



## REACH & Pesticides

2010 Edition

### 1. BACKGROUND

Producers of substances used in pesticides/plant protection products (“PPPs”, currently regulated under Directive 91/414/EEC) are directly affected by the REACH<sup>1</sup> 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 PPP sector has been often misstated and misunderstood. **The reality of REACH for the PPP sector 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 PPPs is one exemption category where the intended exemption largely fails.

### 2. PPPs EXEMPTION REALITY

Article 15(1) of REACH provides that:

Active substances and co-formulants manufactured or imported for use in plant protection products only and included either in Annex I to Council Directive 91/414/EEC or in Commission Regulation (EEC) No 3600/92, Commission Regulation (EC) No 703/2001, Commission Regulation (EC) No 1490/2002, or Commission Decision 2003/565/EC and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.  
(Emphasis added.)

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

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 products<sup>2</sup> and food<sup>3</sup>, cover all main REACH obligations without qualification (Registration, Downstream Users, Evaluation, Authorisation), Article 15(1) only concerns Registration. While REACH’s provisions on Authorisation exclude substances (both active and non-active co-formulants) when used in PPPs, the Authorisation obligations still apply to PPP substances when used in other applications – an important consideration for those manufacturing or importing dual use substances.<sup>4</sup>

Second, regarding the phrasing of the Article 15(1) Registration exemption, “only” is the operative word - totally excluding from the Registration exemption all those active substances in PPPs<sup>5</sup> which are also used in non-PPP applications (such as in medicines, cosmetics and foods). This means that **any dual use of a PPP substance (i.e., PPP and non-PPP 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 biocidal products.)

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

<sup>2</sup> Article 2(5)(a).

<sup>3</sup> Article 2(5)(b).

<sup>4</sup> Article 56(4).

<sup>5</sup> Approved for use under Directive 91/414/EEC, listed in one of the Regulations setting out the programme for the ongoing assessment of active substances in pesticides, or have been deemed (in a European Commission Decision) to have a complete authorisation application dossier.



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Third, **ECHA's Guidance on Registration<sup>1</sup> does not fully acknowledge the legal consequences of the fact that the Article 15 exemption for PPPs (and biocides) 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-PPP 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 and, as a Guidance, it is legally non-binding.<sup>2</sup> If this Guidance concerning PPPs 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, the PPP exemption text covers both active substances and co-formulants. In practice, however, co-formulants are unable to ever satisfy the REACH criteria since they are not the subject of authorisation under Directive 91/414/EEC or subject to the programmes for the ongoing assessment of active substances. **Thus, co-formulants in PPPs will be subject to REACH.** This has been acknowledged in ECHA's Registration Guidance.<sup>8</sup>

Article 29 considerably complicates the situation for PPP producers under REACH. **Even if the Registration exemption applies** (i.e., if the substance is used exclusively in PPPs), **all producers of PPP substances or their representatives will be obliged to participate in a Substance Information Exchange Forum (SIEF)** in which data-sharing is mandatory. **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.

<sup>6</sup> Version 1.4, para 1.6.5.2

<sup>7</sup> 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".

<sup>8</sup> See also the working document on the 'Inter-linkages between the REACH Regulation and the Biocides Directive' (CA-Sept08-Doc.12.1).

### 3. OUR RECOMMENDATIONS

Producers of active substances in PPPs must consider carefully how the Art 15(1) 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 PPP 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 recent major revision of Directive 91/414/EEC<sup>9</sup> appears to have missed an opportunity to address some of these concerns. We believe this is a challenging, but feasible initiative if supported by a sufficient grouping of concerned PPP producers.

StepToe has integrated legal and technical expertise to address REACH issues across the board, and has particular experience in the PPPs/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 PPPs sector.

**To discuss the Pesticides issues facing your business please contact:**

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<sup>9</sup> Final text not yet published in the Official Journal of the EU.