



REACH & Biocides

2009 Edition

1. BACKGROUND

Producers of substances used in biocidal products (“biocides”, currently regulated under Directive 98/8/EC) are directly affected by the REACH¹ regime. Its obligations apply to EU manufacturing, importing, and placing on the market and use of chemical substances on their own, in preparations or in articles. The full extent to which REACH affects the biocides sector has been often misstated and misunderstood. **The reality of REACH for the biocide sector - biocides producers and those with treated articles - is explained below.**

During the development of REACH, legislators expressed the view that substances which are adequately controlled under existing sector-specific EU legislation should not face additional regulation under REACH. Substances used in biocides, pesticides, food, medicinal and certain other products were among those considered to be already adequately regulated and hence to be exempted. However, the final REACH text does not, in all cases, achieve this objective. It includes a number of exemptions but these are not consistent. Indeed, in terms of scope and practical impact, there is a great difference between them. Substances for use in biocides is one exemption category where the intended exemption largely fails.

2. BIOCIDES EXEMPTION REALITY

Article 15(2) of REACH provides that:

Active substances manufactured or imported for use in biocidal products only and included either in Annexes I, IA or IB to Directive 98/8/EC...or in Commission Regulation (EC) No 2032/2003 on the second phase of the 10-year work programme...until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.
(Emphasis added.)

A number of critical aspects of this “exemption” from the need to register warrants comment:

First, the scope of exemption is more limited than that for other substances similarly regulated. While other exemption provisions, e.g., concerning substances

in medicinal products² and food³, cover all main REACH obligations without qualification (Registration, Downstream Users, Evaluation, Authorisation), Article 15(2) only concerns Registration. While REACH’s provisions on Authorisation exclude substances (both active and non-active co-formulants) when used in biocides, the Authorisation obligations still apply to biocidal substances when used in other applications – an important consideration for those manufacturing or importing dual use substances.⁴

Second, regarding the phrasing of the Article 15(2) Registration exemption, “only” is the operative word - totally excluding from the Registration exemption all those active substances in biocides⁵ which are also used in non-biocidal applications (such as in medicines, cosmetics and foods). This means that **any dual use of a biocidal substance (i.e., biocidal and non-biocidal uses by the same legal entity) renders the total tonnage of the substance manufactured or imported in the EU subject to REACH Registration.** In contrast, again, the REACH exemptions for substances in other product categories, for example medicinal products and food, do not include the word “only”, meaning that those exemptions are maintained for the substances so used even if there is a dual use. (This anomaly also appears in the exemptions concerning plant protection products.)

In those dual use cases, Registration is required only for the use outside the exemption category (e.g. food or medicinal products). The biocides “exemption” is thus dramatically less effective than others because dual use totally disqualifies the exemption and the total volume of the biocidal substance manufactured or imported must be registered. The full impact of this provision has been glossed over by ECHA.

Third, **ECHA’s Guidance on Registration⁶ does not fully acknowledge the legal consequences of the fact that the Article 15 exemption for biocides (and PPPs) is limited by this “only” (single use) requirement.** In contrast to the clear position under the Regulation, the Guidance would allow splitting of tonnages, with Registration applying to the non-biocide use(s) only. While the Guidance states what we believe should be the proper end result, we are concerned that it contradicts the REACH text as it stands

² Article 2(5)(a)

³ Article 2(5)(b)

⁴ Article 56(4). See also the working document on the ‘Inter-linkages between the REACH Regulation and the Biocides Directive’ (CA-Sept08-Doc.12.1).

⁵ Listed in Annexes I, IA or IB to Directive 98/8/EC or in Commission Regulation (EC) No 2032/2003 (the so-called “Second Review Regulation” as replaced by Commission Regulation (EC) No 1451/2007.

⁶ Version 1.4, para 1.6.5.1

¹ Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (as amended).

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and, as a Guidance, it is legally non-binding.⁷ If this Guidance concerning biocides is followed, it **could render Registrations applying it subject to legal challenge** by (a) aggressive Member State enforcement authorities and/or (b) commercial competitors who are placed at a competitive disadvantage (because, for example, the splitting of volumes brings their competitor to a lower tonnage category and hence lesser data requirements and longer time to register). This contradiction makes for further uncertainty in the already complex REACH regulatory regime.

Fourth, Article 29 considerably complicates the situation for biocide producers under REACH. **Even if the Registration exemption applies** (i.e., if the substance is used exclusively in biocides), **all producers of biocidal active substances or their representatives will be obliged to participate in a Substance Information Exchange Forum (SIEF)** in which data-sharing is mandatory. This SIEF participation requirement puts in jeopardy the data protection provisions under Directive 98/8/EC. Whereas proprietary data does not currently have to be shared under Directive 98/8/EC (although this is encouraged), under REACH the sharing of certain data with REACH Registrants is mandatory (albeit subject to rules on compensation). **Data owners will be concerned that their data shared for REACH purposes only may be inappropriately used in other contexts.** This underlines the need for data owners to implement a strategy for complying with REACH's data sharing requirements without exposing themselves to unnecessary data leakage.

3. TREATED ARTICLES

Articles or materials treated with biocidal products are currently outside the scope of the Directive 98/8/EC if the biocide is intended to protect the article itself without an external effect (e.g. a product treated with an in-can preservative). The proposed major revision of Directive 98/8/EC⁸ will close the current loophole which allows non-EU manufacturers of treated articles to use any substance for an internal effect only. However, **even before the major revision comes into force, biocidal products used to treat articles are subject to the full force of REACH's rules on articles** – exposing them to possible Notification (for SVHCs) and Registration requirements (if ECHA determines that there is in fact an intended release).⁹

⁷ The Guidance cautions users that "...the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document".

⁸ COM (2009) 267 final

⁹ Regulation (EC) No. 1907/2006 (as amended), Article 4

4. OUR RECOMMENDATIONS

Producers of active substances in biocides must consider carefully how the Art 15(2) Registration exemption applies to their situation in light especially of the "dual use" limitation. With any dual use, planning must be made for Registration compliance, including who should make the Registration and how best to protect proprietary interests within SIEFs. As explained, SIEF issues will have to be addressed even if the exemption applies and the substance is regarded as being registered.

Beyond the compliance concerns, it is evident that the EU legislators failed to draft a biocides exemption that is consistent either with the legislative intentions or even with the exemptions for other substances in similar regulatory circumstances. In our view, the negative consequences of this situation justifies a timely initiative to remedy the defects, through corrective legislative amendment of REACH. There is an increasing list of key issues - including that highlighted in this paper - where the need for a legislative fix is evident.

The forthcoming major revision of Directive 98/8/EC may provide an opportunity to address some of these concerns. (However, the initial Commission proposal does not address this point - it only adds "low-risk" active substances manufactured or imported for use in low-risk biocidal products to those which are deemed registered.)¹⁰ We believe this is a challenging, but feasible initiative if supported by a sufficient grouping of concerned biocides producers.

Step toe has integrated legal and technical expertise to address REACH issues across the board, and has particular experience in the biocides/REACH interface. We are ready to discuss effective compliance solutions based on your company's specific circumstances and develop a legislative strategy to address the exemption and other common problems facing the whole of the biocides sector.

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¹⁰ COM (2009) 267 final, Article 17(4)