

# EU Analyst: Environment & Life Sciences

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### 1. REACH: ONLY REPRESENTATIVE RULES CHANGE AGAIN

By [Craig Simpson](#) and [Darren Abrahams](#)

#### Overview

Pre-registration of substances under REACH started on 1 June 2008 and ends on 30 November 2008. Substances on their own, in preparations or in articles (i.e. finished products) which are not pre-registered during that period cannot be manufactured in the EU or imported into the EU until a fully completed registration dossier is completed – a lengthy process. This means that companies must ensure that all of the substances they use are pre-registered, or else face a period during which they cannot market products. National sanctions (including possible fines and criminal sanctions) could also apply if these obligations are not respected.

An additional complication facing non-EU established companies exporting to the EU is that they cannot pre-register (or register) themselves. Either their EU importer or nominated EU-established "Only Representative" ("OR") must pre-register (and register). Steptoe offers an OR service to clients.

A steady stream of guidance on REACH continues to be issued. Previously issued guidance is also being revised. Guidance on appointment of an OR has changed in a number of important ways, addressing various points which it had previously been argued discriminated against non-EU manufacturers compared to their EU based competitors.

#### Key changes

The following change has been made in the latest (May 2008) European Chemicals Agency ("ECHA") [guidance on registration](#):

**1. ORs who act on behalf of more than one non-EU manufacturer for a certain substance must submit a separate registration for each of these substance manufacturers.**

This removes concerns with the Commission's previously stated position that ORs would, in this situation, need to submit a single registration aggregating those exporting tonnages of the substance in question resulting in non-EU manufacturers potentially having to comply with heavier data submission requirements and earlier registration deadlines (required for higher tonnage bands) than their EU based competitors producing equivalent volumes.

In addition, we understand that the Commission publicly announced the following changes earlier this month and that these will be reflected in further amendments to the ECHA technical guidance documents in the coming weeks.

**2. A non-EU manufacturer of a substance which is exported into Community territory 'indirectly' by a non-EU formulator (which uses that substance in its preparation) can appoint an OR to register the tonnage exported by that formulator.**

The latest (May 2008) ECHA guidance on registration suggests that a non-EU manufacturer may appoint an OR to register tonnages of a substance exported by its non-EU distributor. However, that guidance does not make clear whether the non-Community manufacturer could appoint an OR where such export was made by a formulator. The Commission has now clarified that it can. It appears that this applies both where the non-EU manufacturer also exports the same substance directly to Community and where it does not.

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**3. Instead of having to appoint its own OR to carry out registration of a substance used in its preparation which is exported to the EU market, a non-EU formulator can refer to a registration made by an OR appointed by its non-EU supplier.**

This follows logically from point 2, above, but again has not been clear from ECHA guidance to date.

**4. Non-EU manufacturers that decide to change the OR they have appointed for a particular substance can submit an update to the ECHA and do not need to submit an entirely new registration dossier.**

The latest (May 2008) ECHA guidance on registration states that the newly appointed OR would have to submit a new registration dossier. However, it appears that the Commission has now returned to its previous position stated in an earlier guidance (June 2007) that the new OR can, in agreement with the former OR, simply update the registration dossier.

Step toe's REACH team continues to advise on the latest REACH-related developments and assists client's in achieving compliance. Should you have questions regarding the impending guidance, or other REACH concerns, including the appointment of an OR, please contact us at [REACH@steptoe.com](mailto:REACH@steptoe.com) and one of our team members will be happy to contact you.

## 2. ECJ PROLONGS MARKET ACCESS FOR "FREE RIDERS"

By Bobby Arash and [Darren Abrahams](#)

### Overview

On 22 May 2008, the European Court of Justice ("ECJ") delivered its judgment in case [C-361/06](#), *Feinchemie Schwabida and Bayer CropScience v College voor detoelating van bestrijdingsmiddelen*. This important decision concerns the circumstances under which companies who have not supported an active chemical substance ("free riders") contained in their Plant Protection Products ("PPPs") must withdraw those PPPs from national markets following the active substance's EU authorisation. Authorisation occurs by inclusion in

Annex I to [Directive 91/414/EEC](#) ("the PPP Directive") following submission of a complete dossier.

Given the substantial investment made by those companies who do support active substances through the submission of a dossier ("notifiers"), the period during which competitors who have not made the same investment can remain on the market is of considerable commercial importance.

The ECJ ruling is likely to undermine the value of that investment, at least for those active substances authorised before 2005. The ruling also presents challenges in other commercial fields where a similar regulatory framework exists, such as under the [Biocidal Products Directive 98/8/EC](#) ("the BPD").

### Facts of the case

The case arises from a reference to the ECJ from the Dutch Administrative Court. Following the authorisation of the active substance *ethofumesate* by [Directive 2002/37/EC](#) (an amendment to Annex I of the PPP Directive), the Dutch Board for the authorisation of pesticides ("the CTB") withdrew a national authorisation held by Agrichem ("the company") to place on the market PPPs containing *ethofumesate*.

The company was not considered to have had ownership of or access to an Annex II (PPP Directive) dossier for *ethofumesate* containing the data necessary for evaluating foreseeable risks to humans, animals and the environment. The CTB concluded that it was required to order market withdrawal in such circumstances. Those companies who had supported *ethofumesate* intervened in litigation before the Dutch Administrative Court claiming, amongst other things, that:

- the data protection provisions of the PPP Directive indicate that the holder of an authorisation for a PPP who is not at the same time a notifier of the active substance, must hold or have access to an Annex II dossier; and

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- data submitted by notifiers could not, without their consent, be used by third parties or for the benefit of third parties during the 5 year period set out in the PPP Directive.

## ECJ judgment

The ECJ concluded, relying largely upon the general principle of legal certainty, that in absence of clear and unambiguous wording (in either the PPP Directive or Directive 2002/37/EC) there was no requirement to terminate an existing national authorisation of a PPP containing *ethofumesate* (following inclusion in Annex I) on the sole ground that the holder of that authorisation did not hold or have access to an Annex II dossier.

## Impact on the commercial sector

Since 2005, Directives including active substances in Annex I to the PPP Directive specify, amongst other things, an obligation that existing national authorisation holders must either hold or have access to an Annex II dossier in order to remain on the market following an Annex I inclusion of that active substance. This data access obligation is missing from those authorisation Directives adopted prior to 2005, including that at issue in this case. Hence, the judgment of the ECJ.

This suggests that holders of existing national authorisations would be able to challenge market bans, imposed for reason of lack of access to Annex II data, prior to 2005. Only an amendment to the pre-2005 inclusion Directives would provide the required level of legal certainty and precision sufficient in order to justify market withdrawal. It remains to be seen whether the Commission is willing to launch such a revision exercise.

The European Commission's post-2005 standard wording in Annex I inclusion Directives appears to have plugged the loophole exploited in this case.

In effectively reducing the case to one about legal certainty, the ECJ avoids a lengthy debate on applicable data protection rules under the PPP Directive - a contentious topic in the PPP and biocides sectors.

Similar practical problems may arise not only in the PPP Directive but also within the framework of the BPD. Although the data protection provisions of the BPD are differently worded, the regulatory architecture is the same. An examination of the early active substances inclusion Directives for biocidal active substances suggests that they may not have the necessary level of legal certainty necessary in order to ensure that "free-riders" are excluded. In other words, an application of the approach established by the ECJ might lead to the same conclusion under the PPP Directive. Under the BPD, national authorisations of a biocidal product may only be withdrawn on grounds of a lack of data after the re-evaluation of the biocidal product in accordance with Annex VI to BPD (Article 16(3) BPD), i.e. several years after the inclusion of the active substance into the list of authorised active substances.

There are currently no biocidal products authorised in accordance with the provisions of BPD and only very few active substances have been included into Annex I/IA to the Directive. In order to avoid a further erosion of data protection, the European Commission would be well advised to amend the adopted implementing Directives in order to ensure legal certainty for all stakeholders.

The Commission is in the process of revising both the PPP Directive and the BPD. The judgment clearly identifies a gap in current data protection provisions. The current revision of the legislation could ensure that this gap is appropriately addressed.

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