SEMINAR ON APPLICATIONS FOR AUTHORISATION

07 JULY 2011

Brussels, Belgium

Summary of discussions between ECHA, NGOs and trade unions
23 September 2011

1. Introduction

On July 7, 2011, ECHA met with representatives of NGOs and trade unions,[1] to discuss activities related to the authorisation application process under the REACH Regulation. The meeting was held in the premises of WWF European Policy Office in Brussels and was co-chaired by Lisette van Vliet, Toxic Policy Advisor, HEAL and Matti Vainio, Head of the Risk Management Implementation Unit of ECHA

2. Objectives

The objective of the meeting was for ECHA to provide an update on its preparatory activities for the implementation of the authorisation process and to gather stakeholders' input in an efficient and transparent manner. In particular, it was an opportunity for ECHA to better understand the NGOs' and trade unions' views on ways to ensure the transparency of the authorisation process and on an efficient and meaningful involvement of interested parties in the public consultations on broad information on uses. The meeting also was for NGOs and trade unions to give their views on the authorisation application process, such that its implementation is effective and achieves the goals of the REACH regulation.

3. Summary of discussions

3.1 Topics raised by ECHA

Matti Vainio and Rémi Lefèvre gave presentations on the provisions in REACH for public involvement in the authorisation process and the description of uses applied for. ECHA's presentations related to the transparency and public consultation of the authorisation process, and discussed the following:

- The authorisation process must be impartial, transparent, efficient, and instilling confidence in the scientific validity of authorisation opinions and subsequent decisions.
- The execution of a meaningful and efficient public consultation is instrumental for the effectiveness of the authorisation process.
- The purpose of the public consultation on broad information on uses is to collect, in an efficient manner, meaningful information on suitable and available alternative substances and technologies to substances for which authorisation is sought or reviewed.
- ECHA will be determining the definition of the broad information on uses. The initial approach is to give applicants the opportunity to provide ECHA with a first proposal of the definition. ECHA will subsequently develop a draft and final definition, on the basis of the content of the application file. The applicant will have the opportunity to provide comments on ECHA's draft.
- For the purpose of soliciting information on available suitable alternatives from third parties ECHA will place the final version of the broad definition on uses and potentially other information from the application on its website.

[1] These were ChemSec, ClientEarth, EEB, ETUC, ISTAS, HEAL, University of Darmstadt, WWF European Policy Office. The European Commission (DG Enterprise and DG Environment) as well as the Greens/European Free Alliance in the European Parliament were observers.

What information is made publicly available must be determined by taking into account the purpose of the public consultation and the relevant provisions of the REACH Regulation and other relevant EU legislation, such as the right to access documents and the right to confidentiality and protection of professional and business secrecy.[2]

3.2 Topics raised by NGOs and trade unions

The representatives of NGOs/trade unions generally agreed with ECHA on the purpose of designing the public consultation in such a way that it is transparent, efficient and meaningful for the next steps of the authorisation process. The discussions focused on the best way to achieve this, and in particular on what information from the application should be disseminated as part of and/or together with the broad information on uses.

Tatiana Santos, Tony Musu, Vito Buonsante and Martin Führ presented their views on the type of information from authorisation applications that must be made publicly available for the public consultation part of the authorisation applications procedure. The representatives of NGOs/trade unions in their presentations and discussions made the following observations:

- ECHA's interpretation of 'broad information on uses' must be given in light of Art. 15 of the Treaty on the Functioning of the European Union (TFEU), and take into account the aim of the authorisation procedure in general, and the public consultation on ECHA's website, in particular.
- It is important that sufficient information from the applications for authorisation is made publicly available to allow third parties to provide meaningful input concerning possible alternative substances and technologies.
- The public consultation should last 8 weeks, as stated by ECHA in order to allow time for dissemination and collection of quality information.
- According with Art. 64(2), broad information on uses has to be seen with a holistic perspective. The more comprehensive the public information on uses applied for, the higher the chance to collect useful information on alternative substances and/or technologies. Therefore, in order to facilitate the identification of possible alternatives, it will be important to include the following information in the definition of broad information on uses:
    - use patterns (end-use, service life and lifecycle, map of uses throughout life-cycle stages),
    - performance level (process, operational parameters, production, applicable use, volumetric use), and
    - substance functional use and functional requirement.
- Other important information to be made publicly available for the purpose of the public consultation is: applicant name, substance information, exposure scenarios (including information on operational conditions and risk

[2] Article 15 (agencies shall conduct their work as openly as possible) and Article 339 (non-disclosure of professional secrecy) of the Treaty on the Functioning of the European Union (TFEU) and Article 41 (right to good administration) and Article 42 (right of access to documents) of the Charter of fundamental rights of the European Union.

management measures), description of use via the Use Descriptor System (including the functional use), and the Analysis of Alternatives.

- Other important information the Commission has to consider when granting the authorisation such as all discharges, emissions and losses, including risks arising from diffuse or dispersive uses.
- The Analysis of Alternatives should be made available in order to allow interested parties to validate its content and to make contributions, particularly if the alternatives or processes known to third parties have not been covered by the analysis. Therefore, its availability would increase the efficiency and increase the chances of meaningful results for the relatively short period of 8 weeks foreseen by ECHA.
- The determination of the sufficient level of publicly available information should be driven by:
    - The objectives of the REACH Regulation for the progressive substitution of substances of very high concern;
    - The obligation to ensure that the exposure to substances of very high concern is constantly reduced to as low a level as it is technically and practically possible according to Art. 60(10)
    - The fundamental principle of EU public institutions to conduct business with transparency (Art. 15 Treaty for the European Union: "as openly as possible");
    - The need to ensure that the public consultation can effectively gather information not available in the application, or improve the quality of the information in the application;
    - Provisions for the protection of public interest whilst taking into account confidential business information. The latter has to interpreted in the light of the character of the substances at stake in the authorisation process (i.e. substances of **very high concern**), e.g. the provision in Art. 118(2)b does not apply to the information disseminated under Art. 64(2);
    - The regulations governing access to environmental information and public participation in environmental matters (i.e., Aarhus Convention and Aarhus Regulation); and
    - Following the hierarchy of regulatory provisions in EU law (see paper by Client Earth).
- There is a need to make the whole application for authorisation public (unless there is a justification for confidential business information and no public interest overrides it) on ECHA's website already at the public consultation step, taking into account that a substance of very high concern is under scrutiny and the availability of alternatives is crucial for the final decision. This public access will ensure a targeted and effective public consultation on alternatives and transparency of the overall authorisation process. The information needs to be made available in a user-friendly way allowing the finding of all relevant information, presented in a coherent and user friendly way, at one access point. Thus, the **application itself** should give all information that justifies – from the perspective of the applicant – the granting of an authorisation.
- A meaningful consultation would also help RAC/SEAC in drafting specific aspects of their opinion

- It can be useful for ECHA to provide to third parties a template that facilitates the submission of information on alternatives. SUBSPORT partner[3] template on reporting on alternatives is one example, advice to help third parties when submitting information on alternatives is another.
- There is an expectation for an official response to third parties who submit comments how their contribution is taken into account in the opinion development of the application.
- The checklists for effective control of non-threshold substances and for monitoring substances of very high concern included in the study: *"Effective control" of substances of very high concern (SVHC) with properties for which thresholds are not derivable within the framework of the REACH authorisation regime* could be used to help applicants to draft their application (taking into account, i.e., the need to elaborate a concept for the collaboration of actors in the monitoring phase in case an authorisation is granted), in the assessment of authorisation applications and in the follow up in the light of Art. 61 (Review of authorisations).

4. Conclusions and next steps

The chairs thanked the participants for sharing their presentations, papers and views on what information needs in their opinion to be made publicly available for the purpose of achieving a meaningful public consultation on the possible alternatives with regard to the substances and uses applied for in an authorisation application.

ECHA staff will review and discuss the provided materials with the aim of developing an impartial, transparent, efficient and scientifically sound authorisation process. ECHA thought that it would be beneficial to include a link in the broad information on uses of the dissemination web site so that the use-specific information could be accessed easily. ECHA will look into how this could be carried out technically.

It was concluded that a follow-up meeting with NGOs and trade unions would be helpful. ECHA will arrange this in the latter part of 2011. It was also concluded that it would be helpful at a later stage to hold a joint meeting with representatives of NGOs/trade unions, industry, ECHA and the Commission services to further exchange views on how the application for authorisation process could be implemented in a transparent, efficient and meaningful manner.

[3] ISTAS, ChemSec, Kooperationsstelle Hamburg and Grontmij.