Nanotechnology Industries Association’s view on nanomaterials under REACH

Since the beginning of REACH, discussions have been ongoing as to how nanomaterials ought to be managed under REACH. David Carlander from NIA explains more in his guest column.

Helping SMEs

ECHA’s recently appointed SME Ambassador, Andreas Herdina, shares his thoughts about what ECHA can do for smaller companies.

Want to stay on the market with your biocidal product after 1 September 2015?

If so, you need to be on the list of active substance suppliers? This article will show you how.

Challenges for generating safe use information for mixtures

Communicating information downstream for mixtures is a complex task for industry. The practice has been for formulators to identify ‘lead substances’ to develop safe use information. “This is a good starting point,” our guest contributors say. However, mixture formulators are faced with various challenges.

Moving forward at cruising speed

Autumn has arrived in Helsinki with leaves falling from the trees and nightly temperatures falling below zero. The lovely, romantic Finnish tradition of wood fires and candles is now in full swing. (By the way, a number of you have commented on my regular references to the weather, to which my only response is “I’m British”, and you know how important the weather is for us!).

Looking back over the late summer, we passed a big milestone when the new biocides regulation became operational on 1 September. The entry into operation seems to have passed smoothly and we have already received over 1 200 different applications for biocidal products. I hope that you are finding the information you need to help you comply – take a look at the material on our website. ECHA’s Helpdesk and the national helpdesks are also ready to answer your questions. At the end of August, we published a special e-News covering biocides issues. If you missed it, you can still see it in our News section: http://echa.europa.eu/view-article/-/journal_content/title/biocides-enews-30-august-2013.

We have also checked the completeness of the registrations from the second REACH deadline. 99% of the 9 084 dossiers submitted by 3 June successfully received a registration number. The dossiers that didn’t receive a number either have to be resubmitted with additional information or have been rejected because the registrant did not pay their fees. You can see the detailed results on our REACH 2013 web section: http://echa.europa.eu/reach-2013.
There’s still one major milestone to reach this year: evaluating by the end of the year, 5% of the dossiers from the 2010 registration deadline. We are well on our way to reaching that goal and we will publish the results in early January 2014.

Next year will focus on building for the future. We have gained enormous experience from our work in the last six years: from two REACH registration deadlines, evaluating hundreds of dossiers; bringing the Biocides Regulation into operation; and the European Commission’s review of REACH. We have to build on that, profit from the many valuable lessons we’ve learned, and continue to improve. Helping small and medium sized enterprises to prepare for the 2018 deadline and fulfil their responsibilities as downstream users is one of the key development areas for ECHA in 2014. You can read more about the SME challenge on page 6.

Next year will also bring another regulation under our supervision: the revised PIC Regulation, which becomes operational on 1 March 2014, when ECHA takes responsibility from the Joint Research Centre of the European Commission. We will write more about PIC in the December issue of the Newsletter.

Finally, we have just completed our annual News readership survey, which included questions about the weekly e-News and this Newsletter. By the closing date on 10 October, over 1 300 of you had responded – that’s an increase of 1 156 respondents on last year. Thank you so much for taking your time to tell us what you think and help us to improve the service we offer. I’ve skinned through the raw results and they make very interesting reading indeed – plenty of praise but also many great ideas for improvements. Thank you. We will report back and address your main questions and comments also in the December Newsletter.

I’d also like to say a personal thank you and goodbye to Jef Maes who is shortly to leave us and take a well-deserved retirement. Jef is currently our Director of Resources and is responsible, amongst other things, for training and professional development in ECHA. Jef’s commitment to life-long learning is about to be clearly demonstrated by his next move – to train as a chef! He’s already a wonderful cook, so I can’t wait to be invited round to taste the fruits of his labour when he graduates! All of ECHA wishes Jef well for the future – he will be missed. I wish you all a great autumn.

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Guest column | David Carlander

Nanotechnology Industries Association’s view on nanomaterials under REACH

Since the beginning of REACH, which coincided more or less with the increasing political interest in nanomaterials, discussions have been ongoing as to how nanomaterials ought to be managed under REACH.

As a follow-up to the 6th meeting of the REACH competent authorities in 2008, it is stated that REACH ‘deals with all substances, in whatever size, shape or physical state’. Following the definition of ‘substance’ in REACH’s Article 3.1, nanomaterials are defined as substances, and therefore nanomaterials clearly fall under REACH (see CA/59/2008 rev. 1*). This is a notion supported by NIA.

NIA is of the view that REACH is suitable to regulate nanomaterials, and specific regulatory measures for nanomaterials are not warranted. REACH provides possibilities for requiring information beyond the ‘standard’ requirements described in Annexes VII to X and this can be used for nanomaterials on a case-by-case basis. In this regard, it is the view of NIA that REACH offers all the required possibilities for managing nanomaterials.

The most recent development for managing nanomaterials under REACH was presented as six options in a public consultation** by the European Commission that closed in September. The options ranged from status-quo to far-reaching specific requirements that may hamper European competitiveness while the added information related to health and safety considerations is, in our view, questionable and may run the risk of stigmatizing nanomaterials. The NIA is of the view that option 5, which allows for the enhancement of competitiveness and innovation, while at the same time providing information under REACH to support the safe and responsible use of nanomaterials, is the preferred option.

In the upcoming months, Member States, the European Commission, and stakeholders, including NIA, will discuss the outcome of the public consultation in several meetings. In addition to potential modifications of REACH annexes, it is noted that further modifications may be appropriate for ECHA guidance documents.

ECHA has already embarked upon this and in 2012 published specific requirements for nanomaterials in a number of their guidance documents.

The R in REACH stands for registration, and this key aspect seems to have been forgotten, as several Member States are considering, or have implemented, national nanomaterial registries. This is an unfortunate move as it hampers development and innovation, and severely increases administrative burdens. It would be an ill-fated situation if all the investments in nanotechnologies are driven out of Europe due to excessive administrative burdens in EU.

It is the view of NIA that the registration of nanomaterials in REACH is appropriate, and that additional registration initiatives should be avoided.

As one of ECHA’s accredited stakeholder organisations, NIA will continue to actively provide support and feedback on REACH in order to improve the regulation and boost its functionality for nanomaterials.

David Carlander
Director of Advocacy


** Consultation on the modification of the REACH Annexes on Nanomaterials http://ec.europa.eu/environment/consultations/nanomaterials_2013_en.htm

The Nanotechnology Industries Association (NIA) is the sector-independent expert, membership and advocacy organisation providing a responsible voice for the industrial nanotechnologies supply chains. The association is one of ECHA’s Accredited Stakeholder Organisations.

Does your organisation deal with REACH, CLP or biocides? Would you like to be featured in an ECHA Newsletter guest column? Contact us at echanewsletter@echa.europa.eu.
What happens after a decision has been made on a dossier?

ECHA has published a new fact sheet describing what happens after dossier evaluation decisions. It explains the steps after the registrant has received ECHA’s decision requesting further information by a given deadline.

The purpose of the follow-up process is to ensure that the registrant complies with the issues addressed by the dossier evaluation decision. Of course, new issues may also arise from the new information submitted.

When the deadline of ECHA’s decision has expired, the Agency will examine the dossier. ECHA checks whether the information requested in the decision has been provided and whether conclusions based on the new information are reasonable.

There are several possible outcomes:

1. **If the update is successful** and meets all the requirements of ECHA’s decision, the Agency informs the Member State competent authorities and the European Commission.

   This notification includes the new information provided and the conclusions made. The national authorities may use this information for other REACH or CLP processes, such as substance evaluation, authorisation and restriction or harmonised classification and labelling.

2. **If the registrant has not done** exactly what ECHA asked but has ensured compliance by an alternative method or adaptation, ECHA will consider it and may find it acceptable. If the Agency finds the update acceptable, it will issue the notification mentioned above.

3. **If the registrant complies with the decision but ECHA or the registrant identifies other concerns regarding the same information requirement**, the Agency may issue a new dossier evaluation decision requesting further information.

4. **If the registrant complies with the decision but ECHA or the registrant identify new concerns with other information requirements** as results of the information received, ECHA may open a new compliance check procedure.

5. **If the registrant fails to provide the required information by the deadline**, it is in breach of the REACH Regulation.

   ECHA sends a notification of this fact to the relevant Member State authorities and the registrant.

   This statement of non-compliance following a dossier evaluation decision sets out the reasons for the non-compliance with the Agency’s decision. It documents ECHA’s conclusion that a registrant has not complied within the deadline set.

Registrants should submit the information requested by the deadline set in ECHA’s decision. If meeting the deadline is not possible, the registrant should update their registration dossier and include explanations of when the pending information will arrive.

**ECHA ASSESSES UPDATED DOSSIERS ONLY AFTER THE DEADLINE**

If the registrant requires a clarification on ECHA’s decision, they should contact the ECHA Helpdesk: [http://echa.europa.eu/contact/helpdesk-contact-form](http://echa.europa.eu/contact/helpdesk-contact-form).

However, the Agency cannot change the decision or postpone the deadline. Neither can ECHA advice the registrants on any alternative strategies or approaches to fulfil the information requirements of the decision. The Agency only starts its assessment of the updated dossier when the deadline has passed.

Registrants need to submit the requested information by the deadline set. If meeting the deadline is not possible, the registrant should update the registration dossier as best they can and include explanations and proof concerning the status of the pending information requirements.

This should include the date by when the information will be made available. The national enforcement
authorities can then take this information into consideration.

**MEMBER STATES ENFORCE THE DECISION**

The national authorities in the Member States are responsible for enforcement. Based on a statement of non-compliance by ECHA following a dossier evaluation decision, the Member States will consider national enforcement actions and the registrant will need to deal with the national authorities on their case.

A communication system has been set up between Member States and ECHA to exchange information on these non compliant cases.

**Further information:**

ECHA Fact Sheet - Follow up to dossier evaluation decisions

**DID YOU KNOW?**

Dossier evaluation work involves examining testing proposals and checking dossiers for compliance with REACH.

ECHA initiates compliance checks for at least 5% of all dossiers received within each tonnage band. ECHA can decide which dossiers to check and whether only part of any dossier will be investigated. A compliance check can start at any time in respect of any dossier.

ECHA evaluates all testing proposals within set deadlines. For non-phase-in substances, the examination takes place within 180 days of receipt of a dossier with a testing proposal. For phase-in substances there are three examination deadlines (1 December 2012, 1 June 2016 and 1 June 2022) depending on the registration deadlines.
Undoubtedly, the EU chemicals legislation brings benefits for society, but there are gains for industry, too. Companies have developed a clearer insight into their product portfolios and addressed more systematically the hazards of the industrial chemicals that they place on the market. By identifying their uses, they have helped establish a better picture of the risks that merit dedicated risk management measures. Such stewardship contributes to the protection of human health and of the environment. It also helps identify potential for innovation.

Yet, the regulatory burden has its costs. Companies have needed to adapt their business and production practices. Establishing the data for dossier submissions and handling communication in the supply chain has its expense. Small and medium-sized enterprises are more limited in their means to bear as well as mitigate the effects of this burden. Some have little experience in handling their obligations under REACH or CLP. The new Biocidal Products’ Regulation requires companies even with long practice in the field to acquaint themselves with a new IT tool and novel regulatory processes. SMEs are often formulators preparing for the 2015 CLP deadline for classifying mixtures. Many will also soon be setting out to register dossiers for phase-in substances by the 2018 REACH registration deadline.

To address the challenges ahead, the European Commission attached a specific SME Annex to its REACH Review* published in February of this year, with about a dozen specific recommendations addressed to the Agency and to other actors. Over the summer months, ECHA has been looking for ways in which we can provide additional support for SMEs. These will go beyond the recommendations in the Commission’s REACH Review. However, ECHA needs to act within its boundaries. The Agency is mandated to manage the implementation of the EU’s chemicals safety legislation. It cannot grant SMEs any lenience regarding their legal obligations. SMEs are responsible for their share in ensuring the safe use of chemicals in Europe. Their compliance is imperative to manage the risks emanating from the daily use of chemicals in our modern industrialised societies. This may even result in some restructuring of the market.

Another constraint is that the voice of SMEs is difficult to hear. Small and medium-sized companies and their representatives often see the legislation, as such, as being burdensome, but may not be able to identify the support they might appreciate. To facilitate compliance, ECHA needs to be in a position to duly identify the real concerns and still unaddressed needs of SMEs, even if small and technical, in relation to ECHA’s work and regulatory processes. The Agency should not be second-guessing these needs.

ECHA also wants to reach out to the companies that are not yet aware of their obligations under the EU chemicals legislation. Evidently, readers of this Newsletter do not belong to this group, but it would serve the Agency’s aim if readers could encourage their business partners to subscribe to it and to ECHA’s e-news to help us to make other companies aware of their responsibilities and opportunities: http://echa.europa.eu/subscribe.

ECHA is continuously refining and updating its IT tools, its guidance and its communications with stakeholders and with the general public as well as its support to duty holders. A large part of the body of ECHA’s website, the ECHAterm terminology database and many guidance documents are available in 23 official EU languages. Practical Guides and User Manuals, numerous webinars, web-forms, publications, and other help is provided. Targeted events such as the annual ECHA Stakeholders’ Day address many issues of interest to SMEs. The work laid out in the CSR/ES Roadmap** that ECHA published on 17 July is relevant to facilitate communication in the supply chain. ECHA has recently updated the Navigator tool that allows duty holders to orient themselves on their obligations and published Guidance in a Nutshell on Registration: http://echa.europa.eu/view-article/-/journal_content/title/updated-navigator-tool-to-help-industry-identify-obligations-under-reach-published.

ECHA is currently exploring further proposals and avenues to render its support more SME friendly. The Agency intends to simplify its communication and correspondence with duty holders, to involve SMEs in focus groups to help develop its IT tools and other services, to provide more predictability in its work and stability in its guidance whilst expanding the number of guidance documents in a nutshell, and much more.
Evidently, the complexity of the EU chemicals safety regime and of its implementation sets limitations to any such simplification effort. On many issues, ECHA will need to closely cooperate with partner organisations, for instance through its networks of national helpdesks or Accredited Stakeholder Organisations. To address practical problems in handling substance information exchange forums, particularly with data sharing or the cost of letters of access, ECHA will contribute to a forthcoming SME workshop that the European Commission will be hosting from 10 to 11 December 2013 in Brussels. And, much else is ongoing. This Newsletter will regularly emphasise such activities.

As of this summer, I am involved in the Agency’s efforts to address the needs of SMEs, in the newly created function of an SME Ambassador.

I will interact with the various bodies at EU level that have a generic interest in SME issues, such as the European Union’s SME Envoy network, formations of the European Parliament or the High Level Group on Administrative Burdens, and with associations representing SME interests.

Within the Agency, my role is to raise awareness of SME concerns and act as a catalyst in introducing SME-focused considerations into the Agency’s activities.

Andreas Herdina
Director of Cooperation


REACH SMEs workshop:

New Head of Unit for ICT Infrastructure and IT Security

As of 1 September 2013, Mr Orion Andrews has been appointed Head of the ICT Infrastructure and IT Security Unit. His main task will be to manage the implementation of the Agency’s IT strategy, ensuring that the ICT infrastructure, technical services, and IT security management function well.

Mr Andrews will manage a service driven team of roughly 20 people, overseeing the deployment of an infrastructure in support of the Agency’s business continuity plans.

Mr Andrews is from Wensleydale in northern England and joined the Agency in August 2010. He has a degree in mechanical engineering from Sheffield University, and has spent his professional life working with IT since 1996.
Improving quality of nanomaterial registrations

The first of ECHA’s strategic aims for 2014-2018 is to improve the quality of registration dossiers - including information on nanomaterials.

To support registrants, ECHA has published guidance documents, webinars and other background material on nanomaterials on its website: http://echa.europa.eu/en/chemicals-in-our-life/nanomaterials

The webinars give practical advice for registering nanomaterials, including best practice for human health and environmental hazard assessment and characterisation of nanomaterials. They also inform registrants about latest developments on REACH and CLP related to nanomaterials.

The next webinar is planned for the first half of 2014 and it will include the outcome of the three GAARN (Group Assessing Already Registered Nanomaterials) meetings organised in 2012 and 2013.

The GAARN initiative discussed best practice for representative (already registered) nanomaterials and developed recommendations on how to fill potential information gaps. The best practice report will be published on ECHA’s website in early 2014.

NANO-RELATED REVIEWS ONGOING IN 2014

Currently, the European Commission is reviewing both the EU nanomaterial definition and the revision of REACH annexes for nanomaterials. The outcome of these reviews should be available in 2014. In the event of any changes, ECHA will of course update its guidance documents and manuals accordingly.

ECHA also has a nanomaterials working group (involving experts from Member States, the Commission and accredited stakeholders) that will continue discussing key scientific and technical challenges relating to nanomaterials under REACH and CLP. In addition, ECHA will also be dealing with nanomaterials used in biocides under the Biocidal Products Regulation.

Further information:

Reaching the nano scale, ECHA Newsletter 5/2012
http://newsletter.echa.europa.eu/home/-/newsletter/entry/5_12-nano

ECHA ISSUES FIRST DECISIONS ON NANOMATERIALS RELATED DOSSIERS

ECHA has issued final decisions on compliance checks on three substances. The registrants were requested to submit further information on granulometry.

The scientific and technical aspects underpinning these decisions were discussed in ECHA’s nanomaterial working group.

In future compliance checks, the Agency will treat dossiers with similar nano-related findings in a similar way, the focus being on requesting additional information on the characterisation of nanomaterials.

It is the responsibility of the registrant to indicate nano-specific information in the registration dossier in an explicit manner.

The scope of the registration dossier should be clear, including information on all the different forms of the substance.
Checking compliance - lessons learnt and recommendations

INTERVIEWS BY VEERA SAARI

The final report on the outcomes of the second EU wide harmonised enforcement project was published in September.

The enforcement project (REF-2) organised by the Forum of national enforcement authorities focused on checking the compliance of downstream users – mainly formulators of mixtures. The report found two thirds of the inspected 1 181 companies incompliant with one or more provisions of REACH and CLP. ECHA Newsletter spoke with Ms Natali Promet from the Forum and Ms Magdalena Tloczek from ECHA’s Forum secretariat on the report outcomes and follow up.

INVEST IN KNOWLEDGE-BUILDING

One of the main findings in the project was that awareness of REACH and CLP duties can be very low or even non-existent among smaller downstream user companies. Given the complexity of the new chemicals legislation, a learning phase is to be expected. “We encourage companies to be active, to participate in training and to focus on further knowledge-building within the company,” prompts Ms Natali Promet, the Chair of the Forum REF-2 working group and an Estonian member of the Forum.

“Well trained staff is a good investment and may even be cheaper in the long run than using the services of an external contractor,” she notes. Interestingly, one fifth of the checked companies had outsourced the preparation of safety data sheets to an external contractor.

Ms Promet points out that ECHA and many stakeholder organisations provide lots of useful information for companies. “On a national and international level, stakeholder organisations could do even more to involve companies in their activities and to attract new members. This support should especially target smaller companies and downstream users.”

LOOK FOR STRUCTURE

One of the crucial provisions in the new chemicals legislation is the need to keep an archive of all required information for a period of 10 years. Inspectors found that 20% of the companies had issues in the long-term storing of information on their substances.

“The results indicate that companies with good systems and structures in place were also more likely to provide good quality information on the properties of chemicals downstream to fulfil their duty along the supply chain,” Ms Promet says. “Archiving structures, for example an established document management system, were missing more frequently among smaller companies.”

“As we see an increasing amount of safety data sheets distributed in electronic format, this could further help companies to store their information electronically to successfully meet this duty,” Ms Promet says.

ADVICE TO GET ON TRACK

The most frequent measure used by the inspectors when they found compliance issues with companies was to provide written or oral advice on how to comply. Fines were rarely imposed. “The inspectors advised companies on where to find the information they needed to comply. They for example gave reference to specific ECHA guidance documents or the registered substances database,” Ms Promet stresses, and continues, “advice on how to correct the available information was also mainly given in cases of single, less significant misdemeanours, for example remarks on one section of the safety data sheet or small remarks concerning a label.”

“When measures such as orders were imposed, these were accompanied by explanations on the responsibilities of the company.”

IMPROVEMENTS IN SAFETY DATA SHEETS

Nearly all of the inspected companies (97%) had the required safety data sheets available on site. Moreover, 86% of companies had the safety data sheets available in their national language. “Although the availability of safety data sheets in inspected companies was very high, the quality of these was insufficient in 52% of the cases,” says Ms Magdalena Tloczek from ECHA’s Forum Secretariat. “This is a matter of concern for us,” Ms Promet adds, “and we hope to encour-
Inspectors noticed, however, an improvement in the formats and availability of safety data sheets in comparison to the previous enforcement project (REF-1) which was run in 2009 (although the results are not fully comparable due to the difference in the amount of inspected data).

“Between the first and second enforcement projects, a lot of information had been produced, such as the REACH-EN-FORCE 1 project report and the ECHA Guidance on the compilation of safety data sheets,” says Ms Tloczek and continues, “the increased awareness amongst companies on the provisions of safety data sheets is very welcome and we look forward to further improvements.” Currently, ECHA is working on both an update to the guidance on the compilation of safety data sheets and new guidance in a nutshell on the same topic.

FORUM: MONITORING COMPLIANCE WILL CONTINUE

The Forum will continue to monitor the level of compliance among companies by organising enforcement projects on a regular basis. “The Forum plans to enter into a new, three year cycle for harmonised enforcement projects with each project consisting of a planning, operation and reporting phase. In this way, we will run the operational phase of a different project every year with inspections in the Member States,” Ms Tloczek concludes.

Some of the main recommendations from the REF-2 project could also be implemented in the Forum’s Multi Annual Work Programme. The Forum is, for example, organising further training for national inspectors on exposure scenarios in extended safety data sheets and identified uses.

“Following the training, the inspectors will also be able to provide inspected companies with more detailed advice during the inspections,” she continues.

STAKEHOLDER VIEW:

Sylvie Lemoine, Downstream Users of Chemicals Coordination Group, DUCC

The Downstream Users of Chemicals Coordination Group (DUCC) read the final report of the second REACH enforcement project with interest. The inspection phase lasted from May 2011 until March 2012, which was quite early in the transitional period of REACH. The report showed that the implementation of risk management measures was not yet sufficient.

On the other hand, many extended safety data sheets were either not received or only just received at that time, and many issues were - and still are - pending for downstream users. We are pleased to see that already two thirds of the companies had a system in place to prepare, store and distribute safety data sheets and that 86% of companies inspected had safety data sheets available in their national language.

We look forward to improving towards a 100% compliance target, since the safety data sheets are the most important tool for safe use of chemicals.

DUCC fully recognises the importance of the extended safety data sheets as a central risk management tool with a view to demonstrating good practice within the supply chain. This is why DUCC called for and now actively participates in the activities of ECHA’s CSR/ES Roadmap. With regard to exposure scenarios, we also welcome the suggestion made in the report that training on exposure scenarios for inspectors should be considered.

http://www.ducc.eu
FACTS & FIGURES

- The second REACH-EN-FORCE project (REF-2) was carried out from May 2011 until March 2012.
- The national enforcement authorities inspected 1,181 enterprises - the majority of which were small or medium-sized.
- 29 EEA countries were covered - most checks took place in Germany (228), Spain (161) and France (97).
- The inspections covered 4,500 safety data sheets, 6,900 substances and 4,500 mixtures.
- Non-compliance was most commonly related to contraventions of (pre-)registration (REACH, 8%), notification (CLP, 15%), failure to keep information (20%) and having deficient risk management measures (12%).

FIGURE 1. COMPANIES CHECKED ACCORDING TO THE STATISTICAL CLASSIFICATION OF ECONOMIC ACTIVITIES.

FIGURE 2. TYPES OF MEASURES IMPOSED BY AUTHORITIES ON NON-COMPLIANT COMPANIES.

- Measures related to non-compliance with registration (REACH) and notification (CLP) obligation
- Measures related to non-compliance with regard to providing information down the supply chain and/or downstream users obligation
If so, you need to get on the list of active substance suppliers (Article 95 of the Biocidal Products Regulation). Following the steps below will guide you through the process and tell you where to find additional information and help.

Before getting started, have a look at the Guidance on active substance suppliers, available on ECHA’s website as well as the Information requirements for active substances, laid down in Annex II of the Biocidal Products Regulation (BPR).

**1 Collect the required information for your dossier**

- If the information you need to create a complete data set is available, and/or if you already have a letter of access for the relevant studies, you can go directly to step 2. ‘Create a IUCLID dossier’.

- If this is not the case, you need to collect the necessary data and you have two options.

**1) Get access to existing data**

A. If you already know of a company who has submitted a dossier covering the information you need, contact this company and start negotiations to get access to the data.

B. If you are not sure which companies manufacture or import the same substance and have submitted a dossier, submit an inquiry to ECHA to get the full list of data submitters under the BPR or the Biocidal Products Directive (BPD) for the tests or studies you need.

There is also a provisional List of active substance suppliers available on ECHA’s website where you can find names of companies. However, this list is still provisional, so an inquiry makes sense.

**2) Generate new data**

- If you consider performing new studies or tests on animals for the preparation of your dossier, remember that you first need to submit an inquiry to ECHA to see whether such tests or studies have already been submitted. Check ECHA’s web page for inquiry.

- The inquiry is submitted using R4BP 3. No IUCLID dossier is needed - you only need to indicate the name of the substance you are interested in.

- Detailed information on how to submit an inquiry can be found in the Biocides Submission Manual 3a: Active substances Part A, Initial submission, available in the support section of ECHA’s website.

- In reply to your inquiry, ECHA will use R4BP 3 to send you the names of the companies who have already submitted the test data.

**Share your data**

Data sharing is a mandatory requirement of BPR, so you now need to contact the data owner and negotiate for access to the data. Check the Q&A on data sharing and Guidance on data sharing on ECHA’s website. This document was originally created for REACH but much of it is relevant for biocides too. An explanatory note has been added to clarify those chapters that are particularly relevant for biocides.

If you have made every effort to reach an agreement with the data owner, but have failed, ECHA can assist you. In such a data sharing dispute, you must provide ECHA with records of your negotiations since 1 September 2013, when the regulation entered into operation, and show that you have submitted an inquiry to ECHA. You can read more about data sharing disputes on ECHA’s Data sharing web page.

**2 Create a IUCLID 5 dossier**

- Create a BPR active substance application dossier in IUCLID 5.5 and export it to your computer to be able to submit it to ECHA. Read the following support documents for more details on how to create and build a IUCLID dossier:

**3 Submit and follow-up your application using R4BP 3**

1) Prepare the supporting document

Fill in the required information in the supporting document Application for the inclusion in Article 95 (active substance suppliers) list. You will find a Word template for this on ECHA’s website.
2) Use R4BP 3 to submit your application

Remember to attach the IUCLID 5.5 file and the supporting document to your application. The submission wizard in R4BP 3 will guide you through the submission.

You will find more information and instructions for submitting your application through R4BP 3 in the submission manuals on ECHA’s website:
- Biocides Submission Manual 2: Using R4BP 3 for biocide applications
- Biocides Submission Manual 3a: Active substances Part A, Initial submission

3) Remember to follow up your application in R4BP 3

To complete your application you need to pay the invoice that you receive through R4BP 3. More information related to invoicing and R4PB 3 can be found in the Biocides Submission Manual 5: Invoicing in R4BP 3.

Once the assessment of the application is complete, ECHA will inform you of its outcome. If you are successful, your company name will be included on the list of active substance suppliers.

USEFUL LINKS

All guidance on biocides legislation

Information on chemicals under the BPR (lists)
http://echa.europa.eu/information-on-chemicals

All biocides submission manuals

IUCLID 5 support documents

ECHA’s YouTube channel with video tutorials
http://www.youtube.com/user/EUchemicals

Support pages for use of R4BP 3
http://echa.europa.eu/support/dossier-submission-tools/r4bp

All supporting document templates for biocides

Inquiry

Data sharing

DID YOU KNOW?

From 1 September 2015, a biocidal product cannot be placed on the EU market if the manufacturer or importer of the active substances contained in the product (or where relevant, the importer of the product) is not included in the list of active substance suppliers.

This is based on Article 95 of the Biocidal Products Regulation (BPR).
An industry perspective

Challenges for generating safe use information for mixtures

TEXT BY CONTRIBUTORS FROM CEFIC, DUCC, AND ATIEL

Communicating exposure scenarios and other information for mixtures further downstream is a complex task for industry. One approach formulators take is to develop safe use information based on the substances that present the greatest hazard and risk. “This is a good starting point,” our guest contributors say. However, formulators are faced with various challenges. Our contributors tell us more.

Industry identified difficulties and complexities in handling exposure scenario information for substances in mixtures soon after the first REACH registration deadline and the first Practical Guide was published in 2010.

To communicate this information for substances in a mixture, the formulator typically needs to identify those substances that contribute most to the potential hazard and risk of the mixture. The DPD+, among other approaches, provides a good starting point for developing safe use conditions. Yet, more experience has now been gained and additional insights have become available on how to communicate information on safe use of mixtures. This issue has been explored in the Exchange Network for Exposure Scenarios (ENES) and identified as an action in the Chemical Safety Report/Exposure Scenario Roadmap.

As a joint activity, the European Chemical Industry Council (Cefic) and the Downstream Users of Chemicals Coordination Group (DUCC) are currently collecting approaches and methods used by companies and industry sectors. An initial evaluation of such methods is planned in the near future. These methods will also be presented at the fifth meeting of ENES from 21 to 22 November in Brussels. Several key issues have been identified through this work so far, and these are presented in this article.

OPTIONS FOR COMMUNICATING SAFE USE INFORMATION FOR MIXTURES

Several options for fulfilling the obligation to communicate information on the safe use of substances in mixtures have been identified and are outlined below. The preferred option depends on factors such as the role of the downstream user, the application and composition of the mixture, and the complexity of the supply chain.

OPTION A: Annexing relevant exposure scenarios of the substance components to the safety data sheet for the mixture.

This seems the most suitable option to communicate safe use information to downstream users who are formulators of mixtures, because it provides a good starting point to the downstream formulator for generating the safety data sheet for his (second level) mixture. It is not really a recommended option to communicate to end users of mixtures unless the appropriate risk management measures for the mixture are clearly specified.

OPTION B: Consolidating safe use information derived from substances’ exposure scenarios (top down approach).

In this case, safe use information for the mixture is derived from consolidating the exposure scenarios of the component substances received from suppliers. This is typically done on a case-by-case basis.

Consolidating safe use information can be done in several ways. A key element of this approach is to identify the ‘lead’ substances of the mixture for the various exposure pathways, e.g. through the DPD+ methodology. This drives the selection of the relevant operational conditions and risk management measures to include in the safe use information for the mixture.

OPTION C: ‘Mixture use’ based approach (bottom up approach).

The starting points for a ‘mixture use’ based approach are the composition and typical uses of the mixture.

This approach is mainly used in a generic way. Safe use information for mixtures is developed for typical uses, compositions and hazard profiles for products within specific sectors. An advantage of this is that a large number of mixtures can be covered by a limited number of generic sets of realistic and consistent safe use information. This information can also be provided in sector-specific terminology.

For options B and C, safe use information for a mixture may be communicated by including it in the main body of the safety data sheet or as an annex.
They may choose to consolidate the substances on the market in mixtures, however, if they are placing substances, the underlying assessment is based on the classification of the hazards. Qualitative approaches based on the classification of the mixture are probably needed in such cases. They may also be appropriate when a lead substance exposure scenario is not yet available.

Several challenges for the substances’ exposure scenario based approach (option B) and the ‘mixture use’ based approach (option C) remain:

- The identification of ‘lead’ or ‘risk driving’ substances is a key step and has been shown to be a practical approach. The boundaries, applicability and feasibility of the various methodologies need further evaluation. These include the DPD+ methodology, the CLP++ approach, and the Critical Component Approach*** referred to in ECHA’s guidance. Workable tools for accepted methodologies also need to be developed.

- The rules for systematic selection and/or scaling of the operational conditions or risk management measures for the relevant ‘lead or risk driving substances’ need to be developed. Experiences have revealed that an adjustment is often necessary when consolidating information. This can be handled by transparent mathematical rules if the underlying assessment is based on tools allowing such simple modifications. Such rules would subsequently allow the information to be automatically processed as far as possible.

- Based on the current legal requirements and guidance documents, a formulator performing a chemical safety assessment, either as a registrant or a downstream user, has the obligation to include the exposure scenario for the assessed substances. However, if they are placing substances on the market in mixtures, they may choose to consolidate the safe use information into an annex. A combination of exposure scenarios for substances and annexes for safe use information for the mixture may cause a lot of confusion for the end user and a practical solution is needed for such situations.

- If formulators are required to undertake downstream user chemical safety assessments in such circumstances, the preceding situation would arise more often leading to confusion as mentioned before.

- Substance exposure scenarios may contain operational conditions or risk management measures that are not derived from quantitative assessments for the specific substance (for example, qualitative assessments, such as being hazardous to the eyes or physico-chemical hazards). Qualitative approaches based on the classification of the mixture are probably needed in such cases. They may also be appropriate when a lead substance exposure scenario is not yet available.

Once several methodologies are broadly used and more experience is gained, additional issues are expected to pop up. It will be quite a challenge for industry to find answers to all of these questions. It will also require a lot of time and effort to train all actors and develop expertise, particularly in smaller companies.

Way forward

Despite all of the efforts that industry is currently putting into this, there is no golden solution. Expert judgment will always be needed to support any approach to determine safe use information for mixtures. Further work will be done in preparation for ENES 5 in November and beyond. Detailed discussions during ENES 5 and with the stakeholders involved in ECHA’s CSR/ES Roadmap action 4.4, are needed to develop workable methodologies for generating useful safe use information for mixtures when communicating down the supply chain.

Further information:

- REACH: Exposure scenarios for preparations, Cefic/DUCC, June 2010.


- REACH Guidance for downstream users

  Chemical safety report/Exposure scenario roadmap

Cefic has prepared a methodology based on the Dangerous Preparations Directive (DPD), enhanced for certain health exposure pathways with consideration of the volatility of the substances concerned. It is known as the DPD+ method.

++ Work has commenced on converting the DPD+ method to a CLP based method, termed CLP+. This was presented for the first time at ENES4 in May 2013.

The critical component approach is outlined in ECHA’s Guidance for downstream users. It relies on derived no effect levels (DNEEs) and predicted no effect concentration (PNEC) for all substances, their concentrations in the mixture and on substance- and use-specific availability parameters indicating their potential for exposure. The critical component approach has not been developed in detail yet.

According to REACH, there is no obligation to prepare exposure scenarios for mixtures. Exposure scenarios are part of the chemical safety report for individual substances for which an exposure assessment is required.

However, there is an obligation to communicate exposure scenario information for substance components in mixtures down the supply chain. Relevant information from the exposure scenarios for substances should be incorporated when drafting a safety data sheet for a mixture. This typically includes information on the appropriate conditions of use and risk management measures for the various uses of the mixture.
ECHA’s two Committees, the Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC), prepare ECHA’s opinions on restrictions, applications for authorisation and harmonised classification and labelling. Their task is to help ensure sound scientific opinion making that can be supported by the European Commission and advance the goals of REACH and CLP. But what exactly is it like to be a committee member? ECHA Newsletter finds out.

**SUPPORT FROM MEMBER STATES CRUCIAL**

Spanish Benjamin Piña is a third year RAC member whose professional background is in ecotoxicology. He says the experience in RAC has taught him a lot about how to apply science in regulatory work. “I’ve been able to use my scientific knowledge to bring about a regulatory change,” he says, referring to the work he has done as a rapporteur on harmonised classification and labelling.

Mr Piña admits that since the beginning of RAC, the work is getting more and more challenging. “When the committee work started, my role was to participate in the meetings. Now, with all the advances in the legislation and the increase in the number of dossiers, the committee work is quite intense. You have to dedicate your time in between meetings to the preparatory work too.”

In the future, he expects the membership may become almost a fulltime job. “Support from the Member State competent author-

**STEP UP TO THE CHALLENGE**

**Ms Simone Fankhauser,** an Austrian member of SEAC, is enthusiastic about being a committee member. “It is interesting to work with experts from all of the Member States. Each of them has a different approach and having this regular exchange of views is a very positive experience,” she says.

Socio-economic analysis in the European chemicals legislation is a new element introduced by REACH, and SEAC has basically had to start from scratch. “I’ve been a member from the very beginning, so I have seen all of the developments and the enormous progress that has been made.”

The amount of work coming the committee’s way is bound to increase with more restrictions and applications for authorisations kicking in. “But that can also be a positive development. More work also means more routine. We are getting more used to tackling difficult issues. It would be good if more members were actively involved and took on dossiers to even up the workload,” Ms Fankhauser admits.

She encourages all committee members to be active and to trust that ‘you can learn by doing.’ “Take on dossiers and rapporteurships, and you will get great support from ECHA and the other colleagues of the committee,” she says and continues, “It was a new and challenging experience for me when I took over one of the first restriction dossiers that came in the committee. But I...”
got help from ECHA and studied my way through the process. Now, there is even much more experience than at the start, so nothing can really go wrong.”

**DEVELOPING YOUR PROFESSIONAL SKILLS**

“It’s great to see the development from committee discussions into a decision that is published, for example, in Annex XVII of REACH (list of restrictions). We are part of a process that results in advice to the Commission on their policy decisions,” says Jean-Marc Brignon, a second term French member of SEAC.

For him, it is evident that committee members actively take on cases as rapporteurs. “Being a member means that you will also be a rapporteur at some point. I remember, when I took on my first case, I got a lot of help from the dossier submitter, my SEAC colleagues and ECHA in understanding the dossier. You are never alone.”

**DID YOU KNOW?**

The Committee for Risk Assessment (RAC) prepares ECHA’s opinions related to the hazards and risks of substances for human health and the environment on harmonised classification and labelling, restrictions and applications for authorisation.

The Committee for Socio-economic Analysis (SEAC) prepares ECHA’s opinions related to the socio-economic impact of restrictions and applications for authorisation.

The members of RAC and SEAC are nominated by the EU Members States and appointed by the Management Board of ECHA as independent scientists. The committee meetings are attended by ECHA’s accredited stakeholders and may be open to advisers, invited experts and observers.

Whenever RAC or SEAC starts developing an opinion, a rapporteur is appointed to ‘undertake to act in the interests of the EU’. Their most important tasks are to develop the scientific justification and to properly reflect the views of the Committee in preparing the opinion.

RAC and SEAC each have four plenary meetings a year.

SEAC work has helped to further improve Mr Brignon’s professional skills. “We learn a lot from the dossiers and from other members in the committee. We sometimes criticise and want more explanations, but in a good spirit. These discussions take us forward both in relation to the committee work and individual skills.”

Improving efficiency is one of Mr Brignon’s solutions for managing the workload. “We need to spend less time on each dossier and not try to understand everything in its finest detail. We need to be more collective, trust each other and let the rapporteurs point us to the important parts. And ask questions, of course,” he concludes.

Further information:

Committee for Risk Assessment

Committee for Socio-economic Analysis
Implementing biocides in a Member State - a Dutch perspective

New ways of working internally, new partners to cooperate with and new IT-tools to be used - these are some of the challenges that the Dutch competent authority for biocides, Ctgb, has faced. Since the Ctgb started working with biocides applications long before the Biocidal Products Regulation came along, the structures were already in place to take on the new responsibilities. However, many aspects of the work have changed during the last year. ECHA Newsletter spoke with three colleagues from the Ctgb to find out how the new regulation has affected their daily work and their organisation.

The Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) has in its Secretariat altogether 120 employees and of these around 30 are working directly with biocidal products assessment which is one of their key services. Mr Joost van Galen and Mr Hans Snel both work at the Ctgb as project leaders on biocides and Mr Jan Willem Andriessen works as an account manager responsible for relations with the government. They have all been involved with the preparatory work carried out in the Ctgb for the new regulation. The work began over a year ago, as soon as the legal text became stable enough to be interpreted.

The assessment of biocidal products is performed in the Ctgb Secretariat by experts who specialise in the risks that the products can cause to humans, animals and the environment. “Once all the experts have finalised their separate assessments, we compile them to one recommendation that is given to our board, who takes the final decision on the product authorisation for the Dutch market,” Mr van Galen explains. “This board is an independent group of eight experts who meet once a month to decide on authorisations. These people have their day jobs somewhere else and there is a distance between board members and those in the Secretariat who carry out the assessments,” Mr van Galen says.

FROM A DIRECTIVE TO A REGULATION

Many aspects of the work changed when the old Biocidal Products Directive was replaced by the Biocidal Products Regulation. “Earlier, the application came directly to the Ctgb as a paper copy by post, burned on a CD or delivered using other electronic devices,” Mr Snel explains and continues, “we inserted the information in our own systems and then started to work. Now, we have new IT-systems, R4BP 3 and IUCLID, where we have access to information that exists outside of the Ctgb. This has changed the way we work, from invoicing to communicating with the applicants.”

When it comes to the assessment work itself, Mr van Galen does not foresee such big changes ahead. “We have not yet received any applications under the Biocidal Products Regulation, but we think that the assessment will not change dramatically. It is more the internal procedures that have to change,” he points out.

The regulation, however, indicates clear deadlines for the work of the national authorities and that will have a big impact also on Ctgb. “Before, we had our own deadlines. Now, we are strictly regulated by the legal text and the new deadlines given to us are quite short. This means that we have to ensure that we have enough resources for the assessment because the work must be started immediately, regardless of the workload,” Mr Andriessen reminds.
In addition to the new deadlines, Mr Andriessen points out that applying both the national legislation and the EU-wide Biocidal Products Regulation at the same time is going to be challenging.

"The Netherlands has had a system for authorising biocides since the 1990s and that still remains in place. From now on, perhaps until 2025 when the last biocidal products are authorised according to the Biocidal Products Regulation, we will be running the two systems simultaneously. This naturally makes the work somewhat more complicated," he says.

At the moment, around 80-90% of the applications are still dealt with under the Dutch law but this is gradually changing. According to Mr Andriessen, in eight years the figures could be the other way around.

LOOKING AHEAD

Cooperation with ECHA is one of the new pieces that has been added to the puzzle. This has resulted in new meetings, new collaboration and of course, new IT-systems. “Now we need to figure out which issue should be discussed with which actor. It will take some time to get used to and we also need time to establish a relationship with ECHA," Mr Andriessen says.

“At the same time, ECHA seems to be quite straightforward in the way they handle things," Mr van Galen says and continues “we see many changes and also some difficulties. However, some things we also like a lot, such as the idea of having a central database IUCLID and a tool for data dissemination. These are very much welcomed.”

The colleagues at the Ctgb expect the new regulation to bring more clarity and harmonisation to the world of biocides, especially compared with the directive. The clear deadlines will also make the process faster, which will be beneficial for industry. However, for some companies the costs of the regulation may become too high.

“When it comes to our work, the readiness of our organisation can only be tested once the first applications have been submitted. We are confident that the Ctgb is ready to handle the applications and adjust the way of working to the requirements of the new regulation," Mr Andriessen, Mr van Galen and Mr Snel conclude.

Further information:
http://www.ctgb.nl/

European Commission report:
80% of Europeans are concerned about the environmental impact of products

Most Europeans would be prepared to change their purchasing habits and buy more environmentally-friendly products, but many feel they lack information and distrust manufacturers’ environmental claims reveals a survey on the "Attitudes of Europeans towards building the single market for green products" published on 5 July 2013.

The survey indicates that more than three-quarters of respondents are willing to pay more for environmentally-friendly products if they are confident that the products are truly environmentally-friendly (77%). However, only slightly more than half of EU citizens feel informed (55%) about the environmental impact of the products they buy and use.

Further information:
DG Environment press release
Report:
http://ec.europa.eu/public_opinion/archives/flash_arch_374_361_en.htm#367
“Protecting health and the environment is a global goal”

INTERVIEW BY PÄIVI JOKINENI

REACH plays an important role in protecting human health and the environment from hazardous chemicals. The non-governmental organisations (NGOs) ensure that civil society is represented in the process. ECHA Newsletter met with Tatiana Santos from the European Environmental Bureau (EEB) to discuss the cooperation of NGOs and ECHA as well as the challenges and benefits of REACH.

“REACH is very much welcomed by the EEB. We believe it has great potential to improve chemical risk management and protect citizens’ interests” says Ms Santos. She says that the main principles of REACH, as well as its goal to protect human health and the environment, are key. “However, REACH’s goals should be shared with the whole world, not only in Europe.” Even with a good starting point, there are still many REACH challenges that ECHA needs to tackle, and therefore it is important that the effects of REACH are properly evaluated.

Ms Santos’ main concerns related to REACH are the poor quality of the dossiers submitted to ECHA, what she sees as the obscurity around nanomaterials and the plan to ensure the substitution of substances of very high concern. These are also the main areas of work for the EEB in the areas of chemicals and nano policy during the coming years.

“Our goal is to ensure that no authorisations are granted for substances of very high concern if an alternative is available for that substance and that innovative and green chemistry is prioritised over obsolete and hazardous chemistry in Europe. Therefore, we wish to encourage third parties to submit information on alternatives and we would like to cooperate with ECHA to provide sufficient support for green companies with questions related to substitution,” she emphasises.

RESULTS THROUGH COLLABORATION

According to Ms Santos, it is crucial that civil society is represented in the meetings and discussions concerning REACH so that the whole process can be legitimised. This is especially important during the discussions on authorising substances of very high concern, where citizens have an interest. She represents the EEB in all Committee meetings at ECHA. “It is challenging for the NGOs to be a part of discussions because they do not have the same resources as industry. This is a natural David and Goliath imbalance that ECHA should help to compensate as industry gains huge economic benefits from the chemicals that citizens are exposed to,” she points out. In her view, ECHA should engage public interest organisations in order to reduce the number of hazardous chemicals that the environment and citizens are exposed to.

However, a clear change in cooperation between ECHA, the NGOs and the Committee members can already be seen. “It has not been easy. Our participation in the Committee meetings is still quite a new thing but we have all started to learn how to work together. In the beginning, some Committee members were a little suspicious of us but now they have acknowledged what our role is and have understood that we are also there to represent them as citizens,” she says and continues, “now some members expressed their support to our role in the Committees as it ensures a democratic way of working.”

In addition, the cooperation with ECHA has improved and Ms Santos feels that the views of NGOs are now better received. “We have regular meetings with ECHA that are very useful. We can express our concerns and gain from our mutual exchange of information. For example, at the moment we are collaborating to improve communication to citizens through ECHA’s website.”

The EEB is the largest European federation of environmental organisations and one of ECHA’s Accredited Stakeholder Organisations. It:

• has 140 member organisations that aim to protect environment and health;
• represents the voice of over 50 million European citizens;
• aims to ensure that REACH is properly implemented and enforced.

www.eeb.org
Advocating for transparency of chemical data

INTERVIEW BY EDUARDO ALONSO

As a representative of the NGO ClientEarth, one of ECHA’s Accredited Stakeholder Organisations, Brussels-based Italian lawyer Vito Buonsante regularly travels to Helsinki, where he actively participates in the implementation of REACH. Although sometimes critical of ECHA’s role, Buonsante hopes REACH will be the vehicle for the EU to be a leader in green chemistry.

Why are you interested in REACH?

My organisation decided to work on REACH after it was approved. Until 2006, there were many people working for NGOs on REACH because funding is always more abundant in the phase of approval of legislation. But after its approval, NGO resources to work on REACH implementation decreased considerably. ClientEarth’s role is to foster the implementation of REACH to benefit the environment.

We are an organisation made up mostly of lawyers with the idea of using the law as a tool to promote social change and protect the environment. We try to give a voice to the environment, which has no voice and cannot protest. Our main aim is to concentrate on the implementation and enforcement of existing legislation promoting a public interest interpretation. We deal with climate issues, forests, biodiversity, fisheries, and also focus on transparency and environmental justice. The programme that I work for deals with REACH, nanotechnologies, pesticides and air pollution.

When working with REACH, what are your main goals?

Our main goals are the same as REACH’s, to increase society’s knowledge of chemicals and to substitute the most hazardous ones. Therefore transparency of the information on chemicals has been our first important objective. The reason for this is that the transparency on properties, risks and exposure is crucial for us in order to participate in any decision making. When we sit at the table with public authorities, such as ECHA and the Commission, and with industry, there is an imbalance at the table. Not only in the number of staff that we have but also in the amount of information. We often don’t have access to the information. That’s why our primary focus is transparency. The ultimate aim of our work on chemicals is, of course, substitution, but the path to get there is to be able to implement the other REACH processes.

How do you see the implementation of REACH so far?

With another NGO, the European Environmental Bureau (EEB), ClientEarth published a report that focused on ECHA’s role in the implementation of REACH and we were critical of that role, but in a constructive way. The reason is that while we can agree to a certain extent that REACH works in terms of procedures, we are interested in the quality assessment of the outputs of REACH, which doesn’t seem to deliver as much as it could so far.

What we want to see is REACH delivering the information on chemicals in a transparent way. Secondly, we would like to see the process related to substances of very high concern advance much more quickly. It is clear that the legal text of REACH is not going to change, so we are focusing on the implementation. I strongly believe that it is not only by inviting industry to do a better job that we get results. Public authorities, such as ECHA, have also to make sure that REACH works well upstream by refusing registration numbers to incomplete registration dossiers and making public the names of registrants that are the adresseses of evaluation decisions. Low quality dossiers should become the exception rather than a rule.

Some NGOs have said that REACH represents an opportunity for the EU to be a leader in green chemistry. What do you think?

At the moment, I am positive that this is a challenge that can be won. We have an opportunity and we can take advantage of it. If we had more substances on the Authorisation List, more initiatives for green chemistry could be financed and supported. Currently, the authorisation process is not presented in a way that encourages substitution, but more around the manner in which authorisations are granted. However, we are missing mechanisms that encourage green chemistry and “good” substitution.

What is on ClientEarth’s agenda in the near future?

In July we published a report on the relationship between REACH and endocrine disrupting chemicals. We analysed the data on ECHA’s database to understand if companies that have registered endocrine disrupting chemicals have actually provided all the available information to ECHA, especially independent studies. When it comes to assessing chemicals, we always find differences between industrial science and independent science. Given the lack of bias, we trust studies that come from independent sources (e.g. university and academia) more, whereas regulatory agencies generally consider more relevant studies provided by industry. Our goal is now to follow up on this project and engage industry and enforcement authorities in taking action.

CLIENTEARTH

ClientEarth is a non-profit environmental law organisation, founded in 2008.

In 2012 BusinessGreen gave ClientEarth its NGO of the Year award.

www.clientearth.org
A shock that led to a documentary

“Products on the shelves are not tested for safety”

INTERVIEW BY HANNA-KAISA TORKKELI

The Human Experiment is a new American documentary focusing on chemicals in everyday household products and their potential effect on humans. The film includes interviews with ECHA’s Executive Director Geert Dancet and Director Jack de Bruijn, which showcase the advances in chemicals legislation in Europe. It will premiere at the International Documentary Film Festival in Amsterdam in November. ECHA Newsletter spoke with Dana Nachman, one of the directors, to find out what inspired the film and what she hopes people will get out of it.

Could you tell me a little about the film? What is it about?

The documentary is about the thousands of chemicals we all use in our everyday products, some of which are in our furniture, our make-up and other cosmetics, and how in America, the majority of these chemicals have never been tested for safety. Meanwhile, there are many diseases and health conditions that are on the rise. In the film, we are following a group of activists who believe that chemicals are to blame for the rise in health problems and disease.

What gave you the inspiration to make the film?

I was working as a journalist for the American TV news organisation NBC, when I came up with this idea. I was assigned to do a piece about limiting toxic chemicals in the home in 2009 and learnt that products on the shelves in the stores are not tested for safety. I was shocked! As a consumer I was buying these products all the time. Usually, when I'm shocked about something, it turns into my next documentary.

I started working on The Human Experiment in 2010. Since then, I've been doing a lot of research and reaching out to people from all different walks of life.

Could you tell me a little about the film? What is it about?

The film has three main characters - people who are affected with some kind of a disease or condition. One has breast cancer; one a brother with autism and one has suffered infertility. We also meet many other people in the course of the film, for example, two business men who are making cleaning products and two women who are campaigning for safer cosmetics. We meet people who are on the front-line of these issues doing their own campaigns, even though they do not necessarily have a disease or condition associated with chemicals - yet.

Why do you think the issues raised in the film are important right now?

The main thing is that it touches us all. I've done other films with important issues such as terrorism and wrongful convictions but not everybody is really impacted - even though the topics are interesting. This film impacts everyone: we all have these products; we buy these products; we all, to some degree, play a part in making sure this goes on in the way it does because we support it with our money. That said, everybody needs to become aware of what is going on so that they can make their own decisions instead of letting advertisers and marketers make the decisions for them. Hopefully, this film will be helpful for people to be better informed.

What are the ‘take home’ messages that you wish to convey through the film?

I hope that people come away feeling empowered to make choices for themselves and their family. We can all make a difference by turning a situation that could be scary into something that is empowering, starting with very small changes in our daily purchasing. The more of us that do it, the more it will help people who maybe cannot afford e.g. greener products or who haven't heard this message yet.

Another message is that nobody is doing this for us. In America, unlike in Europe, this is not yet done for us by the government or authorities. Until the authorities act, which I hope will happen soon, we have to take matters into our own hands.

You strongly believe that individual people can have an impact?

Yes, not only do I believe it, I can see it happening. In the years that I’ve been working on this film, things have already advanced. For example, when I go to the drug store, I see that the shelves of non-toxic, non-chemical products are getting bigger with more options. This is directly from customer demand.

We are asking in the film that what if the biggest chemical disaster of our time is not a nuclear meltdown or an oil spill but...
the small chemical exposures happening hundreds of times a day that we inflict on ourselves. Most people are not looking at it this way. We need to change the way we look at the products we bring into our homes or use on our children and see that changes are possible. Hopefully in America, the legislation will follow, but for now, consumer demand is driving the train.

You interviewed ECHA’s Executive Director Geert Dancet and Director of Risk Assessment Jack de Bruijn for the film. Why was that?

We wanted to show Europe as an example that the reform of chemicals legislation is possible and that change can be beneficial for all players. In the US, the change in regulation has not happened, even though it has been tried for quite some time. Our Toxic Substances Control Act (TSCA) dates back to 1976 and we can all agree that a lot has happened since then in the chemicals industry.

When I visited Helsinki, I was overwhelmed by the pride you take in working for safer chemicals, the staff you have and the leadership. You are setting the standard for the world and feel strongly about your work. You know, Americans do not like when they are beaten by other people or they cannot do what others do. That is the case here. We are grateful to the Europeans for paving the way and hope we can follow suit soon.

The latest attempt to reform TSCA, the Chemical Safety Improvement Act (CSIA), was introduced in spring 2013. Do you know what is happening with the reform?

Indeed, the CSIA was introduced by senators Lautenberg and Vitter in May 2013. Unfortunately, soon afterwards, senator Lautenberg died. That was pretty bad for the movement, as he was the biggest champion for reform in the senate and had been an advocate for a long time.

The activists that I have spoken to are encouraged by the bipartisan (democrat and republican) support for the bill. However, they are saying that it still needs strengthening to win the support of the public health community. One of the flaws, according to the activists, is that it diminishes the states’ rights. While we have not had federal regulation in the US, we have had a lot of individual states coming out with chemical related bills over the years, e.g. regulating the use of BPA in baby products in the state of California. A lot of activists want to make sure that this new bill does not undercut the states’ rights to act. We have to see how the situation develops.

In your opinion, what is needed to advance chemical safety in the world?

My personal opinion is that the more people understand, the more they care. What people don’t know about, they don’t even think about. So, the wider we can spread the word, the more likely it is that industry will change and do the right thing; and the more likely it is that the government will change and do the right thing. Knowledge is really paramount.

I know that different people have different philosophies on how the situation should change. Personally, I don’t really think it matters how the change actually happens as long as children and underprivileged, vulnerable people are protected.

How has making the film changed your own behaviour?

I only buy products which I know do not contain toxic chemicals - from my children’s bath products to detergents. Actually, I’ve cut down on how much I buy. I concentrate on the indoor air quality of my home, which I did not even think about earlier. One scientist in the film talks about your home being a toxic box. This means that when you close your windows and keep everything closed up, all these toxins just build up and get into your airways.

I’ve also been trying to teach my kids. For example, when they go to school and there is toxic soap, I’ve told them to just use hot water instead. I try to train them to think about these things, not to get them in trouble.

We don’t really touch food in our film, but I’ve made a big change in food in terms of watching out for pesticides and avoiding canned food. We also filter our water.

Basically, I’ve made changes that empower me. Just yesterday, my husband asked me to bring beans from the store. I went to the store and they did not have the brand that I know does not use BPA, and only brands that did. I could not buy them. Literally, I could not take them off the shelf. I don’t think that one can kill me or my children; I just do not want to support this company until they make a change. But I have to say, I’m not a purist at all. I hope that one day we have a more overarching and protective system, so that we would not have to make so many decisions on our own.

More about the TSCA reform on page 24.

THE HUMAN EXPERIMENT

- Written by Dana Nachman
- Directed by Dana Nachmann and Don Hardy Jr.
- Executive produced and narrated by Sean Penn
- Premiere: October in the US, November in Europe
- More information about the film and trailer: http://thehumanexperimentmovie.com/
- Facebook and Twitter: https://www.facebook.com/TheHumanExperiment https://twitter.com/ChemicalMovie

FEATURING
Modernising the chemicals regulation was one of the priorities of Barack Obama’s administration after the 2008 election. According to the former US Environmental Protection Agency’s (EPA) administrator Lisa Jackson, “most Americans have lost confidence in the federal government’s ability to adequately assess the huge range of chemicals coming on the market.” (usnews.com 22.4.2009)

In 2009, the EPA announced the general principles for the reform of TSCA. It also introduced a new approach to its implementation efforts under the existing TSCA authority, including plans to require companies to provide additional information about the risks of chemicals and increasing public access to such information: [http://www.epa.gov/opptintr/existingchemicals/pubs/principles.html](http://www.epa.gov/opptintr/existingchemicals/pubs/principles.html)

In the US Congress, however, attempts to amend the regulation – driven mainly by senator Frank Lautenberg – were unsuccessful due to the breadth and complexity of the proposed bills. More than four years after the first discussions about TSCA reform began, TSCA’s core elements remain the same as when it was enacted in 1976.

THE CHEMICAL SAFETY IMPROVEMENT ACT – A WAY FORWARD?

In May 2013, senators Lautenberg (Dem.) and David Vitter (Rep.), together with a bipartisan group of supporting senators, joined forces to advance the reform of TSCA and introduced a new Chemical Safety Improvement Act (CSIA).

The CSIA embodies significant compromises, and is hence the most promising attempt so far to modernise TSCA.

In June 2013, the CSIA proposal was shadowed by the death of senator Lautenberg. In addition, California senator Barbara Boxer, an influential head of the Senate Environment and Public Works Committee, signalled that she wanted major changes to the proposed bill, mainly concerning the pre-emption of state law.

Senator Vitter later defended the bill in a Committee hearing on 31 July, saying that the intention of the CSIA is not to eliminate private rights of action under state law, nor to remove the authority of the states to protect the environment or citizens.

The CSIA would amend Title I of TSCA in order to improve the safety of American consumers and ensure that risks from chemical substances are adequately understood and managed. It would also introduce, among other things, a new safety standard that ‘no unreasonable risk of harm to human health or the environment will result from exposure to a chemical substance’ under ‘intended conditions of use.’

Further information:

Chemical Safety Improvement Act (CSIA)
http://thomas.loc.gov/cgi-bin/bdquery/z?d113:s.1009:

Reform TSCA
http://reformtsca.com/Main/csia.html

Safe Chemicals Act of 2013:
http://thomas.loc.gov/cgi-bin/query/D?c113:1:/temp/-c11311LZuy:

Senate Environment and Public Works Committee
hearing, 31 July 2013

Sources:

American Chemistry Council
http://www.americanchemistry.com/

Lexology
http://www.lexology.com

US news