KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

MESSAGE/INFORMATION

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B08-00163

Development of Legislation and Other Instruments

BPC-40: SE Minority opinion on BPC opinion on BIT (PT6)

Since the Biocides Product Regulation (BPR) came into force, Sweden has emphasised that the provisions of the Regulation should be applied as they were intended, which is to enable control of use of active substances in articles, regardless of whether they were manufactured and placed on the market within the EU or whether they were imported into the EU. The wording of Article 58(2) specifically allows for a more specific identification of use than just product type and includes a reference to conditions of approval. Approval decisions for active substances used in treated articles should specify the use areas within which such treatment can occur in accordance with Article 4 (3) d of the Biocidal Products Regulation.

Since then, Sweden has many times and for many years emphasised that the concept of "one safe use" is not applicable to treated articles. Sweden has argued for the implementation of Article 58(2) through the specific listing of categories of uses within a PT for which treated articles can be approved, thus allowing their placing on the market. This approach is possible even now at active substance approval given the amount of information available, for example, for preservatives like BIT. It is particularly important that uses of treated articles for which unacceptable risks have been demonstrated in risk assessments are not included in the list in order to reduce the risks from those uses as quickly as possible.

The established practice of addressing gaps in risk assessments by referring to the evaluation of uses in treated articles at product authorisation has sometimes resulted in restrictions being introduced as conditions of authorisation of a product. However, the legal basis of these restrictions in the absence of corresponding conditions at active substance approval is now being questioned. Furthermore, the import of treated articles is not at all possible to control – irrespective whether risks are known or unknown – unless a restriction for placing on the market has been stipulated in the approval decision since no product authorisation will take place for imported treated articles.

In the present case, Sweden appreciates the work done by the eCA and welcomes the approach of clearly laying out the relevant use-categories for which acceptable risks have been demonstrated and for which they have not. During the meeting Sweden proposed that these categories can already be used in the approval decision to restrict the approval to those categories that have been evaluated and proved to have acceptable risk to humans and the environment and have shown to be effective.

However, the majority of the Committee agreed to postpone risk assessment for use in treated articles to the product authorisation stage. For the reasons given above Sweden cannot support that position and therefore hereby submits this minority opinion.