[54] However, there are exemptions from that basic principle which shall be analysed in the following[55]:

1. After an authorisation has been granted (cf. Art. 66 (3) BPR);
2. an subsequent applicant submits a letter of access (cf. Art. 59 (1) (a) BPR); or

[54] Cf. on the BPD: EU Commission (2008); Health Board Estonia (2012).

[55] Cf. further aspects of confidentiality regarding substance data see Führ (2009).

3. the period for data protection has expired (cf. Art. 59 (1) (b) BPR).[56]

7.1.1 After an authorisation has been granted

Art. 66 (3) BPR contains a list of information that shall not be treated as confidential by the ECHA and national competent authorities after an authorisation has been granted (for types of non-confidential data see Section 4.1). Upon reversion and in accordance with Art. 66 (2) BPR the competent authority is not entitled to disclose types information listed in Art. 66 (3) BPR regarding product A to applicant B before an authorisation has been granted to applicant A.

Moreover, the rules in Art. 71 BPR regarding the Register for Biocidal Products do not stipulate the right or duty of the competent authorities or ECHA to disclose information on product A to producer B. Because according Art. 71 (2) BPR this Register shall be used for the exchange of information between the following groups only:

- Competent authorities,
- the Agency and the Commission,
- applicants and competent authorities, and
- the Agency and the Commission.

Art. 71 (2) BPR does not mention the exchange of information between applicants nor a right of access to applicants regarding data listed in the Register other than his own data. Rather the Register serves as a means for each applicant to submit his data for all procedures covered by the BPR (cf. Art. 73 (3) BPR), for example to apply for a product authorisation or to apply for the renewal of an authorisation. However, if the competent authority has accepted an application specific information listed in Art. 71 (6) sentence 4 BPR, like the terms and conditions of the authorisation, shall be made available via the Register to all other competent authorities and to ECHA (cf. Art 71 (5) BPR).

The competent authority is not entitled, during an authorisation procedure and after an application has been granted for product A, to disclose information on product A outlined in Art. 66 (2) sentence 2 BPR[57] to applicant B - and vice versa -, this regards especially the full composition of product A or the precise tonnage of the active substance.

It must be noted, that ECHA or the competent authorities are entitled to disclose the foregoing data to third parties if “urgent action” is essential to protect human health, animal health, safety or the environment of for other reasons of overriding public interest (cf. Art. 66 (2) sentence 3 BPR). In general, to prevent an immediate and serious threat to the foregoing legal interests presents an urgent action. Though, the application of producer A or B does not constitute an immediate and serious threat as the immediacy of the threat (the necessity to act immediately in order to protect the legal interests) is already missing. Because before an authorisation is granted neither product A nor product B must not be put on the market and it lies in the responsibility of the competent authority to refuse or modify an authorisation if product A or B present a threat to the mentioned legal interests.

[56] Cf. for detailed explanation in Section 4.1.ff.
[57] Cf. the explanations in Section 4.1.

Additionally, it might be possible that applicant B could draw conclusions from the assessment report which he receives in the case of a refusal or modification of his application, especially if there are only two applicants. According to Art. 30 (3) BPR the competent authority drafts a report summarising the conclusions of its assessment and the reasons for authorising the biocidal product or for refusing to grant an authorisation. In this case the competent authority has to ensure that information which it has received from applicant A falling within the scope of Art. 66 (2) BPR, for example the precise tonnage of the active substances A, is not disclosed to applicant B. This duty does also cover information that allows applicant A to draw conclusions on the tonnage of product B.

According to Art. 66 (2) BPR, ECHA and the competent authority shall not disclose information where disclosure would undermine the protection of the commercial interest or the privacy and safety of the persons concerned. Art. 66 (2) sentence 2 BPR contains a list of information which by definition of the law normally undermines the commercial interest or the privacy and safety of the persons concerned:

- details of the full composition of a biocidal product;
- the precise tonnage of the active substance or biocidal product manufactured or made available on the market;
- links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;
- names and addresses of persons involved in testing on vertebrates.

According to Art. 66 (3) (g) BPR, the authority may disclose the summary of these results to third parties, if the data is not qualified as company and business secrets. In the approval process for an active substance, the applicant must submit a dossier for the active substance, which is divided into the following 4 levels:

- Document IV is equal to the original test reports (studies), separated by active substance (Part A) and product (Part B).
- Document III contains summaries (style sheet and examples on adsorption / desorption and acute fish toxicity can be found below), separated by active substance (Part A) and product (Part B).
- Document II in Part A, contains the effect and exposure assessment for the active substance, in Part B it contains the effect and exposure assessment for the product and in Part C the risk characterisation.
- Document I contains the summary and the vote, as well as the list of endpoints.

According to Art. 66 (3) (g) BPR, the test results and the summaries of the data about the effectiveness and potential development of resistance promotion in the documents I to IV do not have to be regarded as company and business secrets and shall not be treated confidential after an authorisation has been granted. Because the “Doc. I”-Level is published in the Assessment Report, after the active substance was included in Annex I of Directive 98/8/EC, the data contained therein are public and an interest to treat it confidential does not exist anymore. Particularly individual data at the level of Doc II, III and IV are operating and business secrets that must be kept confidential. On the basis of a case-by-case

assessment, it has to be determined, whether it is possible to conclude from the particular individual specification to operational know-how, which disclosure may result in an operating loss.

Regarding the options of the competent authority to modify the authorisation of product A and B in case of an aggregated environmental exposure re-reference is made to chapters 3 and 6 of this study.

7.1.2 Use of data after the period for data protection has expired

In this section the rights and duties of the competent authority regarding the use of data from producer A for the subsequent application of producer B are examined according to Art. 60 BPR.

Data protection periods outlined in Art. 60 BPR apply for data submitted for the purpose of the BPD and the BPR (cf. Art. 59 BPR).[58] They grant the data holder the exclusive right to use his data within a given period. Only after the protection period has expired, the competent authority may agree that a subsequent applicant may refer to that data (cf. Art. 64 (1) BPR). It is at the discretion of the competent authority whether a subsequent applicant may refer to data for which the protection period has expired (cf. Art. 64 (1) BPR). However, the competent authority will have almost no discretion to whether it allows a subsequent applicant to use the data if two products are technically equivalent and the subsequent applicant has provided all other data according to Art. 64 (2) BPR. Finally, it must be highlighted that a subsequent applicant has to provide no compensation for the use of data after the expiry of a data protection period.

If applicant B (the subsequent applicant for an authorisation) wants to refer to data of applicant A, he has to provide evidence that the active substance in product B is technically equivalent to that in product A (cf. Art. 64 (1) BPR). Moreover the applicant B has to provide the following information according to Art. 64 (2) BPR:

- all necessary data for the identification of the biocidal product B, including its composition;
- the data needed to identify the active substance in product B and to establish technical equivalence of the active substance B;
- the data needed to demonstrate the comparability of the risk from and efficacy of the biocidal product B to that of the authorised biocidal product A.

Because the dossiers on product A and B have been submitted at the same time it can therefore be assumed the data protection period for product A has not expired. Therefore the competent authority is not entitled to share or disclose protected data with the applicant B. That holds true for the further authorisation procedure of product B as the data protection period lasts for 10 or 15 years. This means that each of them will have to pay the same “application loads" by producing and providing the same data necessary for

[58] For the detailed protection periods see section 4.1.1.

the authorisation of product A and B. This shall not apply, for example in the following case.

7.1.3 Letter of access (Art. 61 BPR)

The competent authority is entitled to share data, which applicant A has submitted to her, with the applicant B, if the applicant B submits a letter of access (LoA) to the competent authority, and vice versa. In this case the competent authority is not committed to the data protection periods for product A (cf. Art. 59 (1) (a) BPR). The applicant B has to provide a LoA that contains the following information (cf. Art. 61 (1) BPR):

- the name and contact details of the data owner and of applicant B (if the data owner and the applicant are not identical);
- the name of the active substance A or of the biocidal product for which access to the data is authorised;
- the date on which the letter of access takes effect; and
- a list of the submitted data to which the letter of access grants citation rights.

Moreover, the active substance in product B should be technically equivalent to the active substance in product A (cf. the condition in case of Art. 64 (1) BPR). Although, this prerequisite is not explicitly mentioned in the case of a LoA (see Art. 61 BPR), the technical equivalence of the active substances appears to be necessary to use the information on product B for an application for product A. Furthermore, both cases (Art. 61 and Art. 64 BPR) address the use of data for subsequent applications. It is not at hand why the use of data in case the data protection period has expired (Art. 64 BPR) should be treated different from the case of a LoA (Art. 61 BPR).

It lies within the responsibility of the contractual partners (here A and B) to determine the terms of conditions according to which a LoA is issued, as they are not regulated in the BPR. The rules for data sharing in order to avoid animal testing according to Art. 63 BPR are not applicable to a LoA. Attention should be paid to the fact, that the authorisation for product B does not become invalid, only because producer A revokes his LoA (Cf. Art. 61 (2) BPR).

7.2 Data sharing in order to avoid animal testing

In case the producer B needs to perform tests regarding the application for product B, which involve the testing of vertebrates he has the duty to ask ECHA whether ECHA itself or any competent authority is in the possession of such tests or studies (see Art. 62 (2) (a) BPR: “shall ... submit a written request). In case applicant B needs data not involving tests of vertebrates, he is authorised to ask ECHA for data (see Art. 62 (2) (b) BPR: “may ... submit a written request). The constellation in Art. 62 BPR is that an applicant “intends to perform test or studies” before he applies for an authorisation, a so called “prospective applicant”. If an application was submitted it can be assumed, that the applicant has produced and collected all data which is necessary and that he has required data - if relevant - according to Art. 62 (2) BPR. In case study 2 the dossiers for products A and B have been submitted and therefore producers A and B are not prospective applicants anymore. However, if

applicant B should be still in the need to submit data involving tests on vertebrates (for example because the competent authority does not accept information applicant B has submitted) and ECHA or a competent authority meanwhile possess the required data from the application for product A, the question is whether ECHA or the competent authority is entitled to inform producer B on available data in an ongoing authorisation procedure. According to the BPR it is the prospective applicant who has the responsibility to request data from ECHA before an application and with regard to Art. 62 (2) sentence 3 BPR ECHA has to enable a contact between the prospective applicant and the data owner, if "such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application, under this Regulation or Directive 98/8/EC." The availability of data in an ongoing authorisation procedure is not explicitly addressed in the BPR. This constellation can be classified as an unintentional regulatory gap which is open for interpretation according to the content and purpose of the provision on data sharing in order to avoid animal testing. The legislator has attached such a tremendous value to the avoidance of animal testing that "testing on vertebrates ... shall be undertaken as a last resort" (cf. Art. 62 (1) BPR). Thus distinct regulations for data sharing and provisions on the compensation for data sharing have been established by the legislator in Art. 62 ff. BPR. By way of derogation from rules on data protection stated in Art. 66 (3) (a) to (c) BPR ECHA can inform a prospective applicant about the name and contact details of a data submitter and owner in order to protect animals. If applicant B has requested from ECHA data that involves tests on vertebrates, the question is whether ECHA can inform the applicant B at any point during the authorisation procedure for product B that such data has become available in the authorisation procedure of product A. According to Art. 62 (2) sentence 2 BPR ECHA has to "verify whether such tests or studies have already been submitted" in connection with "previous applications". The term "previous" does only refer to a chronological order of applications, but does not require that the first application procedure has to be finished. According to the principle of priority the application for product A is a previous application to that for product B. If applicant A has submitted data to a competent authority which applicant B has asked for in order to prevent tests on vertebrates, ECHA is entitled to inform applicant B about the name and contact details of applicant A.

Subsequently, producers B and A „shall make every effort to reach an agreement on the sharing of the results of the test or studies requested" involving vertebrates (cf. Art. 63 (1) BPR). If B and A reach an agreement, A is obliged to make all scientific and technical data related to the tests and studies concerned available to producer B or he has to permit B to refer to his data (cf. Art. 63 (2) BPR).

If A and B cannot reach an agreement, B has to inform ECHA and A on that fact and ECHA is obliged to give B permission to refer to the requested tests or studies on vertebrates at the latest within 60 days of being informed. As condition for that B has to demonstrate to ECHA that he has made every effort to reach an agreement and that he has paid the data owner a share of the costs incurred (cf. Art. 63 (2) sentence 2 BPR).

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7.3 Cooperation in the development of the application dossier

In this section it will be assessed whether and to what extent the competent authority has the possibility to initiate a cooperation between prospective applicants regarding the sharing of data for application dossiers. This will be analysed against the background of the limitations for the competent authority to disclose information according to Art. 66 (2) and (3) BPR.

Basically, the prospective applicant has to produce and submit all data necessary for his application on his own. After submission to the competent authority his data is protected against any unauthorised use. If the prospective applicant wants to share his data with other applicants he can issue a LoA to one or more other applicants and thus is able to refinance his costs to produce the data. A common procedure for applicants, like the registration of substance according to Art. 11 REACH, is not stipulated in the BPR. Besides, an instrument like the Substance Information Exchange Forum (SIEF) does not exist for the authorisation of biocidal products either.

However, Art. 66 (2) and (3) BPR are optional rules (dispositive law) which serve the legitimate expectations of the applicant that data he has submitted to the competent authority in the authorisation procedure is protected permanently (see Art. 66 (2) BPR) or until the applicant has reached a legal position with the granting of an authorisation (see Art. 66 (3) BPR). If the prospective applicant agrees to share his data with one or more other applicant(s), he can waive his right to data protection partially or completely regarding the relationship between the competent authority and other applicants. Though, it is very unlikely that applicant A or B would waive their rights according to Art. 66 (2) BPR for reasons of competition.

In fact, the applicants A and B only need to permit the competent authority to mutually disclose their identity by waiving their rights according to Art. 66 (3) (a) BPR[59]. In practice that could take the following form: The competent authority informs each of the two applicants A and B that another (unnamed) applicant has applied for an authorisation and that a cooperation regarding the application seems to be sensible from the view of the authority. In case both applicants will waive their rights against the authority and signal their interest in a cooperation, the competent authority could inform each of the two applicants about the name and address. From that time on the authority would not be engaged in the further cooperation.

The prospective applicants might cooperate to produce their individual application dossier[60] by exchanging information on the basis of a civil law contract. It is the

[59] Art. 66 (3) (a) BPR protects the "name and address of the authorisation holder". In the context of the application procedure this provision should be read as "the name and address of the applicant" according to the content and rationale of the provision.

[60] Applicants might cooperate in the legal form of a consortium. Consortia are neither regulated in the BPR nor in REACH but offer a possible means of two or more individuals or companies with the objective of participating in a common activity or pooling their resources for achieving a common goal.

responsibility of the prospective applicants to select any cost allocation and compensation mechanisms so that they are fair, transparent and non-discriminatory.[61]

The prospective applicants might also cooperate voluntarily on the basis of the provisions for data sharing in order to avoid animal testing (see Art. 62 ff. BPR). To reach an agreement on a fair, transparent and non-discriminatory compensation for data sharing they can consult the Guidance on data sharing established in accordance with Regulation (EC) No 1907/2006 (cf. Art. 66 (4) BPR).[62] The Guidance document provides cost-sharing models for the players involved. Parameters are data quality, financial evaluation of the data and the allocation of costs to the players involved.

However, it shall be stressed that the rules of competition and anti-trust law, especially Art. 101 TFEU, have to be obeyed in such a cooperation. Therefore, "all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market" are prohibited (Art. 101 (1) TFEU). Respectively the prospective applicants shall restrict their information exchange to what is required in order to avoid a cartel[63]. Art. 25 (2) REACH lists examples of information that muss not be exchanged.[64] These examples are applicable to applications according to the BPR, too, and cover[65]:

- "Individual company prices, price changes, terms of sales, industry pricing policies, price levels, price differentials, price marks-ups, discounts, allowances, credit terms etc.;
- costs of production or distribution etc.;
- individual company figures on sources of supply costs, production, inventories, sales etc.;
- information as to future plans of individual companies concerning technology, investments, design, production, distribution or marketing of particular products including proposed territories or customers;
- matters relating to individual suppliers or customers, particularly in respect of any action that might have the effect of excluding them from the market."

In the light of a risk from an aggregated environmental exposure prospective applicants might want to know the aggregate volumes of produced and imported active substances by exchanging information on individual volumes. This information should be exchanged with caution. Guidelines to avoid the infringement of Art. 101 TFEU are given in the Guidance document.[66]

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[61] ECHA (2012), p. 103 ff.

[62] Cf. ECHA (2012).

[63] A cartel is an illegal practice (whether or not reflected in a formal or informal agreement) between competitors who collaborate to fix prices or restrict supply or their production capacities or divide up markets or consumers and that shield the member of the cartel from competition.

[64] "Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market share."

[65] ECHA (2012), p. 129.

[66] Cf. for the exchange of information regarding a joint CSA/CRS according to REACH: ECHA (2012), p. 129 ff.

8 Case study 3

The constellation of case study 3 is:

Product A containing the active substance XY is assessed in the course of the third list of priority substances and product B containing the same substance XY is assessed in the course of the fourth list of priority substances review. During the assessment of the active substances, there is a time lag.

8.1 Background of the review programme for existing substances

For a better understanding of the third case study the background and the procedure of the programme of work for the systematic examination of all active substances already on the market on 14 May 2000 (called "existing substances" contained in biocidal products (called the "review programme" according to Art. 1 Regulation (EU) No 1451/2007[67]) shall be explained in short.

Aim of the BPR as well as the aim of the expired BPD which entered into force on 14 Mai 2010[68] is to harmonize the European market for biocidal products whilst ensuring a high level of protection of both human and animal health and the environment (see Art. 1 (1) BPR). To achieve this aim a review programme for existing substances was implemented which prioritized the evaluation of substance in product types clustered in four priority lists. The third priority list covers product types 1, 2, 3, 4, 5, 6 and 13 (Art. 9 (2) c)) and the product types 7, 9, 10, 11, 12, 15, 17, 20, 22 and 23 make up the fourth priority list (Art. 9 (2) d)). Regulation (EU) No 1451/2007 includes in its Annex II a list of all notified active substances which will be examined by Rapporteur Member States based on a complete dossiers which the participant (producer, formulator, association or other person) has to submit until certain deadlines. For the third priority list the deadline was 31 July 2007 for the fourth priority list it was 31 October 2008. The complete review program is currently scheduled to be finalized until 2024[69].

8.2 Transitional measures

First of all it must be pointed out that competent authorities in the review programme, too, can act on the level of the approval of active substances as well as on the level of the authorisation of biocidal products. Whether the rules of the BPR or of the BPD are applicable for the approval and the authorisation is determined by transitional measures

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[67] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, OJ L 325, 11.12.2007, p. 3

[68] European Journal of Law and Technology, Vol 2, Issue 3, 2011.

[69] Commission Delegated Regulation (EU) No 736/2013 of 17 May 2013 amending Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the duration of the work programme for examination of existing biocidal active substances Text with EEA relevance, OJ L 204, 31/07/2013, p. 25.

in the BPR. Basically the BPD ceases to be in force from 1. September 2013 and from that time on the regulations of the BPR are applicable. However, transitional measures for active substances and biocidal products are laid down in Art. 89 ff. BPR stipulating:

- Active substances listed in Annex I of the BPD before 1. September 2013 are included in the Union list of approved active substances according to the BPR.
- Applications for the approval of active substances submitted for the purpose of the BPD which have not been completed by 1. September 2013 will be evaluated according to the BPR (cf. Art. 90 (2) BPR).
- Applications for the authorisation of biocidal products which have not been completed by 1. September 2013 will be evaluated according to the BPR (cf. Art. 91 (1) BPR).

Since from 1 September 2013 the BPR is applicable for the evaluation of active substances (cf. Art. 90 (2) BPR), the competent authority has to consider risks from an aggregated environmental exposure in the approval according to Art. 4 in conjunction with Art. 19 (2) and (5) BPR. Likewise in the authorisation of a biocidal product the risk from an aggregated environmental exposure has to be examined according to Art. 19 (2) and (5) BPR. In this case the regulations of the BPR are directly applicable. This is due to the fact that in the third case study the evaluations of active substances in the third and fourth priority have not been completed until 1. September 2013 and biocidal products containing these active substances need to be authorised before a biocidal product is approved.

8.3 Options regarding the approval of existing substances

8.3.1 Applicability of the Principle of priority

It is questionable whether competent authorities can apply the principle of priority to consider the risk from an aggregated environmental exposure in the approval of existing substances. In contrast to the first case study (see section 6.1.1) applicants cannot determine the point in time in which they want to apply for the approval of an active substance. Instead the prioritization of the substances to be evaluated within the third and fourth priority list is determined by a governmental decision. A problem arises if the active substance “xy” in the third priority list has been approved in such an amount that only a small or no further amount of substance “xy” can be approved in the fourth priority list in order to avoid a risk from an aggregated environmental exposure. In this case it seems not be reasonable for the competent authority to refuse or alter an approval for the substance “xy” in the fourth priority list on the basis of the principle of priority. Consequently, other options to assess and approve biocidal substances in the review-programme will be analysed in the following sections.

8.3.2 Tonnage or intended use of the active substance as a condition for approval

Following the opinion that the principle of priority is not applicable in the review-programme, another option for a competent authority could be to calculate the total tonnage of the active substance in the third and fourth priority. Based on the total tonnage and the intended uses the competent authority (see Annex II of Regulation (EU) No 1451/2007 for the substances in the review programme) can draw conclusions on the

risk from an aggregated environmental exposure. If such a risk is to be expected, the substance „xy“ in the third priority list should be only approved under the condition that approvals of the same substance in the fourth priority list will not exceed the tonnage threshold for a risk of an aggregated environmental exposure. After the closure of the review programme the total tonnage for an active substance – not exceeding the level of a risk from an aggregated environmental exposure - could be re-allocated between the holders of an approval, e.g. according to their market share.

A problem of this approach is the competent authority´s limited knowledge on the tonnage of an active substance available on the market. According to Art. 6 BPR the application „shall“ contain a dossier on the active substance according to Annex II BPR and a dossier for at least one representative biocidal product according to Annex III BPR. The core data requirements for an applicant in both Annexes comprises information on the “likely tonnage to be placed on the market per year and, when relevant, for the envisaged major use categories” (see No. 7.5 of the Annexes II and III). Although applicants have to deliver information on the marketed tonnages as a general rule (Art. 6 BPR states “shall”), this does cover only estimations of the producers (“likely tonnage”). The estimated tonnages seem not to be checked for plausibility and significant data gaps exist regarding information on the tonnage throughout the PTs and active substances.[70] Moreover, active substances are restricted rather by their intended use than by limiting tonnage of the active substance.[71] Therefore, the possibility to restrict the intended use of the active substance could be the first priority and tonnage thresholds a second priority.

A condition for the approval of actives substances in the third priority list could be drafted as follows:

“The active substance „xy“ is approved under the condition that an overall evaluation of intended uses of the active substance “xy” in the third and fourth priority list will not result in a risk from an aggregated environmental exposure for the intended use(s) of this substance.”

8.3.3 Merging the evaluation of active substances through changes in the review-regulation

An alternative option - deviating from the setting of the third cases study - could be to amend the review-regulation (EU) No 1451/2007 with the aim to merge the evaluation of all active substance/product type combinations with the same active substance listed in the third and fourth priority list. So the risk from an aggregated environmental exposure of one active substance used in different product types can be assessed by the rapporteur Member State simultaneously and without any time lag between the priorities. Thus the

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[70] See EU Commission (2009), p. 25: „It should be noted that the information provided by the companies for the notification is rather inhomogeneous and far from complete.” Table 3-2 on page 26 of the study states annual production/import volume figures for active biocidal substances in Europe.

[71] A recent example regards the restriction of a biocidal product containing bromadioline: Commission Implenting Decisionof 29 October 2013 approving restrictions of the authorisation of one biocidal product containing bromadiolone notified by Germany in accordance with Directive 98/8/EC of the European Parliament and of the Council, OJ L 289, 31.10.2013, p. 65.

competent authority could recommend according to Art. 14 (6) Regulation (EU) No 1451/2007 the imposition of conditions for the inclusion of an active substance in the Union list of approved active substances (formerly Annex I of Directive 98/8/EC); which the Commission might follow in its final proposal. Possible conditions are the restriction of certain intended uses or a limitation of the tonnage to be put on the market for intended uses in order to avoid risks from aggregated environmental exposure.

8.4 Options regarding the authorisation of biocidal products

For options to include risks from an aggregated environmental aggregation in the authorisation of biocidal products reference is made to the results in the first case study (see section 6.1 ff.).

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