ECHA
EUROPEAN CHEMICALS AGENCY

Accredited Stakeholder Workshop 2013

Proceedings
Brussels, 29 November 2013

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Workshop Proceedings – Accredited Stakeholder Workshop 2013

Reference: ED-AK-14-001-EN-N
ISBN: 978-92-9244-375-7
ISSN: 2315-2818
DoI: 10.2823/72743
Publication date: February 2014
Language: EN

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1 Summary

Accredited Stakeholder Workshop is a platform for strategic discussions between ECHA and its accredited stakeholder organisations, where stakeholders have the possibility to give input to ECHA's work plans and future priorities. This was the third workshop.

This year the workshop had four main topics: the quality of dossiers, the implementation of the Biocidal Products Regulation, ECHA's approach to transparency and the substitution of hazardous chemicals. The topics were proposed by stakeholders and selected as themes where strategic discussion is considered useful at this point in time.

Recommendations from the workshop will be taken into account in the review of the milestones of the 2014-2018 Multi-Annual Work Programme and the drafting of the 2015 Work Programme. ECHA will also take them into consideration in the ongoing development of its processes.

2 Participants

The workshop was attended by 35 participants from 30 accredited stakeholder organisations, representing the following sectors: industry (20), NGOs (7), academia (1) and social partners (2). ECHA currently has 73 accredited stakeholder organisations.

The following four Directors participated from ECHA: Geert Dancet, Executive Director; Christel Musset, Director of Registration; Jukka Malm, Director of Regulatory Affairs and Jack de Bruijn, Director of Risk Assessment. ECHA's Communication Unit staff attended to facilitate the breakout sessions and take care of practical arrangements.

A list of participants is attached as Annex 1.

3 Concept

The aim of the Workshop is to provide a forum for strategic discussions between ECHA and accredited stakeholder organisations, which represent key interest groups for the chemicals legislations managed by ECHA.

Themes of the workshop reflect topical priorities both for ECHA and its stakeholders. The programme includes updates from ECHA, but the main focus is on interactive discussions between participants. The discussions take place in breakout groups where various stakeholder interests are represented, to the extent possible. Key recommendations from the breakout sessions are reported to the plenary by three stakeholder rapporteurs.

Each of the breakout groups focused on one of the key topics. With representatives from different sectors in all breakout groups, reflections were made from several viewpoints. This provided a good overview of the concerns and key questions related to each of the topics. At the end of the session, the groups concluded with shared recommendations which were put forward and will be recorded as key recommendations for future actions. These recommendations were further discussed in the plenary session.

The agenda is attached as Annex 2.

4 Topics

The topics for the workshop were proposed by stakeholders and selected as themes where strategic discussion was considered useful at this point in time. This time, the workshop also included a separate breakout session for biocides.

The following four topics were covered in the Accredited Stakeholder Workshop 2013:

- Improving the quality of data
- Implementing the Biocidal Products Regulation
- ECHA's approach to transparency
- Substitution of hazardous chemicals

Improving the quality of data

ECHA's work for improving the quality of data was presented in the plenary session by Christel Musset, Director for Registration. She highlighted that quality of information is key in ensuring better knowledge on the properties of chemicals and their uses, better safety control measures in the supply chain and better information to the public at large. This is why ECHA set quality improvements as one of its strategic objectives for the next multi-annual planning period.

She presented the various implementation steps to be taken by ECHA to stimulate the increase of data quality, such as a systematic analysis of incoming dossiers for triggering further regulatory action if needed, the preparation of a roadmap for 2018 registration to help registrants, in particular SMEs, to prepare high-quality dossiers and the review and refinement of ECHA's compliance check strategy. She explained the different aspects considered in the implementation plan, such as the consistency of information within the dossier, compliance with the regulatory requirements and the usefulness of information for the defined purpose.

She also highlighted the importance of the accredited stakeholders in both giving input to ECHA and in multiplying information to their members.

Implementing the Biocidal Products Regulation

Implementation of the Biocidal Products Regulation was presented in the plenary session by Jukka Malm, Director for Regulatory Affairs. He introduced the processes and support which are already available, explained what is in the pipeline and presented the main challenges for ECHA.

One of the breakout sessions was dedicated to discuss issues related to the implementation of the Biocidal Products Regulation. The group decided on three discussion topics: coordination with other legislation, harmonisation and stakeholder engagement. The group was divided into three smaller groups and tasked to identify the main challenges related to the topics and to recommend solutions.

Coordination with other legislation

The group highlighted that similarities and overlaps of different legislation are a challenge for industry, as requirements vary and they should be aware of all of them. Challenges are especially related to the identification of borderline cases, different authorities making different decisions and the different data requirements for different regulations. They also noted that finding data generated under different legislation can be challenging.

The group recommended following activities:

- Update guidance on borderlines regularly;
- Communicate decisions/interpretations on treated articles clearly and in a timely way;
- Develop a new or adapt current IT tools to make data available;
- Launch a pilot project to identify gaps and overlaps;
- Support the harmonisation of Member State decisions.

Harmonisation

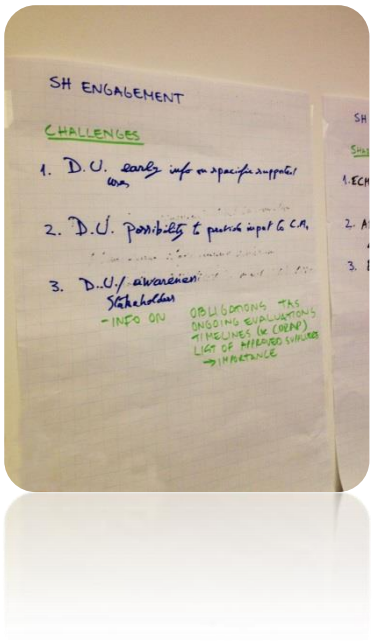
The group discussed the importance of harmonised implementation in all Member States, but also between related legislation. In line with the other group, they considered alignment with existing legislation (PPP, REACH, CLP, Cosmetics, etc.) as a key challenge. The group also considered the harmonised implementation of Biocidal Products Regulation requirements with different Member States as a challenge (e.g. borderline discussions, treated articles). They noted that if Member States are not able to meet the deadlines, the harmonisation could be jeopardised.

The group recommended the following activities:

- ECHA, Commission and Member States should communicate decisions taken and give practical examples on the website and in guidance documents;
- ECHA and Commission should motivate Member States to meet the deadlines and educate about other legislation;
- Long term: ensure that the future reviews of existing legislation refer to the Biocidal Products Regulation and involve ECHA where relevant.

Stakeholder engagement

The group's primary concern was the information available for downstream users, and in particular how their specific use may be impacted by the approval/authorisation process, and their limited possibilities to provide input to ECHA during the processes. They felt a need for awareness-raising targeted at downstream users, especially on information on treated article obligations, ongoing evaluations and expected timelines for active substance approvals. They also noted that the downstream users should be more aware of the importance of the list of alternative suppliers.



The group recommended following activities:

- ECHA to disseminate information to downstream users;
- ECHA/Commission to contact industry associations at an early stage during active substance evaluation;
- ECHA's communication team to suggest awareness-raising activities based on experience from REACH.

ECHA's approach to transparency

Another breakout session discussed ECHA's approach to transparency. Discussions focussed on the balance between confidentiality and transparency and getting stakeholder views on what constitutes a transparent organisation. The group were tasked to come up with five recommendations for ECHA to enable the Agency to become more transparent.

The group commented that, although there is always work to be done, ECHA is already very transparent when compared with other organisations and administrative bodies.

The shared factors for any organisation to be considered transparent were the following:

- Transparency policy: what will be made public and what will be kept confidential, including management processes and conflicts of interest;
- Predictable and consistent decision-making processes and timelines;
- Making information available and understandable to different audiences;

- Contribution and observation of stakeholders in decision-making through open and participatory decision-making;
- Timely publication of key documents and timely responses to enquiries.

Shared recommendations for ECHA

- ECHA's transparency policy to be enhanced in collaboration with stakeholders;
- Review stakeholder participation in ECHA's Committees to ensure useful participation and maintain transparency;
- Increase transparency of the evaluation process and results, the criteria for selection of dossiers for evaluation, timeliness;
- Providing information that is understandable / targeted to more general audiences;
- Timely publication of and responses to correspondence on decisions.

During the plenary, members of the group were asked to further clarify the third recommendation on increasing the transparency of the evaluation process. The group explained that they wanted more clarity on, for example, how many substances had gone through the process and which draft decisions had led to a final decision. There were also several other topics covered under this recommendation such as: the need to know more about cases where unanimous decisions had been taken; a general increase in stakeholders' understanding about ongoing processes such as compliance checks and testing proposals; and increasing clarity on the difference between dossier and substance evaluation where very few of the stakeholders had comprehensive knowledge.

Substituting hazardous chemicals

This breakout group was tasked to identify the key challenges for promoting substitution, getting input on how better to monitor the success of substitution in companies and to encourage discussion between industry and NGOs.

The breakout group had a lively discussion on the promotion of substitution and related challenges. The topics included: the authorisation process and a need for better long-term security for industry in planning their activities; the role of downstream users in the authorisation process; the issue of the global market and manufacturers outside the EU; the use of different risk management options; the need for a transparent process before a substance is placed on the candidate list; and the final goal of substitution: safer use of chemicals.

Shared recommendations for ECHA

- Highlight early warnings on authorisation:
  - Tools for industry to provide early warnings on authorisation and substitution throughout the supply chain;
  - ECHA could contact pre-registered companies registering substances according to art. 57 SVHC (substances to be included in annex XIV);
- Positive messages from ECHA needed about authorisation and communicating best practice on substitution;
- ECHA to give more clarity on the authorisation process and role of the Candidate List.

The challenges of substitution were also highlighted in the plenary discussion. Some participants wished to have more guidance from ECHA regarding authorisation and substitution; they especially pointed out the need to receive information on best practice. More examples of substitution and innovation should be made available. The Subsport portal was mentioned as one source of information on substitution cases. On the other hand, many companies were not keen to make details of their substitution process and new substances public. It was highlighted that the substitution process was very long and that results would only be visible after several years.

5 Follow-up from 2012

The Executive Director of ECHA, Mr Geert Dancet reported back on how ECHA has addressed the recommendations from last year's workshop. The Accredited Stakeholder Workshop 2012 concluded with recommendations on three topics: improving the quality of data; identifying and addressing chemicals of concern; and cooperating within the Committees.

Relating to the improvement of the quality of data, Mr Dancet highlighted the development of the dissemination website, the synchronisation of releases of new IT-tools for submission; and the Chemical Safety Report/exposure scenario roadmap as key follow-up activities.

With regard to the identification and addressing of chemicals of concern, he highlighted the following activities: the SVHC Roadmap 2020; PBT guidance update; publication of further information on public consultations on ECHA's website; and the review of the completeness and compliance check processes as major developments since the previous workshop.

Finally, on cooperation within the Committees, ECHA agreed with the stakeholder recommendation that RAC and SEAC opinions should be science-based and not politically driven and welcomed stakeholder feedback if this was not the case. ECHA also agreed, when not bound by legal deadlines, to try not to publish public consultations during holiday times. In line with the workshop recommendations, ECHA has also increased information explaining confidential business information on the Committee web pages.

Participants received a document with each shared recommendation and a statement from ECHA on the status of the follow-up. The complete follow-up table of 2012 recommendations is available here.

6 Conclusions

Input received during the workshop will be taken into account in the drafting of the Work Programme 2015 and in the review of the milestones of the 2014-2018 Multi-Annual Work Programme.

The recommendations will be reviewed by ECHA's senior management in order to establish a timeline and a follow-up procedure.

ECHA will assess how the recommendations can be addressed in the development of its processes. ECHA will also raise the topic in other relevant fora in cases where the recommendations are not in the Agency's remit. In cases where ECHA does not consider the recommendations feasible, it will explain the reasons to the stakeholders.

Communication on the follow-up activities will be channelled through the Stakeholder update, which is sent bi-monthly to the heads of organisations, nominated contact persons and communications officers of all accredited stakeholder organisations. As before, ECHA will also present the outcomes in the next Accredited Stakeholder Workshop.

Annex 1 List of participants

Name	Last name	Job title	Organisation
Maria José	Amaral	Chemicals and Nanomaterials Policy Officer	Health Care Without Harm Europe (HCWH)
Erwin	Annys	Director - REACH /Chemicals Policy	European Chemical Industry Council (Cefic)
Louis Sylvain	Ayral	Technical Director	European Association of Automotive Suppliers (CLEPA)
Raf	Bruyndonckx	Sector Group Manager	European Chemical Industry Council (Cefic)
Vito	Buonsante	Staff Attorney	ClientEarth
David	Carlander	Director of Advocacy	Nanotechnology Industries Association (NIA)
Sonia	Clarena Baron	Product Stewardship Adviser	European Industrial Minerals Association (IMA-Europe)
Alain	D'haese	Secretary General	European Aerosol Federation (FEA)
Roger	Doome	Technical Director	European Industrial Minerals Association (IMA-Europe)
Luca	Fop	Research Assistant	Health Care Without Harm Europe (HCWH)
Amaya	Jánosi	REACH Manager	European Chemical Industry Council (Cefic)
Uta	Jensen-Korte	Director General	European Association of Chemical Distributors (FECC)
Peter	Kunze	Environmental Policy Director	European Automobile Manufacturers' Association (ACEA)
Gertraud	Lauber	Head of Department	IndustriAll
Didier	Leroy	Technical Director	European Council of producers and importers of paints, printing inks and artists' colours (CEPE)
Sofia	Minero	Public Affairs Officer	European Association for Chemicals and Molecular Sciences (EuCheMS)
Tony	Musu	Senior Researcher	European Trade Union Confederation (ETUC)

Gosia	Oledzka	Technical and Scientific Affairs Manager	International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.)
Rebecca	Ram	Scientific Adviser	PETA International Science Consortium (PISC)
Anne Claire	Rasselet	Adviser	European Engineering Industries Association (ORGALIME)
Kirsty	Reid	Policy Officer research animals	Eurogroup for Animals
Ophélie	Roblot	SHE Manager	European Association of Chemical Distributors (FECC)
Richard	Roden	Executive Committee	Only Representatives Organisation (ORO)
Rocky	Rowe	Adviser	European Crop Protection Association (ECPA)
Tatiana	Santos Otero	Senior policy officer on chemicals and nanotechnology	European Environmental Bureau (EEB)
Berthold	Sessler	Head of Organisation	European Committee for Surface Treatment (CETS)
Elisa	Setién	Secretary General	European Federation for Construction Chemicals (EFCC)
Dave	Sidgwick	Senior Technologist	Aerospace and Defence Industries Association of Europe (ASD)
Youri	Skaskevitch	Secretary General	Association of Manufacturers and Formulators of Enzyme Products (AMFEP)
Katy	Taylor	Senior Science Advisor	European Coalition to End Animal Experiments (ECEAE)
Geoffroy	Tillieux	Director of the Technical department	European Plastics Converters (EuPC)
Rie	Tsuchiya	Regulatory Affairs Manager, REACH Project Leader	Association of Manufacturers and Formulators of Enzyme Products (AMFEP)
Cornelius	Vermeeren	Secretary General	Association of poultry processors and poultry trade in the EU countries (AVEC)
Astrid	Volckaert	Director Environment and Technical Affairs	European Ceramic Industry Association (Cerame-Unie)
Pierre	Wolfs	Technical Director	European Industrial Gases Association (EIGA)

Annex 2 Workshop Programme

Time: 29 November
Venue: European Commission, DG ENTR
Room: ENTR 5/A

09:15 Registration and coffee

09:45 **Opening and follow-up from the 2012 workshop**
Geert Dancet, Executive Director

10:00 **ECHA Update on topical issues**

ECHA's work on improving data quality and next steps
Christel Musset, Director for Registration

Implementing the Biocidal Products Regulation
Jukka Malm, Director for Regulatory Affairs

10:40 **Questions and answers**

11:10 Coffee break

11:30 **Breakout group discussions**

Group 1: Biocides collaboration

Group 2: ECHA's approach to transparency

Group 3: Substitution of hazardous chemicals

13:30 Lunch

14:30 **Joint discussion on the breakout group topics**
Recommendations from the breakout groups by stakeholder rapporteurs and further discussion

16:00 **Closing remarks**
Geert Dancet, Executive Director, ECHA

16:15 End of the meeting

Annex 3 Feedback Summary

This feedback report presents feedback statistics and an analysis of open text comments received from 19 out of 35 participants (54% response rate) that attended the Third Accredited Stakeholder Workshop.

Overall satisfaction

Based on feedback received through the open text comments, participants generally felt that the workshop gave a good overview of key on-going actions and that the topics were relevant to the diverse range of stakeholder interests present at the workshop. Some requests were made to devote more time on how stakeholders could be further involved in ECHA's work. Participants pointed out that as more stakeholders attended this year than in previous years, the debate was also much broader and successfully dealt with issues from all interest groups involved. Participants appreciated not only the number of ECHA staff attending the event, but also the quality of their presentations and their willingness to engage and listen. Participants also highlighted that although they were satisfied with the workshop, the determining factor influencing their perception of ECHA and the usefulness of the event would be the follow-up of the main points and shared recommendations derived from this workshop.

The overall score for the event has 90% of participants ranking it as either: good, very good or excellent, out of which 79% rate it as very good or excellent.

Presentations and Q&A

The highest ranking presentations during the plenary sessions were those that highlighted new developments. The presentation on ECHA's actions towards data quality and next steps received clearly the highest rank with approximately 90% ranking it as either very good or excellent. The presentation on the follow-up from the 2012 workshop which mainly covered how ECHA had responded to stakeholder recommendations from the previous year was also found very useful with 90% finding it either good or very good.

Question and answer sessions received very good scores with 94% ranking them as either good or very good. From the open text comments, participants wished for more time for discussions after the presentations but were conscious of time constraints due to many topics that needed to be covered.

Breakout groups

Overall the breakout groups received high scores and the facilitation methods, discussion topics and facilitators were appreciated. The topics chosen for the groups received the highest ranking with 80% rating them as very good or excellent. The shared recommendations reached by the groups was ranked the lowest with only 48% ranking them as good or very good and nearly 32% as satisfactory. Based on comments received in the open text fields, participants felt that more precise topics should have been elaborated to allow for more concrete recommendations. With regard to the substitution group, participants appreciated that ECHA brought the topic for stakeholder discussion

but noted that as the topic is very extensive, the scope of the discussion could have been further clarified ahead of the event to enable more focussed discussions.

It was felt by some of the participants that as the majority of ECHA's accredited stakeholders are industry representatives (71%), discussions in the plenary groups were sometimes too industry oriented and not enough time was given for everyone to express their views. On the other hand, some comments were also received stating that the balance between industry and civil society interests was optimal.

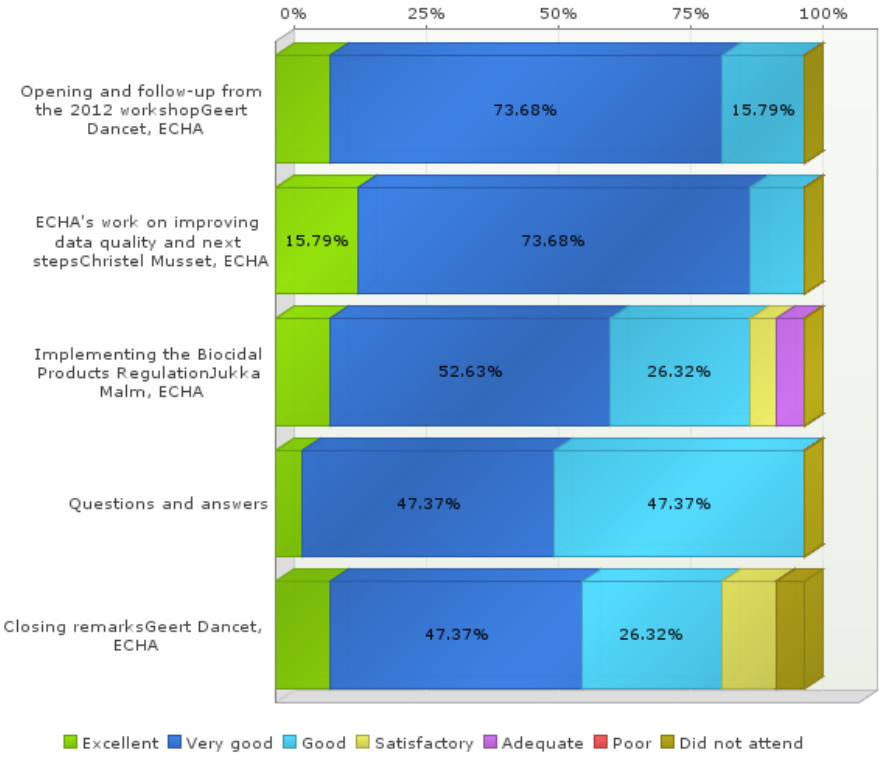
Topics for future events

Some topic suggestions for the next event included downstream user obligations and challenges as well as their involvement in the evaluation and authorisation processes, transparency towards biocides applicants, procedure and criteria to identify SVHCs as well as the CLP implementation for mixtures. Other high priority topics included reaching out to SMEs in Europe and worldwide, the authorisation process and a follow-up on transparency. Several other topics were also suggested and are available in question 4 below.

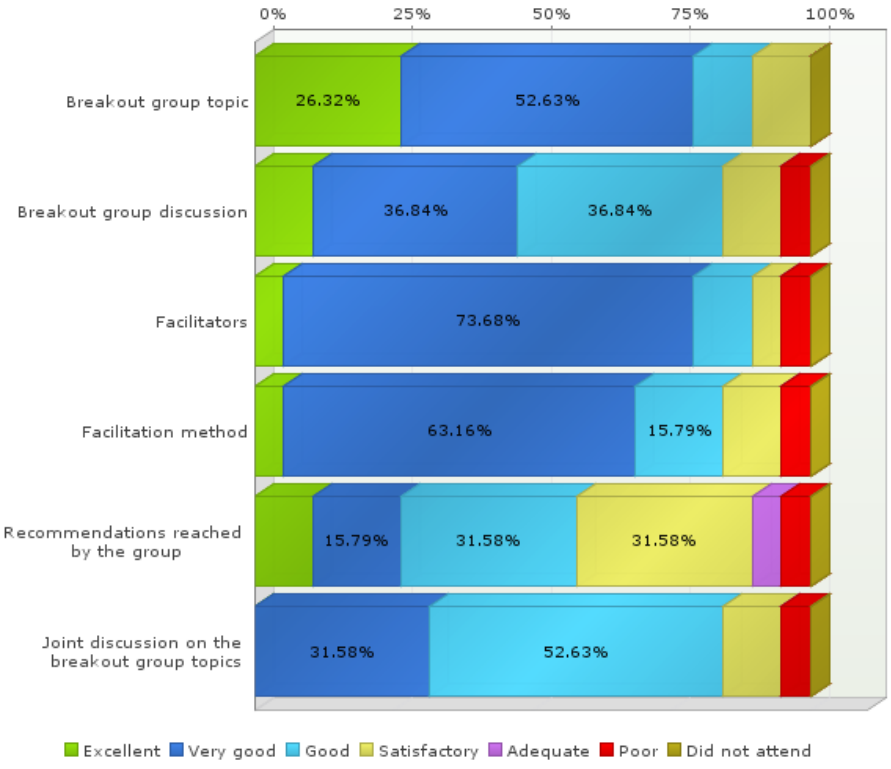
Perception

Regarding the perception of ECHA in terms of its corporate values, participants felt that ECHA was particularly open to dialogue with 90% who either agreed or strongly agreed. Trustworthiness also ranked high with 74% that either agreed or strongly agreed. The lowest corporate value was independence with 75% that either somewhat agreed or agreed and 22% that either somewhat disagreed or disagreed.

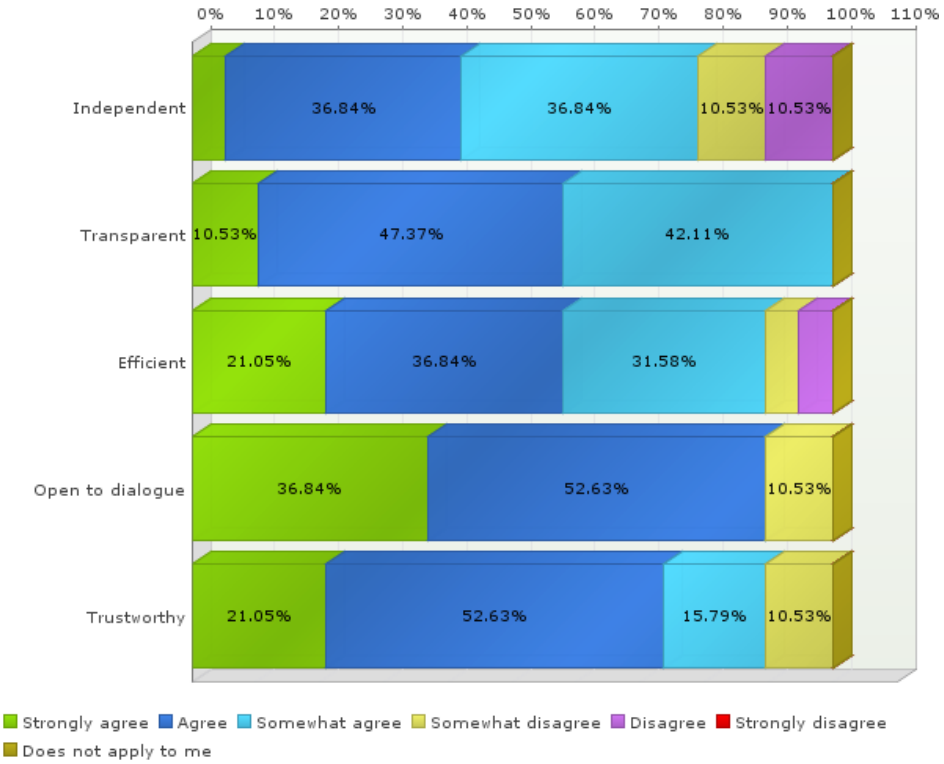
1. Rate the content of the plenary session



2. Rate the content of the breakout session you attended



3. What was your perception of ECHA after the workshop?



4. Suggest in order of importance, 3 topics that you would like to see addressed during the next Accredited Stakeholder Workshop

High priority

- Downstream user obligations and challenges as well as their involvement in the evaluation and authorisation processes
- Transparency towards applicants (Biocides)
- Procedure, criteria to identify SVHCs
- CLP implementation for mixtures - Experience, lessons learned and developments
- Reaching SMEs in Europe and worldwide
- Authorisation process
- Is REACH overcoming knowledge gaps on chemicals?
- Follow-up on transparency
- Overview of review of chemical testing proposals

Medium priority

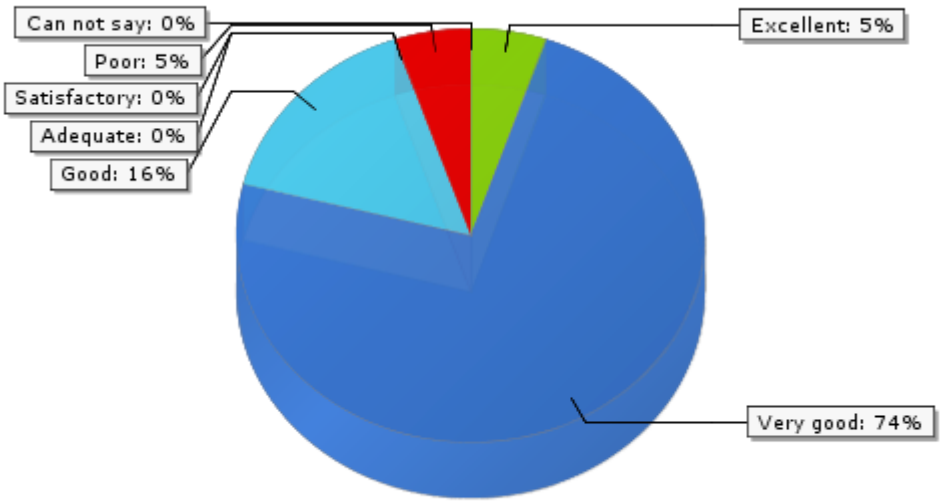
- Detailed uses supported under the review program and downstream user involvement (Biocides)
- ECHA's contribution to the efficiency of the regulatory process
- Substance evaluation and testing proposals - experience, lessons learned and developments
- Biocides update
- How stakeholders can improve the C&L Inventory
- Green chemistry

- 2018 REACH registration deadline
- How to ensure Independence
- Participation of non-profit organisations in ECHA's meetings, trainings, workshops and balance between civil society observers and industry accredited stakeholders

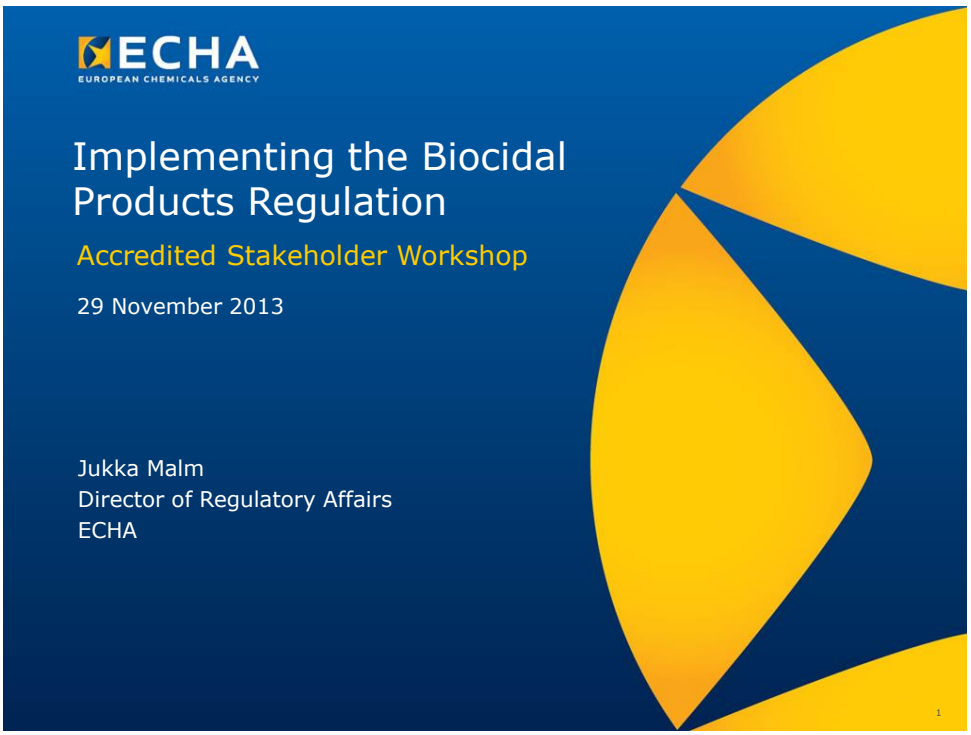
Lower priority

- Increased communication
- ECHA's role in the implementation of the Prior Informed Consent Regulation (PIC)
- Best practice from biocides dossiers for the benefit of new applicants
- Chemicals in consumer products
- Dissemination
- Data quality

5. Give your overall rating for the Accredited Stakeholder Workshop



Annex 4 Presentations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