CHEMICALWATCH
European business briefing

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# Pre-registration hopes and fears

**As the start of the critical REACH pre-registration period approaches, *Chemical Watch* asked seven diverse firms how their preparations are going and what their expectations are.** Mamta Patel **and** Emma Chynoweth **report.**

We posed five questions to gain a snapshot of the firms' preparations, hopes and anxieties, with the intention of revisiting these after pre-registration to see if they are borne out in reality. Our questions were:

* How many substances do you intend to pre-register? Do you have substances that are difficult to identify or establish "sameness" for?
* Are your IT systems ready for pre-registration?
* How much time do you think it will take?
* How do you plan to gauge the success of your pre-registration effort?
* What are your hopes and fears?

## Umicore

Materials technology group Umicore has activities in advanced materials, precious metals products and catalysts, precious metals services and zinc specialities. With headquarters in Brussels, Belgium, the company has operations across the globe.

The company estimates the number of substances it plans to pre-register will run into several hundreds. With many operations across Europe, these will be handled in a decentralised way by each legal entity.

Dr Marleen Van den Bergh, Umicore's REACH implementation manager notes that the company has not had any issues relating to substances that are difficult to identify or establish "sameness" for. She adds that if questions do arise, they are likely to be answered through discussion with other companies via consortia.

Umicore was putting the final touches to its IT system at the end of April and had still to decide whether to submit pre-registrations *via* the IUCLID 5 plug-in or create reference substance files with a view to registration in the longer-term. Dr Van den Bergh says the second option would require more work upfront, but would make registration easier.

Her hopes are that pre-registration will be as easy as it is claimed to be and that the company's IT tools will be in place in time so that it can start attempting to pre-register substances as soon as possible. "If we do not make an early start, we will run into the summer holidays and then we will only have the autumn left."

## Shell Chemicals

As a major EU-based multinational petrochemicals company, Shell Chemicals has been preparing for REACH implementation for several years already and has been closely involved in developing technical guidance. It estimates that it has spent more than 200 days preparing for pre-registration since early 2007. This work has been spread across its businesses, including manufacturing sites, and its product regulatory support service through allocated 'product stewards'.

The company plans to pre-register around 150 substances for its chemicals business alone. In addition, it says it may decide to pre-register critical materials it purchases

where suppliers have not provided surety that they will continue supply. The company has worked with other producers through the Hydrocarbon Solvent Producers Association to try to agree on the most appropriate identification and naming of some solvent streams that are difficult to characterise. Discussions to determine the "sameness" of substances are being held in advance of the pre-registration process when substances will be allocated to substance information exchange fora (SIEFs).

An agreed process has been put in place to submit pre-registration entries using the IUCLID 5 pre-registration plug-in tool. The submission will be made through a single organisational contact point to act on behalf of all Shell businesses, including chemicals.

The company will pre-register a few substances early on as a trial and hopes to complete pre-registration by the end of October. It envisages that the upload of data will take a skilled operator one to two weeks to complete. It will measure the success of the process by ensuring that it has a pre-registration number for all of its substances for each of its agreed legal entities. This will be checked by its product stewards. "Our hope is that the ECHA REACH IT system is available and fully functional for the duration of the pre-registration period," the company says in response to our questions.

"Our concerns are in the lack of control we have on the IT system. We are also concerned about our inability to track pre-registrations to allow us to see the commitments of suppliers as there may be a lack of awareness to (pre)register, especially if they are located outside the EU." This cannot be checked until early 2009 when ECHA publishes a list of all pre-registered substances, the company notes, and even then the list will not reveal whether Shell Chemicals' own suppliers have pre-registered.

Difficult to predict, this lack of awareness "may well be a significant problem across the industry and so we hope the ECHA will review and add some flexibility to this mandated time line if there is a lower than anticipated take up," the company says. Continuity of business after 2008 will be a key measure of success, it concludes.

### Japanese chemical firm

Most products are imported into the EU, although there are some substances manufactured within Europe. The number of substances requiring pre-registration is said only to be "substantial", according to a representative of this large and diverse chemicals firm, who preferred it not to be identified.

An 'only representative' (OR) – again undisclosed – has been appointed to handle imports. While the use of an OR means the pre-registration workload is lower, the cost related to outsourcing this function is said to be significant. The company plans to submit pre-registration information over a fairly short period.

**'We are about to begin pre-registration and most of the guidance is written in English… I want to understand my obligations.'**

**– Giovanni Colombo Bixa Chem**

It describes itself as well advanced in its IT preparations, but notes that uncertainties persist as the European Chemicals Agency (ECHA) is still fine tuning the REACH-IT and IUCLID 5 plug-in systems. The company plans to meet in the first half of May to discuss the situation.

"There are so many things to be solved and communicated in a consistent form by ECHA and the European Commission," said the representative. "The IT system has recently changed again. It is not a fully set out, consistent system you can just log into and submit information. It seems to be left to the manufacturers to solve the problems and handle the infrastructure – there is still a lot of uncertainty."

The company believes that ECHA is certain to be overloaded during pre-registration, predicting it will receive millions of applications. "We are just hoping to get through it. We would hope to get some confirmation that our registrations have been received. We shall submit our pre-registrations as a one-off exercise and then wait until early December to find out if our submissions have been successful.

"There appears to be no scheme for evaluating if the pre-registrations have been successful – the IT system should produce some kind of confirmation so that we can double check our substances are covered. Our fear is that we miss something or a glitch in the system may result in several substances not being pre-registered. That is our biggest fear as the impact will be very significant."

### Bixa Chem

Bixa Chem is an Italian-based importer of around 30 substances used in the inks and coating sectors. Products are sourced from the USA, Brazil, China, and others.

The company's manager Giovanni Colombo sees REACH as a serious threat to his business and entrepreneurs in general. He has found larger enterprises that will handle the pre-registration of most of the products that he imports, but this service comes at a price. Furthermore, he notes that while pre-registration with ECHA is free, there is a substantial resource cost in terms of understanding and responding to the requirements of REACH. Limiting this impact is Mr Colombo's main target.

If any of the substances he handles require additional testing he will have to cancel the imports, he concludes. "ECHA has estimated the costs of such work at between €200,000-€300,000 per substance. This is unacceptable."

Bixa plans to pre-register around ten products. Mr Colombo has downloaded the IUCLID 5 programmes and worked through the instructions, but says he cannot get the system to work properly. He is not sure if it is something he does not understand, or if a window in the plug-in area is not working. "The IUCLID 5 plug-in is not friendly. It may be made for multinationals, which have large computer systems but it is not made to take care of the standard wishes of entrepreneurs. I have not heard of one person that does not have a problem with it."

Mr Colombo's biggest complaint against REACH is the lack of guidance available in Italian. "We are about to begin pre-registration and most of the guidance is written only in English. This is not only impolite, but also, I think, illegal", he alleges. "On this question alone, I think we should make a stand against ECHA." He

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COMMENT

# Pre-registration IT jitters

It is a truism that public bodies are seriously likely to damage their reputations when they try to install major IT systems. When the body itself is new, and has only taken over responsibility for delivering the system six months before it is due to go live, the risks are even higher.

It is no wonder then, that jitters about the preparedness of the European Chemicals Agency (ECHA) with its REACH-IT system for pre-registration dominate the concerns of the seven firms we interviewed this month to ask about their hopes and fears for the crucial six-month period that starts on 1 June. Their concerns range from SafePharm's measured comments about likely "teething problems" to our unnamed Japanese chemical firm's conviction that "ECHA is certain to be overloaded during pre-registration".

Rumour has it that a pilot trial of the IT system this month did not go well. But ECHA is said to be publicly phlegmatic about the outcome, saying it will use the lessons from the trial to ensure the system is up and running by June. Speaking at the joint European Commission/ECHA pre-registration launch workshop in April, Director-General of DG Enterprise Heinz Zourek summed up the fears of many by warning that "The REACH IT system has to be ready... the alternative would be a nightmare. It would mean sending tonnes of paper to Helsinki" ***CW* 14 April 2008** .

Another striking feature from our conversations with the seven firms is the considerable resources they have already committed to implementing REACH, not without some pain, as Bixa Chem notes. Even Boots, which as a retailer is hoping to avoid primary (pre)registration obligations under REACH, has invested heavily in ensuring its suppliers are well informed of their obligations. Each firm, from its different starting points and with varying levels of complexity to handle, is ready for pre-registration. They are relying now on ECHA to be ready with its part of the bargain – and the agency must not let them down.

The world is watching the EU's REACH experiment attentively. Many are wishing it well as it holds the promise of restoring public confidence in the safe use of chemicals. But it also has its critics who are already proclaiming its failure, lest they should be asked to undertake something similar. Speaking at a Senate hearing in April, a representative of the US Synthetic Organic Chemical Manufacturers Association warned against any attempt to try REACH in that country, saying "REACH has outreached the [European Union's] capabilities" ***CW* Newslink 1 May 2008** .The efforts of our firms would suggest that he is underestimating their capabilities. One hopes the same can be said of ECHA.

Mamta Patel
Editor
Chemical Watch

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adds that the IUCLID guidance is also all in English. "I want to understand [my obligations], I do not like to have responsibility for something I do not understand," he says.

### Azelis

As one of Europe's largest distributors, Azelis says it will need to pre-register at least 1,000 substances sold by its companies. But this could rise to more than 80,000 if it were to include the trace, minor or possible substances in line with its "defensive" registration strategy, says chief operating officer Peter Fields.

He expects there may be difficulties in establishing "sameness" for some substances when it comes to joining substance information exchange fora (SIEFs). "But, at the moment, we are unable to say if it will be for one or for a hundred substances."

The company has invested substantially in software and says its IT system is on track to interact once ECHA's REACH IT system goes live. It will glean data from Azelis' corporate SHEQ product stewardship database which holds more than 30,000 documents for at least 40,000 products. These data will be married with information from the company's 'business intelligence' database and formatted to allow bulk upload to ECHA's pre-registration IT platform in three to four months' time.

Whether or not pre-registration has been successfully achieved will be measured against three core objectives. One is to ensure that, where possible, substances that are currently sold by Azelis will continue to be sold after 1 Jan 2009, after pre-registration is over. The aim is to avoid business interruption at minimum costs. In addition, in its customers' interest, the company needs to be in a position to ensure that substances that may occur in future products are also pre-registered – even if Azelis is not currently selling them. Whether this can be secured to ensure continued business growth for major customers will be a second long-term measure of success.

Azelis is also offering a REACH 'only representative' service to pre-register and register substances on behalf of non-EU manufacturers (see pages 6-7). Its third measure of success is therefore the uptake for this new line of business

Mr Fields remains critical of what he perceives to be the indiscriminate volume-based prioritisation of substances for registration under REACH, as well as other aspects of the law. "Our primary fear is that we will be flooded by an unmanageable amount of data and enquiries received from manufacturers, customers and regulators alike," he says. There are many uncertainties as to how the regulations will actually operate and the implementation of "bad law" is rarely successful, he complains. The worst case is that a business could effectively be paralysed by data requirements and regulatory uncertainty.

### SafePharm Laboratories

With 800 clients in more than 30 countries, SafePharm has expanded its chemicals team to cope with increased business under the REACH Regulation. Its services range from regulatory consultancy to advice on cost-effective testing strategies, to OR services.

**'Lack of awareness of the need to pre-register may well be a significant problem across the industry.'**

**– Shell Chemicals**

As an OR, SafePharm expects to pre-register at least 200 substances, some of which are likely to pose challenges in terms of ensuring that they are allocated appropriately to SIEFs based on their sameness.

SafePharm's IT systems are said to be ready to handle pre-registration. The company has developed two separate Excel pre-registration forms which it encourages clients to complete. One allows for pre-registration of single component substances, the other for multi-component submissions.

If ECHA's REACH IT systems work properly, in particular for bulk pre-registration, the company anticipates that the pre-registration upload should not take more than one hour per substance. Its indicator for gauging the success of the effort will be timely confirmations from ECHA of its submissions.

If the IT systems fail, "we will all have big problems," the company concludes. "We think it is inevitable that there will be teething problems so we will recommend to clients not to try to pre-register during the first few days. We hope that any problems with the IT systems are dealt with quickly."

### Boots

A leading UK health and beauty retailer, Boots has around 1,500 stores in the UK and Ireland. It also manufactures its own consumer products and has always kept a substantial database of information on the properties and hazards of the chemical ingredients it uses. Through management of a 'restricted substances list', it has taken a precautionary approach to avoiding substances of concern where possible.

According to sustainable development manager Stephen Johnson, the company's primary objective is to ensure that suppliers take on their REACH responsibilities. "Our ultimate intention is not to pre-register any chemicals in our portfolio." If it can achieve this without losing any chemicals and products, it will consider pre-registration to have gone well.

However, contingency plans are in place to pre-register chemicals if it looks as though they are not being handled by other firms.

Mr Johnson says there are a number of materials that have posed some interesting questions in terms of establishing sameness for SIEF allocation. These mainly concern common materials that have been assumed to be bulked under one EINECS number but on further review of their chemistry, this is no longer regarded as accurate.

With its long-standing IT systems to track the use of chemicals in products, "we are in reasonably good shape" to manage REACH implementation says Mr Johnson. However, "we recognise that our current system was not specifically designed for REACH so over the next 12 months, I'm in no doubt that we will need to change our current ways of working and update our systems to ensure REACH is implemented successfully across our business."

His biggest fear is that "a large proportion of the supply chain may not understand REACH and is still continuing to do business in blissful ignorance." Once such companies realise the implications of REACH, it may be too late after pre-registration to do anything about it.

"My hope is that our communications programme will have equipped our supply base with a basic understanding of their responsibilities to ensure we achieve seamless implementation. My other hope is that for all the forthcoming pain, REACH will provide long awaited standardisation of both safety and environmental data for many common chemicals to enable consumers to gain trust in the chemical industry again."

# Russia plans for REACH with Responsible Care

**The EU is Russia's largest export market, so the REACH Regulation, with its potential to ban exports of certain chemicals unless registered is viewed as a serious threat. Some 20 percent of chemical exports could be diverted to other countries, according to the Russian Chemists Union.** Lauri Kinnunen **reports.**

According to Igor Kukushkin, executive director of the Russian Chemists Union (RCU), the body is being proactive in preparing for the realities of the new EU chemicals market.

Together with the Russian Industry and Enterprise Union it has been working to raise awareness of obligations under the REACH Regulation. It has just decided to organise a permanent commission of experts to carry on this task. The two organisations have also established a REACH centre to provide guidance and practical assistance to companies.

"Now, we are gathering information, and try to inform both business and public bodies," Mr Kukushkin says. The Russian REACH centre organises REACH seminars and publishes regular recommendations.

It is also building expertise on the chemicals database software for REACH, IUCLID 5, as this will play a central role for many companies planning to register their substances under REACH.

More hands-on help is also on offer, for instance to help firms draw up their substance inventories. "Currently, we are realising identification works of chemical substances for some companies," Mr Kukushkin says.

Another aspect of the RCU's work is to contribute to the development of a federal chemicals safety law designed to be harmonised with the REACH Regulation in order to aid Russian businesses.

But Mr Kukushkin is concerned about what he describes as the absence of developed REACH policy for non-EU countries, which has left them with many unanswered questions. Though many companies and public bodies from third countries have turned to the European Chemicals Agency (ECHA) helpdesk for advice, Mr Kukushkin complains that frequently they are just told to wait for the finalisation of guidance on the issues concerned.

"This complex law changes many rules, so the absence of methodical help for third countries such as Russia means heavy consequences for them", he says. "For instance, it raises many risks connected with custom appearance, transport questions, registration of loads, documentation, currency regulation, among others."

**Igor Kukushkin, executive director, RCU**

## Disquiet

Large firms in Russia realise the social and ecological importance of REACH, but the possible consequences of commercial barriers and unsettled questions about its effects on SMEs are rousing intense uneasiness.

"Export conditions in the EU are [uncertain] for Russian companies," Mr Kukushkin says. "By our estimation, up to 20 per cent of exports are planned to reorient in other countries at the initial stage."

The RCU joined the international chemical industry's Responsible Care programme last October. Its acceptance was facilitated by having worked closely with the Chemical Industry Federation of Finland (CIFF) to prepare for Responsible Care adoption, for example, through exchanges of experts.

Adoption of Responsible Care is regarded by the RCU as a basis for effective REACH implementation, although the union adds that it is at a very early stage. "It is difficult to move from "zero point", but we understand that this programme is the first step to entry into the international [trade association] community, " Mr Kukushkin says.

The RCU is implementing Responsible Care 'safety and quality assessment systems" for its transport and logistics operations.

One feature distinguishing chemicals trade with Russia from that with EU countries has been the nature of the products involved. Traditionally, Russian imports have comprised mainly oil products and basic chemicals.

However, Hannu Vornamo, general director of CIFF, believes that Russian exports to Finland and other EU countries might be about to diversify.

"Thus, cooperation over proper implementation and information exchange on the REACH system is still more important for continuing chemical trade in the European area as well as globally," Mr Vornamo stresses.

REACH is only a regional solution to the global problem on chemical safety. If the aim is to improve global chemical safety and to boost innovation it should be widened worldwide, he feels.

If businesses refuse or cannot observe the rules of REACH in all parts of an industrial chain, access for Russian exports into EU markets will be closed.

"If the result of REACH is that production and use of the most hazardous chemicals migrates outside Europe to countries where safety issues are much lower on the agenda, one might consider it as a step backward not forward," Mr Vornamo warns.

Juha Pyötsiä, CIFF assistant director, warns that implementation of the REACH Regulation will be extremely demanding for importers.

He cites several pressing questions concerning the quality of test data, ownership of original studies, intellectual property rights, competition legislation, confidential business information, cooperation between companies, effects on R&D and consistency of REACH requirements with World Trade Organization rules.

# Crucial role for distributors in REACH implementation

**EU chemical distributors are gearing up to play key roles in REACH implementation as conduits of data between suppliers and customers on thousands of chemicals.** Sean Milmo **reports.**

During negotiations of the REACH text, the focus was on ensuring that manufacturers take responsibility for the risks of chemicals entering into the EU. The fact that many chemicals enter the EU market and are supplied to customers through distributors, however, was somewhat fudged under the Regulation. Nonetheless, distributors are now carving out their own places in the regime.

"There is no doubt that distributors will play a key role in implementing REACH," says Hendrik Abma, director general of the European Association of Chemical Distributors (FECC). The body represents 1,400 distributors, which account for 80-90 percent of the total in Europe.

"REACH demands a significant contribution of information in the supply chain and chemical distributors have a crucial place between producers and downstream users," Mr Abma continues.

"Distributors often have a large product range and customer base, compared with producers," he adds. "The challenge will be communication of the relevant information to the appropriate partner in the chain, such as properties of the substances, use information or conditions for safe use." In cooperation with the European Chemical Industry Council (CEFIC), FECC has drawn up a standardised supply chain communication procedure to make this communication more efficient and accurate.

Among distributors in the EU, most of whom serve local customers, there are several large pan-European operators with subsidiaries or affiliates giving them a network across the region supplying thousands of companies.

Brenntag of Germany, now one of the world's biggest chemicals distributors after a series of acquisitions, has more than 100,000 European customers with a portfolio of around 25,000 chemicals from over 5,000 suppliers.

Because a large proportion of the chemicals which distributors handle come from outside Europe, they will in some cases be registering many more substances than even the largest chemical producer in the EU. A lot of the products going through distributors are imported formulations, leaving distributors with the task of breaking them down into individual substances for single registrations. Brenntag says that all the substances it supplies will be pre-registered under REACH to ensure their future availability. For some distributors, not all the chemicals in their existing portfolio will need to be registered because they are already covered by other EU legislation on products like pharmaceuticals and food ingredients.

"Out of the 20,000 chemicals we supply, around 10,000-15,000 which are not pharmaceutical or crop protection chemicals or food ingredients will need to be registered," says Peter Fields, chief operating officer of Azelis Group, another large distributor which operates in 26 European countries.

"We ourselves will probably register around 2,000 of those because they are core products in our business. With the others we will have to decide on the basis of costs and commercial factors whether we ourselves or the supplier or someone else does the registration. There will be a lot of data to collect, particularly on uses. Citric acid, for example, is a food ingredient but it is also a substance for cleaning products, which brings it under REACH."

Azelis, in common with some other distributors, is planning to pre-register – and perhaps later even register – substances which currently they are not even selling.This is to ensure that they have provided details of all substances that they may possibly sell in the future.

The Chemical Business Association (CBA), representing UK distributors, estimates that a distributor wanting to take into account other future possible combination of raw materials may have to more than quadruple its number of pre-registrations.

PHOTO CREDIT: Danny Cornelissen


**Distributors have a crucial place between producers and downstream users**

**'The challenge will be communication of the relevant information to the appropriate partner in the chain'**

**– Hendrik Abma, FECC**

"We're being proactive on behalf of suppliers," says Mr Fields, whose Azelis Group will be pre-registering chemicals outside its present portfolio. "It will make it easier for suppliers, for example, to change their formulations."

Azelis is one of a number of larger distributors which offers an 'only representative' (OR) service to companies exporting products into the EU. An OR is effectively the EU-based legal entity of a non-EU company. It can be appointed by overseas manufacturers, formulators or article producers to take on REACH compliance duties, in particular pre-registration and registration of substances on their behalf.

"We have around 80 non-European manufacturing suppliers who are exporters into Europe and feel they cannot handle the complexities of REACH so they have asked us to become their ORs," says Mr Fields. "We have, as a result, set up an OR system as a commercial service ."

There have been claims that distributors taking on OR responsibilities may find that they are confronted by conflicts of interest because they could have access to data about the activities of other competing distributors in the EU.

"Although the OR receives some information from other distributors wishing to use the same supplier, this will be of a non-competitive detail or advantage," says Michael Cooke, director for safety, health, environment and quality at Univar, one of Europe's largest distributors.

Although Univar is planning to become an OR for suppliers, it is wary about the expense of the job. "The costs of acting as an OR may be very high so each case will be evaluated in detail before we are able to agree to act as an OR," says Mr Cooke.

ReFaC, a REACH services company set up by around 15 UK distributors, hopes that its own OR service will be able to take advantage of concerns about conflicts of interest. Although owned by distributors, ReFaC says it does not act as a commercial competitor within the chemical industry, and so, it argues, the non-EU manufacturers that it represents will not need to worry about retaining a freedom of choice of importers throughout Europe.

"A lot of these non-EU suppliers using a single distributor as their OR will have other distributors handling their products within the EU, " says ReFaC's company secretary Peter Newport who is also CBA director.

ReFaC also offers services as a 'third party representative' to EU suppliers, enabling them to remain anonymous during the registration process to all but the European Chemicals Agency (ECHA), in order to protect confidential information in registration dossiers. Individual distributors are also putting themselves forward as third party representatives.

Confidentiality will increasingly become an issue for distributors as they are expected to become major contributors to the exchange of information on uses for registration purposes. They will also have responsibility for communicating chemical safety reports back down the supply chain to downstream users.

"We have worked closely with some of our suppliers and customers to develop effective ways of handling data flows under REACH," says Univar's Mr Cooke. Once use data have been finalised, his company intends to ensure they are shared with its customers, and where a use is not covered, it will facilitate discussions on the best ways of registering it. "Confidentiality issues will be one of the biggest problems for our customers," he predicts.

According to FECC's Mr Abma, European distributors supply products to over one million downstream users – many of which are SMEs. "The chemical distributors who supply these small users across Europe will play a vital role in terms of communication of information" he says. "Our members provide technical support and compliance advice, which are particularly needed for small users. Moreover, they have a good knowledge of the applications of substances and preparations and can therefore offer a customised service to their customers."

PHOTO CREDIT: w:User:Paranoid


**In some cases distributors will be registering many more chemicals under REACH than even the largest EU producer.**

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* EU body to review biodegradability of detergent ingredients 04-Apr-08 **chemicalwatch.com/605**
* New restrictions on fragrances under EU cosmetics directive 04-Apr-08 **chemicalwatch.com/607**
* EU body to judge safety of UV filter, vitamin K1 in cosmetics 04-Apr-08 **chemicalwatch.com/606**
* **CW article** EU classification and labelling law moves on 03-Apr-08 **chemicalwatch.com/603**
* MEPs urged to act on hormone-mimics linked to breast cancer 02-Apr-08 **chemicalwatch.com/589**

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## International policy



## National policy



## Industry REACH news



## Other industry news



## Other news

# North American nations make progress on SPP

**Canada, Mexico and the USA have each put in place plans to implement a commitment made last summer to enhance chemicals assessment and risk management, as part of a Security and Prosperity Partnership (SPP).** Francis Gillis **and** Emma Chynoweth **report.**

The SPP pact is widely promoted as a model for developed and less developed nation cooperation. It aims to enhance regulatory cooperation and accelerate actions to protect humans and the environment from the harmful effects of chemicals, while allowing each country to maintain its regulatory sovereignty. Moreover, it plans to achieve this in a cost-effective way.

Each country is starting from different points in terms of the level of information already available on the risks of chemicals in commerce. Canada is ploughing on with an assessment programme begun in 1999, the USA is extending its voluntary programme on high production volume (HPV) chemicals, while for Mexico, the most important milestone is to put in place an inventory of chemicals and build capacity to disseminate information on risks.

## Progress on risk prioritisation

The American commitment under SPP was publicised under the new brand of the Chemicals Assessment and Management Program (CHAMP) at the recent 'global chemical regulations' conference organised by the American Chemistry Council (ACC) and the Synthetic Organic Chemical Manufacturers Association (SOCMA). The Environmental Protection Agency (EPA) highlighted progress on its aim to deliver risk characterisations for HPV chemicals, building on hazard assessments of 200 HPV substances. It published the first 19 risk-based prioritisation documents in March

***CW* Article 18 March 2008**.

By 2012, the agency aims to assess and initiate action where necessary on over 6,750 organic chemicals produced in the USA in quantities above 25,000lbs/year (11 tonnes per year). The total includes 2,750 HPV and some 4,000 'medium production volume (MPV) chemicals.

The HPV Challenge Program was originally launched in 1998 to fill basic hazard data gaps that existed for many large volume chemicals. The initiative involves the EPA, NGO Environmental Defense Fund (EDF), the American Petroleum Institute (API) and ACC. The aim was to collect hazard data for chemicals produced or imported in the USA in quantities of one million lbs/year or more, accounting for an estimated 95% of the commercial chemicals market by volume.

**The ultimate goal is a single integrated screening level risk characterisation for each of the HPV chemicals by 2012, and a preliminary idea of next steps.**

**– Jim Willis, EPA**

Under the programme, chemical manufacturers and importers agreed to sponsor and collect basic hazard data for 2,750 organic HPV chemicals. For these substances, the USA will complete risk characterisations and take action, as needed, by 2012.

## Chasing 'orphans'

EPA spokesperson Jim Willis says that the Agency now has at least screening level hazard data – equivalent to OECD 'screening information data sets' (SIDS) – provided by the chemical industry on most, though not quite all, of the sponsored HPV chemicals. There are a number of unsponsored or "orphan" chemicals that EPA is "chasing via the regulatory process." This gap will be filled "in due course," Mr Willis says.

Mr Willis says the EPA will release basic hazard characterisations "on an *ad hoc* basis." At the same time, the Agency is enhancing its data with human and environmental exposure information. The ultimate goal, he adds, is to have by 2012 a single integrated screening level risk characterisation for each of the HPV chemicals and a preliminary determination of next steps, guided by risk-based prioritisations.

Where no further action is required, a document covering the initial prioritisation will be posted on the web. Where additional information or action is needed, the EPA has a menu of options to choose from:

* Contact producers with a request for information or informal action;
* Obtain data from other sources such as the OECD or Canada;
* Implement Toxic Substances Control Act (TSCA) reporting rules including, for example, exposure or release data;
* Implement TSCA significant new use rules;
* Engage with stakeholders to pursue voluntary action;
* Implement TSCA testing rules;
* Develop or implement programmes, such as the HPV Challenge, or other risk reduction actions;
* Initialise creation of a 'risk list' under TSCA.

## First MPV characterisations

Director of the EPA's Office of Pollution Prevention and Toxics Charles Auer says the potential facility within TSCA to create a risk list has never been used, but might provide an incentive to improve stewardship. However, he adds that such a step might require additional legislation and the introduction, as a minimum, of a "may present an unreasonable risk" classification.

Available data for the approximately 4,000 MPV organic chemicals covered by the USA's SPP commitment is "less robust" than that for HPV chemicals says Mr Willis. The Agency will publish the first MPV characterisations later this year. It will apply categorisation results from Canada's chemicals management plan to help in its assessment of MPV chemicals.

The EPA has also announced two other goals – to improve monitoring of the number of chemicals used commercially in

the USA (see box) and to introduce assessment of inorganic HPVs.

"We believe this effort would provide the Agency, industry, and the public with a more complete picture of the hazards and risks of all HPV chemicals presently used in US commerce," EPA administrator Stephen Johnson told the GlobalChem conference.

James Gulliford, assistant administrator for the EPA's Office of Pollution Prevention and Toxics, announced that inorganic compounds would be included for the first time in the 2006 Inventory Update Reporting (IUR) programme, which is in the process of being published.

The Agency estimates that between 400 and 500 HPV inorganic chemicals will be affected. It is planning to apply established EPA and OECD guidance to determine data needs for inorganic chemicals and is currently identifying stakeholders with which to develop the programme. No exposure data are expected until 2011.

**'We believe our efforts will provide the Agency, industry and public with a more complete picture of the risks of HPVs used in US commerce'**

**– Stephen Johnson, EPA**

ACC's managing director of regulatory and technical affairs Mike Walls says it is still assessing the impact of including inorganic chemicals under the programme. Overall, the ACC has long-supported the SPP agreement: "It is a reasonable way of leveraging existing information in the region," says Mr Walls.

## Canada's rapid screening

In 1999, Canada became the first country in the world to undertake systematic examination of chemicals with the implementation of its Environmental Protection Act. This saw, by 2006, some 23,000 substances categorised in terms of persistency, ability to bioaccumulate, toxicity and likelihood of human exposure. These were "existing" chemicals in commerce in the three years before 1987 and had been registered on the Domestic Substances List.

In late 2006, the Canadian government launched its ambitious chemicals management plan based on the completed categorisations. The programme quickly determined that, of the 23,000 substances, 19,000 can be used without needing further assessment.

The remaining 4,000 substances were initially earmarked for assessment, but a rapid screening approach is whittling that number down. So far, 700 substances have been assessed as posing no risk to the environment or health. Summaries of all government assessments and recommendations are made public in draft form and are subject to stakeholder review and comment.

Under the chemicals management plan, approximately 200 chemicals have been prioritised as potentially harmful to human health or the environment. The government is now challenging industry to provide new information about how it is managing these substances. To date, the release of information is on track so that screening assessments for all 200 substances should be completed within three years, with risk management actions to be in place within a further three years. Canada's goal is to complete the entire chemicals management plan by 2020.

## Impressive results

All "new" substances in Canada undergo pre-manufacture or pre-market assessment and, if a health risk is identified, the substance or product is controlled or even banned. Roughly 800 new chemicals and polymers are introduced into the Canadian market each year.

Gordon Lloyd, vice president of technical affairs at the Canadian Chemical Producers' Association (CCPA), says the approach and achievements of the Canadian programme are impressive – and should be applied globally.

The programme offers potential synergies with the US programme – the EPA is thought likely to apply Canada's streamlined approach to determine the chemicals that can be set aside as low risk, and those that need to be investigated further. At the same time, the SPP agreement will allow Canada to use the results of US assessments of HPV and MPV chemicals.

"The Canadian and US approach indicates that most chemicals in commerce don't need to be assessed or re-assessed, based on current information" Mr Lloyd says. "The industry can use those chemicals, knowing there is a greater degree of public confidence in them. This should boost our competitiveness."

## NGO reaction

Dr Kapil Khatter of Toronto-based Environmental Defence describes Canada's chemicals management plan as "just getting going," but agrees that, so far, the assessment process is efficient and effective. He notes that most attention since the programme's launch has been on the 200 substances for which the government has challenged industry to provide information. He feels the draft assessments of the first batch of 15 chemicals, now published for public comment, are well done and are based on a reassuringly conservative approach.

There is little information on what actions the government will take to manage these chemicals, says Dr Khatter. However its intention appears to be to move as fast as it can. It is trying to look at risk management options and work with industry from the start rather than waiting for completion of the assessment process. "At least that's what they're telling us."

The chemicals management plan features an expert stakeholder advisory panel with a mandate to vet the government's application of the precautionary principle in assessing the 200 challenge substances. Asked if the precautionary principle is being effectively applied, Dr Khatter says he thinks it is, at least to date in terms of assessment (as opposed to management) of substances. On the SPP chemicals agreement, Dr Khatter says Environmental Defence has concerns about the potential "harmonising down" of standards, but so far has not seen any regulatory outcomes. "We support

better sharing of information," he adds, "as long as the Canadian government retains the right to its own decision-making regarding assessments."

### Mexico makes good progress

Under the SPP agreement, Mexico has committed to establish an information system for dangerous materials by 2012, and by 2020 its objective is to have an enhanced capacity to assess and manage chemicals and to have developed a substance inventory.

Speaking at the GlobalChem meeting, the EPA's Mr Auer said Mexico had made good headway since signing the agreement thanks to strong support from its domestic environment agency coupled with technical assistance from the USA and Canada. A workshop to discuss the scope of the dangerous materials information system involved several government agencies, industry, academia and NGOs.

Meeting earlier this year, the Sound Management of Chemicals (SMOC) group of the NAFTA Commission on Environmental Cooperation (CEC) committed funds to help Mexico develop guidance documents for its dangerous substance information system and to collect a list of chemicals currently regulated in Mexico.

Officials from the US, Canadian and Mexican governments have a range of opportunities to discuss chemical issues, for example at workshops of the tri-national CEC SMOC – which focuses on regional implementation of the Strategic Approach to International Chemicals Management (SAICM) in North America.

**'We support sharing of information, as long as the Canadian government retains the right to its own decision-making'**

**– Kapil Khatter, Environmental Defence**

The SPP effort aims to complement SMOC's work to achieve four key objectives:

* To establish a foundation for chemicals management across North America;
* To develop and implement a sustainable regional approach to monitoring, including biomonitoring;
* To reduce the risk from chemicals of mutual concern to North America;
* To improve the environmental performance of sectors.

According to the EPA's Mr Willis, "we have quite a number of bilateral phone calls with Canada regarding how best to connect their [management of chemical] issues with ours." Such phone calls take place "at least once a month," and there are frequent face-to-face meetings.

There are also opportunities for synergies between SPP chemical assessment work and REACH, according to Mr Auer, particularly given their similar time frames. Data can be transferred to the benefit of both schemes, he feels.

### REACH or Canada's approach?

CCPA's Mr Lloyd contrasts Canada's chemicals management plan with the REACH system, for which "reams of information must be provided on all chemicals in commerce."

That the USA is building on the Canadian program, he says, will prompt other countries to make a choice. They can follow Canada's approach, or they can choose the "much more all-encompassing and complex" REACH approach, or another alternative.

He acknowledges there are opportunities for trans-Atlantic cooperation on the assessment of chemicals, but fears REACH will not allow foreign companies to use data, even if already submitted to other regulatory agencies, or will "force them to provide information through consortia of European companies with associated costs and potential anti-competitive constraints of market entry."

# Refreshing the TSCA inventory

**The central statute covering the management of chemicals in the USA is the Toxic Substances Control Act (TSCA), passed by Congress in 1976 to give the EPA the ability to track the industrial chemicals then produced or imported into the country.**

The Agency can require reporting, testing and restrictions of any substances on the TSCA inventory that may pose an environmental or human health risk. Since 1979, chemicals developed or marketed for the first time have had to be assessed under a 'New Chemical Review' law.

The original (1979) TSCA inventory of 62,000 "grandfathered" chemicals, together with 21,000 "new" chemicals added since 1979, gives a total of 83,000 chemicals in the current TSCA Chemical Substance Inventory. But the American Chemistry Council (ACC) estimates that only about 10 percent of these chemicals are actually bought and sold in the USA today.

EPA representatives say it is likely that many of the 83,000 chemicals are no longer manufactured or imported, or they are produced only in low or episodic volumes. It has announced plans to revise the inventory to better reflect the chemicals actually used by businesses in the USA. "By resetting the inventory, we can more effectively manage those chemicals actually in use, and thereby avoid debate focused on chemicals that are only theoretically in commerce," says EPA administrator Stephen Johnson.

The Agency's James Gulliford notes that it has a legal obligation to "compile, keep current, and publish [the] TSCA Inventory". It will consult stakeholders in doing this, he says.

There is some debate within the chemical industry over the value of revising the inventory, with some regarding it as a waste of time. However, ACC's Mike Walls argues that it is important we know what is on the market in North America. "Those who are seeking substantial reform in TSCA have been able to get away with saying there are 80,000-100,000 chemicals on the market – that is plainly not the case." But the review should use industry and agency resources minimally, he warns.

# LATEST FROM REACH TOOLKIT

What's new on the *Chemical Watch* REACH Toolkit. For links to these and more than 50 other REACH-related resources, visit:

**www.chemicalwatch.com/toolkit**

## EU REACH legislation

✱ Commission Regulation on the fees and charges payable to the European Chemicals Agency
Council of the European Union
Adopted April 2008

✱ Draft Commission Regulation laying down test methods pursuant to REACH Regulation
European Commission
Adopted March 2008

## ECHA Resources

✱ Pre-registration website
European Chemicals Agency
Launched April 2008

✱ FAQs on REACH
European Chemicals Agency
Updated April 2008

✱ IUCLID 5 training videos
European Chemicals Agency
Issued April 2008

✱ IUCLID 5 plug-in
European Chemicals Agency
Issued March 2008

## European Commission REACH documents

✱ REACH pre-registration and registration Q&As
European Commission
Issued April 2008

## EU technical guidance on REACH

✱ Guidance on registration (from RIP 3.1 project)
European Chemicals Agency
Amended April 2008

# EVENTS

For contact details relating to these events, and to have your events listed here, visit:
**www.chemicalwatch.com/events**

### 7 May 2008
Risk management for nanobusinesses
European Nanotechnology Trade Alliance, London
Half-day introduction to risk management techniques for individuals involved in nanotechnology research and development
Website: **Workshop details**

### 7-8 May 2008
IUCLID 5 training for REACH registrants.
REACHReady, London
Hands-on practical exercises to teach you how to produce your REACH registration dossiers using IUCLID 5.
Website: **Training details**

### 12-15 May 2008
Regulation of agrochemicals in Europe
Informa Life Sciences, Brussels
Keep up to date with regulatory requirements, feedback on reviews and progress with worksharing initiatives
Website: **Conference details**

### 13 May 2008
All you need to know about pre-registration
REACHReady, Manchester
Workshop covering the latest on how to gather information needed to pre-register and how to submit pre-registration to ECHA using the REACH IT system
Website: **Workshop details**

### 16 May 2008
Pre-registration in practice.
ReachCentrum, Webinar
The practicalities of pre-registration. The various tools and how best to optimise time during compilation of registration dossiers.
Website: **Training details**

### 20-22 May 2008
Conference on chemical safety
Helsinki REACH Centre
Meeting chemical companies, service providers and importers, just days before REACH pre-registration period begins
Website: **Conference details**

### 21-22 May 2008
White biotechnology European summit
Informa Life Sciences, Frankfurt
A specialist event dedicated to the chemicals and materials industries in Europe
Website: **Event details**

### 29 May 2008
REACH for business managers
ReachCentrum, Brussels
This workshop gives business managers with a basic understanding of REACH. Find out the scope of REACH and its likely financial and strategic impact on your business
Website: **Workshop details**

### 29 May 2008
Effective tools for consortia management
The REACH Centre, Haydock
This course provides a tool kit for consortia/SIEF management – the do's and don'ts relating to competition law, how to manage data sharing under REACH, how to protect confidential business information
Website: **Course details**

### 29 May 2008
Importing goods into the EU – what REACH means for you
REACHReady, London
This workshop, jointly organised by LGC and REACHReady, will bring the latest information on what REACH means for "articles" and explain how to comply
Website: **Workshop details**

### 29-30 May 2008
REACH SIEF and consortia business essentials
REACHReady, Manchester
This programme will equip attendees with presentation, negotiation and questioning skills and the essential technical knowledge to give the edge within SIEFs and joint registration consortia
Website: **Programme details**

### 20 June 2008
Successful substitution beyond REACH
Defra, London
Organised by the UK's Environment Ministry and its Chemicals Stakeholder Forum. This conference will examine obstacles and opportunities in relation to chemical substitution, with presentations on textiles, plastics and cleaning products
Website: **Event details**

# Twelve tricky pre-registration questions answered

*Q1. Do cosmetic ingredients need to be pre-registered?*
Yes, unless exempt. Importers of finished cosmetics face the unintended consequence that some ingredients may currently not meet phase-in status. The European Commission and affected stakeholder groups are attempting to find a suitable solution **CW European Business Briefing January 2008**.

*Q2. Does the ink in a pen need to be pre-registered?*
Yes, if imported. A pen is considered as an article (delivery system) containing a preparation (ink). The substances in the ink must therefore be pre-registered, either at point of manufacture or import.

*Q3. Do chemical substances in a cleaning wipe need to be pre-registered?*
Yes, if imported. Just as with a pen in Q2, the substances in the cleaning wipe are considered as part of a preparation. The wipe material is considered separately as an article (delivery system).

*Q4. Do substances 'intended to be released' from an article need to be pre-registered?*
Yes, if imported and also when an article is produced in the EU. Some substances will be considered 'intended to be released' from articles rather than 'substances in delivery systems'. Current understanding is that a producer of such an article, must pre-register relevant substances even if these are already pre-registered by an EU manufacturer or an importer in that same supply chain.

*Q5. Do re-imported substances need to be pre-registered?*
Yes, in all likelihood. Some regulators may take a pragmatic view of allowing re-import if you can demonstrate that the substance is the same as one that is already pre-registered in that specific supply chain (e.g. with analytical data). Nevertheless, the advice is to pre-register.

*Q6. Must an Only Representative submit multiple pre-registrations for the same substance, if appointed by several non-EU companies in different supply chains?*
Yes, in all likelihood. The European Commission has clarified that the Only Representative must submit one registration per non-EU company it represents (according to substance and supply chain). This indicates that a corresponding pre-registration should be submitted on behalf of each relevant non-EU company.

*Q7. Can substances with an ELINCS number be pre-registered?*
Probably not. Substances that appear on the European List of Notified Substances (ELINCS) are considered as 'already registered'. Companies holding a notification for these substances must apply to the European Chemicals Agency for a registration number rather than pre-register. Any non-EU company must ensure that a Sole Representative under previous legislation is replaced with a REACH Only Representative.

*Q8. Can phase-in substances be registered immediately?*
No, an inquiry must first be made. This inquiry can commence after pre-registration. An 'early bird' registration can then follow.

*Q9. Should reaction masses be pre-registered?*
Yes, unless a company has reasons to only separately pre-register the constituents. In many cases, when following RIP 3.10 guidance on the identification and naming of substances, both the reaction mass and the separate constituents may be pre-registered. Engaging in all the 'substance information exchange fora' (SIEFs) may then facilitate an assessment of available data for the reaction mass and the constituents.

*Q10. Will there be a pre-registration template that can be easily used?*
Yes, it is expected that the European Chemical Industry Council (CEFIC) and the oil industry group for Conservation of Clean Air and Water in Europe (CONCAWE) will release a user-friendly pre-registration template that companies can use for substance inventories. Alternatively, companies can use IUCLID 5 for creating files. Regardless, pre-registration must always be made via the REACH-IT system. Some companies will choose to just manually enter data directly into REACH IT.

*Q11. Will the Agency publish the names of all pre-registered substances?*
Yes, in all likelihood. Companies that want a name for a substance to appear on the ECHA list of pre-registered substances should pre-register accordingly, e.g. INCI (International Nomenclature Cosmetic Ingredients) names for EINECS (European Inventory of Existing Commercial Substances) entries. While companies may need to protect confidential information, they must ensure that data-sharing is maximised and appropriate SIEFs can be formed.

*Q12. Will the first pre-registrant become the SIEF formation facilitator if no one in the pre-SIEF volunteers?*
Probably not. Because a SIEF formation facilitator does not exist in the legal text of the REACH Regulation, it is expected that this role will always remain voluntary. However, the possibility of being a SIEF formation facilitator will occur on a first-come-first-volunteer basis. Confirmation and further clarification on the process of designation is anticipated in the next few weeks.

**Send questions to Dr Steffen Erler and read his previous answers**
**http://chemicalwatch.com/dr_reach**

# End of OR controversy? Probably not

**Of all the issues and areas of uncertainty addressed by the REACH Implementation Projects (RIPs), the provisions on Only Representative (OR) have certainly been among the most controversial, write** Giovanni Indirli **and** Jean-Philippe Montfort**.**

Initially, the debate centred around the concerns expressed by non-EU based companies wishing to see more flexibility in which entities in the supply chain could appoint an OR. The situation changed dramatically and in February 2008 the European Commission came forward with an unexpected "clarification" of the role of the OR, which would likely have put non-EU companies at a competitive advantage over EU companies. Most recently, and while some non-EU based exporters were planning to adapt to this new development, the Commission has made a U-turn. In April it announced at a conference on pre-registration its new interpretation of the REACH OR provisions ***CW* Article 14 April 2008**.

The latest Commission interpretation of the OR provisions is one of the most spectacular developments since the launch of the RIPs. Its previous position, as reflected in the updated February 2008 guidance document on registration, was that the OR should be regarded as an importer in its own right, with the following consequences:

* Once the OR has pre-registered and registered, the OR becomes the exclusive owner of the (pre-)registration. The principal/non-EU manufacturer has no right whatsoever to the (pre)registration: they cannot transfer it to another entity nor can they invalidate it by putting an end to the original mandate;
* If the same EU entity is appointed as OR by two or more non-EU manufacturers of the same substance:

- the OR is regarded as a single potential registrant for data and cost-sharing purposes
- only one registration should be submitted and only one fee should be paid;
- the quantities exported by non-EU manufacturers the OR represents should be aggregated for the purposes of information requirements and the fee to be paid.

The Commission's previous interpretation took everybody by surprise. It was contrary to what industry had always believed was the role of the OR and was not even requested or lobbied for by the non-EU industry.

## Common understanding

Importantly, the text of the recently adopted Regulation on fees and charges approved by the REACH Regulation's regulatory committee at the end of 2007 seems be based on the initial, common understanding of the role of the OR ***CW Newslink* 16 April 2008**. The Commission interpretation, as made clear in February 2008, would have enabled exporters of high volume commodity chemicals to considerably reduce registration costs by appointing a single EU entity as OR for all of them, with the consequences mentioned. Most importantly, they would have been able to claim equal sharing of the cost of data, which is the default rule in case of disagreement between potential registrants in a SIEF as stated in REACH Article 30(1). Aggregation of quantities would have had no impact on them in terms of increased information requirements and higher fees as the individual quantities being exported would already be above the highest tonnage threshold. As a result, the costs of registration for each non-EU manufacturer would have been only a fraction of those incurred by EU manufacturers – an inequality which did not escape the attention of certain Member States like the UK.

PHOTO CREDIT: Fiona Swan

Contrary to the Commission interpretation of February 2008, the common (and initial) understanding of the role of the OR has always been that it is nothing more than what its name suggests, a representative of the non-EU manufacturer. As such, its role is to act on behalf of and, we believe, in the name of the non-EU manufacturer, meaning that the OR does not ultimately have ownership of the REACH (pre-) registration but rather the non-EU manufacturer does. In line with this understanding, if the OR loses its status as OR, it and its successor could submit an update of the current registration, still linked to the non-EU manufacturer, in line with the current system for 'sole representatives' of non-EU manufacturers in the framework of the notification regime under the Directive 67/548/EEC on classification, packaging and dangerous substances, as amended by Directive 92/32/EEC.

## Practical consequences

If the Commission – and stakeholders, including Member States – decide to go along this route, the expected practical consequences would be that:

* The appointed OR entity in the EU (pre-) registers and the identity of the non-EU manufacturer(s) they represent should be included in the (pre-)registration dossier;
* If the same entity is appointed as OR by two or more non-EU manufacturers of the

same substance, the OR:
- is regarded as multiple potential registrant for data and cost-sharing purposes;
- will have to submit as many separate (pre-) registrations and pay as many fees as the number of non-EU manufacturers they represent, with information requirements and level of fees depending on the aggregation of quantities restricted to the same supply chain.

The latest Commission interpretation of the OR provisions is good news for EU-based industry, whereas exporters who have relied on the earlier Commission interpretation will now have to reconsider their REACH compliance strategies and budgets.

## Review

Is this the end of the story? Unfortunately it does not look like it. The details and the practical effects of the proposed new interpretation which we attempted to outline above still need to be confirmed and there might still be surprises on other important aspects of interest to exporters, where the Commission is currently reviewing the strict interpretation taken by the ECHA and the REACH helpdesk network.

The main issue here is whether a non-EU manufacturer of a substance or a non-EU formulator of a preparation can appoint an OR for a substance on their own or in a preparation or in a polymer which they do not export themselves, in other words, the issue is whether an OR can cover "indirect" imports. There may be several scenarios. We have selected three not to overly complicate the analysis:
1. A non-EU manufacturer supplies the substance to a non-EU distributor who then exports it to the EU;
2. A non-EU manufacturer supplies a substance to a non-EU formulator who then exports a preparation containing the substance as constituent to the EU;
3. A non-EU manufacturer supplies a monomer to a non-EU polymer manufacturer who then exports it to the EU.

## Different interpretation

Article 8 provides that an OR may be appointed by "the manufacturer of a substance, on its own, in a preparation or in an article, the formulator of a preparation or the producer of an article" that is imported into the Community. The non-EU industry argues that all the relevant actors up the non-EU end of the supply chain – manufacturers of substances, including monomers and polymers, formulators and article producers – should be permitted to appoint an OR and that should this actor be the non-EU manufacturer, all actors concerned should be able to decide by mutual agreement which "indirect exports" will be covered by the OR. In previous opinions, ECHA and the REACH Helpdesk network indicated that they did not share this interpretation. In their view, only the company that has manufactured the product that is exported to the EU may appoint an OR and indirect imports are covered only in the case of exports via non-EU distributors, including

PHOTO CREDIT: Akzo Nobel

distributors of preparations and articles. As such, their answers for each of the above scenarios would presumably be as follows:
1. The non-EU manufacturer of the substance can appoint an OR as the product imported is the substance itself, even if it is exported by a distributor;
2. Only the non-EU formulator may appoint an OR as the exported product is the preparation;
3. We are not aware of any clarification having been given for this scenario. However, in the light of the interpretation outlined above, their answer would probably be that only the non-EU polymer manufacturer is entitled to appoint an OR as the substance imported is the polymer, not the monomer.

## New clarification

The Commission and the ECHA reiterated this interpretation during discussions with stakeholders during finalisation of the updated guidance on registration in February 2008. However, the new clarification is not clearly reflected in the new version of the guidance. While it is expressly stated that non-EU manufacturers of substances on their own are permitted to appoint an OR in the case of exports via a non-EU distributor, the guidance does not address the other scenarios. This may be a deliberate choice.

## Potential obstacle

The Commission's Legal Service has been asked to give an opinion on these issues, which should be made available shortly. It is hard to predict the outcome of this consultation. Clearly, the absence of flexibility may constitute a major obstacle in cases where the information to be communicated down the supply chain is regarded as Confidential Business Information (CBI). The non-EU manufacturer can avoid disclosure by requiring non-EU actors down the supply chain to appoint an EU entity they trust as OR for the substance concerned, such as one of their EU affiliates. However, this would require agreement between all actors in the supply chain, which may prove difficult in many cases. In fact, the non-EU manufacturer would be able to identify through the OR the ultimate recipients/customers/importers in the EU, which their direct customers may well regard as CBI.

What are the next steps? The Commission and ECHA should present their new position to the Member States and other stakeholders, and seek to reach consensus, after which ECHA will publish updated guidance on registration, with new clarification of the OR scheme.

With the deadline of 1 June approaching, we can only hope that the new clarification and the solutions proposed will be convincing enough to avoid risks of compliance failures and litigation.

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*Giovanni Indirli and Jean-Philippe Montfort are members of the REACH team of Mayer Brown, a global law firm with extensive experience in the field of chemicals regulation*
**www.mayerbrown.com**

# NGOs will press consumer rights under REACH

**Under REACH, consumers for the first time have the legal right to obtain information about whether the products that they purchase contain substances that are toxic to their health and the environment. Consumer access to this information will be triggered by release of the first 'candidate list' by the European Chemicals Agency (ECHA).**

The list will contain "substances of very high concern" that have been identified as carcinogenic, mutagenic or toxic to reproduction or that are persistent and bioaccumulative or warrant equivalent concern for serious effects. Industry will have to apply for authorisation to continue using these substances once they have been moved to the 'working list' for authorisation.

By empowering consumers to obtain information on which hazardous substances are in the products that they buy, REACH allows consumers to exercise their right to choose. By choosing not to purchase products containing substances on the candidate list, consumers can signal their preference for toxic-free products. It is important that retailers transfer the market signal to suppliers by demanding information on potential substances of very high concern in products well in advance of publication of the list.

Producers seeking to increase their market share should interpret consumer demand for information as a signal to eliminate toxic substances from their products in favour of safe substitutes. Access to information on chemicals of very high concern in articles thus represents a powerful tool for promoting substitution. In order to help catalyse this effect, environment, health and women's NGOs are actively raising public awareness of the right to request information on hazardous substances in everyday products.

## Obligations under REACH

Article 33 of REACH outlines the obligation of suppliers to communicate information on substances in articles down the supply chain so that retailers are in a position to respond to requests for information from their consumers. As such, suppliers of articles containing a substance of very high concern in a concentration above 0,1 % weight by weight (w/w) must provide recipients with sufficient information to allow safe use of the article. Retailers must be prepared to provide consumers with this information upon request, free of charge and within 45 days of receipt of the request. The minimum information that must be conveyed down the supply chain to the consumer is the name of the substance. Retailers have the right to turn to their upstream suppliers and demand relevant information, with EU suppliers legally obliged to provide such information.

**EEB would like consumers to have access to a database of SVHCs present in every day articles**

**– Catherine Ganzleben**

## What we expect

A successful system can be expected to catalyse the flow of information down the supply chain from producer or importer to consumer regarding the presence of toxic substances in products. From the perspective of the consumer, the most appropriate and reassuring response from producers will be "we do not use substances of very high concern in our products".

But where toxic substances are present, EEB advocates using a standardised format for the systematic presentation of information in order to optimise the transfer of information and make it more digestible for the consumer. Producers concerned with delivering sufficient information to ensure protection of the environment and human health will include the following:

- One standard chemical name (CAS number, EINECS or IUPAC);
- One non-technical name or trade name;
- Classification function in the product;
- Restrictions and conditions of use and safe disposal, including relevant warnings.

In addition, EEB would like consumers to have access to a centralised database where information on substances of very high concern in articles that they may be buying on an every day basis is available. Article 7 of REACH obliges producers or importers of an article containing a candidate list substance in a concentration above 0.1% w/w and present in those articles in quantities totalling over 1 tonne per producer or per importer per year to notify the European Commission. This information should be made publicly available on ECHA's website to give consumers a one-stop site for determining which products contain substances of very high concern and as such should be avoided.

## How to get there

Identifying substance of very high concern raises practical challenges and it is clear that industry will need to be proactive in order to meet consumers' expectations. Firstly, publication of the first candidate list is expected in Spring 2009. Requests for information may immediately follow its publication, so retailers need to start demanding information from their suppliers now to be ready to respond. Secondly, the first candidate list will not include all substances that qualify as being of very high concern, but will be limited by the capacity and will of Member States to propose dossiers on specific substances by June of this year.

The list will be updated regularly, with new substances included following submission of a dossier by a Member State and their subsequent identification as a substance of very high concern. Once a Member State submits a dossier on a substance, the Agency will flag this on their website, so sending a signal on what may end up on the list. In order to bridge the gap in time and scope, proactive producers should look to existing lists of toxic substances, both regulatory and non-regulatory, as a guide to what they might expect to find on the candidate list. Producers that act early to eliminate toxic substances from their products will gain first mover advantage over competitors.

*Dr Catherine Ganzleben is EU Policy Officer for Industrial Policies and Chemicals, European Environmental Bureau.* EEB

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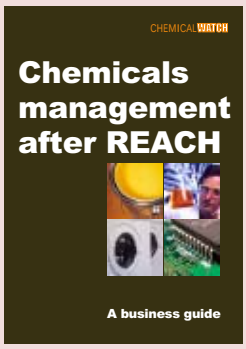


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