May 2014

DOSSIER SUBMITTER'S AND ECHA'S RESTRICTION TEAM'S INVOLVEMENT IN THE RESTRICTION PROCESS (Restriction Task Force)

1. Background

In the context of the Restriction Efficiency Task Force (RETF) assessment, it was considered necessary to further clarify and develop the role and the involvement of the Dossier Submitter (DS) in the restriction process. The document presents the DS's role in the different steps of the restriction process and includes the relevant recommendations made by the Task Force (see in addition Annex 1). The paper will also clarify the role of the European Chemicals Agency (ECHA) Secretariat's (ECHA-S) in the process[1] (this was another recommendation of the RETF).

2. Pre-submission phase

According to REACH Regulation, an Annex XV restriction dossier can be submitted either by a Member State (MS), by ECHA on request of the Commission or by ECHA on its own initiative (article 69(2)). It is vital for planning and operational purposes that submitting MS make their intention known to the Registry of Intentions (ROI) 12 months before the dossier is to be submitted and if possible to the pre-RoI before that. If the Annex XV dossier is prepared by two MS or one MS and ECHA, one authority should be identified as having the formal role of DS; both can be indicated in the website of ECHA.

In terms of the ECHA-S, there are 2 main teams involved: a pre-submission information meeting (PRIM) team[2] will be appointed at the time of entry in the ROI and the Restriction Team (ECHA-RT)[3] is normally appointed 4 months before the submission of the Dossier.

ECHA will offer potential DSs the opportunity to discuss their prospective restriction 6-9 months in advance of the formal submission of the dossier, either in the form of a PRIM or by providing comments on the draft dossier. This is strongly recommended to all DSs and a letter will be sent to the DS to this end once a ROI entry has been made.

In addition, ECHA will offer to assist the DS with regard to collecting evidence by publicising their call for evidence on the ECHA website and in the eNews. The above mentioned letter in response to the ROI entry will also repeat this offer.

In addition, specific questions from the DS (e.g. on scope) can be discussed in a forum; more general comments on the dossier itself will be facilitated using another media format e.g. Circabc. ECHA will normally also organise, once a year, a workshop for potential DSs to discuss relevant issues.

The DS as part of their preparation of the dossier[4] will consider including the key uncertainties in their dossier, possibly in a separate section of the introductory section, to include any uncertainties around the scope of the proposal.

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1 ECHA-S' provides support for the DS and the Rapporteurs/Committees throughout the whole restriction process and the composition of the support staff changes.

2 The PRIM team will normally be the restriction process co-ordinator, a SID expert, the potential Restriction Team Manager and a Socio-economic expert (if not the RTM). The Committees secretariat and the Forum Secretariat will also be invited to join the PRIM.

3 The ECHA-RT consists of the Restriction Team Manager, where relevant a co-Manager, a Committees Co-ordinator and a team assistant.

4 Now agreed to be 30-60 pages in length and summarising key information with additional information in appropriate Annexes.

The DS should use the 'clear scope' document endorsed by the RETF and the Enforcement guidance (in addition to consulting with their relevant Forum member) in drafting their Dossier.

3. Conformity check phase

The conformity check is a shared responsibility of ECHA's Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC) Committees who work in parallel during the 30 day period as stipulated by REACH Regulation. The conformity check procedure is launched by providing the Annex XV dossier to the Committees. The Committees need to agree on the conformity of the dossier within 30 days from the Committees' receipt of the Annex XV dossier[5]. The ECHA-RT will assist in this process by providing the Rapporteurs of both Committees a 'pre-conformity' check document based on their detailed initial assessment of the dossier[6]; this is to help the Rapporteur with undertaking their assessment but does not mean the Rapporteur cannot disagree with or add additional issues. The RETFs clear scope document will aid in determining if the proposal conforms in terms of its scope.

To facilitate a potential dialogue between the Rapporteurs and the DS, through the ECHA-RT, during the conformity check period, the Dossier will be submitted 2 weeks earlier than normal[7]. The ECHA pre-conformity check will be carried out at an earlier stage and any issues raised by the Rapporteurs can be more easily clarified with the DS, facilitated by the ECHA-RT.

The DS will continue to provide a short, focussed introductory presentation on the dossier (timing to be agreed with the Chair on a case-by-case basis) to RAC and SEAC members during the plenary meetings where the outcome of the conformity check on the specific dossier is to be agreed. The DS representatives will follow the discussion as observers (either at the meeting or through WebEx); they are not expected to actively defend the dossier as any discussion with the rapporteurs will already have taken place. DS may be given the floor to make relevant clarifications regarding the dossier at the discretion of the Chair.

If the Annex XV restriction dossier is found to be in conformity according to both RAC and SEAC, the Secretariat informs the DS about the outcome and launches the six month public consultation on the restriction report. If there are recommendations for improvement of the Annex XV dossier by the Rapporteurs, these should be prioritised by the Rapporteurs assisted by the ECHA-RT, at the latest just after the relevant RAC/SEAC meeting[8]. The priority recommendations may, where relevant, be used as the basis of specific questions for the public consultation. These questions should be agreed between the rapporteur and the DS to ensure information is gathered that will assist with the Committees assessment of the Dossier.

If the dossier is not found to be in conformity by either or both Committees, the DS is informed of this outcome together with the detailed reasons for non-conformity. The DS is requested to bring the dossier into conformity within 60 days of the day of receipt of the reasons from the Committee(s); the ECHA-RT will be available to offer comments on a revised version of the Restriction Dossier if requested. If needed a meeting between the Rapporteurs and the DS can also be organised by the ECHA-RT; this would take place as soon as possible after the Committees have given a non-conformity opinion.

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5 Working procedure for RAC and SEAC on conformity check of Annex XV restriction dossiers (agreed at RAC-14 and SEAC-9)

6 Only for MS dossiers

7 It is proposed to implement this starting from the 2015 Submission dates.

8 The Committees may provide initial prioritisation to the rapporteurs.

4. Opinion development phase

According to Articles 70 and 71 of the REACH Regulation, RAC shall formulate an opinion within 9 months and SEAC within 12 months from the start of public consultation on an Annex XV restriction proposal. The DS is normally involved in the restriction process as part of the Restriction Support Group (RSG: consisting of the ECHA-RT, the (co-)rapporteurs and the DS) throughout the opinion making process as they have a vested interest in the success of the dossier. The Forum secretariat or contact person may also be invited to the dialogues if requested by the Rapporteurs. It is the role of the support group to agree the input requested from the DS but in general it should be the aim of the process to limit additional information/assessment requested from the DS to the beginning of the process (this does not preclude an agreement between the parties for additional participation at any stage of the process).

The DS also has a role during the preparation of the Public Consultation in regards to the discussion on specific questions to be asked. ECHA-S will consult the Rapporteurs and the DS on potential questions.

The ECHA-RT provides support to the Rapporteurs and the Committee throughout the opinion making process in terms of:

- Additional data gathering from stakeholders/3rd parties or communication within the Committees;
- Commenting on draft Key Issue's Document and opinions;
- Preparing documents for the Rapporteurs to complete e.g. Preparing documents for the Rapporteurs to complete e.g. Response to Comments (RCOM), response to comments table on the RAC/SEAC members' comments (ORCOM) etc. and supporting the completion of these documents;
- Manage the PC and provide information to DS and Rapporteurs;
- Facilitating the dialogues and coordinating the RSG work with the revision and finalisation of the Background Document[9]; and
- At the request of the Chairs any other scientific support to the Committees;
- No legal support on developing the Annex XVII proposal is necessary but rather support for clarifications on text

a. Participation at the plenary meetings

The DS is invited to participate in RAC/SEAC meetings 'in person' as an observer when the Committees discuss, agree or adopt the relevant opinions; the presence of the DS is welcomed at the meetings, as it might make the interactions much smoother and efficient. The travel and participation expenses of the DS representatives are not reimbursed; there is also a possibility to follow the plenary discussions via a WebEx connection (even if the DS also attends the meetings).

During the plenary discussions on the opinion development, the DS can follow the discussions and provide additional clarifications regarding their dossier to RAC/SEAC members when requested or at the discretion of the Chair.

In terms of the key issues papers or opinions, the DS may be asked to comment on the documents at the request of the Rapporteurs.

Where necessary, there might be a need for ad hoc groups to discuss the specific issues regarding the opinions in the margins of the plenary meetings. The DS (and stakeholders)

[9] See sub-section c for more details on responsibilities

can be invited to these ad hoc groups on a case-by-case basis as deemed necessary by the Chairmen (after consulting the (co-)rapporteurs).

b. Participation at the Rapporteurs' Dialogues

On request of the RAC and SEAC (co-)rapporteurs, the DS is invited to the (co-)rapporteurs' dialogues (this is normally the case), foreseen by the Working Procedures of RAC and SEAC, which can be up to three dialogues per restriction dossier[10]. Sometimes it can be that the (co-)rapporteurs consider holding the dialogues only among themselves (usually towards the end of the opinion development process.)

There is no limitation of the number of DS representatives attending the dialogue meetings in person at ECHA, but the participation of only one DS representative is reimbursed. Attendance by WebEx or by conference call is also supported, in particular for the final dialogue.

The RT facilitates the meeting (i.e. drafts agendas and prepares action points) and chairs the sessions if the Rapporteurs do not wish to do so themselves. By the third dialogue the Commission's view if the opinions are fit-for-purpose should have been sought.

c. Input to the process related documents such as Background document, response to comments etc.

The DS as part of the Restriction Support Group (RSG: consisting of the ECHA-RT, the (co-)rapporteurs and the DS) provides input to the process related documents, such as the Background Document, the relevant RCOMs and ORCOMs related to the PC and the Forum advice.

According to the current working procedure, the DS should provide input for the first version of the Background Document; this should include answering all the relevant recommendations (as agreed between the DS and the Rapporteurs). This document should be made available to the Committees together with the versions of the draft opinions to the RAC and SEAC Committees (i.e. *by week 20* of the opinion development procedure). Following this, all additional information will in general be added to the Background Document by the Rapporteur or the ECHA-RT, in the form of RAC and SEAC 'boxes', to reflect the development of the opinions. However, if further information becomes available, for example during the PC that changes the previous information in the BD, the RSG should decide who will update the BD.

Furthermore, the DS provides responses to comments (RCOM) received within the public consultation (i.e. by *week 30* of the opinion development procedure). In some cases, the DS is also asked to provide written responses to comments submitted by the Committee members during the internal consultation rounds on the Annex XV dossiers or the different versions of the opinions.

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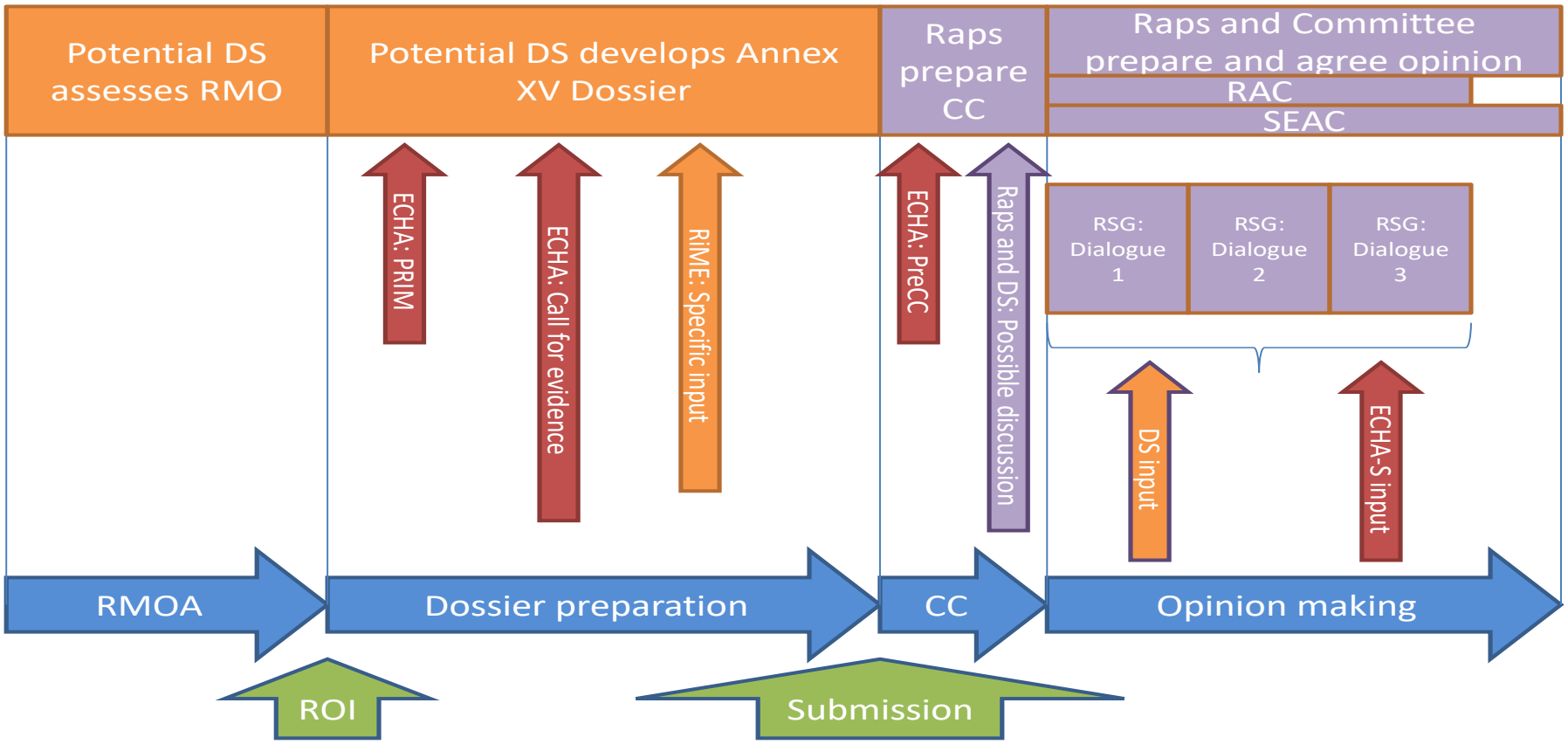
[10] Working procedure for RAC and SEAC on developing opinions on Annex XV restriction dossiers (agreed at RAC-28 and SEAC-22)

Annex 1: DS's and ECHA Secretariat's role in the different steps of the restriction process



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