

Streamlining Applications for Authorisation



Workshop Programme

(as of 11 November 2015)

17 November 2015 The Berlaymont building (meeting room Schuman) Rue de la Loi 200, 1040 Brussels

Sessions marked with an asterisk (*) will be web-streamed live. Remote participants can send in questions using the chat panel.

Registration (8.30 - 9.00)

Welcome (9.00 - 9.30)*

- Klaus Berend (European Commission, DG GROW)
- Thierry Nicot (ECHA)

Status of simplification of applications in specific cases (9.30 - 10.00)*

- Update from the European Commission by Anna Borras (DG GROW)
- Questions and answers

Coffee break (10.00 - 10.30)

Session 1 Downstream user applications*

Moderators: Cristina de Avila (DG ENV) and Matti Vainio (ECHA)

Session 1.1 What should be in a "fit-for-purpose" application (10.30-11.30)*

Presenters:

- Experience from preparing a focused single downstream user application by Elke Van Alsbroeck (Apeiron-Team)
- Experience from preparing an application for a process chemical with multiple applicants by Patrick Levy (SOCOTEC) and Panos Zarogiannis (RPA)
- Specific issues from RAC & SEAC by Tim Bowmer (RAC)

Session 1.2 Panel discussion (11.30 - 12.30)*

Panellists: Vito A. Buonsante (ClientEarth), Roger van der Linden (Borealis), Stavros Georgiou (SEAC), Finn Pedersen (Danish EPA)

The presenters, panellists and audience discuss and answer questions:

- 1. What makes a downstream user application fit-for-purpose? Have previous downstream user applications been fit-for-purpose?
- 2. What kind of data needs to be included in a fit-for-purpose application to demonstrate that the risks are low?



Streamlining Applications for Authorisation



- 3. When it can be demonstrated that risks are low, what data is required to demonstrate the costs of a non-granted authorisation (i.e. through the non-use scenario and suitability of alternatives)?
- 4. What could be done to facilitate the work of applicants, Committees and other actors?

Lunch at 12.30

Session 2 Upstream applications*

Moderators: Klaus Berend (DG GROW) and Jack de Bruijn (ECHA)

Session 2.1 Upstream applications from a risk perspective (13.30-14.45)*

Presenters:

- Experience from industry, in particular on preparing upstream applications covering multiple downstream users by Silke Tenbrock (Olin Corporation)
- Specific issues from RAC by Urs Schlüter (RAC)

Panellists: Dolores Romano (EEB), Geoffroy Tillieux (European Plastics Converters), Sonja Kapelari (RAC), Keith Bailey (Defra)

The presenters, panellists and audience discuss and answer questions:

- 1. From a risk perspective, what were the main lessons learnt from the preparation and evaluation of past upstream applications?
- 2. What are the challenges in defining the use in upstream applications? How can they be overcome?
- 3. How can the representativeness of exposure scenarios best be ensured in upstream applications? E.g. in terms of:
 - Defining workplaces, operating conditions and risk management measures
 - o Role of modelling and measurement data
 - Geographic spread
 - o Other relevant issues
- 4. What could be done to facilitate the work of applicants, Committees and other actors?

Coffee break (14.45-15.15)

Session 2.2 Upstream applications from a socio-economic perspective (15.15-16.30)*

Presenters:

- Experience from industry, in particular on preparing an upstream application for complex supply chains covering multiple uses and users by Julius Waller (EPPA)
- Specific issues from SEAC by Jean-Marc Brignon (SEAC)

Panellists: Tony Musu (ETUI), Simone Fankhauser (SEAC), Richard Luit (RIVM), Richard Dubourg (The Economics Interface Limited)



Streamlining Applications for Authorisation



The presenters, panellists and audience discuss and answer questions:

- 1. From a socio-economic perspective, what were the main lessons learnt from the preparation and evaluation of past upstream applications?
- 2. How can the applicant best ensure that the Analysis of Alternatives is credible in upstream applications? E.g. in terms of:
 - o Obtaining information on alternatives from downstream users
 - o Suitability of alternatives from the perspective of different downstream users
 - o Other relevant issues
- 3. How can the credibility of the socio-economic analysis best be ensured in upstream applications? E.g. in terms of:
 - Identifying a non-use scenario, including the perspective of downstream users and operators further downstream
 - o Estimating the costs of a non-granted authorisation
 - o Estimating the benefits of a non-granted authorisation
 - o Other relevant issues
- 4. What could be done to facilitate the work of applicants, Committees and other actors?

Conclusions and the way forward (16.30-17.00)*

• Cristina de Avila (DG ENV)