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ECHA's Approach on Engaging Third Parties in Public Consultations

40th Meeting of the Management Board 16-17 December 2015

Item	14
Action	For information
Status	Final – Public

Proposal

This note informs the Management Board on how and for what purpose ECHA carries out consultations and gathers information through calls for evidence under REACH and CLP Regulations. It is concluded that:

- ECHA has continuously improved its public consultation processes to make them transparent and efficient and to ensure that all relevant information becomes available early in the opinion- or decision-making processes.
- ECHA has identified options to further improving its consultation practices and seeks further feedback and suggestions from its stakeholders.
- ECHA considers that overall coordination can be ensured within its current functions and structures. The preparation of this note was helpful to the Agency to bring together the approaches and to take stock of the lessons learned.

The Management Board is invited to take note of the approach and provide comments, as appropriate.

Background

At the September 2015 Management Board meeting an interest party representative made a proposal to the ECHA secretariat to appoint a Third Party Ambassador (similar to ECHA's SME Ambassador) to make best use of input from various third parties, mainly by means of internet based public consultations, but also through their role as accredited stakeholders. Overall the idea was found interesting and deserving further consideration, in particular about the right tools to achieve the desired impact.

The Secretariat committed to prepare for the September Board meeting a high level paper on how and what kind of case-related public consultations ECHA carries out, what kind of improvements have been made until now to ensure interested parties are being reached and how ECHA involves third parties in its REACH and CLP processes (especially in the context of public consultations related to potential alternatives to SVHCs[1]). This note concentrates on public consultations for substance specific processes, i.e. classification and labelling, authorisation, restriction and testing proposals.

[1] SVHC - Substances of Very High Concern

Rationale

Role of public consultations

As required by the legal text, ECHA carries out a high number of public consultations on substances under the specific REACH and CLP processes. In addition, in some cases specific calls for evidence or comments are made. The main aim of carrying out these consultations is to ensure that all relevant information becomes available early in the opinion- or decision-making processes. The aim is also to ensure that interested parties are informed, allowing them to provide their views on the proposals made or to submit further information, as appropriate. Hence, these public consultations provide a contribution to the openness of the regulatory processes and the aims of the Regulation in terms of ensuring a high level of protection and promoting innovation and competitiveness.

Depending on the particular regulatory process the purposes of doing these public consultations can be different as well as the target audiences that are meant to be reached. These are summarised in Annex I.

ECHA's current consultation practices

Given the high number of public consultations organised (see Annex II) ECHA uses its traditional communication vehicles to alert stakeholders to their launch. That means that all ECHA's news subscribers and website users are informed immediately about them.

The public consultations are published on dedicated webpages which are linked to the front page of the Agency's website. There is also an RSS feed about consultations available on the website. This allows users to be notified whenever a new consultation is launched. The announcements of consultations are also included in ECHA's weekly e-News which is sent out to subscribers (currently around 18,000) all over the world free of charge. Subscribers represent companies, industry associations, academia and other stakeholders. Public consultations are also advertised in the bi-monthly Stakeholder update, which is sent to all of ECHA's accredited stakeholder organisations (ASOs) – currently 90 in total. ASOs are continuously reminded of their responsibility to multiply the message to their contingencies.

For selected public consultations, ECHA has increased awareness by using social media, alerting sector-specific media and targeting EU-level sector bodies.

ECHA provides advice on its website about the types of information that we are looking for in response to each type of consultation. For example, data that is specific to the substance under consultation is more likely to be a valuable contribution than a generic statement.

In response to stakeholder feedback to some consultations, the Agency provides a summary of the responses received, together with a summary of the actions taken as a result of the consultation. For example the comments received and the follow-up actions are published after public consultations are organised on adding new substances to the Candidate List, Annex XIV recommendations and restrictions.

For applications for authorisation the comments are made public and the applicant has the opportunity to give responses. Since the public consultation can generate additional information on possible alternatives, and there will be a need for the Committees to understand the significance of this information, an application for authorisation 'trialogue' between the applicant and the RAC and SEAC rapporteurs has been established as part of the opinion-making procedure. This trialogue allows rapporteurs to discuss with applicants any information on alternatives generated through the public consultation or any other technical or scientific issues with the application. The suppliers of alternatives that have provided input to the public consultation are also invited to the trialogues, as relevant.

ECHA also addresses the information from third parties in its decision on the related testing proposal, and responses to these comments. For third party consultations on vertebrate testing proposals, the received information is forwarded to the registrant for consideration. In addition, any scientifically valid information and studies that address the relevant substance and hazard endpoint, relating to the testing proposal, is taken into account by ECHA in preparing the decision. ECHA publishes on the website non-confidential versions of its dossier evaluation decisions after they have been sent to the registrants. These decisions also address ECHA's conclusions drawn from the information provided by third parties. In this way, ECHA wishes to increase the transparency of the dossier evaluation outcomes and encourage submission of relevant information by third parties.

Discussion

ECHA has collected feedback from stakeholders on how it carries out public consultations. For instance, in 2012 in the ASO workshop the feedback was that ECHA needs to explain more clearly what information is essential during public consultations and provide guidance, as long as it is not too prescriptive. A plea was made to avoid public consultations during the summer and Christmas breaks, as it is difficult for stakeholders to provide input during these periods. Also the request was to allow as much time as possible for providing input.

ECHA's annual stakeholder surveys have also provided feedback. There is a sentiment that comments were not always treated in the same, neutral way irrespective of the submitter. There was also a suggestion that the comments and the responses would be published sooner. Furthermore, it was suggested that ECHA would better advertise the comments received on the website and in its communications (e.g. eNews).

Also in the context of the MB WG on Dissemination feedback was provided from stakeholder representatives arguing that ECHA should strive to focus more on third parties that do not have direct obligations under the legislation and are therefore more difficult to identify and reach. Thus, additional efforts were asked from ECHA in order to promote comprehensive but also more effective and efficient processes.

The consultations have fulfilled their purpose resulting in the receipt of valuable information for the opinion forming or decision-making. Through the improvements made in the announcements and further communication, the information received has gradually become more fit-for-purpose. The approaches applied provide transparency and trust that ECHA is carrying out its regulatory obligations well.

A specific challenge is to making sure that all potentially interested third parties are reached. This is partly a problem relating to ECHA not necessarily knowing who would potentially be impacted by the regulatory action. For instance, when the proposals for classification or identification of a substance of very high concern are consulted on, it is often not known how the substances are used, and thus, which specific stakeholders would need to be alerted about the consultation. Moreover, many companies, in particular SME's, have limited capacity to continuously keep an eye on the ECHA website.

Experience tells that even if ECHA knew who should give comments, this does not necessarily mean that the party is willing to engage itself in the public consultation. This particularly applies to the public consultation under the application for authorisation process where downstream users can potentially provide useful information regarding alternatives (what they use, how they use it, and if they experienced a cost increase when shifting to this alternative) but may not be interested in investing the required time and energy.

Further improvements

ECHA will continue to use multipliers such as stakeholders from industry, trade unions and civil society, MSCAs, Commission, Enterprise Europe Network (EEN), the Association of Eurochambers and its own scientific staff's professional networks during the consultation. Especially the role of MS's and EU level associations in reaching out to national and local actors will help raise awareness of public consultations among target audiences.

ECHA will try to use more of the targeted communication on consultations which could perhaps increase the likelihood of attracting relevant feedback. Within the current staff and time constraints, ECHA will target specific sectors of industry or the media or academic disciplines as part of public consultations.

ECHA is planning to better target its efforts through social media networks. In particular in LinkedIn, ECHA could target existing discussion groups or could create groups of its own.

More consistent advice on the types of information requested, and case studies of information that had an impact on decision-making would help stakeholders to provide the "right" kind of information and make best use of their own time. For example, when a new public consultation is launched, targeted messages are sent that include advice regarding the kind of information that would be particularly helpful for that particular consultation.

Acknowledging feedback received and informing those who have provided comments about what has happened would reassure stakeholders that their information has been taken into account. Currently in most consultations ECHA posts the responses to comments on its website. Further options such as personalised feedback with an offer for more explanations, or specific consultations with follow-up workshops will be considered. For instance, once the opinion-forming and decision-making on applications for authorisation of a particular (group of) substance(s) are concluded, it could be helpful to all interested parties to discuss before the next review what the longer-term possibilities are for substitution. This type of activity would require additional effort of ECHA staff.

ECHA intends to further improve its IT tools to better serve different needs of stakeholders, e.g. in 2016 the new dissemination service will provide the users with a possibility to follow the lifecycle of any substance they are interested in. ECHA will be in contact with different MSCA's and Agencies to find out about best practices in order to see, if it could benchmark its consultation practices. The particular challenge is to make the information gathered from consultations searchable, for instance with keywords, across consultations.

Finally, ECHA could, apart from the ASO meetings and requesting more explicit feedback through the stakeholder surveys, initiate further actions to obtain dedicated feedback on how it currently runs its consultation processes in order to get further ideas for improvements. This feedback could be asked through questionnaire(s), webinar(s) or dedicated face-to-face meeting(s) either in general terms of specific to a process.

Conclusion

ECHA has continuously improved its public consultation processes to make them transparent and efficient and to ensure that all relevant information becomes available early in the opinion- or decision-making processes. It has solicited and received feedback on how to improve its practices both in terms of content and IT tools. ECHA will continue to invite for feedback and suggestions for improvement from its stakeholders whilst noting that the challenges of reaching the right audiences are different and hence need specific targeted actions. This particularly applies to the applications for authorisation process where specific efforts are needed to engage third parties that have relevant information on alternatives.

ECHA considers that overall coordination can be ensured within its current functions and structures. The preparation of this note was helpful to the Agency to bring together the approaches and to take stock of the lessons learned.

Alternative options

ECHA could follow the suggestion to nominate a third party representative who could provide oversight of the way public consultations are carried out and could suggest specific actions for improving third party engagement. However, given that the number of affected processes is large, the potential audiences vary substantially and hence there is no common drive as there is for SMEs, this would be a particularly big challenge for one person. Since the secretariat is in general committed to ensuring effective third party involvement, it is considered more efficient to identify targeted actions within each process.

Drawbacks

Possibilities for further improvements of ECHA's practices of carrying out public consultations have been identified in this note. As indicated above, in particular the options that will need specific and targeted action to engage specific (groups of) interested parties are likely to involve substantial staff and possibly further IT-development. Hence, such activities will need to be piloted first in order to ensure that such investments will deliver enough benefits to the opinion- or decision-making processes.

Attachments:

- Annex I: Overview of case-related public consultations
- Annex II: Number of consultations held in ECHA in 2013, 2014 and 2015 (estimate)

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Annex I: Overview of case-related public consultations

CLP: Public consultation on proposals for harmonised classification and labelling

Purpose: to obtain comments on proposals for harmonised classification and labelling made by a Member State (and in some specific cases by industry), in particular on substance identification and on the proposed classification, the hazard information considered in the proposal, or the justification provided.

Evaluation: third party consultation on testing proposals

Purpose: to ensure that the best use has been made of existing information before new animal testing is carried out. ECHA publishes all testing proposals involving vertebrate animals, for endpoints specified in REACH Annexes IX and X inviting third parties to submit scientifically valid information and studies that address the relevant substance and hazard endpoint. Manufacturers and importers can in specific cases request that the substance name, including the IUPAC name, is kept confidential. ECHA will then publish a public generic substance name derived according to a Data Submission[2] to allow as much of the substance identity to be disclosed as possible without jeopardizing the confidential business information.

Authorisation: Public consultation on proposals to identify Substances of Very High Concern

Purpose: to receive information and comments on the substance identity of the proposed Substances of Very High Concern. Furthermore information and comments on intrinsic properties is called for if the proposal is not based on a harmonised classification (e.g. for PBTs, vPvBs or substances of equivalent concern). This information helps to assess if the substance should be included in the Candidate List, and eventually in the Authorisation list.

Authorisation: Public consultation on ECHA's draft Annex XIV recommendations

Purpose: to receive information and comments on the priority of substances on the Candidate List for inclusion in the authorisation list, factors affecting the time needed to prepare an application and uses which should and can be exempted from the authorisation requirement[3].

Authorisation: Public consultation on applications for authorisation

Purpose: to receive information on alternative substances or technologies for the uses of substances of very high concern included in applications for authorisation.

Restriction: Public consultation on restriction proposals

Purpose: to obtain comments on the restriction proposal made by the Dossier Submitter or on the SEAC draft opinion, in particular on resulting costs, and impacts on health or the environment that had not been included or analysed accurately in the proposal.

Other: calls for comments and evidence

Purpose: to get factual or scientific evidence or comments to help in the preparation of restriction proposals, guidelines or reports on substances in articles that ECHA is preparing with view of a restriction. ECHA may also host similar calls for Member States on request. Evidence and comments are welcomed in particular on uses, alternatives and possible impacts affecting costs, health or the environment.

[2] http://echa.europa.eu/documents/10162/13653/dsm17_public_name_en.pdf

[3] During the development of the 6th and the 7th recommendation ECHA has as well supported the European Commission in its calls for information on the possible socio-economic consequences of including substances in the Authorisation List.

Annex II: Number of consultations held in ECHA in 2013, 2014 and 2015 (estimate)

	2013		2014		2015 (until Oct.)	
	Consul-tations started	Comments received	Consul-tations started	Comments received	Consul-tations started	Comments received
• Classification and labelling*	51	519	33	272	37	213
• Testing proposals	63	20	317	140	91	21
• SVHC identification	17	221	14	193	9	105
• ECHA's draft recommendation	5	394	23	521	11	n.a.
• Applications for authorisation*	17	13	38	547	13	129
• Restrictions*	7	86	9	923	8	335
• Calls for evidence	2	19	2	56	5	83
Total	**162**	**1272**	**436**	**2652**	**174**	**886**

Source: ECHA * Consultations counted in the year when was the start date.