

Adjuvant Newsletter

Editor in Chief: [Hans de Ruiter](#)

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Regulation

LATHAM & WATKINS LLP

REACH: ARE YOU READY?

REACH is a complex and comprehensive regulatory scheme that imposes an array of requirements on companies that manufacture and import adjuvants and other substances into the EU. REACH also affects companies that export into the EU. Julia A. Hatcher and Matthew Brewer of [Latham & Watkins](#) were willing to provide in a nutshell the basics of REACH and the implications for EU importers and exporters of adjuvants into the EU (Ed.).

REACH BASICS

The European Union's new regulations for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) took effect on 1 June 2007. Under REACH, all chemical substances manufactured or imported in quantities of one tonne per year (tpy) or more, and not otherwise exempted, must be registered with the newly created European Chemical Agency (ECHA). The registration requirement applies to all companies that manufacture or import substances—whether on their own or in preparations (mixtures) or present in certain articles—at or above the one tpy threshold. For each substance covered by REACH, registration involves:

- The preparation of a Technical Dossier containing data on the intrinsic properties and hazards of each substance and identified uses of the substance.
- The generation, in many cases, of additional substance-specific health and safety data.
- For substances manufactured or



REACH regulations affect many of chemicals producing companies; EU.

imported in quantities of 10 tpy (tpy=tonnes per year) or more, preparation of a Chemical Safety Report containing an assessment of the risks posed by the substance, including relevant exposure scenarios and the development and communication of appropriate risk management measures.¹

The registration obligation also extends to non-exempt downstream uses of a substance. A downstream user may rely on the manufacturer or importer to fulfill its registration obligations as long as the downstream user makes available to the registrant, in writing, information on its use(s) of the substance. A downstream user may instead choose to submit its own registration where it wishes to maintain the confidentiality of its specific use of the substance.

In addition to registration, substances deemed by ECHA to be of "very high concern" will require authorization to remain in commerce. Under Article 60, for authorization, applicants must prepare a substitution plan that identifies "safer alternatives" and where none are available, they must create a research and development plan for finding them. Authorization will be granted only if the applicant can demonstrate that the risk

from the use of the substance is adequately controlled. If not, authorization may be granted if it can be shown that the socio-economic benefits of the use of the chemical outweigh the risks and there are no suitable alternative substances.

REGISTRATION DEADLINES

Under Article 23, registration for pre-registered "phase-in" substances may occur in three phases, based primarily on the total tonnage manufactured or imported (i.e., its "tonnage band"), but also on the substance's toxicity:

Phase 1: high volume substances (more than 1,000 tpy) or Carcinogens, Mutagens or Reproductive Toxicants (CMRs) manufactured or imported in excess of 1 tpy, or substances qualifying as "very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment" must be registered before **1 December 2010**.

Phase 2: medium volume substances (100 – 1,000 tpy) must be registered before **1 June 2013**.

Phase 3: low volume substances (1 – 100 tpy) must be registered before **1 June 2018**.

Footnote

¹ECHA, REACH Guidance on Registration (June 2007) at pp. 12-13. Available via this [hyperlink](#)

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Companies that already have the necessary information may instead opt for immediate registration beginning on 1 June 2008. For other companies, to take advantage of the extended registration deadlines for phase-in substances, they must "pre-register" their substances with ECHA between **1 June and 1 December 2008**. Pre-registration, which requires the submission of certain basic information on both the substance and the pre-registrant, will permit companies to continue manufacturing or importing the substance until the extended registration deadline is reached. The pre-registration period is intended to fulfill REACH's "one substance, one registration" mandate by allowing potential registrants (i.e., all companies that manufacture or import the substance above the one tpy threshold) to identify and negotiate with other potential registrants with whom they can share data necessary for registration.

New or "non-phase-in" substances—i.e., those that are not listed in the European Inventory of Existing Chemical Substances (EINECS) and were not produced in or imported into the EU prior to 1 June 2007—must be registered before they can be manufactured, imported or placed on the market in the EU.

"REGARDED AS REGISTERED" EXEMPTION FOR PESTICIDE ACTIVE INGREDIENTS

Under Article 15, certain substances or uses of substances that are considered to be adequately regulated by other EU regulations are "regarded as registered" and are therefore exempt from REACH's registration requirements. This exemption applies to active substances in plant protection products and biocidal products.² ECHA has explained that only the quantities of the active substance "for use in plant protection products" or "for use in biocidal products" are exempted from the registration obligation. If active substances are used in other non-plant protection or non-biocidal products, the quantities so used must be registered.³



In the near future, adjuvants without REACH registration cannot be applied anymore; [Alberta Agriculture and Food](#)

DATA SHARING

To reduce testing on vertebrate animals and overall costs to industry, REACH requires the sharing of data necessary for registration and contains several provisions to facilitate data sharing among registrants and other holders of relevant data. In particular, under Article 29, all potential registrants, downstream users and third parties who will submit data on a substance to ECHA during the pre-registration phase must join a Substance Information Exchange Forum (SIEF) for that substance. The SIEF allows potential registrants of a substance to come to agreement on how

the data necessary for registration will be shared, and allows other "data holders" (i.e., downstream users and other stakeholders who have and are willing to share relevant data) to provide or sell their information to the potential registrants. Aside from requiring the appointment of a "Lead Registrant" to oversee the organization of information and the preparation of the joint registration submission, REACH provides SIEF members with flexibility to decide how to manage data sharing and compensation for data sharing. Under certain conditions enumerated in Article 19, for example if submitting the information jointly would lead to the disclosure of "commercially sensitive information" that would cause the company "substantial commercial detriment," potential registrants may opt-out from the joint registration submission, though not data sharing.

CO-FORMULANTS/ADJUVANTS

Unless otherwise exempt, pesticide co-formulants (inerts) in plant protection products and biocidal products must be registered if they are manufactured or imported, either on their own or in a preparation, at quantities of one tpy or more. Article 15 of REACH defines "active substances" as substances "having general or specific action on or against harmful organisms" or, for plant protection products, "on or against . . . plants, parts of plants or plant products." Adjuvants, such as surfactants, compatibility agents, anti-

Footnotes

² Article 15(1) also includes co-formulants (inerts) "manufactured or imported for use in plant protection products." However, ECHA has clarified that to be eligible for this exemption, a substance must also be included in at least one of the EU documents referenced in Article 15(1) and that since those documents include only active substances, only active substances qualify for the exemption.

³ REACH Registration Guidance at pp. 39-40.

⁴ Registration Guidance at p.40.

Available at:

<http://www.hse.gov.uk/reach/casestudies/bloxford.htm>

REACH continued

foaming agents, spray colorants (dyes), and drift control agents, do not have such action on or against organisms, and are therefore considered co-formulants subject to registration.

Where multiple adjuvants (or other co-formulants) are present in a pesticide formulation, a separate registration must be submitted for each adjuvant for which the total amount manufactured or imported into the EU exceeds one tpy.

IMPLICATIONS FOR IMPORTERS OF ADJUVANTS

If the total annual volume of the adjuvant that is imported reaches the one tpy threshold, whether in a single product or aggregated in different pesticide formulations, the importer must submit a registration. To satisfy REACH's registration requirements, therefore, an importer of a "built-in" adjuvant (i.e., one that is included in the pesticide formulation as sold to downstream users, or "applicators") will need to know the specific identity of the

adjuvant as well as its precise fraction in the pesticide formulation so that it may determine which REACH tonnage band has been met and which, if any, registration provisions apply.

However, the non-EU manufacturer supplying that importer may consider the precise identity and fraction of the adjuvant in the pesticide to be proprietary data. If so, REACH Article 8 provides a solution. Article 8 allows such non-EU manufacturers to appoint an Only Representative (i.e., a "natural or legal person established in the EU" with a "sufficient background in the practical handling of substances and the information related to them") to carry out the registration on their behalf. In this case, the EU importer assumes the status of a downstream user, which allows the exporter to avoid having to disclose proprietary information to the importer. Absent an Only Representative, or the exporter establishing an EU entity to import the pesticide and take on the registration obligation, the proprietary data would have to be shared with the importer.

Independent of the data propriety issue, the non-EU manufacturer's appointment of an Only Representative also may be advantageous to the extent it simply relieves importers of the obligation of having to submit a registration for adjuvants and other co-formulants.

Because "tank-mix" adjuvants (i.e., those that are added to the pesticide formulation by the applicator) are manufactured or imported independently, and not as a co-formulant, they are subject to standard registration requirements. In this case, an applicator is a downstream user and may rely on the manufacturer or importer to register the substance as long as they provide notification of their use in writing. If an applicator considers its specific formulation or use to be proprietary data, it may undertake its own registration.

Julia A. Hatcher and Matthew Brewer
Latham & Watkins

ABOUT LATHAM & WATKINS

[Latham & Watkins](#) has substantial expertise and experience in both European and US chemical regulatory compliance and litigation. For more information or to discuss any REACH related issue facing your company, you may contact:

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You also may visit the EU's REACH website at: http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

One-day workshop Adjuvants and Pesticide Application in Australia

[Andrew Hewitt](#) and colleagues of the University of Queensland organize a one-day workshop in Gatton, Australia on March 7. They invited well-known speakers who will present the interaction between adjuvants/formulation and application technology.

Topics of the day are:

- Adjuvant effects on atomization through different nozzles (A. Hewitt and G. Dorr, UQ)
- Atomization, velocities and spray formation (P. Miller, TAG Silsoe, UK)
- Adjuvant effects on air inclusions in droplets (P. Miller)
- Adjuvant effects on impaction (J.A. Zabkiewicz, PPCNZ, NZ)
- Adhesion, inertial activity, extensional viscosity, and droplet rebound (P. Miller)
- Uptake mechanisms (J.A. Zabkiewicz)
- Leaf interactions: surface structure and topography (H. Combella, SSE)
- Adjuvant effects on efficacy, drift management and spray performance (A. Hewitt and G. Dorr)
- Formulation and application volume optimization (J.A. Zabkiewicz)

Literature

FORMULATION TECHNOLOGY

Effect of soil moisture on the release of alachlor from alginate-based controlled-release formulations [Journal of Agricultural and Food Chemistry 56\(2008\)4: 1322-1327](#)

Controlled release of herbicide acetochlor from clay/carboxymethylcellulose gel formulations [Journal of Agricultural and Food Chemistry 56\(2008\)4: 1336-1342](#)

HERBICIDES

"Pesta" and alginate delivery systems of *Fusarium* spp. for biological control of *Striga hermonthica* (Del.) Benth. under Sudanese field conditions. [Biological Control 44\(2008\)2: 160-168](#)

INSECTICIDES

Do diatomaceous earths have potential as grain protectants for small-holder farmers in sub-Saharan Africa? The case of Tanzania. [Crop Protection 27\(2008\)1: 44-70](#)

Development of PVC-resin-controlled release formulation for pheromones and use in mating disruption of yellow rice stem borer, *Scirpophaga incertulas*. [Crop Protection 27\(2008\)2: 248-255](#)

NEMATOCIDES

Efficacy of neem (*Azadirachta indica*) formulations on biology of root-knot nematodes (*Meloidogyne javanica*) on tomato. [Crop Protection 27\(2008\)1: 36-43](#)

FERTILISERS

Effect of two nitrogen forms on the growth and iron nutrition of pea cultivated in presence of bicarbonate. [Journal of Plant Nutrition 30\(2007\)12: 1953-1965](#)

New slow-releasing molybdenum fertilizer [Journal of Agricultural and Food Chemistry 56\(2008\)4: 1343-1349](#)

Patents online



By clicking on the icon, you will be connected to the SURfaPLUS Patent Alert Service. Information on patents dealing with adjuvants and formulations.

Agenda online

The [agenda](#) includes international and national meetings whereby attention is paid to formulations and adjuvants. In case readers want to insert information about important meetings, please [contact](#) us.

Online lists of companies

COMPANIES ACTIVE ON ADJUVANTS AND FORMULATIONS

When you try to find out who is doing what, you may use our online lists. In case your company has an interest to be included in the lists please [contact](#) us.

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Colophon

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