



REACH Dissemination of information on chemical substances

CARACAL Agenda item 5.2
13th October 2009

Summary:

The public interest organisations are very concerned about the way ECHA envisions dealing with public access to information on chemical substances, such as the dissemination of registration data to the public.

ECHA seems to lean rather towards keeping data confidential than providing access to information. For example, ECHA's preliminary setting for data falling under Article 119.2 is confidentiality, whereas the legal text says information shall be published unless a confidentiality claim has been submitted that has been "accepted as valid by the Agency". In our view the Aarhus Regulation 1367/2006¹ needs to be fully considered, in particular that, beyond ensuring access to information via individual requests, it also provides for an active information policy.

Furthermore, we are concerned that ECHA has not yet developed a policy on how to decide on accepting or rejecting the justifications for confidentiality claims. Instead, several issues discussed in the ECHA documents seem to be treated as simple IT or technical issues, although they imply crucial interpretations of the REACH text and should be discussed, and criteria be set at the policy level. A careful balance of public and industry interests is needed in the considerations of the benefits of disclosure.

We ask the delegations at the CARACAL meeting to take note of our concerns, which are outlined below:

1. **"The Public" is more than the average consumer**
2. **Other EU laws on access to information must be considered**
3. **Clear procedures and objective criteria on deciding confidentiality claims are needed**
4. **Contextual information for data is necessary**

ECHA has so far not yet made the non-confidential information of already submitted registration dossiers publicly available on the Internet and we urge ECHA to fulfil their respective obligations as soon as possible.

We call on Member State delegations to ensure Aarhus requirements are incorporated into all access to information policy and that ECHA develops a considered and balanced information policy.

¹ Regulation (EC) No 1367/2006 of 6 September 2006 On the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies; OJEU L 264/13 of 25.09.2006

1) **“The Public” is more than the average consumer**

We would like to emphasize that access to data, particularly but not exclusively via the electronic site, is important for a wider ‘public’ than ECHA seems to be envisioning. The ‘public’ interested in the details of substance data includes a diverse set of groups from individuals and watchdog groups in civil society to independent scientific experts, university and other researchers and medical professionals. Even more important, all Member State regional and local government entities such as environmental and consumer protection agencies as well as occupational health institutions which are NOT the REACH Competent Authorities will depend largely on the information provided through the ECHA database. In particular given the current discussions related to IT access for the Member States, the national agencies will have difficulties in fulfilling their monitoring and enforcement obligations by relying on their intra-governmental access via the REACH Competent Authorities. In this context, information not only on the final DNEL/ PNEC values but also the assessment factors and the scope of the testing schemes will be essential to such regional and local authorities for fulfilling their statutory obligations. We recommend that these entities and public stakeholders should also be targeted in the planned User Needs Survey and given adequate time for commenting.

2) **Other EU laws on access to information must be considered**

One of the key objectives of REACH and other international/community laws is to generate information on substances for the purposes of enforcement, evaluation and transparency. As it is clearly stated in recital 14 of REACH, available information, including that generated under REACH, should be used by the relevant actors in the application and implementation of other Community legislation. For this purpose ECHA shall provide the Member States and the institutions of the Community with the best scientific and technical advice on questions relating to chemicals (Art 77). The objectives of the other laws and a careful interpretation of the REACH provisions, including the recitals, must underpin the decision-making relating to data access.

Therefore it is legally very doubtful if ECHA is right in assuming that confidentiality can be the preliminary default setting for data falling under Art 119.2, in particular given the problem of “toxic ignorance” REACH is seeking to remediate. We urge ECHA to fully examine the legal implications of the Aarhus provisions (i.e. Regulation 1367/2006² and Regulation 1049/2001³) in this respect, and use these to subsequently inform the process of developing criteria to be used in determining the acceptability of justifications for confidentiality.

From the Aarhus Regulation 1367/2006 in particular the following recitals are helpful:

(12) The Aarhus Convention calls for public access to environmental information either following a request or by active dissemination (--> Art. 119 REACH) by the authorities covered by the Convention.

² *ibid*

³ Regulation (EC) No 1049/2001 of 30 May 2001 regarding public access to European Parliament, Council and Commission documents; OJEC L145/43 of 31.5.2001

(14) For the right of public access to environmental information to be effective, environmental information of good quality is essential. It is therefore appropriate to introduce rules that oblige Community institutions and bodies to ensure such quality.

Moreover, Art. 4(6) of Regulation 1049/2001 states the following: "If only parts of the requested documents are covered by any of the exceptions, the remaining parts of the document shall be released."

3) Clear procedures and objective criteria on deciding confidentiality claims are needed

The criteria by which the confidentiality requests are decided still remain substantially undeveloped. It is not clear whether there will be any guidance document for the criteria, or what further steps will be taken to develop them.

ECHA must develop

- a) a scrutiny procedure for the granting/rejection of confidentiality claims with internal deadlines and
- b) criteria by which it can consistently and objectively judge when to accept/reject a confidentiality request.

Especially the criteria will need careful elaboration in order to safeguard environmental, health protection and transparency aims of REACH. We consider this to be a policy issue which involves interpretation of the REACH text and urge ECHA to plan for proper involvement of Competent Authorities and all stakeholders.

The acceptance or rejection of requests for test waiving will have important consequences for whether certain data is available for the public. It will be important for ECHA to ensure that waiving is permitted only according to the reasons in the REACH text. Given that the political debate on waiving was highly controversial, it will also be important for ECHA to have a sound and trackable procedure and assessment criteria by which to judge when to accept / reject data waiving.

We re-iterate that the justification for data waiving must be disclosed, even where it concerns uses (Art 64.2), or emissions to the environment, so that the 'overriding public interest' in information relating to emissions into the environment is fulfilled (Regulation 1367/2006 Art 6.1, Regulation 1049/2006 Art 4.2 and Aarhus Convention⁴ Art. 4.4d). The reasons for waiving must be more detailed than just 'harms competitiveness'.

4) Contextual information for data is necessary

We would like to underline the importance that it is not possible to publish only the bare result without a minimum of contextual information related to the ecotoxicological and toxicological information on substances (e.g. is it a measured data or a QSAR, what is the OECD guideline followed etc). Moreover, not only

⁴ Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, done at Aarhus on 25 June 1998

information on the final DNEL / PNEC numbers but also the assessment factors and the scope of the testing scheme will be important data.

We therefore ask for the development of a hypothetical dossier as an example to illustrate how this could look like in practice, and in order to have a test of the process and potential results and problems in publishing registration data.

ECHA considers some kind of information as “not related to substance safety”, e.g. the entry “sponsors -type” is considered as “not relevant for REACH” and not published. The same applies to all entries on substance endpoints “testing laboratory” and “owner company” of the studies. However, in our view obtaining information on who (e.g. in general terms private/public/related to producer) financed the study as well as by whom (e.g. whether it is in house laboratory or private laboratory) the study on substances was performed will give valuable indication to the assessors on the objectivity and quality of that study.

We would also like to remind ECHA that the Agency is entitled to even disclose information that is normally deemed to undermine the protection of commercial interests, if urgent action is essential to protect human health, safety or the environment, such as emergency situations (REACH Art 118 (2)).

ECHA has informed us that they are considering aggregating information from multiple dossiers on the same substance. We would like to stress the importance of ensuring access to the entire range of the different values and respective contextual information, instead of one selected (representative) value.

We also would like to see the information on classification and labelling available in the public information for the early registration dossiers, prior to the publication of the full classification & labelling inventory later.

We also have specific comments to the proposed filter rules which will automatically process data from registration dossiers for internet publication and are willing to discuss this further.

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