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Comparative assessment under the BPR: state of play June 2015

Comparative assessment, as introduced in the Biocidal Product Regulation (BPR), may cause multiple challenges to competent authorities, and may justify a multidisciplinary approach by companies rolling out their product defence strategies, involving arguments of a legal, socio-economic and scientific nature.

Process and actors

Comparative assessment is the mandatory process, foreseen in Article 23 of the BPR, that biocidal products undergo as part of the evaluation of product authorisation applications, if they contain an active substance that is a candidate for substitution (CfS) under Article 10 of the BPR.

Biocidal products subject to comparative assessment may be prohibited or restricted where there exists a suitable substitute authorised biocidal product, or non-chemical control or prevention methods.

The eligible alternative biocidal products or non-chemical alternatives should:

- present a significantly lower overall risk for human health, animal health and for the environment;
- offer no other significant economic or practical disadvantages; and
- be sufficiently effective for the use considered.

The elements taken into consideration are either risk or hazard-based (for example, RMMs and/or hazard or precautionary statements). Examples of economical or practical disadvantages could be, the need to adapt technology (such as in situ installations), compliance with workers safety legislation or use of higher amounts of products to control the target organism.

For a product restriction or prohibition decision to be lawful, the competent authority must necessarily conclude that the chemical diversity of the available alternative substances, within the identified alternative biocidal products, can be considered as adequate to minimise the occurrence of resistance in the target harmful organism(s). Companies will be well advised to focus on this necessary condition as part of their product defence strategy, and in general to involve a multidisciplinary team of legal, economic and scientific experts to demonstrate that comparative assessment should result in the authorisation of the relevant product.

An authorisation for biocidal products containing CfS can be granted (and/or renewed) for a maximum period of five years instead of the maximum period of 10 years applicable to most biocidal products. The approval of the CfS they contain is for a maximum of seven years, except where the assessment report was submitted before 1 September 2013 in which case the approval period can be a maximum of 10 years under transitional provisions of the BPR.

An active substance will be considered as a CfS if any of the following criteria is met:

- it meets at least one of the exclusion criteria (under Article 5 BPR);
- it meets the criteria for being classified as a respiratory sensitiser;
- its toxicological reference values are significantly lower than those of the majority of approved active substances for the same product-type and use;

- it meets two of the criteria for being persistent, bioaccumulative and toxic (PBT);
- it causes concerns for human or animal health and for the environment even with very restrictive risk management measures; or
- it contains a significant proportion of non-active isomers or impurities.

A comparative assessment of two or more products is undertaken by the competent authority of the receiving member state in the case of applications for national product authorisation, or by the evaluating member state in the case of a Union authorisation application. In the latter case, the decision is taken by the European Commission assisted by the Standing Committee on Biocidal Products, taking into consideration the opinion issued by Echa's Biocidal Products Committee (BPC). However, a system of referral to the Commission exists in cases where the relevant member state deems that the question, by reason of its scale or consequences, would be better addressed at Union level. Examples of products for which this referral option will be used are the second generation anticoagulants (see below).

The comparative assessment will involve weighing up the risks and benefits detailed in Annex VI to the BPR. Risks and benefits must be identified not only for the biocidal product under comparative assessment, but also for alternatives (including non-chemical alternatives) identified through the Echa consultation process. In 2014, 12 consultations were carried out, while so far, only two active substances have been the subjects of consultation in 2015[1].

The result of the comparative assessment is forwarded to the competent authorities of other member states, Echa and where applicable, to the Commission. The conclusions from the comparative assessment are integrated into the product assessment report.

Issues with comparative assessment

Firstly, the commercial value of the approval of active substances that are CfS is contingent upon the comparative assessment of products at a later stage, which is based on external factors such as the existence, or not, of suitable alternatives.

Secondly, there is an inherent discriminatory effect resulting from early evaluations of certain substances, where substances that could potentially be used in alternative products are still in the review programme. There is therefore value in aligning the approval dates (triggering the need for comparative assessment) of CfS used for the same applications.

Thirdly, comparative assessment is under the responsibility of a national competent authority, except where Union authorisation and/or the Commission referral system are used. Hence, there is a potential for diverging assessment conclusions and a fragmented EU market despite the application of harmonised rules. However, this risk is less than that under Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. The latter foresees that comparative assessment will take place with plant protection products authorised in the same member state, thereby precluding consideration of potentially suitable alternatives authorised elsewhere in the EU and increasing the potential of conclusions based only on external factors.

Available technical guidance

The Commission has issued a draft technical guidance note (TGN) on comparative assessment of biocidal products (CA-May15-Doc.4.3.a) for the purposes of discussion with the member states competent authorities at their 60th meeting. The TGN sets out the method to be applied by competent authorities, which is a tiered and stepwise approach.

As a first step, the competent authority is to map the existing alternatives of the relevant biocidal product, after having identified the uses, based on six criteria:

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[1] http://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations).

- product type;
- exact description of the authorised use;
- target organism(s) (including development stage);
- field of use;
- category(ies) of users; and
- application method(s) (deemed less critical for comparison than the other five).

The competent authority then proceeds with a tiered comparison. Firstly, a Tier 1 step focuses on the comparison of the relevant biocidal product with the alternative biocidal products (broken down in Tier IA and Tier IB for deeper investigation. Secondly, in the absence of suitable alternative biocidal products, Tier II involves comparison with eligible non-chemical alternatives.

Both at Tiers I and II, the competent authority will have to follow a stepwise approach and the exercise can stop at the earliest step, where appropriate.

At the end of the assessment, the competent authority compiles a report with a final recommendation in terms of restricting any of the intended uses in the application or not authorising, amending or cancelling, where appropriate, the relevant product.

The case of anticoagulant rodenticides

The Commission has issued draft guidance, which aims at developing the concept of 'product class' in comparative assessment. This is deemed to be particularly relevant to anticoagulant rodenticides that all share the same mode of action and have broadly the same pattern of use (and for which the active substance approvals are due for renewal more or less at the same period) in order to avoid unnecessary work duplication. It was agreed in the 58th CA meeting that the comparative assessment of anticoagulant rodenticides would not start before the BPC opinions on the renewal of the active substances become available on 30 June 2016. By April 2017, the Standing Committee will be consulted on a draft Commission implementing decision.

The case of rodenticides shows a pragmatic approach to the specific case of the products and active substances concerned, but it also reveals that the application of the comparative assessment requirement under the BPR, faces substantial challenges which the legislator may not have envisaged.

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