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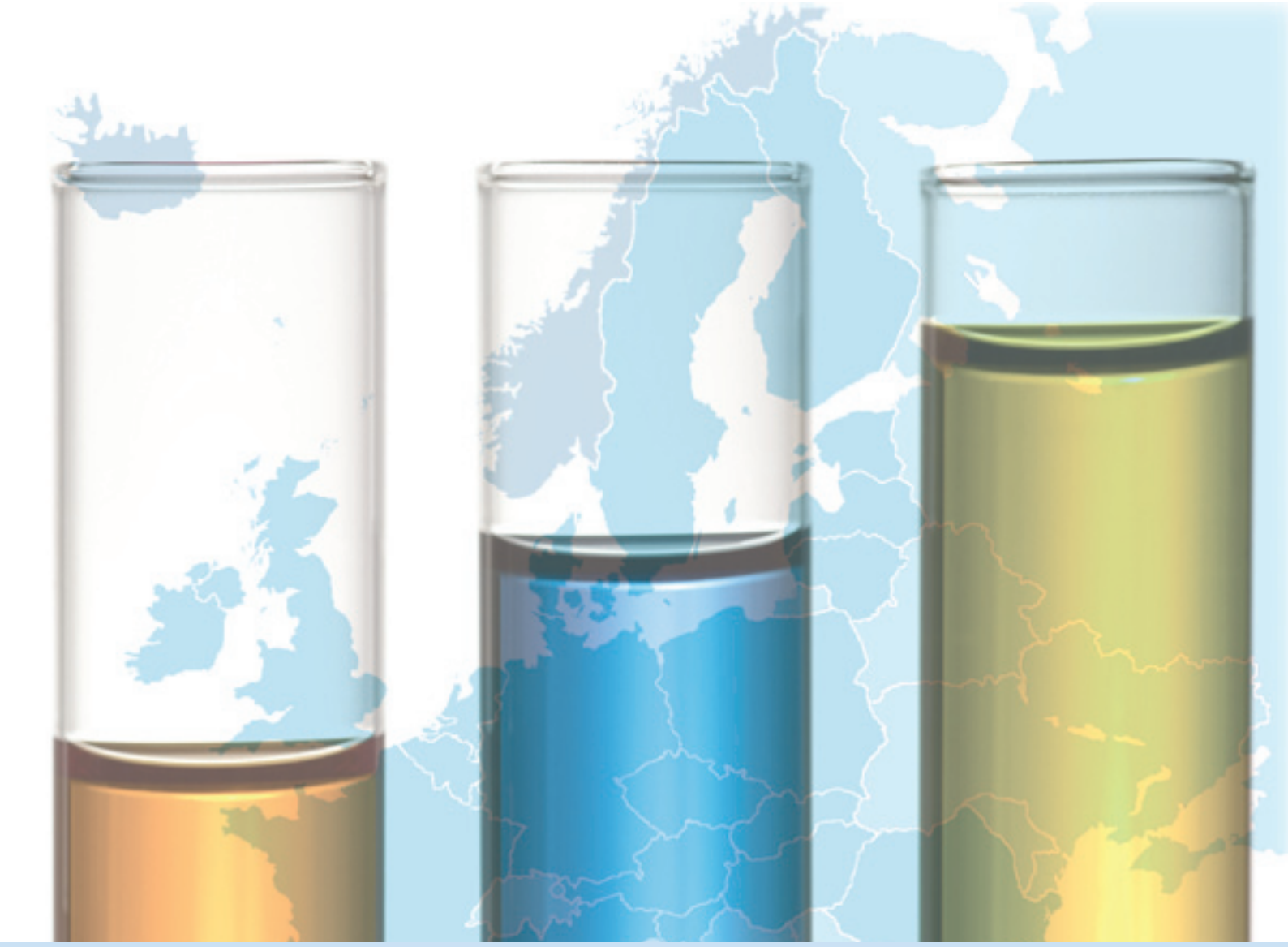

ECHA
European Chemicals Agency

Congratulations to all!

I would like to begin by saying congratulations to all of those who submitted their dossiers by the November 30 deadline. I am very happy that you rose to the challenge and submitted your registration dossiers on time.

By the deadline, we received 24 675 registration dossiers, which is in line with the baseline number included in our Work Programme for 2010.

2010 has however been a very challenging year. There were concerns that dossiers would not arrive. I am very proud that my staff managed to cope with the large number of dossiers and that everything from the IT system to the processing of dossiers went smoothly. We are very thankful for the support we have received from our stakeholders over the last years and for the faith you have put in REACH and in us.

I am also very happy for the Lead Registrants and SIEF member companies to have successfully registered their high-volume and most hazardous substances. All companies that truly tried to submit also managed, and where there were problems, we made all efforts to help the companies by contacting them directly on the phone. ECHA's website contains information for registrants which highlights what is important after the deadline.

Of course, there is still a lot of work to be done. We still have to process all the dossiers we have received and make non-confidential data available on our website over the coming months.

Furthermore, now that this REACH milestone has been achieved, the next is already around the corner - the Classification and Labelling notification deadline on 3 January. ECHA expects to receive over two million notifications. We will continue to work through Christmas to assure that everything will again go smoothly.

Finally, I would like to extend my very warm wishes to all of you for the holiday season and I wish you a successful and productive New Year! My personal wish for 2011 is that we continue to work together for a safer and more competitive Europe.

Geert Dancet
Executive Director

9 11

In this issue

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First REACH registration was a success!

The 30 November 2010 was the first REACH registration deadline for high volume and the most hazardous chemical substances manufactured or imported into the European Union. Industry needed to submit substance information to ECHA. Most of it will be made publicly available via the internet in 2011.

At ECHA, 30 November was a surprisingly quiet and calm working day. All the busy preparations and the work done over the previous years and months really paid off, and the submission of registrations from all over the EU went very smoothly. The REACH-IT system that during pre-registration in 2008 was tested to its limits had been further developed and was working without problems.

ECHA's registration unit monitored the registrations, and if a registrant had major problems, they picked up the phone and called the company, offering assistance. In this way, around 500 registrants, one third of them small and medium sized companies, were guided through the process in the days before the deadline.

On 1 December, the statistics showed that the registration process had been a success. By the deadline, ECHA had received 24 675 registration dossiers, on around 3 400 substances.

Nearly 400 registered substances are classified as carcinogenic, mutagenic or toxic to reproduction and more than 150 as very toxic to aquatic organisms. Of these substances, 27 are already on the Candidate List of Substances of Very High Concern.

The majority of the registrations will be processed by 28 February 2011. A small minority failed the technical completeness check. These registrants need to submit further information via an updated dossier. These will be processed in 2011. ECHA's website will be updated regularly with the latest statistics.

Executive Director Geert Dancet, Director of Registrations and IT Tools Christel Musset and Head of the Registration Unit Kevin Pollard were very satisfied with the way the submission worked. "It went extremely well," said Mr Dancet. Ms Musset and Mr Pollard said that as result of the planning carried out in the months before the deadline, ECHA had sufficient staff in place to carry out the work smoothly and to a high degree of quality and to offer considerable direct support to companies who were having difficulties with submissions.


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Christel Musset, *Director of Registration and IT Tools.*

"Our staff approached the challenge with great commitment and enthusiasm. The REACH-IT system has been enhanced considerably since pre-registration and it remained available throughout the whole period with no ICT problems, thanks to the high quality support provided by our IT staff," said Ms Musset.

"The registrations received were in line with the numbers on which we based all our planning," said Mr Dancet. "We got information from industry that numbers could potentially be higher, but this did not materialise."


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ECHA's ICT team *monitoring the system on 30 November.*

REACH text amended by the CLP Regulation:

Consequences on registrations submitted from 1 December 2010 on

On 1 December 2010, the REACH Regulation ((EC) No 1907/2006) was amended by Article 58 of the CLP Regulation on classification, labelling and packaging of substances and mixtures ((EC) No 1272/2008).

Classification plays a key role in REACH. It must be included in the registration dossier for a substance and it triggers certain provisions, such as the performance of an exposure assessment and risk characterisation as part of the Chemical Safety Assessment and the obligation to provide a Safety Data Sheet. Classification of a substance as mutagenic, carcinogenic or toxic to reproduction may also lead to restrictions and the need to apply for authorisations.

The CLP-linked amendment of the REACH Regulation has an impact on registration dossiers from 1 December 2010 onwards. More specifically, registration dossiers are affected in the following way:

- Registration dossiers will have to include the information on classification and labelling according to the criteria specified in the CLP Regulation (Article 58(11) of CLP);
- The dissemination of information contained in registration dossiers will take into account the hazard criteria established by the CLP Regulation (Article 58(7) of CLP);
- The content of the chemical safety report will also be impacted by the hazard criteria established in the CLP Regulation (Article 58(1) of CLP).

ECHA is committed to help registrants comply with these regulatory provisions. To this end, ECHA released updated versions of the following manuals and tools on 1 December 2010:

- **Data Submission Manual 5** - How to complete a technical dossier for registrations and PPORD notifications: **http://echa.europa.eu/reachit/dsm_en.asp**;
- **Technical completeness check plug-in** (TCC plug-in). Released on the IUCLID website: **http://iuclid.echa.europa.eu/**;
- **Fee calculation plug-in**. Released on the IUCLID website: **http://iuclid.echa.europa.eu/**.

Furthermore, a new **Questions and Answers document** "Changes in requirements for registration dossiers submitted from 1 December 2010" was also published on ECHA´s website at: **http://echa.europa.eu/doc/publications/Q_A_changes_requirements_dossier_after_20101201.pdf**.

The document describes the most relevant modifications introduced by the CLP Regulation that affect registration dossiers. The questions and answers deal with changes affecting the technical completeness check of dossiers, changes affecting the fee to be paid and changes concerning the dissemination of the information in the dossier.

Update of already submitted dossiers

All registrants need to include in their dossiers the information on classification and labelling according to the CLP Regulation **without undue delay** from 1 December 2010, if not already done.

In the case of joint dossiers already submitted, the lead registrant is in principle responsible for the update of the lead dossier according to the CLP criteria, if they were not included in the original submission. In that case, the member registrant does not need to take any further action.

A member registrant has also the option of updating individually its member dossier by including the information on classification and labelling. However, this update will be treated as an opt-out according to Article 11(3) of the REACH Regulation. Any opt-out must be justified by concerns relating to disproportionate costs, confidentiality of the information submitted or disagreement with the information selected for the lead dossier. Opting-out not only triggers a higher invoice but would also result in the dossier being prioritised for compliance check under Article 41(5)(a) of the REACH Regulation.

Read more:
http://echa.europa.eu/clp_en.asp

New TCC plug-in checks provision of classification and labelling

A new version of the TCC plug-in was made available on 1 December 2010 on the IUCLID website (**http://iuclid.echa.europa.eu/**). This new release of the TCC plug-in was adapted to include the requirements introduced by the CLP Regulation.

1 December 2010

Registration statistics

These statistics cover the number of dossiers submitted between 1 January and 30 November 2010. The dossiers accepted for processing by the 30 November 2010 legal deadline cover nearly 3 400 phase-in substances.

1. Number of submissions

Dossier Type	Accepted for Processing		Successfully completed	
	Total *	For the 2010 deadline **	Total *	For the 2010 deadline **
Registration	19 702	17 174	14 265	12 312
Transported Isolated Intermediate	3 544	2 692	2 699	1 979
On-Site Isolated Intermediate	1 429	857	1 037	492
Total	**24 675**	**20 723**	**18 001**	**14 783**

* Total includes dossier updates during the period.

** Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline.

2. Dossiers accepted for processing in 2010 by country

Country	For the 2010 deadline **	
	Number	Percentage
Germany	4 727	23 %
United Kingdom	2 430	12 %
The Netherlands	1 922	9 %
France	1 838	9 %
Belgium	1 676	8 %
Italy	1 504	7 %
Spain	1 251	6 %
Poland	705	3 %
Sweden	582	3 %
Finland	546	3 %
Czech Republic	444	2 %
Austria	392	2 %
Greece	313	1.5 %
Romania	302	1.5 %
Norway	289	1.4 %
Ireland	227	1.1 %
Portugal	217	1.0 %
Bulgaria	212	1.0 %
Hungary	212	1.0 %
Slovakia	170	0.8 %
Denmark	161	0.8 %
Luxembourg	141	0.7 %
Cyprus	105	0.5 %
Lithuania	101	0.5 %
Slovenia	86	0.4 %
Estonia	77	0.4 %
Latvia	66	0.3 %
Iceland	16	0.08 %
Malta	8	0.04 %
Liechtenstein	3	0.01 %
Total	**20 723**	**100 %**

3. Breakdown of submissions

	% Accepted for Processing	Ratio Member/Lead **
Joint - Lead registrant	12 %	
Joint - Member registrant	82 %	6.7
Individual registrant *	6 %	

* Includes individual submissions for non-phase in substances

** Number of Member Registrants for every Lead Registrant

4. Dossiers by company size and by Only Representatives

Company size	% Accepted for Processing For the 2010 deadline *
Large	86 %
Medium	9 %
Small	4 %
Micro	1 %
Dossiers submitted by an Only Representative	19 %

* Dossiers submitted by companies indicating a phase-in substance meeting the criteria for the 2010 deadline.

New manual on how to derive a public name

Registrants must provide a public name if they want to keep the chemical IUPAC name for their substance confidential. ECHA has published a new manual which explains to registrants how to derive a public name for a substance in this case. Keeping the IUPAC name confidential is permitted under certain circumstances in accordance with Article 10(a)(xi) of the REACH Regulation. Read more: **http://echa.europa.eu/doc/reach-it/ds17_public_name_en.pdf**

ECHA starts estimating abatement costs for chemicals

ECHA is starting to work with the EU Member States and stakeholders to collect data on the costs of reducing the negative impacts of chemicals. This work was launched in a workshop organised by ECHA on 6 October.

Reductions in the negative impacts of chemicals can take place through process modifications or "end-of-pipe" control technologies (such as waste water treatment or air filtration) or through the substitution of other substances or technologies. All such costs to reduce the negative impacts of chemicals are called abatement costs.

ECHA wishes to establish the capability to systematically use information about the costs of reducing the negative impacts of chemicals. To initiate this work it organised a workshop[1] where some 30 experts from Members States, industry, NGOs, academia and ECHA discussed the issues on 6 October 2010. "We would like to do this together with the Member States and industry, as we believe that this would also be beneficial for them," said Matti Vainio, Team Leader of Socio-economic Analysis at ECHA, when opening the workshop.

Matti Vainio, team leader of Socio-economic Analysis at ECHA

In the workshop there was general agreement that having good, transparent information on abatement costs should be beneficial for the authorities, for instance in identifying the most cost-effective ways to reduce the negative impacts of chemicals when developing restriction proposals. Companies would also benefit from such information by being able to identify cost-effective means to reduce the negative impacts of chemicals, for instance when assessing Risk Management Measures and Operating Conditions.

Abatement costs can be represented as a "cost curve" that usually slopes upwards at an increasing rate. This is because there are more options and thus it is cheaper to abate the first tons of a chemical compared to the last tons. In other words, tackling the first 10% of the problem is usually much cheaper that tackling the last 10%.

"It is important to understand that a cost-curve methodology works for single chemical/single effect problems," said Dr. Markus Amann of the International Institute of Applied Systems Analysis in a keynote presentation. "Therefore a standardised methodology for cost assessment and reporting would be very useful," he concluded.

ECHA's recently published "cost guidance"[2] was thought to be a helpful contribution. A draft report Abatement cost curves for chemicals of concern: Report on a pilot study – methodology and indicative examples, prepared by the Environment Agency in the UK, provided important input to the workshop. "This report demonstrated the potential for estimating abatement costs. It also showed the kind of simplifying assumptions that are needed to make the approach work using currently available data," summarised Bill Watts, coordinator of the project in the UK Environment Agency.

It seems that the practical application of cost-curves may suit in particular those substances where the minimisation of emissions would be one overall goal and where the environmental effect of the substances is broadly comparable.

During the discussion it was emphasised that buy-in from all stakeholders is vital for this kind of work to be fruitful. "Therefore, before testing the methodology in 2011, we will collect the views of stakeholders and discuss the issue in ECHA's Committee for Socio-Economic Analysis as well," Matti Vainio concludes.

Sixth Stakeholders' Day on 18 May 2011

ECHA will organise its sixth Stakeholders' Day on 18 May 2011. The event will take place adjacent to the third Global Helsinki Chemicals Forum which will be held on 19-20 May at the Helsinki Exhibition and Conference Centre.

The programme of the Stakeholders´ Day includes presentations on the feedback from the first registration deadline and on authorisation and evaluation. The popular one-to-one sessions with ECHA staff will also be continued.

We are looking forward to inviting you to yet another day packed with presentations, discussions and the latest information about REACH and CLP.

1 The conclusions and presentations will be made available on ECHA's website.

2 See http://echa.europa.eu/reach/sea_en.asp

ECHA's Helpdesk:

Submitting a Classification and labelling notification

The first deadline to submit a classification and labelling notification to ECHA is 3 January 2011. In cases where a substance is placed on the market on or after 1 December 2010, a notification has to be done no later than one month after placing it on the market.

If you want to know whether you need to submit a notification to the Classification and Labelling (C&L) Inventory, the following website is a good start: (**http://echa.europa.eu/clp/inventory_notification/notification_who_en.asp**).

Use the following tools to prepare your C&L notification:

1. Excel tool to create a bulk notification: allows you to submit notification information for several or a large number of substances defined by their EC or CAS number in a single file. Additionally, no M-factor or SCL can be set, if it is not already specified in Annex VI to the CLP Regulation

2. Online notification tool: When applicable, REACH-IT will automatically display the C&L from a harmonised C&L, a registration dossier or a previous C&L notification, and you will be able to agree with an existing entry in the Inventory for the same substance or provide further information

3. IUCLID 5: You can specify all requested information in IUCLID 5 and create a C&L notification dossier in IUCLID. For submitting several compositions for one substance you need to use IUCLID 5.

Do not forget to use the group of manufacturers and importers module in REACH-IT to submit a C&L notification on behalf of a group that agrees on a common C&L for the same substance.

ECHA has published supporting documents in 22 EU languages: **http://echa.europa.eu/clp/inventory_notification/notification_how_en.asp**

Remember also that your CLP National Helpdesk is the first point of contact to provide you support regarding CLP advice. A list of National Helpdesks is available at the Help section of the ECHA website: **http://echa.europa.eu/help_en.asp**

REACH-IT and Helpdesk opening hours

To help industry submit their CLP Notifications on time, ECHA will keep REACH-IT and the Helpdesk open as follows between 17 December 2010 and 5 January 2011.

REACH-IT

Normal opening hours (except for public holidays): Monday 08:00 to Friday 19:00 (GMT)

- 24–26 December closed
- 27 December 10:00 to 30 December 19:00 open for notifications to the Classification and Labelling Inventory only
- 03 January open 24 hours until 24:00
- 04 January closed for maintenance
- 05 January reopen at 08:00

Read more:
http://echa.europa.eu/news/na/201012/na_10_78_reachitopenings_20101210_en.asp

http://echa.europa.eu/reachit_en.asp

ECHA Helpdesk

- 17 December 15:00 contact web forms will be closed, except for the forms that are relevant for the C&L notifications
- Until 23 December close of business the Helpdesk will be responding to REACH & CLP questions
- 27 –30 December responding only to questions on CLP and REACH-IT user account management
- 02 January responding only to questions on CLP and REACH-IT user account management
- 3 January questions can be submitted until 17:00. The Helpdesk will be responding to CLP questions received by 17:00 until 20:00. REACH questions will be answered depending on the workload; CLP questions have priority.

Cooperation for sound management of chemicals

The implementation of REACH is monitored around the globe, and many countries and organisations are interested in cooperating with ECHA. Activities that enhance safe management of chemicals are a priority for ECHA.

REACH also assigns ECHA the task of cooperating with organisations and countries to advance the safe use of chemicals. To ensure appropriate coordination, ECHA agrees its international work plan with the European Commission. The plan is approved by ECHA's Management Board and published on ECHA's website.

ECHA is providing technical and scientific support to the European Commission on issues related to the safety of substances. Such work is, for instance, the joint development of the IUCLID format, the QSAR Toolbox and the eChemPortal with the OECD and work being done under the Stockholm convention on Persistent Organic Pollutants.

ECHA's international work plan for 2011 gives priority to work on international standards such as harmonised tools and assessment, especially with the OECD and the United Nations. Also, activities that support the understanding of REACH and CLP implementation in third countries (which are neither EU Members nor EEA countries*) are a priority.

ECHA will further develop cooperation with other regulatory agencies to exchange scientific and technical information. By contrast, any exchange of confidential information requires an agreement between the EU and the other party. In 2010, ECHA and Canada agreed a Memorandum of Understanding, and a Statement of Intent has been signed between ECHA and the United States Environmental Protection Agency. Initial discussions with Australia are also taking place.

EFTA member Switzerland has expressed its intention to partly implement REACH, and ECHA is following the discussions between the country and the Commission.

ECHA's Management Board may invite third countries to participate in the work of the Agency, in agreement with the relevant Committee or the Forum, as well as international organisations in the field of chemicals regulation as observers. Industry and NGOs can participate as observers in the Committees and Forum according to the policy confirmed by the Management Board. This has not yet been applied to any country.

ECHA contributes to international exchange by arranging webinars, Stakeholder Days, visits and presentations.

Read more: **http://echa.europa.eu/doc/about/organisation/mb/mb_49_2010_work_plan_international_activities_2011.pdf**

* Apart from EU Member States, non-EU members of the European Economic Area (Iceland, Liechtenstein and Norway) also implement REACH and participate in the work of ECHA's Committees and the Forum, based on the EEA agreement. They have no voting rights but they can make proposals for risk management of substances, and they have observer status in the Management Board. In 2010, the EEA country Iceland also submitted a membership application to the EU.

Candidate countries preparing for REACH and CLP implementation

The candidate countries Croatia, the former Yugoslav Republic of Macedonia and Turkey, and the potential Western Balkan candidates to the EU are a special target group. The Commission has allocated funds through the Instrument for Pre-Accession Assistance programme to support the candidates in preparing for working with ECHA.

They are introducing new chemicals legislation and building up structures to be able to fully implement REACH and CLP, pending on their admission to the EU. Companies and authorities are being trained and helpdesks set up.

A special challenge will be the situation of the companies which currently have no trade with the EU and no registration obligations. Croatia has asked the European Commission for a transitional period to help such companies.

This autumn, delegates from the three countries participated in a workshop in ECHA focusing on the work of the three committees, the Forum, the Helpdesk and guidance and giving a more in-depth view on how the EU Member States cooperate with the committees and the Forum.

The cooperation continues with further workshops in the candidate countries.

Workshop with the candidate countries in autumn 2010

ECHA Registration and Dossier Submission Unit staff

First registration deadline

Behind the scenes

With the REACH milestone successfully behind us, Mike Rasenberg, the Contingency Manager at ECHA, is adding up the numbers. His task as Contingency Manager was to ensure that ECHA was well prepared for the 2010 deadline, taking into account the different estimations in the number of dossiers likely to arrive as well as the timing of the submissions. "We aimed at planning and executing everything in such a way that registrants did not even realise that we had contingency plans in place", Mr Rasenberg says.

ECHA set up a contingency task force in late 2009 with the purpose of identifying the level of resources needed for the Registration and Dossier Submission Unit to be able to process the registration dossiers received during 2010. The Task Force came up with three different scenarios, each based on varying estimations of the number of dossiers to be submitted to ECHA.

"We estimated that the Registration Unit would be able to work independently within ECHA up to around 25 000 dossiers. This was the original European Commission estimate. For numbers beyond that we knew we would need help from other parts of ECHA", says Mr Rasenberg. To ensure sufficient staff levels, the Registration Unit trained around 80 internal staff who would be able to work on the different stages of the registration process if needed. This so called "flexible deployment" of staff became a reality a few weeks before the end of September. "We then experienced that not only the number of dossiers is critical, but also the timing of their arrival. There was a huge peak in submissions just before 30 September. Many registrants wanted to submit before that date to get the Technical Completeness Check result within three weeks instead of three months. We also used internal help as needed in order to free our own resources to test a new version of our IT system." In addition to the internal shifting of staff, the Registration Unit had support from other units in ECHA, for instance to recruit statutory and temporary staff. "We went from a unit of 20 people to a unit of 60-70 people. That requires a lot of human resources and facility management", Mr Rasenberg adds.

An important part of the task force work was the optimisation and automation of the registration process. ECHA put a lot of effort into IT development. The ICT unit supporting the operational IT and the unit for Scientific IT tools played a crucial role in this success. "What the registrants probably recognised is that initially when they submitted a dossier it would take at least a day before the processing would start, and now they have the result of the very first step within hours. We still verify manually if the registrant has failed in the Technical Completeness Check. And the very last step – the decision sending - is verified manually", Mr Rasenberg explains. With the development of IT, the monitoring and reporting on the status of registrations got easier. "We are now able to monitor the current situation accurately, run predictions on the workload and produce statistics without too much effort."

The task force also planned how to support the ECHA Helpdesk in their communication with registrants. It was decided to open a call centre, a special service for registrants. "Creating a call centre enabled the Helpdesk staff to call registrants back in a professional way. We also followed the Helpdesk enquiries with a considerable number of staff from other units," Mr Rasenberg explains. For instance the Registration Unit staff called back registrants who failed in the first step of their submission. All in all ECHA proactively contacted over 500 companies during the last quarter. "We also developed a REACH-IT back-up system and extended the opening hours of REACH-IT to weekends to help industry submit their dossiers on time," Mr Rasenberg adds.

ECHA is said to have matured after the deadline from a young agency to an established one. Mr Rasenberg, however, thinks that by carrying out a contingency exercise which involved the whole Agency, and by showing an incredible internal flexibility, ECHA can already be considered to be a mature agency when it comes to dealing with great challenges. "The industry rose to this great challenge, and so did our staff. We have our staff to thank for the fact that everything went so smoothly", he concludes.

eChemPortal - A powerful tool

The OECD eChemPortal is a powerful, freely accessible internet portal for scientific information on chemical substances. It can be very useful for scientists, companies having regulatory obligations like the C&L notification, competent authorities, students and the general public interested in chemistry.

The portal helps authorities for instance to assess confidentiality claims. Under REACH, the official substance name can only be claimed confidential if it is not yet available on a public domain.

Facilitating functionalities

The eChemPortal gives access to information on over 600 000 substance records in 19 databases. For example, US EPA, Japanese, Australian, Korean, Canadian and Finnish governmental databases and ECHA database of registered substances all participate in this project.

Queries can be made on substances and their properties. Currently, only the ECHACHEM database and the OECD Existing Chemicals Screening Information Data Sets (SIDS) Database allow a search on properties, 27 000 endpoint records. Early 2011, two other databases will allow a search on property information, and there will be more when authorities have their data in the OECD harmonised template format. Data in IUCLID format can easily be uploaded.

The level of the data depends on the provider and this is indicated. There is no separate review for the portal. There are no commercial databases, and an OECD Steering Group decides which databases will be accepted.

Many useful search functionalities facilitate the work. You can combine up to 10 searches, using different logical combinations, save your query, bookmark a query and retrieve updated information, and import the results into Excel with the links to the databases. A kind of synonym database in the background enables a search for instance in Chinese or Japanese.

Power will be added

ECHA scientists Sandrine Lefevre-Brévart (project manager), Roberta Bernasconi (scientific project manager) and Tommy Hägg (IT technical supervisor) are members of the project team managing the development of the portal. Ms Sally DeMarcellus, project manager from the OECD and Mr Clemens Wittwehr, IT project member from the European Commission also make up the team. ECHA funded the project and was responsible for the timing and quality of the delivery. ECHA is hosting the portal, and the OECD takes care of the administrative operational work.

Sandrine, Roberta and Tommy say that the database is a very powerful tool and more power will be added. They think that in future it could be possible to access for instance the Classification and Labelling Inventory via the portal and to include regulatory information like the REACH Annex XIV. But all extensions will be agreed in the OECD, they underline.

The data will be regularly updated, and when new substances are published on the ECHA dissemination website, they will also be made available via the eChemPortal.

www.echemportal.org

ECHA's Member State Committee:

Eight SVHCs to go on Candidate List

ECHA´s Member State Committee identified unanimously at its meeting in Helsinki on 3 December eight new Substances of Very High Concern (SVHCs). The Committee agreed that the following eight Substances of Very High Concern should go on the Candidate List:

- Chromium trioxide, acids generated from chromium trioxide and their oligomers, cobalt(II)sulphate, cobalt(II)dinitrate, cobalt(II)carbonate, cobalt(II)diacetate, 2-methoxyethanol and 2-ethoxyethanol, which are either carcinogenic, mutagenic or reprotoxic (CMR) substances.

The eight substances were included in the Candidate List as ECHA took a decision on their inclusion on 15 December. They may in future become subject to authorisation.

The Committee also gave a favourable opinion on ECHA's draft recommendation to add eight substances to the Authorisation List. See page 14.

Bulgarian • Czech • Danish • Dutch • Estonian • English • Finnish • French • German • Greek • Hungarian • Italian • Latvian • Lithuanian • Maltese • Polish • Portuguese • Romanian • Slovakian • Slovenian • Spanish • Swedish

ECHA's home page now in 22 languages!

http://echa.europa.eu/

Liisa Rapeli-Likitalo:

It's not the end but just the beginning

With the first registration deadline now behind us, sighs of relief can be heard across Europe. Liisa Rapeli-Likitalo, Manager of Kemira Product Safety development and REACH Team, is especially happy now that the bulk of the hard work is done. Over the last two years she has led a team of forty people, with eight in the core group, who have worked together to comply with the requirements of REACH.

Kemira is a global chemicals company focused on serving customers in water-intensive industries. Kemira submitted nearly a hundred registrations, acting as Lead Registrant for sixteen of them. We asked Liisa to tell us about the registration process from the perspective of a large company.

Did it all go according to plan?

It went better than expected. We feared quite a lot after the continuous updates of IUCLID and REACH-IT over the summer but it went much better than expected. After a few registrations it started to go more and more smoothly.

With the benefit of hindsight, what advice can you pass on to other companies?

First of all I would like to tell industry to plan, prepare and allocate resources. They are the most important things. And along with resources you must have expertise. Small companies should establish a relationship with an experienced service company. The message is to prepare, prepare, prepare. For 2013 check if the substances have already been registered in 2010 and if so then the lead dossier already exists. In this case the process is not too complicated for a member registrant. But if you have substances for 2013 that have not been registered in 2010 make sure that the Lead is agreed without any delay.

One of the challenges during this registration phase was that consultants were busy and some of them were not able to deliver, so you need to ensure you have the necessary service providers available. Another important aspect is that in your own organisation you will need support from all units. It's not only REACH experts doing the job but all functions of the organisation need to be involved.

Remember that registration is not the end but just the beginning. Now we have to start communicating and working towards the safer use of chemicals and we have to have the systems in place. REACH requires fundamental changes in companies' IT infrastructures so that substances and their uses can be tracked. It is not simple at all.

And for ECHA?

It would be great if member registration could be simplified so that still more information could be contained in the lead file. Simplify the guidance documents! There are so many that even those who use them daily can't find the detailed information we are looking for. Accessing information needs to be easier and quicker.

What were the challenges of being the Lead registrant?

Time was at a premium. We had to deal with tasks for which no support system existed. We would have failed as a lead without a proper SIEF communication system. We used a commercial tool to deal with 1600 companies. It allowed us to document correspondence so we could go back and forth to check the status. By just using e-mails we would not have made it.

Some smaller companies asked for a reduced fee for the letter of access. Our REACH experts needed to act as a helpdesk for these companies and also to our business people. They explained repeatedly that all members of a SIEF need to be treated equally fairly and transparently. Special arrangements could not be agreed with individual SIEF members.

As a lead, another challenge was the collecting of samples. In total we needed to collect and analyse about 200 samples.

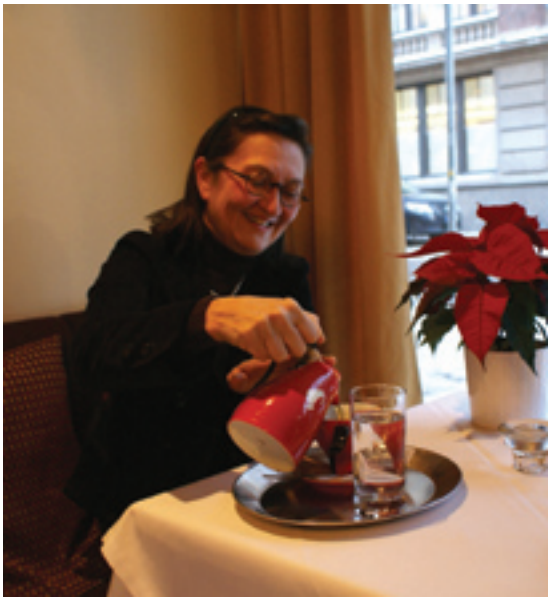
And as a member?

In this case time was an even more important issue, because we were waiting for the Lead!

How do you feel now?

Great. We did it! Or at least this phase is done… with a few extra grey hairs. We'll try to relax over Christmas, but we still have to finalise several hundred CLP notifications and then it's time for the safety data sheets and the exposure scenarios. One important milestone has been reached and now it is time to prepare for the next ones.

Finally time for a nice cup of tea, says **Liisa Rapeli-Likitalo.**



Mr Dancet at EP Committee on the Environment, Public Health and Safety

"Exciting and momentous time"

Executive Director Geert Dancet visited the Committee on the Environment, Public Health and Safety of the European Parliament for exchange of views on 9 November.

This is an extremely exciting and momentous time for us working to protect people and the environment from the potentially hazardous effects of chemicals," Mr Dancet said and added that he was very proud of ECHA managing the work with high level of proficiency although the Agency is new and still growing.

The Executive Director informed the Committee of the state of play of registrations and CLP notifications and the work that was done to assist companies to register successfully, in cooperation with the stakeholders. He said that ECHA has actively listened industry and stakeholders and responded to the issues raised by developing practical solutions within the legal framework and offering support that was not necessary foreseen when ECHA's resources were planned. He thanked the Parliament for their continuous support to ECHA.

Mr Dancet raised the situation of SMEs and downstream users as some of the main concerns. Especially the CLP notification and the next registration deadlines will demand a lot from the SMEs, and ECHA is supporting them by helpdesk services, translations, simplified guidance, webinars and publications. The downstream users have faced uncertainties, as it was often difficult for them to get a confirmation on the registration plans of their suppliers.

Among the priorities are the 2013 registration deadline, enforcement of REACH which is task of the Member States, identification of a higher number of Substances of Very High Concern, scientific evaluation of registrations, and contributions to the regulatory work on new scientific developments, such as nanomaterials and endocrine disruptors. ECHA is currently preparing its report to the European Commission on the functioning of REACH.

The Members of the Committee who have been following ECHAs activities very attentively since the start of the Agency used the opportunity for questions and exchange of opinions on various issues like the availability of IT systems in all EU languages; working of SIEFs, nanomaterials, animal testing, transparency and conflict of interests, problems of downstream users and REACH implementation issues for SMEs. Their general perception was that ECHA is performing very well under the given circumstances

New Year, new organisation

After having tackled the registration and the C&L notification deadlines, ECHA's organisational structure is changing in the New Year. Four new Directorates will be created: Regulatory Affairs, Evaluation, Risk Management and Information Systems. These changes will take effect on 1 January 2011.

In the coming years, the number of ECHA staff is expected to increase to over 500. ECHA is expected to be given new responsibilities under a regulation on biocides, based on a Commission proposal, and the Prior Informed Consent Regulation. Other additional tasks could also emerge from the review of the REACH Regulation in 2012.

New Head of Unit

▸ Ms Elina Karhu has been appointed as the new Head of Risk Management Unit as of 1 December 2010.

National authorities inspect REACH infringements

The first REACH registration deadline has passed and one historical milestone achieved. However, to make REACH operate successfully across Europe, the role of enforcement in the Member States is vital.

REACH enforcement in the EU Member States, Norway, Iceland and Liechtenstein is carried out by the national enforcement authorities. At the moment, the first EU-wide REACH enforcement project on registration, pre-registration and safety data sheets, so called REACH-EN-FORCE 1, is still on going. The project started in 2009 but was extended to last until spring 2011 to assess how companies are complying with the first registration deadline. The national authorities are checking for instance that manufacturers and importers have registered or pre-registered their substances and that correct Safety Data Sheets are in place.

As enforcement is a national responsibility, each EU Member State ensures an official system of controls and determining the penalties that apply to the infringement of REACH requirements in its territory.

Harmonised inspection at EU-level

To strenghten the enforcement of the REACH and CLP Regulations, ECHA hosts the Forum for Exchange of Information on Enforcement (Forum). The Forum coordinates the network of national enforcement authorities. Through the network, the inspectors participate in joint enforcement projects and inspections in order to achieve a harmonised approach to enforcement across the EU.

The Forum will start another EU-wide enforcement project in 2011 – the so called REACH-EN-FORCE 2. It targets formulators of mixtures, and the inspectors will check the supply-chain related obligations, the CLP notification requirement, as well as the registration or pre-registration status for substances in mixtures.

…and at national level

The national authorities produce their own strategies and campaigns; the Forum's strategy and common minimum criteria for inspections serve as templates. Examples of national campaigns are available on the respective websites of the authorities - list available on ECHA's website.

Read more: **http://echa.europa.eu/reach_enforcement_en.asp**

Full composition of the Board of Appeal meets

On 25-26 November, the full Board of Appeal, including the alternate and additional members, met in Helsinki, just after the three new alternate Chairmen had been appointed. In the near future, a new regular Technically Qualified Member will also join the Board of Appeal in Helsinki.

The annual meeting of the Board of Appeal with alternate and additional members brings together the regular members and the Registry who are located in Helsinki and the alternate members located in Spain, UK, Germany, Ireland, Italy, Greece, The Netherlands, France and Belgium.

The meeting provides a platform for updating information and enhancing the necessary coordination and cooperation among all the members and the Registry of the Board of Appeal, to guarantee the full and smooth operability of the Board.

Read more:
http://echa.europa.eu/appeals_en.asp

Technically Qualified Member retires

The Technically Qualified Member of the Board of Appeal, Harry Spaas, has retired from his position, as he has reached the age of retirement. He will, however, take up the position of an alternate/additional Member of the Board of Appeal. Mr Spaas has a scientific background and vast experience in industry.

Mr Harry Spaas

ECHA recommends that eight Substances of Very High Concern be subject to authorisation

The European Chemicals Agency has submitted to the European Commission a recommendation that eight additional chemical substances of very high concern should in future not be used without authorisation. Four of the substances are classified as both carcinogenic and toxic to reproduction, three as carcinogenic and one as toxic to reproduction. They are all used in processes or products to which workers or consumers are exposed.

The protection of human health and the environment is at the heart of REACH. Making these eight Substances of Very High Concern subject to authorisation seeks to ensure that their risks are properly controlled and that the substances are progressively replaced.

The eight substances are:

- **Diisobutyl phthalate** – DIBP (toxic to reproduction). A substance used as plasticiser for nitrocellulose, polyacrylate and polyacetate dispersions;
- **Diarsenic trioxide** – As203 (carcinogen). A substance used in the manufacture of glass with special properties and of zinc;
- **Diarsenic pentaoxide** – As205 (carcinogen). A substance which could be used as a replacement for diarsenic trioxide, no known current uses in the EU;
- **Lead chromate** (carcinogen and toxic to reproduction). A substance used as pigment and in the manufacture of pyrotechnics;
- **Lead sulfochromate yellow** - C.I. Pigment Yellow 34 (carcinogen and toxic to reproduction). A pigment used to colour plastics and coatings;
- **Lead chromate molybdate sulphate red** - C.I. Pigment Red 104 (carcinogen and toxic to reproduction). A pigment with similar uses as lead sulfochromate yellow;
- **Tris(2-chloroethyl)phosphate – TCEP** (toxic to reproduction). A substance used as a plasticiser and viscosity regulator with flame-retarding properties for coatings;
- **2,4-Dinitrotoluene - 2,4-DNT** (carcinogen). A substance mainly used in explosives and propellants for ammunition.

The final decision on the inclusion of the substances in Annex XIV of the REACH Regulation will eventually be taken by the European Commission following the regulatory procedure with scrutiny. Then, substances on the List can only be used within the EU when authorised for specific purposes.

Further information

This is the second time that the Agency recommends substances for authorisation (the first was in June 2009). From its list of candidate substances, ECHA prioritised in spring this year the eight substances based on their hazard properties, the volumes used and the likelihood of exposure to humans or the environment. The Agency took into account the comments received from interested parties during the public consultation on its recommendation, which took place between the beginning of July and the end of September. It also considered the opinion of the Member State Committee, who supported ECHA's conclusion that the substances should be subject to authorisation and that there are no grounds to recommend exemptions of particular uses of these substances from authorisation.

Recommendation
http://echa.europa.eu/chem_data/authorisation_process/annex_xiv_rec/second_annex_xiv_rec_en.asp

MSC opinion
http://echa.europa.eu/doc/about/organisation/msc/opinion_draft_recommendation_annex_xiv_second.pdf

Overview of the authorisation process under REACH
http://guidance.echa.europa.eu/authorisation_en.htm

Evaluation of registration dossiers

ECHA starts to publish statistics on dossier evaluation, compliance checks and testing proposals. Registration statistics will also be published.

▸ Each registration dossier includes a detailed description of the identity of the substance and safety related information on the substance and its identified uses. ECHA carries out a technical completeness check before it issues a registration number. These checks do not include any assessment of the quality or adequacy of data, but this can be assessed during the process of dossier evaluation as a follow-up to registration.

Dossier evaluation is subdivided into compliance checks of registration dossiers (Article 41 REACH) and examinations of testing proposals (Article 40 REACH). Both processes use the same decision-making process (Articles 51 and 52 REACH) and result in requests for further information to be provided in updated dossiers.

Compliance checks are used to verify whether the information submitted by registrants is in compliance with the legal requirements. The legislator has provided that at least 5 % of registration dossiers must be selected for checking. The Agency can either evaluate the quality of the information throughout the whole dossier, including the chemical safety report, or can target the evaluation to a certain limited part of the dossier e.g. to the human health information or to specific parts of the chemical safety report.

Registrants submit testing proposals and seek permission from ECHA to undertake tests as required by REACH Annexes IX and X, in cases where they identify a data gap and cannot otherwise fulfil the information requirements. ECHA evaluates all such proposals with the aim of avoiding unnecessary vertebrate animal testing and to ensure that adequate and reliable data is generated when necessary. Therefore, testing proposals which include animal tests are published and third parties are invited to submit relevant data before a decision is taken. When a testing proposal is examined, the grounds for conducting the proposed test is evaluated, taking into account both the dossier information and all relevant and scientifically valid information received from third parties.

Both dossier evaluation processes comprise tasks in which the ECHA secretariat makes scientific and legal judgments. These judgements consider whether the information provided in the dossier meets the requirements of REACH. If ECHA concludes that additional testing or other information is required, it prepares a draft decision which is then adopted through a decision-making process. All draft decisions made by the Agency must be unanimously supported by EU Member States and will only then become final legally binding decisions. The need for unanimity underlines the intention of the legislator to avoid unnecessary (animal) testing and ensures at the same time that reliable and adequate data will be developed and all available information considered. If unanimous agreement cannot be reached the European Commission prepares the draft decision to be taken in the Committee procedure referred to in Article 133(3) REACH.

The scientific judgement necessary in dossier evaluations requires expert knowledge from different areas as well as legal scrutiny, which makes the evaluation process demanding in relation to both time and resources. ECHA has to prepare a draft decision within one year of the initiation of a compliance check. A draft decision on testing proposal evaluation for a non phase-in substance has to be prepared within 180 days of receiving such a registration. For phase-in substances registered by 30 November 2010, a draft decision must be ready by 1 December 2012. The subsequent decision-making phase is governed by the legal deadlines provided in REACH and about additional 5 months are needed to bring the draft decisions through all the commenting phases until they are adopted and become final decisions.

All testing proposal examinations will lead to a formal decision, for compliance checks a formal decision is the outcome only when the dossier does not comply with the information requirements in REACH. During the compliance check stage, the Agency may also identify other shortcomings which are not necessarily related to a lack of information. For example, the risk management measures proposed by the registrant may be inadequate if the proposed classification and labelling does not reflect the reported study results. For a compliance check, therefore, ECHA uses quality observation letters to invite the registrant to update the dossier in such cases. Furthermore, ECHA informs the Member States which may take action if the registrant does not clarify the issue. The findings made through dossier evaluation may be used for further risk management processes under REACH, such as substance evaluation, restriction or authorisation.

▸ The tables below report on the statistics of the dossier evaluation processes from 1 June 2008 to 30 November 2010. Please note that the number of registered dossiers in table B also contains dossiers with testing proposals (see table A) and covers both normal registration dossiers and registrations of transported isolated intermediates. On-site isolated intermediates are not reported as they will not be subject to compliance checks. A testing proposal examination may be terminated due to withdrawal of the testing proposal before a draft decision is issued, and therefore not all testing proposals lead to a decision. The phase-in status is reported as indicated by the registrant in the dossier.

A. Testing proposals

		Phase-in*	Non phase-in**	Total
No of registered dossiers [1]	Containing testing proposals	515	30	**545**
	Containing testing proposal for vertebrate animals	383	22	**405**
No of testing proposals	Covered by registered testing proposals	1 269	83	**1 352**
	Testing proposals for vertebrate animals	1 000	68	**1 068**
No of third party consultations	Closed	4	9	**13**
	Ongoing 30 November 2010	2	3	**5**
	Planned	377	10	**387**
Dossiers with testing proposals opened for examination [2]		79	23	**102**
Draft Decisions sent to the registrant [3]		0	4	**4**
Final Decisions sent to the registrant		0	5	**5**
Terminated testing proposal examinations [4]		1	2	**3**

[1] Successfully registered (accepted and fee paid).
[2] Dossiers ever opened for examination notwithstanding their current status
[3] Draft decisions which did not become final by 30 November 2010 nor withdrawn due to termination of TPE.
[4] Terminated at the decision-making stage upon further information provided by the registrant (e.g. cease of manufacture or withdrawal of a testing proposal).

B. Compliance check

	Phase-in	Non phase-in	Total
No of registered dossiers, submission motivated by the 2010 deadline [5]			**14 350**
No of dossiers opened for compliance check [6]	41	117	**158**
Draft Decisions sent to the registrant [7]	3	22	**25**
Final Decisions sent to the registrant	3	5	**8**
Quality Observation Letters sent to the registrant [8]	8	30	**38**
Terminated compliance checks [9]	2	25	**27**

* phase-in
substances subject to transitional arangements in REACH registration

** non phase-in
new substance to the EU-market

[5] Successfully registered (accepted and fee paid). Further breakdown of a dossier will be conducted in the next issue. The number will change in the coming months after the registration of all the submitted dossiers has been processed
[6] Dossiers ever opened for compliance check notwithstanding their current status.
[7] Draft decisions which had not become final by 30 November 2010.
[8] Some quality observation letters have been sent together with draft decisions.
[9] Terminated upon further information being provided by the registrant or without administrative action.