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Role of the ECHA Committees in the Application for Authorisation Process

41st Meeting of the Management Board 17-18 March 2016

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Action	For discussion
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Key messages

The Management Board is invited to

- take note of the Secretariat's analysis concerning the role of the ECHA Committees, RAC and SEAC[1], in one application for authorisation case subject to a European Parliament Resolution of 25 November 2015. This follows an initial debate in the December 2015 Management Board meeting.
- discuss action areas and provide strategic orientation to the Agency for further improving the application for authorisation process under REACH and the functioning of the ECHA Committees.

Background

The purpose of this note is to allow an informed discussion on potential implications of the European Parliament Resolution of 25 November 2015[2]. In its last meeting the Management Board considered that such a discussion is necessary in order to ascertain that ECHA's opinions are formulated in a scientifically rigorous manner[3].

ECHA has analysed the Resolution, both internally and with the Commission services. The Secretariat's initial reflections on the key points raised in relation to the functioning of the ECHA Committees are outlined below. The Executive Director will formally reply to the responsible Committee of the European Parliament (ENVI), after the Management Board has considered the matter. The reply will address all points raised in the Resolution and take into account the response of the Commission as the main addressee of the Resolution.

The Secretariat organised a background discussion with parliamentary staff on 26 February. The RAC was informed about the Resolution and the SEAC will discuss it at its meeting of 8-11 March. At its meeting of 17-18 March, the Management Board will be debriefed on the discussions in the Committees. Finally, it should be noted that the Commission has planned a further discussion and vote on the draft Commission Implementing Decision for the case at hand at the next REACH Committee meeting on 16 March.

[1] Committees for Risk Assessment and Socio-Economic Analysis.
[2] European Parliament resolution of 25 November 2015 on draft Commission Implementing Decision XXX granting authorisation for uses of bis(2-ethylhexhyl) phthalate (DEHP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2015-0409+0+DOC+PDF+V0//EN. Hereinafter "The Resolution"
[3] See draft minutes of the Management Board of December 2015, MB/M/04/2015

The meeting with Parliament staff was an important opportunity to discuss in more depth the key concerns expressed in the Resolution, especially questions concerning the minimum requirements for valid applications, the information available to the Committees during the process and the level of scrutiny performed, the distribution of responsibilities between ECHA and the Commission and the approaches developed by the Committees. Overall the meeting helped to achieve a better understanding of the concerns raised by the Parliament and provided an opportunity for explaining how ECHA and its Committees actually work. ECHA wants to build on this positive experience and maintain a closer dialogue with the European Parliament, also at technical level, as ECHA has already done with other stakeholders.

A paper that describes how Socio-economic Analysis (SEA) is applied under the REACH Regulation and what role SEAC plays in the opinion- and decision-making under authorisation and restriction processes is annexed to this note. SEA is a systematic, scientific method to assess what the health, environmental, economic and social impacts of an envisaged measure (regulatory or others) are. SEA strives to improve the understanding of the implications of an action and thus complements the analysis carried out in risk assessment. As such, SEA is a methodology to support decision-making but not to replace it. SEA at Agency level and the establishment of SEAC as a Scientific Committee are new elements introduced by the REACH Regulation. The purpose of ECHA's SEA activities is to provide scientific and evidence based opinions to the Commission on proposed EU-wide restrictions and on applications for authorisation. To this end, dedicated guidance documents have been prepared in consultation with the Committee members, the Commission, Member States and stakeholders. In addition, working procedures of ECHA's Committees as well as all formats on how opinions are formulated have been established in consultation with the Commission[4].

Rationale

The ECHA Secretariat ascertains that ECHA's opinions are developed in conformity with the REACH Regulation. At the same time, the European Parliament Resolution underlines that it is essential for ECHA and its Committees to be conscious of the broader regulatory context of their work and to continuously look for opportunities to improve the established processes and the quality of its regulatory output.

In relation to the role of the ECHA committees in the application for authorisation process, the European Parliament Resolution raised in particular concerns about a) ECHA or its Committees overstepping their mandate by getting involved in policy discussions and b) ECHA's Committees doing the work for applicants for authorisation. Discussions with parliamentary staff provided an opportunity to clarify what ECHA's and its Committees' roles are in the application process. These are also clarified in this note.

ECHA is not to take views on policy matters

ECHA and its Committees are firmly committed to making the REACH processes work and do recognise and accept that is not within their role to make judgements on policy matters. As explained in the Annex to this note, SEA is technical-scientific work that informs the decisions to be made by policy makers, in particular of the socio-economic implications of a restriction proposal or of the socio-economic benefits and remaining risks of an authorisation potentially to be granted. SEA itself and neither of ECHA's relevant Committees (RAC or SEAC) are designed to make policy judgements. However, the Secretariat is of the view that there are two aspects of the SEAC opinion discussed by the European Parliament where the wording

[4] Furthermore, the Committees have documented how they will evaluate the applications and give opinions in several notes (e.g. how to establish reference DNELs and dose-response functions, how to assess economic feasibility and how to recommend the length of the review periods). These were prepared by ECHA in close cooperation with the Commission and are publicly available on ECHA's website.

used in the opinion on the application for authorisation of DEHP should indeed have been clearer to avoid any misunderstandings.

The first point relates to a list of general arguments considered by SEAC in the course of the opinion forming[5]. This list includes a reference to *"political and societal incentive to promote recycling as a sustainable way to handle natural resources".* While this consideration was one element amongst many and not decisive for the outcome of the opinion, it could be regarded as inconsistent with ECHA's scientific-technical role. At the same time, it should be noted that this opinion was finalised in autumn 2014, at a time when the authorisation process was nascent. SEAC will duly discuss the issue of avoiding policy-related statements in its opinions in its next meeting of March 2016 and certainly draw the necessary lessons for its future work.

A second important concern raised by the Parliament relates to the role of SEAC in providing conclusions on "proportionality" given that in this case the opinion was concluded by saying that *"….SEAC considered that the authorisation of the use would be proportional".* In fact, some of the Parliament experts challenged the way ECHA, and in particular SEAC, is implementing its mandate under REACH.

Here it should first be noted that in the application for authorisation process[6], the REACH Regulation[7] requires that SEAC provides *"an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application and of any third party contributions submitted."* In other words, ECHA's role is to provide an assessment of the socio-economic benefits and costs (i.e. "factors") should an application be granted or not granted.

As described in the ECHA "Guidance on the preparation of socio-economic analysis as part of an application for authorisation"[8], SEAC assesses and compares several socio-economic factors when forming an opinion. These factors include the socio-economic benefits of continued use as well as the (possibly monetised) health and environmental impacts to society. In applications for authorisation neither the applicant nor the SEAC is asked to present or verify aspects related to proportionality. The standard wording for the SEA conclusions in ECHA's opinions[9] is meant to reflect the task that the Committee has in reviewing the information provided in the application.

Unfortunately, the wording used in this specific case, which was one of the first cases that went through the entire opinion-making process, indeed refers to "proportionality" and was not following the standard formulation used in the opinion template. The Secretariat has ascertained that similar inappropriate formulations have not been used in other opinions of SEAC on applications for authorisation and will raise this issue as well in the discussion with SEAC. Given that the current approach for documenting the SEA conclusions in ECHA's opinions was agreed with the Commission services when setting up the applications for authorisation process, ECHA will initiate further discussions with the Commission to reflect on the standard formulations in light of current discussions and experience gained.

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[5] See page 18 of the joint RAC/SEAC opinion http://echa.europa.eu/documents/10162/b50d9fc3-f6db-4e91-8a95-c8397bb424d2

[6] See annex for details, including also ECHA's role in the socio-economic assessment of restrictions.

[7] See Article 64(4)(b)

[8] http://echa.europa.eu/documents/10162/13643/sea_authorisation_en.pdf

[9] The standard formulation (which was unfortunately not used in the DEHP opinion) opinion for SEAC is (if it recommends that an authorisation be granted):
"SEAC considered that the applicant's assessment of: (a) the potential socioeconomic benefits of the use, (b) the potential adverse effects to [human health] [and/or] [the environment] of the use and (c) the comparison of the two is based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the use outweigh the risk to human health or the environment, whilst taking account of any uncertainties in the assessment."

For restrictions, the case is different. The relevant Annex of the REACH Regulation states that proportionality relates to a comparison of the measures related to risk reduction (and thus socio-economic benefits) with its costs. In restrictions, the assessment of SEAC is as well meant to support considerations by the Commission and Member States on the specific proportionality (limited to a comparison of costs and benefits) of a restriction, not as an overall proportionality assessment of the final regulatory measure taken comprising all policy considerations. For example, in its standard opinion formulation, SEAC concludes that *'the proposed restriction is the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs'.* It is thus clear that the proportionality to which the opinion refers only relates to the assessment of costs and benefits. Furthermore, it is evident that there are other considerations that can be taken into account by the Commission and the Member States during decision-making[10]. Nevertheless, also for restrictions ECHA will initiate further discussions with the Commission to see if alternative terminology could be used in future opinions to avoid potential confusion.

ECHA's Committees evaluate and verify the work of applicants

The Resolution raises concerns about the Committees making scientific or technical analyses that should have been done by the applicants. This was in particular raised in connection with statements in the opinion about significant deficiencies in the analysis of alternatives presented by the applicant. On this, the Secretariat points out that the Committees need to carry out their own calculations to verify the work done by the applicants. However, neither in this nor in any other authorisation case they do the work for the applicants.

REACH requires that for each authorisation application both RAC and SEAC deliver opinions, irrespectively of the quality of the applications and irrespective of whether the authorisation will be granted under the so-called 'adequate control' route or under the so-called 'socio-economic' route[11]. Obviously, if RAC confirms that the exposure assessment in the application demonstrated adequate control of risks from the use applied for, SEAC's assessment focusses on whether there appear not to be suitable alternatives in terms of their technical and economic feasibility for the applicant. Where RAC concludes that risks are not adequately controlled, SEAC will as well address the question whether the socio-economic benefits outweigh the risk to human health or the environment. An applicant may, but is not obliged to, prepare an analysis of the socio-economic impacts on itself, the supply chain and the society, should an authorisation be granted or refused. Thus far, all applicants have provided a SEA, usually in conjunction with the analysis of alternatives. This information is also of help to SEAC for recommending the length of the review period.

In the case at hand, the Committees indeed identified shortcomings in the application when they were verifying the work documented by the applicants. However, both Committees confirmed that all legally required information was present. RAC stated clearly the difficulties it had encountered in evaluating the application with regard to assessing the risks because the worker exposure assessment was not adequate to cover the broad scope of the application. In addition, RAC concluded that it could not propose sufficiently specific additional conditions or monitoring arrangements that could justify a conditioned positive opinion that adequate control was demonstrated. Therefore RAC recommended a short review period. In the case of SEAC, the application did contain a socio-economic assessment which the Committee analysed in order to develop its opinion. The societal benefits of not stopping the recycling activities were expressed in terms of the avoided economic costs of the non-recycling scenario. SEAC concluded that the methodology used for the assessment seemed plausible. Given that it was not possible to arrive at a quantitative health impact assessment, a qualitative assessment of

[10] In this context it is useful to note the recently adopted opinion on the proposed restriction on Bisphenol A, where SEAC clearly recognised that this can be the case and concluded that "Comparing the socio-economic benefits to the socio-economic costs, the proposed restriction is considered unlikely to be proportionate. However, there may be favourable distributional and affordability considerations. "

[11] Article 62(4) and (5) respectively of the REACH Regulation. It should however be noted that the applicant does not choose between these routes when applying for authorisation.

health impacts and risks of continued use was made.

In the discussion with the Parliament experts and, in response to the concerns raised that no sufficient quantitative cost assessment was made, ECHA explained that – in this application – much of the relevant cost information was confidential[12], i.e. only available to the Committees. Therefore, it was not possible to refer to this information in the opinion. Nevertheless, cost information was critically analysed by the SEAC. ECHA also emphasised that since the time this application was made, it had changed the application format in particular for socio-economic analysis. Today, all essential information provided in new applications (including the analysis of alternatives and SEA) is publicly available on ECHA's website. Thus, the public, including the Parliament, now has nearly the same information available as the Committee members. This increased transparency will improve the trust that stakeholders have on ECHA's Committees to carry out their tasks as specified in the REACH Regulation.

ECHA is continuously reviewing and improving the authorisation process

ECHA regularly seeks for and receives suggestions for improving the REACH authorisation application process. For instance, it asks for feedback from each applicant after they have submitted an application and when the opinions have been sent to the Commission. It has also used the Task Force for the Workability of Applications for Authorisation in 2014-15 to get suggestions both to itself and the Commission[13]. Other sources of feedback include events organised by the Agency on the authorisation process[14], industry events attended by ECHA[15], industry position papers[16] or publications from Accredited Stakeholder Organisations[17].

Re-occurring issues in this context include the scope of authorisation applications in terms of uses covered (in particular so-called 'upstream' applications) or the required level of information on alternatives.

Concerning the required information on alternatives, for example, NGOs request from ECHA to require more comprehensive information before starting the assessment by accepting an application as conforming with the REACH requirements. Industry on the other hand asks not to burden companies with too detailed requests, especially in cases where applicants consider their case as rather clear.

For 'upstream applications' (i.e. those submitted by manufacturers/importers of substances rather than by downstream-users) on the one hand, industry submits that companies should not face disadvantages when using this option as foreseen in the legislation, for example in the form of short review periods. NGOs, on the other hand, view upstream applications critically arguing that their broad scope would make the discussion on alternatives and a specific assessment in general difficult. Experience from the first years of running the authorisation process has demonstrated that the development as well as opinion-forming on 'upstream' applications can indeed be challenging, in particular for applicants who need to describe the use conditions, benefits and risks related to the authorisation for the entire supply chain. Options for obtaining this information have also been addressed by a Task Force on the

[12] The confidential version of SEA had 82 pages while the public version had 5 pages.
[13] See e.g. the Task Force on the Workability of Applications for Authorisation: Report of activities in 2014-15 and objectives for work for 2016-17. January 2016, which has been submitted to CARACAL meeting of 8-9 March 2016.
[14] E.g. http://echa.europa.eu/web/guest/news-and-events/events.
[15] E.g. a recent workshop organised by CEFIC http://www.cefic.org/Documents/Media%20Center/News/23-9-2015-Worskhop-ProcessChemicals.pdf
[16] E.g., a recent position paper of 26 February 2016 by ASD with concerns regarding Upstream Applications in the REACH Authorisation System
[17] E.g. a 2015 EEB report on the authorisation process http://www.eeb.org/index.cfm/news-events/news/obsolete-chemicals-will-remain-on-eu-market-unless-chemicals-law-tightened-warns-new-report/, or a 2015 ChemSec position paper on how to improve the SEA in SEAC: http://chemsec.org/images/Chemsec_SEAC_150604.pdf

Workability of Applications for Authorisation and a specific workshop on this theme was organised by the Commission and ECHA in November 2015[18].

With the help of the Task Force on the Workability of Applications for Authorisation, which was established in July 2014, ECHA intends to provide further clarifications on these and other issues so that applicants can produce 'fit-for-purpose' applications which can be evaluated in a meaningful manner by ECHA's Committees so that the Commission decisions can be taken with a clear understanding of their impacts. The Management Board's steer in the context of the present discussion is particularly welcomed and will be taken into account by the participants of ECHA and its Committee members in the Task Force, for instance when setting the core objectives for providing a new practical guide to clarify and streamline the application process. This guide will specifically include sections on 'low impact' and 'upstream' applications, which are known to be the most challenging application types. In addition, it has also been suggested that the Task Force would help in clarifying the minimum information requirements for an application and thus, improve the grounds when they would be declared non-conforming.

ECHA is also aware that authorisation applications are complex dossiers composed of many documents which partly cross-refer to each other. In order to keep the opinions concise they make reference to the relevant parts of these dossiers without necessarily copying all relevant information. The Secretariat continuously improves the presentation of the complex authorisation application files as part of ECHA's transparency commitment.

In this regard, lessons can indeed be learned from the European Parliament Resolution about the need to give comprehensive contextual explanations on the authorisation process. For example, the Parliament mentioned in its Resolution that, according to the Committee for Risk Assessment (RAC), it would not be appropriate to grant an authorisation based on adequate control. However, whereas RAC did recognise that the risk assessment included in the application was based on limited exposure data, it did in fact not come to the conclusion that it would be appropriate to refuse the authorisation[19].

Taking into account the importance of trust in ECHA's work on socio-economic issues for the Agency's reputation in general and also the confidence of stakeholders in the authorisation process, ECHA will continue to proactively approach stakeholders for their feedback and to discuss and explain the role of SEA under REACH. To this end the ECHA Secretariat plans to organise a meeting with Member States authorities on the role of Socio-economic Analysis (SEA) in REACH implementation in connection with the 29-30 June 2016 CARACAL meeting. More generally, ECHA will strive to promote a good understanding of the purpose and functioning of the REACH authorisation process. This will underline the Agency's commitment to its core values of transparency, trustworthiness and independence.

Attachment:

- Background note on the Application of Socio-economic Analysis under the REACH Regulation

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[18] More information on the Workshop on 'Streamlining applications for authorisation' can be found here: http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8399

[19] See page 18 of the joint RAC/SEAC opinion http://echa.europa.eu/documents/10162/b50d9fc3-f6db-4e91-8a95-c8397bb424d2. RAC concluded: "*The applicant did not demonstrate adequate control because the worker exposure assessment was not adequate to cover the broad scope of the application. RAC therefore concluded that it could not propose sufficiently specific additional conditions or monitoring arrangements that could justify a conditioned adequate control*".

17 March 2016

Annex: Background Note on the Application of Socio-economic Analysis under the REACH Regulation

1. Purpose

The purpose of this information note is to explain how socio-economic analysis (SEA) is applied under the REACH Regulation. In particular, it details how the SEA is used when the Committee for Socio-economic Analysis (SEAC) provides opinions to the Commission for decision making on applications for authorisation and restriction proposals.

The context of this note is the recent discussion about the use of SEA among ECHA's stakeholders, Member States and the European Parliament, notably a European Parliament resolution of 25 November 2015 as well as the discussion in the Management Board in December 2015 related to a European Commission draft Decision on an authorisation application for DEHP. This topic has also received attention in discussions between the Commission, Member States and ECHA in the context of restrictions.

The note describes the basic principles how SEA is applied under REACH. It also characterises the institutional setting of SEAC taking into consideration the European Commission's policy with regard to impact assessments in the decision making phase.

2. Socio-economic analysis and its scientific basis

SEA is an evidence-based, systematic and scientific analysis of the information at hand. It attempts to organise and analyse information in a coherent manner essentially placing the "pros" (i.e. positive impacts) and "cons" (i.e. the costs / resource implications) in a comparable manner to support decision-making. Methodologically, SEA is applied through cost-benefit, cost-effectiveness analysis or multi-criteria analysis, depending on how much information is at hand. The purpose of SEA is to identify impacts of proposed options that are beneficial or detrimental and inform the decision-taking and policy-making process. In the context of REACH, the decision on whether a measure is acceptable or not, is taken by the Commission in consultation with the Member States and should be based on as much as possible factual information on costs and benefits of that decision.

The main value added of SEA often relates to two issues: what are the impacts on human health or the environment of a specific measure, and what are the actual costs from implementing the measure.

REACH does not define SEA but sets out in Annex XVI what a SEA may include. ECHA has, in full consultation with Member States, the Commission and stakeholders, developed two related guidance documents (SEA for restrictions and SEA for applications for authorisation). In the context of REACH, SEA can be defined as follows:

Socio-economic analysis informs about the likely social and economic consequences of regulating a substance. The overall aim is to identify action that would increase the social welfare as there is usually a trade-off between human health or environmental impacts and the economic impacts. The economic impacts are closely tied to the cost of using alternative substances, i.e. the cost of substitution.

In practice, all relevant information is seldom available which implies that a SEA is a combination of qualitative and quantitative information. Therefore, one needs to be transparent about the assumptions made and the uncertainties that relate to those assumptions.

3. Where is SEA used in REACH?

SEA is applied in REACH in two processes: the assessment of restriction proposals and of applications for authorisation.

1. In restriction proposals, the dossier submitter, among other things, analyses the alternatives and conducts a socio-economic analysis of the proposed restriction. The purpose is to identify the most appropriate EU-wide measure to address the risk that has been identified. According to Article 68(1) a decision on a restriction shall take into account its socio-economic impact, including the availability of alternatives.

2. In the authorisation process, if an adequate control of risks cannot be demonstrated, an applicant may prepare an analysis of the socio-economic impacts on itself, the supply chain and the society, should an authorisation be granted or refused. Thus far, all applicants have prepared a SEA as this is rather straight forward to do in conjunction of the analysis of alternatives.

In both processes ECHA organises a public consultation, which may result in additional information that is relevant to SEA. SEAC will take all information into account in its opinion making. Obviously, the dossier submitter and the applicant, as relevant, will have the possibility to give their views of the significance of the new information. They have always exercised this possibility.

The ultimate users of the outcome of SEA are the Commission and the Member States when deliberating on a draft Regulation to amend Annex XVII for a restriction or on a draft Decision to grant or refuse an authorisation. The SEA presents the Commission and the Member States with the factual basis and analysis necessary for the decision-making process. The dossier, including SEA, and in particular the opinion of the SEAC and the RAC, play an important role when the policy decision is taken.

4. Institutional setting of SEA and SEAC given Commission's impact assessment requirements

As a general rule, all legislative proposals of the Commission and Comitology Acts that are expected to have significant impact are subject to Impact Assessment. As there is a similar requirement under the REACH Regulation, ECHA initiated in September 2007 a discussion with the Commission services to clarify the relationship. The Commission services consulted the Impact Assessment Board (IAB) on 18 June 2008 (Annex 1) to see to what extent the processes under REACH would be deemed sufficient.

In its response of 9 October 2008 (Annex 2), the IAB clarified that:

"*any restriction proposal will be accompanied by a socio-economic analysis and by a risk analysis and that the quality of the former dossier will be primarily verified by the Socio-economic Assessment Committee and subsequently by the Commission services"* (currently DG GROW and ENV).

The IAB further stated that:

"this should provide a sufficient basis for the Commission to prepare any decisions on restrictions, and that there is no need for the involvement of the IAB".

Should there be no SEA accompanying a restriction proposal, the SEAC would not be able to scrutinise the socio-economic impacts. Consequently, the Commission would need to carry out the impact assessment, if it proposed to add a restriction to Annex XVII of the REACH Regulation. In essence, the SEA in the Annex XV dossier and the

SEAC opinion effectively replace the need of a separate impact assessment carried out by the Commission.

In 2008, the IAB did not comment on its involvement in the case of applications for authorisation, which are Commission decisions relating to individual applicants rather than measures of general application. In practice, the Commission has adopted its decisions on the applications without its own impact assessment as the Commission's decisions are made per application and socio-economic impacts are a key factor in the decision-making. These take into account the scientific advice contained in SEAC's opinion.

One of the objectives of the REACH Regulation is to reduce the length of the decision making process for restrictions compare to the pre-REACH situation. Obviously, the decision making phase for authorisation applications should also be efficient. An informative SEA, scrutinised by SEAC provides a meaningful underpinning to the Commission's decision-making.

5. Role of the SEAC

SEAC evaluates restriction proposals and applications for authorisation based on REACH Articles 64(3), 64(4) and 71, respectively. SEAC reviews the analysis of alternatives and the SEA prepared by the applicant for authorisation or by the dossier submitter of a restriction proposal. Based on the review it formulates opinions to be considered in the Commission's decision making. During this review process, SEAC's rapporteurs collaborate with their counterparts in RAC as the information in the dossiers and from the public consultation often relate to the remits of both Committees. In particular the information on the exposure of people or the environment to a substance is of importance to both.

The ECHA Secretariat supports the SEAC through methodological development and capacity building. It does so also by providing additional information to the Member States (i.e. dossier submitters in restrictions) and applicants for authorisation. Examples of these are the research on the willingness-to-pay values, quality or disability adjusted life year, how cost or economic feasibility are estimated, and how PBTs and other similar substances can be evaluated.

ECHA, including its Committees, and the Commission services developed the opinion formats in close collaboration so that they serve well the tasks of the Committees and the purpose of the decisions. The guiding principle was that the two Committees should provide opinions that would provide the Commission with the necessary evidence and analysis to underpin the decision-making phase. Particular attention has been paid to the possible situation in which the conclusions of the two Committees and thus, the recommendations to the Commission point into different directions. In such cases, it is important for the Commission (and Member States) to know why this is the case, so that they are fully informed when taking the decision.

Annex 1 shows the basis for the opinions, and consequent standard formulation of the opinions that SEAC uses. In this context there are two pertinent issues:

1. For the opinion on applications for authorisation the formulation states clearly that SEAC has evaluated the application and refers to the applicant's conclusion of the benefits and risks. The crucial point is whether SEAC raises a concern about the applicant's conclusion or not. SEAC does not and should not take a stand on proportionality in authorisation cases.

2. For restrictions, the opinion takes a stand on proportionality as this is a requirement of Annex XV. It specifies that the restriction dossier should conclude and thus what SEAC needs to evaluate. In particular SEAC needs to review the justification that "*the restriction must be … proportional to the risk*". This is thus reflected in the standard formulation of the opinion.

6. Relationship between the SEAC (and the RAC), the Commission and the Member States

In the EU regulatory system before REACH there was no direct equivalent to the SEAC. The equivalent to the RAC did exist, however: one body (Technical Committee on New and Existing Substances (TC NES)) assessed, if substances posed a risk based on the risk assessments developed by the Member States, and another body (Risk Reduction Strategy Working Group (RRS WG)) assessed the proposed risk reduction strategies. If the conclusion of the latter body was that a risk should be reduced through a restriction, the Commission services (at that time, the predecessor of DG GROW) prepared the actual restriction proposal and the related Impact Assessment.

Under REACH a new institutional arrangement was created. The tasks of TC NES and the RRS WG were handed to the RAC and a new body, the SEAC, was created. Also, Member States were entrusted with the right to take the initiative to propose restrictions. In turn, they are required to take on a larger share of the analytical work in analysing the appropriateness of the EU wide measures proposed (see also section 4). At the same time, the two Committees of ECHA (in particular the SEAC) scrutinise the relevant parts of the restrictions and provide their opinions. Member States have needed some time to adapt to this new institutional setting and in particular to the inclusion of the socio-economic impacts of the proposed restrictions. The SEAC also needed some time to build its capacity to scrutinise proposed restrictions.

Authorisation is completely new in the legislative system in the EU for industrial chemicals. Nothing comparable existed in the previous system. Thus, ECHA established with the Commission the authorisation system in the first years of REACH, consisting of the identification, prioritisation, placing substances to the "Authorisation List" (i.e. Annex XIV) and the whole application process. Once the first applications for authorisation arrived in late 2013, the SEAC and RAC started to gradually carry out their evaluations, as provided for in the REACH Regulation.

In one of the first opinions[20] adopted on an application for authorisation, the wording used refers to "proportionality". This wording was unfortunately not following the standard formulation used in the opinion template. The Secretariat has ascertained that similar inappropriate formulations have not been used in other opinions of SEAC. ECHA intends to ensure that this will also be the case in the future as it is clear that it is not in the remit of SEAC to provide an overall proportionality assessment of the final regulatory measure taken, comprising all policy considerations, but merely to advice the Commission.

Thus, it is important that SEAC, as well as all others, continue to learn from the past cases. It is equally important that the role of the SEAC is discussed with and clarified to all stakeholders.

[20] Opinion on an Application for Authorisation for Bis(2-ethylhexyl) phthalate (DEHP) use: Formulation of recycled soft PVC containing DEHP in compounds and dry-blends. ECHA/RAC/SEAC Opinion N°AFA-O-0000004151-87-16/D adopted on 22 October 2014. The European Parliament's resolution of 25 November 2015 on this application raises this issue, too.

7. Conclusions

SEA is a systematic, scientific method to assess what the health, environmental, economic and social impacts of an envisaged measure are. It is evidence based. SEA strives to improve the understanding of the implications of an action and thus complements the analysis carried out in risk assessment.

SEAC as an institution is a new body introduced in the REACH Regulation with specific tasks under restrictions and applications for authorisation. Many of the initial questions on how an SEA as part of a restriction proposal or an application for authorisation should look like have been clarified and their evaluation in SEAC is maturing fast.

The SEAC scrutinises restrictions and applications for authorisation with only one purpose: to provide meaningful opinions to the Commission and the Member States for decision-making. This it does in close cooperation with RAC. SEAC bases its scrutiny on the evidence given to it both in the dossiers and in the information from pubic consultations. The scrutiny and conclusions are based on quantitative and qualitative information.

The ECHA Secretariat supports the SEAC through methodological development and capacity building. It does so also by providing additional tools to the Member States (i.e. dossier submitters in restrictions) and applicants for authorisation.

Given that not all parties have similar expectations on the roles of SEA and SEAC under REACH, ECHA has agreed with the Commission to discuss these issues in the meeting of the Management Board in March 2016 and with the Member States and stakeholders in the CARACAL meeting in June 2016. The aim is to bring clarity to all on what is possible and meaningful to carry out as part of SEA and how the opinions of SEAC are derived in practice for the benefit of efficient decision-making.

Appendix

Basis for opinions and standard phrases used in SEA related opinions

In this Annex the basis for the opinions as well as the standard phrases used by SEAC to recommend to the Commission that a restriction should be adopted or an authorisation be granted. The standard phrases of the opinions are the opposite if the committees suggest that a restriction should not be adopted or an authorisation should not be granted. There are variations of these, i.e. when derogations (for restrictions) or conditions or monitoring arrangements (for applications) are proposed. These variants are not presented below, to keep this Annex simple.

Restrictions

Basis for the restriction

According to Article 68 of the REACH Regulation, when there is an unacceptable EU-wide risk, ECHA (on request of the Commission) or a Member State are to propose a restriction on which the Commission shall decide. Any such decision shall take into account the socio-economic impact of the restriction, including the availability of alternatives.[21]

Basis for the opinion

According to Article 71 of the REACH Regulation, SEAC shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact.[22]

Standard formulation of the opinion

The standard formulation of SEAC's opinion that it normally uses is the following:

"SEAC has formulated its opinion on the proposed restriction based on an evaluation of

[21] Article 68 Introducing new and amending current restrictions

1. When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Union-wide basis, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4) by adopting new restrictions, or amending current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in mixtures or in articles, pursuant to the procedure set out in Articles 69 to 73. Any such decision shall take into account the socio- economic impact of the restriction, including the availability of alternatives.

[22] Article 71 Agency opinion: Committee for Socio-economic Analysis

1. Within 12 months of the date of publication referred to in Article 69(6), the Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to Article 69(6)(b), if there are any. The Agency shall publish the draft opinion on its website without delay. The Agency shall invite interested parties to give their comments on the draft opinion no later than 60 days from the publication of that draft opinion.

2. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set. This opinion shall take account of the comments and socio-economic analyses of interested parties submitted under Article 69(6)(b) and under paragraph 1 of this Article.

the information related to socio-economic impacts documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the restriction proposed by the Dossier Submitter on ***[substance name, CAS & EC numbers]*** is the most appropriate Union wide measure to address the identified risks, as concluded by RAC, taking into account the proportionality of its socio-economic benefits to its socio-economic costs [provided that the scope or conditions are modified as stated in the RAC opinion] as demonstrated in the justification supporting this opinion.

It is noteworthy than Annex XV[23] specifies what the restriction dossier should conclude and thus what SEAC needs to evaluate. In particular SEAC needs to review the justification that "*the restriction must be … proportional to the risk*". This is thus reflected in the opinion.

Application for authorisation

Basis for the decision

The basis for SEAC to give its opinion stems from Article 60(4)[24] of the REACH

[23] Annex XV, Section 3. Dossiers for restrictions proposal

… Information on alternatives

Available information on alternative substances and techniques shall be provided, including:

— information on the risks to human health and the environment related to the manufacture or use of the alternatives,

— availability, including the time scale,

— technical and economical feasibility.

Justification for Restrictions at Community Level

Justification shall be provided that:

— action is required on a Community-wide basis,

— a restriction is the most appropriate Community wide measure which shall be assessed using the following criteria:

(i) effectiveness: the restriction must be targeted to the effects or exposures that cause the risks identified, capable of reducing these risks to an acceptable level within a reasonable period of time and proportional to the risk;

(ii) practicality: the restriction must be implementable, enforceable and manageable;

(iii) monitorability: it must be possible to monitor the result of the implementation of the proposed restriction.

[24] Article 60(4)

If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements and taking into account the opinions of the Committee for Risk Assessment and the Committee for Socio- economic Analysis referred to in Article 64(4)(a) and (b):

(a) the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;

(b) the socio-economic benefits arising from its use and the socio- economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;

(c) the analysis of the alternatives submitted by the applicant under Article 62(4)(e) or any substitution plan submitted by the applicant under Article 62(4)(f), and any third party contributions submitted under Article 64(2);

Regulation. It states that if an adequate control of the risks cannot be demonstrated an "*authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies.*" It further states that the Decision shall be taken after consideration of several elements. The most pertinent is Article 60(4)(b) which states "*the socio-economic benefits arising from its use and the socio- economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;*" Finally, Article 60(4) states that in the decision making the opinions of SEAC and RAC shall be considered.

Basis for the opinion

Article 64(4)(b)[25] gives the scope of SEAC's work when it gives its opinion on an application. It states that SEAC's draft opinions shall include the following elements:

- an assessment of the socio-economic factors and
- the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application…

Standard formulation of the opinion

The standard formulation of SEAC's opinion that it normally uses is the following:

SEAC considered that the applicant's assessment of: (a) the potential socioeconomic benefits of the use, (b) the potential adverse effects to [human health] [and/or] [the environment] of the use and (c) the comparison of the two is based on acceptable methodology for socio-economic analysis. Therefore, SEAC did not raise any reservations that would change the validity of the applicant's conclusion that overall benefits of the use outweigh the risk to human health or the environment, whilst taking account of any uncertainties in the assessment.

(d) available information on the risks to human health or the environment of any alternative substances or technologies.

[25] Article 64(4)

The draft opinions shall include the following elements:

…

(b) Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under paragraph 2 of this Article.