CheMI

European Platform for Chemicals Using Manufacturing Industries

Together with:

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During the 48th Competent Authorities (CAs) for Biocidal Products meeting, 2 papers on treated articles (both numbered *CA-Sept12-Doc.5.1.h*) were discussed:
(1) A **flowchart** for determining whether a given product is a treated article, a biocidal product, or neither, and
(2) A list of **Frequently Asked Questions (FAQs)** and suggested answers from the UK in relation to treated articles

A. Treated Articles Flowchart

We welcome this flowchart, as it is potentially a very powerful tool for both authorities and industry alike. Further revision of the flowchart should aim to make the document as straightforward and practical as possible for 'non-experts' to follow.

That said, following certain steps in the flowchart – such as how to determine whether a primary biocidal function is conferred to a treated article – are likely to require more in-depth guidance for 'experts' once the flowchart is finalised.

As a practical measure going forward, we strongly encourage the Commission to work with the CAs and industry to first reach agreement on the individual steps of the flowchart, and **then** work on determining the status of example products. Wherever possible, the flowchart should be based directly and solely on the text of the BPR.

In this vein, we propose the following concrete changes to the Flowchart:

(1) Step 3.4 (plus Step 3.5 and Steps 17-19) should be rephrased "*Out of scope of the BPR*"

Justification: Articles can only be in the scope of the BPR if they are treated articles or biocidal products. The BPR clearly states in Article 3(a) that "*a **treated** article that has a primary biocidal function shall be considered a biocidal product*" (emphasis added). Articles not meeting the definition of a treated article cannot be biocidal products (or treated articles). **Step 3.4** relates to articles that are not treated articles because they have neither been treated with nor intentionally incorporate one or more biocidal products. Such articles are therefore out of scope of the BPR.

The fact that an article "*contains an active substance*" does not automatically imply any obligations under the BPR. The presence of an active substance in an article can only result in obligations when that active substance relates to a biocidal product intentionally incorporated in or used to treat that article. Concretely, the presence of an active substance in an article only results in obligations under the BPR where:
(a) that active substance comprises, is contained in, or generates a substance(s)/mixture(s), *and where*
(b) that substance(s)/mixture(s) is intentionally incorporated in, or has been used to treat, the article, *and where*
(c) that substance(s)/mixture(s), in the form in which it is supplied to the user, is intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, harmful organisms

Certain substances present in an article may meet the definition of active substances without necessarily being present because of their biocidal properties. This is because the substances may have "*an action on or against harmful organisms*" as one of their properties, but may nevertheless be used to manufacture an article because of other properties that they have.

This principle is very clearly established in the definition of a biocidal product. Moreover, this principle is already recognised in **Step 10** of the flowchart, which gives the example of chlorine used for bleaching. Chlorinated substances used for bleaching may have biocidal properties, but are only in the scope of the BPR when used for those biocidal properties. A similar example is surfactants, which may be used in articles (or mixtures) for a variety of technical reasons, *e.g.*, as wetting agents, foaming agents, dispersants, or as emulsifiers. The fact that these substances may also have biocidal properties in addition to technical properties does not trigger obligations, unless those substances are intentionally used for their biocidal properties.

This principle (of substances having multiple possible uses) was also recognised in the definition of 'basic substance' in the BPD Article 2.1.c: "*A substance which is listed in Annex I B, whose major use is non-pesticidal but which has some minor use as a biocide either directly or in a product consisting of the substance and a simple diluents which itself is not a substance of concern and which is not directly marketed for this biocidal use.*"

(2) Certain products identified in Steps 12, 17 and 19 are misunderstood and should be moved

Justification: The flowchart mistakenly identifies toilet seat disinfecting wipes, plug-in insect repellents, and ozone generators, as articles. These products are actually mixtures/preparations meeting the definition of a biocidal product. They have been confused as articles because their applicator / delivery system is in the form of an article. These products are actually containers for mixtures/preparations, because their shape, surface or design determines their function to a lesser degree than does their chemical composition. In other words, where such products are containers/applicators for mixtures that are biocidal products, their function is determined primarily by the biocidal products (*i.e.*, the chemical composition). We therefore suggest that these product examples be moved to **Step 4** in the current draft of the flowchart (although we repeat our above recommendation: that product examples only be allocated places in the flowchart after the steps of the flowchart have been definitively agreed).

B. UK FAQs and Suggested Answers

Like the flowchart, we welcome these FAQs for their clear and straightforward engagement of practical implementation issues that authorities and industry are facing. The article-manufacturing industries in particular have an urgent need for guidance on these issues, given that many such industries are entering the scope of biocides legislation for the very first time.

We in particular welcome the way in which the UK directly bases its suggested answers – for the majority of FAQs given – on the text of the BPR, without unnecessarily complicating the issues raised. Overall, we agree with the majority of responses that the UK has proposed, and encourage the CAs and the Commission to base any proposals for change by making direct reference to the passages of the BPR that substantiate those proposals.

In this vein, we propose the following concrete changes to the FAQs:

(1) In Question 1, remove the commentary about REACH

Justification: Although there is indeed a parallel between **Question 1** and the 0.1% threshold for SVHC in articles under REACH, to mention this parallel in the document only opens the door for potential disagreement over how to answer this question. The 0.1% threshold has been debated for several years, and the so-called 'dissenting Member States' have not changed their position on this issue, despite the fact that both of the 2 legal opinions from the Commission's legal services support the views of the majority of Member States. As a result of this *impasse*, the article-manufacturing industries risk experiencing a non-harmonised enforcement of REACH, and potentially even distortion of the internal market. We therefore consider it essential to avoid a similar *impasse* in the regulation of articles under the BPR

The answer to **Question 1** suggested by the UK is based directly on the definition of a treated article as found in the BPR legal text. For this reason, we support the UK's suggested answer. If other CAs or the Commission wish to propose alternative answers, they must follow the UK's practice of referring to specific language in the BPR that substantiates their proposal (and not, for instance, to 'objectives' of the BPR that are not stated in the legal text). We remind the CAs that even in the context of the 0.1% SVHC threshold under REACH, the so-called 'dissenting Member States' argue that their view is the most accurate interpretation of the REACH legal text. The 0.1% threshold should not be mentioned in this document, however any debate about the UK's proposed answer to **Question 1** should remain focused on reaching the most direct and accurate interpretation of what the BPR says.

More generally, we would like to point out that REACH only provides definitions for the terms 'substance,' 'mixture' and 'article' in the BPR. The term 'treated article,' however, is unique to the BPR. Therefore, beyond providing definitions for the terms it shares with the BPR, REACH does not help in the interpretation and implementation of the BPR and should be left out of the discussion altogether.

(2) In Question 6, remove the commentary about 'internal/external effect'

Justification: Again, while there is indeed a possible analogy to be drawn with the old language of 'internal/external effect' when attempting to establish what constitutes a claim by a treated article manufacturer (about the biocidal properties of the treated article), we do not believe that this analogy adds clarity to the FAQ. The language of 'internal/external effect' relates to the Manual of Decisions implementing the BPD (*i.e.*, a different legal text that has been repealed and replaced by the BPR) and was deliberately left out of the BPR legal text during the legislative procedure.

Moreover, the distinction between internal and external effect was originally proposed as a borderline between treated articles and biocidal products. Article 58(3) is not about this borderline; it is more about distinguishing between treated articles that require labelling and those that do not (*i.e.*, 2 different products but both treated articles).

In the interest of harmonised enforcement, industry certainly needs concrete and agreed guidance on what constitutes a claim about the biocidal properties of a treated article. If such guidance cannot be derived from the BPR, it should be derived from existing Commission guidance on product claims in other sectors, to ensure consistency across industries.

We look forward to continued collaboration with the CAs and the Commission regarding both of these 2 documents and the topic of treated articles generally.

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What is CheMI?

Founded in 2003, CheMI is a platform of 15 trade associations representing downstream users of chemicals in article manufacturing industries. Its members represent a variety of sectors and collectively comprise approximately 400,000 companies (mainly SMEs) and 7 million employees, for an annual turnover of more than €670 billion.
CheMI website: http://www.intergraf.eu/chemi.html

What is AISE?

The International Association for Soaps, Detergents and Maintenance Products (AISE) is the official representative body of this industry in Europe. Its membership totals 34 national associations in 39 countries and also 9 direct member companies, covering about 900 companies ranging from SMEs to large multinationals active both in the consumer goods market and the industrial & institutional (I&I) domains.
AISE website: http://www.aise.eu

What is EPDLA?

The European Polymer Dispersion and Latex Association (EPDLA) is a Cefic Sector Group covering polymer dispersions and latex. It regroups 15 European companies and represents a major part of the European sector partners.
EPDLA website: http://www.cefic.org/epdla

What is ETS?

Founded in 1971, the European Tissue Symposium (ETS) is a trade association representing the majority of tissue paper producers throughout Europe and about 90% of the total European tissue production.
ETS website: http://www.europeantissue.com