

Analysis & Perspective

PESTICIDES

EUROPEAN UNION

Pesticide manufacturers and formulators who export to the European Union must not fall into the trap of assuming that the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) regulation applies only to the chemical industry. The authors of this article say manufacturers and formulators can be expected to experience first hand REACH's impact and need to become ready. Inert ingredients in pesticide formulations are subject to REACH, as are nonpesticidal uses of active ingredients. With a preregistration period now less than eight months away, information requests can be expected soon from pesticide exporters' European customers, who need to assess their own potential registration obligations as importers of inert ingredients. This article discusses these aspects of REACH and outlines what pesticide formulators and others need to know about the new regulation.

REACH and Pesticides: What U.S. Exporters May Not Realize

By LYNN L. BERGESON, IRA DASSA,
AND STEVEN GREEN

Pesticide manufacturers and formulators may believe (blissfully so) that the European Union's Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation is someone else's headache. After all, it applies to industrial chemi-

Lynn L. Bergeson is managing director of Bergeson & Campbell, P.C. (B&C), a Washington, D.C., law firm focusing on chemical, pesticide, and other specialty chemical product approval and regulation; environmental, health, and safety law; chemical product litigation; and associated business issues. Ira Dassa is an associate with Bergeson & Campbell. Steven Green is the business and regulatory manager of The Acta Group EU, Ltd, B&C's U.K.-based consulting affiliate specializing in chemical product approval, support, and regulatory defense. Acta EU serves as an Only Representative for numerous entities.

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icals, not pesticides. Think again. Inert ingredients included in pesticide formulations are subject to REACH, as are nonpesticidal uses of active ingredients. This article discusses these aspects of REACH and outlines what pesticide formulators and others need to know about the new regulation.

Basics of REACH

REACH is the European Union's complex new chemical management regulation.¹ In total, it encompasses over 140 different articles, 17 distinct annexes, almost 300 pages of (reformatted) text, and hundreds of pages of guidance, with the latter figure expected to grow considerably as more guidance is issued.

The core of REACH is its registration requirement, which mandates that all chemicals manufactured or imported into the European Union in quantities of one metric ton or more per year be registered with the newly created European Chemicals Agency (ECHA).²

¹ REACH is available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf. The regulation entered into force on June 1, 2007, although most of its key provisions will not apply until June 1, 2008. See REACH Art. 141.

² See *id.* Art. 5-7. Under Article 5, the nonregistration of a substance that is required to be registered means that the substance cannot be manufactured, imported, or otherwise placed

The registration obligation applies to legal entities—all manufacturers and importers of “substances” on their own or in “preparations” (i.e., mixtures), and all producers and importers of “articles” meeting certain criteria—that are established within the European Union and that meet the one metric ton per year threshold.³

Registration will entail the generation of substance-specific health and safety data, preparation of a technical dossier and, for those substances manufactured or imported in quantities of 10 metric tons or more per year, an assessment of the risks posed by the substance, including relevant exposure scenarios, and the development and communication of appropriate risk management measures.⁴

For “phase-in substances,” the term applied to existing chemicals,⁵ the registration process will proceed in phases. To obtain the benefit of extended registration deadlines—three-and-a-half, six, and 11 years from June 1, 2007, depending on the annual volume and hazard of the substance—manufacturers and importers (as well as producers and importers of certain articles) must preregister their substances between June 1, 2008, and Dec. 1, 2008.⁶ Importantly, preregistration will enable a company to continue manufacturing or importing the substance until the extended registration deadline is reached.⁷

Thus, for most entities, the initial step under REACH will be the preregistration of phase-in substances. Preregistration will entail the electronic submission to ECHA of certain basic information on the chemical and the preregistrant.⁸ By Jan. 1, 2009, ECHA intends to publish on its website a list of the preregistered substances. The list will not identify the preregistrants, but this information will be available to all companies that have preregistered the same substance.⁹ The companies will then be required to participate in a Substance Information Exchange Forum (SIEF) for the substance, with the aim of the SIEF being to facilitate the sharing of existing data on the chemical, the collective identifi-

on the EU market. This REACH principle is often referred to as the “no data, no market” principle.

³ See *id.* Art. 3, 6-7; see generally ECHA, *Guidance on Registration* (June 2007) at 19-21 (*Registration Guidance*), available at http://reach.jrc.it/03_rdds_web_content/registration_en/registration_en.pdf. Definitions of the key REACH terms appear in Article 3 of the regulation.

⁴ See *Registration Guidance* at 12-13.

⁵ The term “phase-in substance” is defined in REACH Article 3(20).

⁶ See REACH Art. 23, 28; see generally *Registration Guidance* at 41-44, 52. Final guidance on the preregistration process is expected shortly.

⁷ See REACH Art. 21(1), 23(1)-(3); see generally *Registration Guidance* at 52; ECHA, *Guidance on Data Sharing* (Sept. 2007) at 20 (*Data Sharing Guidance*), available at http://reach.jrc.it/docs/guidance_document/data_sharing_en.pdf. Preregistration is not required, but for a phase-in substance that is not preregistered, the company cannot legally manufacture and/or import the substance subsequent to June 1, 2008, until three weeks after it has submitted a complete registration. See *Registration Guidance* at 52; *Data Sharing Guidance* at 23.

⁸ See REACH Art. 28(1); see generally *Data Sharing Guidance* at 23-24.

⁹ See *Data Sharing Guidance* at 31-32.

cation of data gaps, and cost-sharing with respect to the generation of any new data.¹⁰

Unless they import the chemicals they utilize, downstream users of chemicals (e.g., formulators of mixtures, users of chemicals in industrial activities) do not have registration obligations under REACH. Each downstream user, however, must identify, apply, and where suitable, recommend appropriate risk management measures, and may have certain risk assessment, communication, and notification obligations under the regulation.¹¹

Under the REACH authorization provisions, “very high concern” chemicals will be included on a list of candidate chemicals that ECHA is expected to publish in late 2008.¹² Eventually, approximately 1,500 substances of very high concern (SVHC) are expected to be taken from the candidate list and included in REACH Annex XIV, the list of substances that will be subject to REACH authorization. Once included in Annex XIV, authorization from the European Commission will be needed before the substance can be marketed or used.¹³ An application for authorization must include an analysis of alternatives and a substitution plan where a suitable alternative exists.¹⁴ Thus, the REACH authorization system is designed to “assur[e] that . . . [SVHCs] are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.”¹⁵ It is widely anticipated that some, perhaps many of the manufacturers of SVHCs will cease manufacturing them, forcing downstream users either to reformulate their products or cease producing those products in the absence of substitute substances. Some uses of chemicals, moreover, may be restricted under the REACH restriction provisions, and authorization for those uses would not be granted.

As the EU authorities have explained, “REACH is very wide in its scope”¹⁶ and “applies to all substances with a few exemptions.”¹⁷ Exemptions from all aspects of REACH exist for radioactive substances, substances under customs supervision, non-isolated intermediates, the transport of dangerous substances, and waste.¹⁸ In addition to these full exclusions, partial exemptions ex-

¹⁰ See REACH Art. 29; see generally ECHA, “Data-Sharing,” available at http://reach.jrc.it/data_sharing_en.htm.

¹¹ See REACH Art. 31-39; see generally ECHA, “Downstream Users,” available at http://reach.jrc.it/downstream_users_en.htm. Note that only EU entities are downstream users under REACH. See REACH Art. 3(13).

¹² See ECHA, “Authorisation,” available at http://reach.jrc.it/authorisation_en.htm.

¹³ See REACH Art. 56. Annex XIV will specify for each SVHC a date after which the placement on the market and use of the substance will be prohibited unless an authorization is granted. See *id.* Art. 58(1)(c)(i).

¹⁴ See *id.* Art. 62(4)(e)-(f).

¹⁵ *Id.* Art. 55.

¹⁶ EC, *REACH in Brief* (Feb. 2007) at 6, available at http://ec.europa.eu/environment/chemicals/reach/pdf/2007_02_reach_in_brief.pdf.

¹⁷ ECHA, “Chemicals Covered,” available at http://reach.jrc.it/chemicals_covered_en.htm.

¹⁸ See REACH Art. 2(1)-2(2); see generally ECHA, *Guidance for the Navigator* (June 2007) at 7-9 (*Navigator Guidance*), available at http://reach.jrc.it/03_rdds_web_content/navigator_en/navigator_en.pdf. Given that all aspects of the regulation are inapplicable, it is probably more accurate to state that these substances are excluded from REACH.

ist for, inter alia, substances listed in Annex IV (minimum risk substances) or covered by Annex V (e.g., incidental reaction products, byproducts, natural substances) and re-imported substances,¹⁹ and “[a] number of other substances are exempted from parts of the provisions of REACH, where other equivalent legislation applies.”²⁰

Pesticides Under REACH

Under REACH, active substances and co-formulants in plant protection products and active substances in biocidal products are deemed registered because other “relevant legislation requires the submission of substantial information.”²¹ Plant protection products are regulated in the European Union under Directive 91/414/EEC, and biocidal products are regulated under Directive 98/8/EC.²²

In the context of plant protection products, the term “active substance” refers to “a substance or micro-organism, including a virus, having general or specific action against harmful organisms or on plants, parts of

¹⁹ See REACH Art. 2(7); *Navigator Guidance* at 11-17.

²⁰ ECHA, “Chemicals Covered”; REACH Art. 2(5)-2(6).

²¹ EC, *Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants* (Oct. 29, 2003) at 21, available at <http://europa.eu/eur-lex/en/com/pdf/2003/act0644en03/1.pdf>. Pesticides in the EU are divided into two major groups: (1) “plant protection products,” which mainly encompass agricultural pesticides; and (2) “biocidal products,” which is the EU term for antimicrobial pesticides. See EC, *Commission Staff Working Document—Technical Annex* (July 12, 2006) at 3, available at http://ec.europa.eu/environment/ppps/pdf/sec_2006_0895.pdf; EC, *Questions and Answers on the Pesticides Strategy* (July 12, 2006) at 1, available at <http://europa.eu/rapid/pressReleasesAction.do?reference=MEMO/06/278&format=HTML&aged=0&language=EN&guiLanguage=en>

²² Article 15 of REACH therefore provides in full:

1. 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.

2. 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 of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market or in Commission Regulation (EC) No 2032/2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, 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.

REACH Art. 15 (footnotes omitted; emphasis added).

plants or plant products,” while the term “co-formulant” refers to “a non-active substance in a plant protection product which is a [mixture].”²³ In the context of biocidal products, the term “active substance” refers to “a substance or micro-organism, including a virus or a fungus having general or specific action on or against harmful organisms.”²⁴ “Active substance” therefore is the EU term for an active ingredient, and “co-formulant” is the EU term for an inert ingredient.

With respect to plant protection products, ECHA has explained that “[o]nly the quantities of the active substance for use in plant protection products are exempted from the registration obligation. If they are used in another product, they are not exempted.”²⁵ Likewise, ECHA has made clear that for biocidal products, “only the quantities of the active substance for use in biocidal products are exempted from the registration obligation. If they are used in another non-biocidal product, they are not exempted.”²⁶

Based on the foregoing, if an EU entity manufactures or imports an active substance for use in (e.g., as a component of) both a plant protection or biocidal product and a nonplant protection or nonbiocidal product, only the former use is regarded as registered under REACH.²⁷ The use of the substance in the nonplant protection or nonbiocidal product is not exempt from registration under Article 15, such that if the manufacture or import of the substance for that use is not otherwise exempt and equals or exceeds one metric ton per year, a REACH registration obligation exists.²⁸

²³ *Registration Guidance* at 39; *Navigator Guidance* at 22; see also Directive 91/414/EEC, Art. 2(4) (definition of “active substances”), available at http://europa.eu/eur-lex/en/consleg/pdf/1991/en_1991L0414_do_001.pdf; EC, *Proposal for a Regulation of the European Parliament and of the Council Concerning the Placing of Plant Protection Products on the Market* (July 12, 2006) at 19 (defining “active substances”), 20 (defining “co-formulants”), available at http://ec.europa.eu/food/plant/protection/evaluation/com2006_0388en01.pdf.

²⁴ *Registration Guidance* at 38; *Navigator Guidance* at 21; see also Directive 98/8/EC, Art. 2(1)(d) (definition of “active substance”), available at http://ec.europa.eu/environment/biocides/pdf/dir_98_8_biocides.pdf.

²⁵ *Registration Guidance* at 40; *Navigator Guidance* at 23. Although ECHA explains that “REACH does not exempt active substances and co-formulants for use in plant protection products (pesticides) from registration,” *Navigator Guidance* at 22, the net effect of Article 15 is the same as an exemption—a substance that is regarded as registered does not have to be registered by a manufacturer or importer.

²⁶ *Registration Guidance* at 38; *Navigator Guidance* at 22.

²⁷ A strict and literal reading of Articles 15(1) and 15(2), specifically each provision’s inclusion of the word “only,” suggests that any nonplant protection or nonbiocidal use of an active substance renders the relevant registration exemption completely inapplicable (i.e., the volume of the substance manufactured or imported for use in the plant protection or biocidal product also must be considered for registration). Although this interpretation of the regulatory text must be acknowledged, it does not correspond with ECHA’s view as expressed in the *Registration Guidance* and the *Navigator Guidance*.

²⁸ No registration obligation would exist if, for example, the substance’s use in the nonplant protection or nonbiocidal product is covered by one of the REACH Article 2 registration exemptions (e.g., the Article 2(5)(a) exemption for substances used in a medicinal product for human or veterinary use within the scope of particular EU legislation).

Turning to REACH's treatment of inert ingredients, Article 15(1) includes "co-formulants manufactured or imported for use in plant protection products."²⁹ ECHA has clarified, however, that to be "eligible for the [Article 15(1)] exemption," a substance must be included in at least one of the documents referenced in that provision.³⁰ ECHA states that "since only active substances [are included in the legislation referenced in Article 15(1)], only active substances can qualify for the exemption."³¹ Consequently, inert ingredients in plant protection products, unless otherwise exempt, are subject to the REACH registration requirement and must be registered by manufacturers and importers if the ingredients are manufactured or imported, either on their own or in a mixture, at quantities at or above one metric ton per year.³²

Unless otherwise exempt, inert ingredients in biocidal products also are subject to REACH registration and may have to be registered by manufacturers and importers of those products, albeit for an entirely different reason—Article 15(2) does not apply to co-formulants. As ECHA explains, "[t]o benefit from the [Article 15(2)] exemption," a substance must be an active substance and be included in one of the legislative documents referenced in that provision.³³

Implications

U.S. industrial and agricultural chemical manufacturers and processors understand the sometimes tricky jurisdictional issues that arise under the Toxic Substances Control Act (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Nonpesticidal uses of active ingredients are covered under TSCA, and inert ingredients are subject to TSCA but cease being subject to it and fall instead under FIFRA's jurisdiction once the inert ingredients are included in a pesticide formulation.³⁴ The former is true under EU law, but the latter is not. REACH's registration provisions apply to inert ingredients even after the inert ingredients have been included in a pesticide product. This is a major distinction of which companies, especially U.S. pesticide exporters and EU importers, must be mindful. It means that while the EU importer of a pesticide formulation containing both an active and an inert ingredient need not consider for possible registration the active ingredient in the pesticide, the importer must consider the registration implications of the inert ingredient.³⁵

REACH's application to inert ingredients included in pesticide formulations has important consequences for

²⁹ REACH Art. 15(1).

³⁰ *Registration Guidance* at 39-40; *Navigator Guidance* at 22-23.

³¹ *Registration Guidance* at 39; *Navigator Guidance* at 22.

³² Irrespective of the annual volume, a registration obligation would not exist if one of the REACH Article 2 registration exemptions applies (e.g., the inert ingredient is listed in Annex IV, covered by Annex V, or exempt as a re-imported substance under Article 2(7)(c)).

³³ See *Registration Guidance* at 38; *Navigator Guidance* at 21.

³⁴ See 42 Fed. Reg. 64,572, 64,585-86 (Dec. 23, 1977) (responses to comments 37-39); see also Environmental Protection Agency, *Questions & Answers for the New Chemicals Program (Q&A)* (undated draft) at 2-18—2-19, available at <http://www.epa.gov/opptintr/newchemicals/pubs/qanda-newchemicals.pdf>.

³⁵ The pesticide formulation will be considered a preparation under REACH.

U.S. pesticide exporters and EU importers. The most pressing consequence relates to the EU importer's need to know the specific identity of the inert ingredient so that it can assess which REACH tonnage band has been met and thus identify which registration provisions, if any, apply. While this is not welcome news to U.S. pesticide manufacturers and formulators, the EU importer will need to know the identity of the inert ingredient along with the pesticide's compositional details (i.e., the precise fraction or percentage of the inert ingredient), either or both of which the U.S. pesticide manufacturer may consider to be proprietary data. If the total annual volume of the inert ingredient that is imported reaches the one metric ton per year threshold, the pesticide importer must submit a registration. U.S. exporters must understand that if the same inert ingredient is present in several different pesticide formulations, the EU importer must aggregate the volume of the inert ingredient from each imported pesticide product. Similarly, if the importer imports the pesticide at different sites, the inert ingredient volumes imported at each site must be aggregated.³⁶

To the extent the identity and/or fraction of the inert ingredient is considered proprietary data by the U.S. exporter, REACH Article 8 offers relief. This provision enables the exporter, as the non-EU formulator of a preparation that is imported into the European Union, to appoint an Only Representative (OR) and thereby relieve the EU importer of its obligation to register the inert ingredient.³⁷ The OR, rather than the importer, would carry out the registration (and fulfill all other importer obligations), and the importer would be regarded as a downstream user of the substance.³⁸ Although it does not obviate the need for a registration, appointing an OR thus allows the exporter to avoid having to disclose to the EU importer the proprietary inert ingredient information. Absent an OR (or the exporter's establishment of an EU entity to import and distribute the pesticide throughout the European Union, with the "friendly" affiliate entity then having the registration obligation), the sensitive information must be shared with the EU importer.

For some exporters, appointing an OR may be imperative less from the standpoint of protecting confidential information and more from the standpoint of maintaining customers. Certain EU importers may be reluctant or unwilling to register an inert ingredient, to the point where they may be prepared, if necessary, to cease importing pesticides formulated outside the European Union. In these instances, the exporter's only option, assuming it wants to continue selling into the European Union and does not wish to establish an EU entity, may be the appointment of an OR.

Article 8 details the prerequisites for an OR. First, the OR must be "a natural or legal person established in the [EU]."³⁹ Thus, only an EU-based individual or an EU entity can function as an OR.⁴⁰ Second, the OR must "have a sufficient background in the practical handling

³⁶ See *Registration Guidance* at 25.

³⁷ See REACH Art. 8(1).

³⁸ *Id.* Art. 8(2)-(3).

³⁹ *Id.* Art. 8(1).

⁴⁰ See *Registration Guidance* at 19 (OR "located within the EU"); EC, "Questions and Answers on REACH" (July 2007) at 10 (OR "must be based in the EU"), available at http://ec.europa.eu/environment/chemicals/reach/pdf/qa_july07.pdf.

of [chemicals] and the information related to them.”⁴¹ This requirement is not elaborated upon in ECHA’s *Registration Guidance*, but is widely interpreted to mean that the OR must be a technically qualified individual or entity with a sound understanding of REACH and the hazard and risk management of the relevant chemical. Finally, the OR must “keep available and up-to-date information on [the] quantities [of the chemical] imported and [the] customers [the chemical is] sold to, as well as information on the supply of the latest update of the [chemical’s] safety data sheet”⁴²

ECHA has explained that a particular OR “can represent one or several manufacturers, formulators or producers of articles outside of the EU and exporting to the EU.”⁴³ Given this and the fact that the appointment of an OR is made by “mutual agreement” between the non-EU company and the OR,⁴⁴ exporters wishing to appoint an OR are strongly advised to enter into a formal written agreement with the person or entity being appointed. The written agreement should clearly delineate the OR’s roles and responsibilities (e.g., to preregister the substance, participate in the Substance Information Exchange Forum, submit the registration) as

⁴¹ REACH Art. 8(2).

⁴² *Id.*

⁴³ *Registration Guidance* at 19; see also *Data Sharing Guidance* at 22.

⁴⁴ REACH Art. 8(1).

well as the non-EU company’s roles and responsibilities (e.g., to provide the information and data needed for the preregistration and registration of the substance), and should address such issues as confidentiality, termination of the appointment, and remedies in the event the OR is remiss in carrying out its duties and obligations.

Conclusion

Pesticide manufacturers and formulators who export to the European Union must not fall into the trap of assuming that REACH is a regulation that applies only to the chemical industry. Manufacturers and formulators can be expected to experience first hand REACH’s impact and, therefore, need to become REACH ready. With the preregistration period for phase-in substances now less than eight months away, information requests can be expected soon from pesticide exporters’ EU customers, who need to assess their own potential registration obligations as importers of inert ingredients. Exporters should gather promptly key data for each inert ingredient in each exported pesticide product, including the ingredient’s identity, the constituent fractions, and the total quantity exported, as well as any available scientific studies and technical data. Finally, when confidential information is involved, or to maintain the company’s customer base, serious consideration should be given to the appointment of an OR.