

The report was welcomed by a joint press release from the leaders of Kingfisher, Ocado, M&S and the Wildlife Trusts.

Kingfisher group chief executive, Sir Ian Cheshire said: "Valuing natural capital enables businesses to understand the resource dependencies in their supply chain. Protecting these assets makes absolute business sense in mitigating risk, as does getting ahead of the curve to seize potential new opportunities." ■

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➤ 1. *The state of natural capital: restoring our natural assets*

## REACH non-compliance referrals rise

■ The European Chemicals Agency is stepping-up action against non-compliant registration dossiers.

Some 32 non-compliant substance registration dossiers submitted under the EU REACH chemicals regulation were referred to member states for possible enforcement proceedings last year. This is up from nine in 2012.

The figure was revealed in the European Chemicals Agency (ECHA) annual enforcement report.<sup>1</sup> This is the first time it has contained information on the number of referrals sent to member states.

Two thirds of referrals related to problems ECHA found during its dossier compliance checks ([endsreport.com/42421](http://endsreport.com/42421)). The other ten related to safety tests proposed by registrants.

The referrals are the result of 222 follow-up checks that ECHA made on formal decisions sent to registrants asking for improvements to their dossiers or test procedures.

ECHA is unable to say what action countries are taking on the statements. It has the power to withdraw the registration numbers from dossiers, rather than referring the cases to member states. That would mean the company could no longer make or import the substance. However, ECHA has not yet used this power.

The agency last year reached its target of assessing 5% of the dossiers for medium- and high-volume substances submitted in 2010. It will begin assessing 2013 dossiers later this year.



**Doug  
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Comment

## Keeping an eye on your ingredients

■ Industry should remain watchful of its processes and supply chains to ensure compliance with the new provisions of the EU's Biocidal Products Regulation.

Biocidal household and industrial products, such as disinfectants and insecticides, have been regulated in the EU for a number of years. But the entry into force of the EU's Biocidal Products Regulation in September 2013 extended this market-access regime to cover 'treated articles' – substances, mixtures or articles that are either treated with or incorporate 'biocidal products'.

At first glance the regulation's key provision on treated articles appears straightforward. It prohibits all economic operators (from manufacturers to importers) from placing treated articles on the EU market unless all of the active substances in the biocidal product used to treat the article are on the EU's list of approved actives or low-risk substances.

However, in this prohibition (and the regulation more generally) are key implementation challenges for industry, including: the appropriate classification of articles; correct labelling; working with misdrafted transitional provisions; and global compliance hurdles.

To address the first point, industry is faced with a classification challenge. Are products treated articles or are they, by virtue of their characteristics, more appropriately classified as biocidal products? In terms of costs and administration, the difference is

The evaluation report also contains advice to firms on how to keep their dossiers updated, react to decisions asking for more information and justify the safety tests they propose.

Meanwhile ECHA is consulting on four additions to the candidate list of substances of very high concern (SVHC). (ENDS Report 469, p42).

They are: dihexylphthalate, branched and linear; cadmium chloride; sodium peroxometaborate; sodium perborate and perboric acid, sodium salt.

SVHCs may be considered for authorisation rules under REACH. They are also subject to specific rules on information disclosure. The consultation runs until 17 April.

Nine substances were added to the annex XIV authorisation list at a meeting in February. Companies wanting to use the substances will have to seek authorisation.

ECHA recommended the nine substances be prioritised for authorisation in January 2013 (ENDS Report 456, p21). They are: formaldehyde, oligomeric reaction products with aniline (technical MDA); arsenic acid; bis(2-methoxyethyl) ether (diglyme); 1,2-dichloroethane (EDC); 2,2'-dichloro-4,4'-methylenedianiline (MOCA); dichromium tris(chromate); strontium chromate; potassium hydroxyoctaoxodizincatedichromate; and pentazinc chromate octahydroxide

A tenth substance N,N-Dimethylacetamide (DMAC) was also recommended but

considerable. For example, biocidal products require individual authorisations in each EU member state (subject to mutual recognition and the welcome 'union authorisation' procedure).

Given the importance of correct classification, one would have thought that the European Commission and member state competent authorities would have drawn up clear guidance on the issue. Think again. While the commission's guidance has evolved into a useful document, prior versions contained contradictions, leaving industry confused.

The guidance on classification has swayed from a narrow focus on public health and claims of biocidal effectiveness to a much broader set of indicators. While it appears that the guidance is now settled, further amendments by the European Chemical Agency's Biocidal Products Committee cannot be ruled out. Industry would be well advised to be aware of the classification criteria, in particular the fact that marketing claims can, on the present guidance, have the unwanted effect of 'upgrading' a product from a treated article to a biocidal product.

Second, industry must comply with comprehensive labelling requirements for treated articles from 1 September 2013. This includes a statement that the treated article incorporates biocidal products, a description of the biocidal property associated with the treated article and a list of the active substances contained in the biocidal product. There is also an explicit obligation to include the name of all nanomaterials contained in the biocidal product used to treat the article.

However, these labelling requirements are not mandatory in all cases. These requirements are triggered where either a claim is made regarding the biocidal properties of the treated article (such as kills bacteria), or the conditions of approval of the active substance within the biocidal product specifically require labelling. Industry may therefore have a degree of flexibility as to the need to label their treated articles.

This is not a loop-hole per se, rather a reflection of the EU's drive to support and substantiate efficacy claims. Accordingly, if an operator wishes to take their treated article to market with a claim regarding its biocidal properties, they must be prepared to publicly disclose the labelling information and substantiate efficacy in line with the Biocidal Products Regulation and where appropriate, EU and member state marketing law.

Industry must also take a view on complex and misdrafted transitional provisions. While the regulation applied from September 2013, the transitional provisions for treated articles provide a der-

ogation where applications for the approval of active substances within the treating biocidal product have been submitted prior to 1 September 2016.

The EU has, in error, created a *prima facie* technical ban on placing new treated articles on the market, where actives are not already approved. The commission has moved to rectify this mistake and an amending regulation is in the legislative pipeline.

Accordingly, while the enforcement risk is low, some operators have had to come to terms with the fact that they are technically in breach of EU law. Overall, while clearly not intended, this kind of scenario is frustrating for technical and legal in-house teams who may be obliged to report such compliance issues to their board.

Finally, the extension of the regulation to cover treated articles adds an additional layer to global biocides product regulation. Other jurisdictions have well-developed biocides laws with a strong enforcement history, which multinationals should be aware of.

### **"The lack of clarity from the commission on this emerging regime has not aided practical implementation"**

One particular regime that companies should familiarise themselves with is the US Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This contains lighter-touch regulation for certain treated articles as per the approach under the Biocidal Products Regulation.

However, from first-hand experience advising on a transatlantic basis, there are legislative subtleties and divergent enforcement risks: one cannot assume that the principles of the regimes apply equally on either side of the pond. This is especially the case given the potential reputational ramifications of a breach of biocides regulation, where public health concerns are often foremost.

While the drivers behind the extension of the EU biocides regime to treated articles are well understood by industry, the lack of clarity from the commission on this emerging regime has not aided practical implementation. If not already commenced, operators would be well-advised to review their use of biocides within their processes and supply chains to ensure compliance with this potentially onerous market-access regime. ■

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the European Commission has not decided if it should be added because a restriction under annex XVII of REACH is being considered for a similar substance, N-Methyl-2-pyrrolidone (NMP). The EU executive wants to ensure a consistent approach.

ECHA suggested applications for authorisation should be required within 18-21 months of the substances being added to annex XIV but the commission has decided to allow 35 months for the last four substances on the list because that is the time limit for other chromium (VI) compounds in annex XIV.

The sunset dates after which only authorised uses will be allowed will be 18 months following application deadlines.

● ECHA has sent legally binding letters to 46 firms that may have wrongly registered substances as intermediates under REACH.

Registering intermediates that are made and used by industry under strictly controlled conditions is simpler and cheaper than the normal REACH registration process.

The companies contacted by ECHA have one month to provide more information on the 118 chemicals affected, change which uses they have registered or upgrade their registrations. If they do not respond, ECHA will pass their details to national law enforcement agencies.

In September 2012, ECHA warned 574 registrants that automated checks showed there were problems with their registration

of one or more intermediates (ENDS Report 436, p45). In total, 2,388 registration dossiers were affected covering 760 substances.

#### **Maintaining status**

Just under 2,000 of these dossiers have now been updated, 95% of which have retained their intermediate status.

Later this month ECHA will update the screening tool companies can use to check their registration dossiers before submitting them. The changes will include improved checks on the uses section of intermediates dossiers. ■

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1. ECHA: REACH evaluation report 2013