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Update of the ECHA Transparency Approach

45th Meeting of the Management Board 30-31 March 2017

Proposal

The Management Board is invited to:

- take note of a report of the actions undertaken in 2015-2016 to improve transparency
- agree not to amend the ECHA Transparency Approach
- agree on goals for continual improvement 2017-2018.

Background

In December 2014, the Management Board adopted ECHA's Approach to Transparency, which was an effort to summarise in one single document the many actions that ECHA has been undertaking throughout the years to ensure the openness and transparency of its activities. ECHA consulted its accredited stakeholders and CARACAL during the drafting phase and communicated the final result to the European Ombudsman.

At the same time, ECHA committed to three areas of continual improvement for 2015-2016:

1. Further developing ECHA's work to improve the dissemination of information on chemicals and extending it to cover decisions taken by the Agency, so as to give a "start to finish" picture of what's happening to dossiers and substances;
2. Improving our communication, by reviewing the website structure and making all our communication clearer;
3. Improving the transparency of Committee meetings, by providing more explanation and information on the processes and decision making and by reviewing observer and third party involvement.

Rationale

A lot of effort has been put over the last two years into the three areas for improvement and therefore the Management Board is presented in Annex 1 with a full report of actions that have been undertaken during 2015-2016.

As ECHA's transparency principles have not changed, it is proposed not to amend the ECHA Approach to Transparency as such. More in particular, ECHA's efforts towards openness and transparency remain focused around three basic pillars as before:

1. ECHA clearly explains activities and processes in a way that is understandable by a general audience. The Agency therefore describes its role, its activities, how it works, who works there and how it achieves its results.
2. ECHA practices open decision making. It describes clearly who makes decisions, who is involved, how and when it consults the public, how stakeholders can observe and contribute and how bias is avoided.
3. ECHA makes information available, in a timely manner. It makes information available proactively and provides it in such a way that citizens can easily understand and reuse it, in whole or in part.

However, while ECHA's performance in this area has generally been regarded as very good (see e.g. stakeholder survey), it cannot be considered as finished. Therefore it is important to set additional targets for the coming two years to maintain and further enhance ECHA's strong reputation in this field. It is thus proposed to set new goals for improvement within the same three areas of work as before for the years 2017-2018 (see Annex 2).

Alternative options

ECHA could rely on its merits from the past, but without a continued focus there is a risk that stakeholder satisfaction in this area will drop and/or its good reputation would decline.

Drawbacks

While ECHA is already one of the most transparent agencies, it is an impossible task to fully satisfy all stakeholder demands and therefore some form of criticism cannot be avoided. Transparency is also a moving target, constantly requiring a recalibration of what is expected of an EU institution. In this light, a proactive approach including continual improvement, will help ECHA remain best in class. Proactively tackling aspects that are known areas for improvement will also give more credibility than a reactive response.

Attachments:

- Annex 1: Report on transparency improvements during 2015-2016
- Annex 2: Goals for continual improvement in transparency 2017-2018

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Annex 1 - Report on transparency improvements during 2015-2016

1) Further developing ECHA's work to improve the dissemination of information on chemicals and extending it to cover decisions taken by the Agency, so as to give a "start to finish" picture of what's happening to dossiers and substances

- Revamp of the Dissemination Portal completed in January 2016: information on up to 120 000 chemicals enriched and structured in three layers: infocard, brief profile and detailed source data.
- At the end of June 2016, additional information from companies' registrations, such as endpoint summaries, exposure scenarios and new elements introduced by IUCLID 6[1], was made publicly available.
- The location of information claimed confidential under REACH Article 119(2) is clearly marked as such in published dossiers and information covered by rejected confidentiality claims (e.g. IUPAC names) is published since December 2016.
- Classification and Labelling Inventory updated in June 2015 to include the categorisation of harmonised substances according to the Seveso III Directive.
- Publication of a pre-alert list of substances that ECHA plans to address via compliance checks and thereby encourage timely dossier updates. This has been effective since Q1/2015 with two annual updates.
- ECHA compiled an inventory of substances likely to meet the criteria of Annex III to the REACH Regulation. The aim was to support registrants in identifying whether reduced minimum information requirements or a full Annex VII information set is required.
- The European Chemical Industry Council (Cefic) has been given access to certain data from ECHA's chemicals database to develop a new tool for predicting toxicity of chemicals (AMBIT) in February 2016.
- In order to increase transparency ahead of the 1 September 2015 deadline for the compliance with Article 95 of the BPR, ECHA published in March 2015 a list of all pending Article 95 applications.
- Information on the Authorised uses of SVHCs in the EU is being published since mid 2015, see: https://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation/du-66-notifications

2) Improving our communication, by reviewing the website structure and making all our communication clearer

- Continual improvement of the ECHA website's accessibility addressed, e.g.:
  - Enhanced search function and Q&A section.
  - Simplified contact pages, to reinforce a "single point of access".
  - A "Transparency" section added to the ECHA website, which gives an overview of the transparency initiatives of the Agency.
  - Agenda of the Executive Director published on the ECHA website (meetings with external stakeholders).
- Roll-out of ECHA's social media strategy to reach the general public.
- Further Guidance in a Nutshell documents (available in 23 EU languages) to accompany more extensive Guidance documents.
- Executive summary documents ("facts and figures", available in 23 EU languages) published to accompany major corporate reports.
- Simplified decision templates.
- In addition to its regular communication activities to enable companies to fulfil their duties, a number of extraordinary initiatives were taken to increase transparency:
  - Multi-media campaign about ECHA's glyphosate opinion-making. This is a matter

[1] IUCLID is the essential tool for any organisation or individual that needs to record, store, submit, and exchange data on chemical substances in the format of the OECD Harmonised Templates.

of interest to many stakeholders. Consequently, ECHA produced written and audio-visual material in 23 languages to show what we are doing on glyphosate, how they can have an impact, and what the opinion will mean. We also hosted an online media briefing on the opinion when it was reached.
  - First multi-lingual social media campaign.
  - Making use of the European Union's rapid alert system for dangerous products and promoting them on social media.

3) Improving the transparency of Committee meetings, by providing more explanation and information on the processes and decision making and by reviewing observer and third party involvement

- Observers from ECHA's Accredited Stakeholder Organisations are allowed specific speaking rights in the plenaries of the Committee for Risk Assessment and the Committee for Socio-Economic Analysis with the intent of having contributions with regards to consistency and procedural matters – comments on the cases themselves are avoided (see also MB/52/2014).
- The Member State Committee discussed its practices for discussions in open and closed sessions in September 2016. This has led to a significant increase of the amount of time evaluation cases are discussed in open session, with a concurrent decrease in closed sessions.
- The Member State Committee introduced a briefing session for the Accredited Stakeholder Organisations on evaluation cases agreed in written procedure.
- Additional transparency on the work of the expert groups of ECHA (ED expert group, PBT expert group), in particular a full list of members was published on the ECHA website.
- Detailed statistics on received applications for authorisation published on ECHA website.
- Pre-notification of the upcoming public consultations on applications for authorisation published on the ECHA website well in advance.
- RSS feeds[2] implemented on ECHA website, e.g. to alert on new public consultations.
- Webinar published in February 2016 on "Applications for authorisation: How to respond during public consultation".
- Instructions of how interested third parties can submit information for the public consultation on alternatives for applications for authorisation updated in November 2015.
- Instructions for submission of information in the public consultation on potential candidates for substitution under the Biocidal Products Regulation updated in August 2015.
- A practical guide for applications for authorisation was published in December 2016.

[2] Subscribing to a website RSS removes the need for the user to manually check the website for new content. Instead, their browser constantly monitors the site and informs the user of any updates. The browser can also be commanded to automatically download the new data for the user.

Annex 2 – Goals for continual improvement in transparency 2017-2018

1) Further developing the dissemination of information on chemicals

ECHA has a legal duty to make certain information on substances publicly available, free of charge. However, instead of simply disseminating data from the registration dossiers 'as is', ECHA has invested heavily into making this data easily accessible to enhance its usability and transparency.

Continued efforts will be invested in further enhancements of the Dissemination Portal (InfoCard, Brief Profile and detailed source data) also in the coming years. ECHA will further strive to integrate the information on substances arising from different legislations and regulatory processes (e.g. informing on ongoing dossier evaluation running on specific substances) so that users can easily obtain an overview of the available data for that substance and follow the progress on its evaluation.

ECHA will carry out a feasibility study in 2017 on extending the dissemination website with an "EU chemicals legislation finder", i.e. giving an overview of how a substance is regulated at EU level. Subject to the outcome of the study and its reception, ECHA may be asked to develop the EU chemicals legislation finder in 2018.

In addition, other improvements to the Dissemination Portal will also be implemented, such as enriching the dissemination of biocides information with the automated publication of data extracted from biocides dossiers and an improved search for biocidal products. The searchability of nanomaterials will be enhanced and improvements to how classification and labelling are displayed in the Brief Profiles will be implemented. Finally, ECHA will improve the collection and dissemination of information from the notifications of Substances of Very High Concern (SVHC) in articles on the EU market.

Based on a delegation agreement between the European Commission and ECHA the Agency is going to start hosting the EU Observatory for Nanomaterials. The objective of the observatory is to provide publicly available information on nanomaterials in the EU market, their safety aspects, and related research activities. The Nanomaterials Observatory also aggregates, evaluates and interprets the data, and communicates the results to decision-makers, authorities and the general public in a user-friendly and easily understandable way. ECHA plans to publish the first version of the observatory by June 2017 based on readily available data and information sources and start preparations for the second version to be published in 2018 including new information on sectoral legislation (e.g. food and cosmetics), further information on products and articles where nanomaterials are present, updated information on nanomaterials in EU market, and wider information on relevant research activities.

Furthermore, ECHA will strive to make data more readily available to a wider audience (e.g. academia, companies, researchers, regulators in the EU and third countries) so they can benefit from the vast amount of scientific data contained in ECHA's databases and use it to enhance chemicals safe use, promote innovation and avoid unnecessary testing on animals. Downloadable sets of key information from the dossiers (e.g. substance identifiers and study results) will be made available via the IUCLID 6 website. ECHA will carry out a data value discovery study, which aims at analysing how to extend the data access and to explore use cases for exploiting the data.

Finally, ECHA will further explore the re-use of ECHA data for regulatory purposes by the Commission, Member States and other EU agencies. Specific data exchange frameworks with sister-agencies such as EFSA and EMA will be explored.

2) Improving our communication, including more focus on specific target groups

Open communication

ECHA will continue to invest in direct dialogue with its stakeholders. Accredited stakeholder organisations receive regular updates which gives them advance notice of news and invites their participation and comments. They are invited to an annual strategic workshop and to a variety of events throughout the year. Wider stakeholders are invited to interact with ECHA through workshops and online webinars, where they can directly interact with ECHA in an open forum. These events are all free to attend, and increasingly they are conducted online, or recorded and made available online, so that a wider audience can benefit.

As our window to the world, the ECHA website provides a wealth of information on the chemicals in use in Europe today, the work and decisions of the Agency and the regulations it implements. After an in-depth customer insight survey carried out in 2015 a number of improvements will be made in 2017 to improve the website's usability. The changes are based on the needs of users and will bring to the forefront those topics that are most relevant for them, such as the information on chemicals, public consultations, support and information relevant for SMEs and consumers. The possibility to create a profile on the ECHA website and subscribe to news updates in an area of interest will also be implemented in 2017 or 2018.

More targeted communication for general audiences

Understanding chemicals, their impact on health and the environment and the steps being taken to control the risks that they present is not easy. It requires some scientific and administrative understanding. And yet ECHA's work and its impact is of importance to every citizen in Europe and they have a right to be able to make sense of it. Therefore, specific attention is now being given to initiatives to reach concerned citizens and workers. Infographs to visualise data and social media campaigns are an excellent way to reach out to consumers and provoke some interest in understanding the impact of chemicals on their lives.

A new website, specifically for consumers will be developed in 2017, to enable consumers and workers to find information on how authorities are working to protect them from hazardous chemicals and enabling them to make safer choices, exercise their rights, and to provoke a demand for more information on chemicals. Information on nanomaterials will also be provided on the site. The look and feel of the site will be very different from the main website, thereby signalling that it is for consumers. This site will be further developed in 2018.

3) Continual improvement of the transparency of Committee meetings, regulatory decision making and third party involvement therein

Transparent decision making

ECHA strives to ensure predictability of its regulatory decision-making in several ways. Apart from further developments to the Public Activities Coordination Tool (PACT)[3] , integrating further processes into the tool (e.g. CoRAP), also the foreseen inclusion into the Dissemination Portal of information on ongoing dossier evaluations will make it possible to closely follow the evaluation of individual substances.

Transparency on how the Agency reaches its decisions and opinions will continue to be ensured and ECHA will maintain, and where necessary further enhance, its high standards in conflict of interest prevention and transparency about the interests held by its decision-makers. The initiative to give full access to the Executive Director's agenda of meetings with external stakeholders will be extended to all senior managers of the Agency in 2017.

Also the transparency of the work of the Committees, Forum and expert groups will remain a priority. Further improvements to the transparency of the work of the (PBT, Endocrine Disruptors and nanomaterials) expert groups in particular are already in the pipeline with the gradual introduction of public summary reports of the expert group meetings in 2017.

Third party involvement

ECHA's accredited stakeholders can support ECHA's work through various bodies and networks. As observers they can participate to the discussions at the discretion of the Chair. Closed sessions will be further limited to the extent necessary.

Public consultations are another opportunity to participate in the development of ECHA's opinions. ECHA already makes a lot of effort to proactively inform interested stakeholders of ongoing public consultation procedures. Besides expanding the automatic notification of substance relevant consultation procedures from registrants to CLP notifiers, it will be investigated in 2017 if further actions can be taken to promote participation among registrants, industry associations or companies producing alternatives.

[3] The PACT tool informs on the substances that are scrutinised by authorities (with the concern being investigated) with the aim to increase predictability for registrants and stimulate dossier updates.