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Comments on ECHA's position paper related to Downstream User notifications (Article 66)

ClientEarth

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1 General remarks

We welcome the development of a policy for the collection and dissemination of the information notified by downstream users under Article 66. We also welcome the fact that ECHA contacted NGOs to receive feedback on the early draft.

We hope however that this first consultation will be followed up by a deeper discussion on how to integrate our comments.

Our main concern is that **ECHA is missing an opportunity to make substantial improvements to the system because it underestimates the scope of its power, and of its obligations, under REACH due to undue fear of affecting market dynamics.**

ECHA's incorrect interpretation of its power to require and disseminate information from downstream users comes from two mistakes:

- It wrongly interprets the silence of Article 66 on the information that the downstream users have to send as a limitation of the type of information which should be required from them.

  The correct interpretation requires an application of Article 66 in light of its objective and the objectives of REACH. It leads to a different conclusion: ECHA has the power, and the obligation, to require all the information needed to check whether the conditions of the authorisation are respected and if the circumstances are changing.

- It wrongly interprets the provisions on access to information, extending the scope of which information held by the EU institutions may be kept confidential far beyond what is warranted by EU law.

2 The scope of the information covered by the obligation to notify

Article 66 does not give an explicit list of the information which has to be notified to ECHA.

ECHA currently interprets the absence of list as a sign of very limited power. This is why it considers that it can only require from downstream users their names, address and contact information while it leaves to downstream users the decision to notify other crucial information.

However, this interpretation is unduly restrictive. The interpretation rules of EU law require ECHA to interpret its power under Article 66 **in light of the objectives of REACH and Article 66 –** and the only logical conclusion of this interpretation is that ECHA has the power to make compulsory the notification of the information currently left optional.

As identified by ECHA, Article 66 pursues three objectives:

1) 'Identify companies using SVHC after sunset date to identify which are covered by an authorisation and which are not' aka giving to the Member States the means to identify which companies use the SVHC illegally;

2) 'Monitor the authorised uses of SVHC while confirming that companies which have notified perform in accordance with the authorisation conditions' aka giving to ECHA, the Commission and the Member States the means to identify whether the users comply with the conditions and whether the conditions suffice to achieve REACH's objectives;

3) 'Support the Review Report process' aka whether there is a need to withdraw the authorisation, either because the assessments on which the authorisation rely were inaccurate or because the circumstances have changed.

Article 66 gives to ECHA the power to require from downstream users the information it needs to perform its share of the achievement of these three objectives. It also makes ECHA responsible for collecting the information that the Member States need to perform their share, as Article 66 makes ECHA a bridge between downstream users and national authorities. This is confirmed by the *travaux préparatoire* of REACH which affirm that the purpose of what is now Article 66 is 'that the authorities are **fully aware of how and where** substances of very high concern are being used'[1].

ECHA's current position on downstream user notifications ignores, however, the power it received from Article 66 in light of REACH objectives. ECHA considers that its power is limited to asking from downstream users the notification of their identity (name, address, contact information) and

[1] Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (Reach), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) (SEC(2003 1171) (COM/2003/0644 final - COD 2003/0256) (emphasis added).

the identity of the authorisation at stake (authorisation number). Such information is needed for the achievement of objective 1, but is clearly not enough to achieve objective 2 or 3.

ECHA needs to recognise that the three objectives are equally important and that, in order to achieve objective 2 and 3, it needs to require from downstream users information beyond their identity and the identity of the SVHC concerned. In order to achieve these objectives, in order to protect human health and the environment as well as to promote substitution as required by REACH, ECHA and the Member States need at least the following information:

- Information related to exposure (annual volume, number of staff potentially exposed);
    - Indispensable to verify whether the estimations made in the assessment of the risk were accurate, to prove adequate control or to prove that the socio-economic benefits of the use outweigh the risks;
    - Indispensable to estimate whether the authorisation should be withdrawn or if new conditions should be set upon review.

- Information related to the function of the SVHC (function of the SVHC itself, function of the end-use or end product obtained by using SVHC and function as service: the usefulness of the end-use or end-product);
    - Indispensable to verify whether the downstream user has the right to be covered by the authorisation, as the authorisation is given for one or several specific use (s);
    - Indispensable to estimate whether, upon review, the scope of the authorisation should be limited to more specific niche uses;
    - Indispensable to do a reality check on the assumptions made in the socio-economic assessment.

- Information on alternatives (known, tested or in development).
    - Indispensable to verify whether the assumption and estimation of the first analysis of alternatives were accurate;
    - Indispensable to verify whether, upon review, the scope of the authorisation should be limited to more specific niche uses for non-threshold substances;
    - Indispensable to evaluate whether, upon review, the circumstances in relation to the development of alternatives have changed.

Without this information, public authorities remain blind as to how authorisations are actually used in practice - which considerably reduces their ability to effectively achieve the objectives of REACH.

Article 66 gives power to ECHA to collect information which is indispensable to fulfil its role in the authorisation and review process, but makes ECHA a bridge between downstream users and Member States, by charging ECHA to send to Member States the information they need to fulfil their role in the enforcement of REACH.

It is only logical to interpret Article 66 as giving to ECHA the power to require from downstream users the information that it, and the Member States, need to fully perform their role in order to achieve the objectives of REACH**.**

ECHA does not have the power to require from downstream users a chemical safety report, socioeconomic assessment or an analysis of alternatives under Article 66. However, it has the power and the obligation to require from them the information that ECHA considers, in the current version of the paper, as only voluntary.

Recommendations

ECHA needs to modify its current position paper to make the communication of the following information compulsory:

- Information about their specific use, such as ranges for the typical annual volume and the number of staff using the substance;
- A brief additional description about their use (e.g. the type of products they make or the sector where these products are used);
- Any involvement in potential substitution activities.

If ECHA decides to maintain its policy despite our comments:

- ECHA committees should systematically recommend to add to each authorisation an obligation to notify the information listed above
- The Commission should systematically made this obligation one of the conditions of each authorisation

3 The scope of information kept confidential

3.1 Comments on the general approach

Under EU law, citizens have the 'widest possible' right to request, and obtain, access to information held by the EU institutions[2]. The EU Regulations on Access to Information (namely, Regulation 1049/2001 and Regulation 1367/2006) provide few exceptions to the right to access in order to protect specific interests such as commercial interests. But the EU Court obliges the EU institutions to apply these exceptions strictly.[3]

[2] Since such exceptions derogate from the principle of the widest possible public access to documents of the European Union's institutions, they must be interpreted and applied strictly" See Case T-677/13, paragraph 35. See also judgments of 17 October 2013 in Council v Access Info Europe, C-280/11 P, ECR, EU:C:2013:671, paragraph 30, and 3 July 2014 Council v in't Veld, C-350/12 P, ECR, EU:C:2014:2039, paragraph 48.

[3] See Case T-677/13, paragraph 35. See also judgments of 17 October 2013 in Council v Access Info Europe, C-280/11 P, ECR, EU:C:2013:671, paragraph 30, and 3 July 2014 Council v in't Veld, C-350/12 P, ECR, EU:C:2014:2039, paragraph 48.

In addition, when there is an 'overriding public interest' in disclosure[4], which is systematically the case when the information concerns emissions into the environment[5], the EU institutions do not have the right to allow commercial interests to trump transparency.

Information notified by downstream users to ECHA concerns the use of substances of very high concern, which have potential impact on the environment and on health. Citizens therefore derive from the Access to Documents Regulation (1049/2001), the Aarhus Regulation (1367/2006) and REACH the widest possible right to obtain access to this information, with strictly limited exceptions.

Conscious that citizens have the right to request and obtain access to Article 66 notifications, and aware of the important role that this information could play in the promotion of REACH objectives, ECHA decided **to disseminate proactively the information it holds. We welcome this initiative, but disagree with the scope of the information ECHA plans to publish upfront.**

ECHA's current approach is to disseminate proactively as little information as possible. **We invite ECHA to take a more pragmatic and ambitious approach by disseminating all the information that, in any case, it has the obligation to disclose upon request.** Active dissemination will promote transparency, substitution and better chemical safety. At the same time, a wide dissemination will benefit ECHA by being less resource-intensive than handling the many requests to access the notifications that it will without doubt receive. Finally, a policy of active and wide dissemination will also give more clarity to companies by setting clear expectations and saving the time of discussing different requests. Such policy is also not unusual - it follows the path of the European Medicines Agency, which decided to proactively disclose information that is potentially sensitive but serves public interest. Finally, such approach would bring ECHA into compliance with Article 4(1) of the Aarhus Regulation, which obliges the EU institutions to make 'environmental information progressively available in electronic databases that are easily accessible to the public'. [6]

The next section reviews which information ECHA should plan to disclose systematically, either because it has the obligation to do so under the Aarhus Regulation or because it has, in any case, the obligation to disclose it upon request.

3.2 Legal basis for widening the scope of information disclosed

Regarding the classification of information and colour coding applied in its system for active dissemination**,** ECHA distinguishes between information never disclosed, information always disclosed and information which may be kept confidential if requested by the downstream user.

[4] Article 4(2) Regulation 1049/2001

[5] Article 6(1) Regulation 1367/2006 sets that an 'overriding public interest' according to Article 4(2) Regulation 1049/2001 "shall be deemed to exist where the information requested relates to emissions into the environment".

[6] "Environmental information" within the meaning of Article 2(1)(d) of Aarhus Regulation includes: "factors, such as substances, […], emissions, discharges and other releases into the environment, affecting or likely to affect the elements of the environment".

We welcome the commitment to always make public: the **country of site**, the **substance name** and the **current status of the use**. We do not oppose the confidentiality of contact details.

However, we object to the current scope of information that ECHA considers should always be withheld**,** or should be claims-dependent. The following details the legal reasoning which explains why, and the approach which would bring ECHA into compliance with the applicable law.

a) ECHA overestimates the scope of information disclosure of which undermines commercial interests

ECHA claims that its current approach is justified to respect 'confidentiality concerns' such as business information or information that would raise competition law issues. It is true that EU provisions on access to information recognise that transparency must be balanced with commercial interests, which is an exception to the right to access information in application of Article 4(2) of Regulation No 1049/2001. However, ECHA's position extends the scope of what can be legally protected by this exception.

First, not all information relating to business activities is to be protected from disclosure. The Court has clearly stated that it is not possible to regard all information concerning a company and its business relations as requiring the protection which must be afforded to commercial interests. Doing so would indeed go against the obligation to give the public the widest possible access to documents held by the institutions.[7] Only very limited information, for example concerning business secrets, is actually covered.

In the context of REACH, some information is deemed to undermine the protection of commercial interests. This is the case for the information listed under Article 118(2), such as:

> ‘(a) details of the full composition of a preparation;
>
> (b) without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or preparation, including information about its precise use as an intermediate;’

It is essential to keep in mind that, as an exception to the right to access information, Article 118(2) must be interpreted strictly.[8]

ECHA seems to think that Article 118(2)(a) and (b) justifies its decision to make the disclosure of the **use name** claim-dependent, but it erred in law by doing so. Article 118 intends to protect business secrets such as special expertise or patented process/products by listing 'the precise use, function or application' of a SVHC as of commercial interest. However, there is no doubt that the use name, which is indispensable to knowing whether the downstream users are rightly claiming to be covered by an authorisation, is not included in this category.

For the same reason, ECHA erred in law in including the **description of use** in the information always kept confidential. In the context of the authorisation procedure, and as explained by the

[7] Case T-189/14 paragraph 55. See also judgments of 15 December 2011, CDC Hydrogene Peroxide v Commission, T 437/08, EU:T:2011:752, paragraph 44, and of 9 September 2014, MasterCard and Others v Commission, T 516/11, not published, EU:T:2014:759, paragraph 81.

[8] See Case T-677/13, paragraph 35. See also judgments of 17 October 2013 in Council v Access Info Europe, C-280/11 P, ECR, EU:C:2013:671, paragraph 30, and 3 July 2014 Council v in’t Veld, C-350/12 P, ECR, EU:C:2014:2039, paragraph 48.

new guidance on use, companies need to give a precise description of the function for which the SVHC is used. The description must be precise enough to allow for a meaningful analysis of alternative substance or technology (decreased amount of the substance, alternative product or process or systemic change making the use of SVHC redundant). The 'use' as so defined is not a business secret, it is information indispensable to understanding how and why the SVHC is used.

ECHA therefore cannot consider that the use name and the description of use correspond to Article 118(2)(b).

When information is not covered by the list in Article 118(2), the EU institution cannot presume that business information is of commercial interest, or that disclosure would threaten this interest. The institution concerned (ECHA for example) must be able to explain why the document could 'specifically and actually undermine'[9] commercial interests. The risk to undermine the interest has to be high: it must be a risk to 'seriously undermine' the commercial interests at stake[10] and the risk must be 'reasonably foreseeable' and must not be 'purely hypothetical'.[11]

ECHA therefore cannot make the use name and description of use systematically confidential. The same conclusion can be made for **information** on the **involvement in substitution activities**, that ECHA decided to include in the category of information never disclosed even though it is not listed in Article 118(2).

Disclosure of this information may risk harming commercial interests in some circumstances, for example if it relates to R&D strategy. But it is not always the case, which is one of the reason why it is not listed under Article 118 REACH. It is therefore for the company to prove that disclosure would undermine its commercial interest specifically and actually as per the case law detailed above. In addition, downstream users might be interested in having this information made public. As a result, this information cannot be systematically kept confidential, it needs to be claims-dependent.

ECHA has decided to unduly extend the presumption provided for in Article 118(2) to another item which ECHA included in the category of information never disclosed: **the number of staff**. This information cannot be presumed of commercial interest. In addition, even if ECHA were to find, on the basis of the justification given by downstream users, that the number of staff is of commercial interest, it would still need to disclose it as explained below. This is also the case for the use name and description of use. Some information must be disclosed even if disclosure undermines commercial interests.

b) ECHA ignores that some information must be disclosed even if it undermines commercial interests

Even when information is covered by Article 118(2) or demonstrated to be of commercial interest, it does not mean that ECHA has the right to systematically maintain confidentiality. Information of commercial interest has to be made public when there is an overriding public interest in

[9] See T-677/13 paragraph 36.

[10] Case T-189/14 paragraph 56.

[11] See T-677/13 paragraph 36.

disclosure[12] and the disclosure of some information notified by downstream users is without doubt of overriding public interest.

Article 6(1) of the Aarhus Regulation created a category of information disclosure of which should be deemed of overriding public interest: information on **'emissions into the environment'**. Such information should always be made public, even when it undermines commercial interests.

The European Court of Justice has started to define the concept of 'emissions into the environment'. It affirmed that the concept 'must be understood to include, inter alia, data that will allow the public to know what is actually released into the environment or what, it may be foreseen, will be released into the environment under normal and realistic conditions of use of the product or substance in question, namely those under which the authorisation to place that product or substance on the market was granted'.[13]

Consequently, the Court held that this concept must be interpreted as covering, inter alia, three categories of information:

1) 'information concerning the nature, composition, quantity, date and place of the actual or foreseeable emissions, under such conditions, from that product or substance' aka **information on what is or could be emitted, how, when and where**[14]**:**

- **Address of the site and Name of downstream users**

  ECHA seems to think that Article 118(2)(d) requires to make the access to **name and address of the downstream users** claims-dependent. Article 118(2)(d) provides that disclosure of 'the links between a manufacturer or importer and his distributors or downstream users' is deemed to undermine commercial interest. According to ECHA, disclosing the name and address of downstream users would reveal the links between the authorisation holder and the downstream user which would undermine the protection of commercial interests.

  But this information is indispensable to know the location of **foreseeable emissions into the environment**. **It must therefore be systematically disclosed rather than be made claims-dependent**. By extension, the name of the company should also be released as in this context keeping the name of the downstream user confidential would not make sense.

  In any event, there is an additional overriding public interest in the disclosure of the name and addresses of the downstream users. When it comes to SVHCs, the goal of REACH is to promote the substitution of these substances and disclosure of this information supports this goal. This overriding public interest should prevail over the interest of the supplier of the substance to maintain its market shares. ECHA's paper recognises this objective when affirming that impacts of the supply chain might happen but 'at the same time, these are supply chains of SVHCs and promoting eventual substitution (and therefore competition by alternatives suppliers) is along the aims of Authorisation'. Since the only competition that the sole holder of an authorisation may have is a provider of a safer alternative, such commercial protection should not be granted.

[12] Article 4(2) Regulation 1049/2001.
[13] Case C-673/13 P, European Commission v Greenpeace Nederland and PAN Europe (ECLI:EU:C:2016:889), para.79.
[14] Case C-673/13 P, para. 79.

ECHA should therefore make the name and address of downstream users public.

- **Tonnage information of downstream users**

  Information on tonnage per use is key to verify the quantity of the "foreseeable release into the environment" arising from the use covered in the application for authorisation.

  As explained in ECHA's guidance, in relation to environment exposure assessments: "*In most cases, the* **release rates** *will not be measured* **but calculated from a release factor applied to the tonnage** *assumed to be present in a use process*".[15] This is also acknowledged by, for example, DEZA in its application for authorisation, which presents in the section on "*assessment of the exposure into the environment", "tonnage" as an "important input data for the release estimation" together with "emission days" and "release factor*".[16]

  To replace this necessity in the context, it is important to remember that companies have to disclose quantities of pollutants by the kilogramme in the context of the E-PRTR.[17] In addition, Article 4(1) of the Aarhus Regulation charges the EU institutions to create public register of the data they hold relating to 'environmental information", defined as: "factors, such as substances, […], emissions, discharges and other releases into the environment, affecting or likely to affect the elements of the environment"[18].

  ECHA highlights the case where companies would have interest in disclosing when they use low volume. ECHA needs to realise that **there is an overriding public interest in disclosing this information, particularly when high volumes are concerned**. This information must be systematically disclosed and not be made claims-dependent. Actual annual quantity should be requested and disseminated, or by default precise range per site.

- **Use name, condition of use (authorisation conditions), description of use**

  This information is indispensable to understanding 'the nature, composition, quantity, date and place of the actual or foreseeable emissions, under such conditions' as listed by the Court. The conditions of use determine what can be emitted, the description of use and use name inform on how much is emitted and how. This information must be systematically disclosed.

2) "information enabling the public to check whether the assessment of actual of foreseeable emissions, on the basis of which the competent authority authorised the product or substance in question, is correct' **aka information needed to scrutinise public decisions on emissions:** [19]

Information sent by downstream users have an important role to play in the analysis of the review report by ECHA's committees and the Commission, and in the decision to maintain or withdraw the authorisation. Its disclosure is therefore a precondition to enable the public to check whether the assessment made by public authorities is

[15] ECHA Guidance on information requirements and Chemical Safety Assessment, Version 3.0, https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf/b9f0f406-ff5f-4315-908e-e5f83115d6af, p. 32.
[16] DEZA Chemical Safety Report, p. 407.
[17] http://prtr.ec.europa.eu/#/home .
[18] Article 2(1)(d) of Aarhus Regulation.
[19] Case C-673/13 P, Para. 80.

accurate. The **quantities, number of staff, description of use and conditions of use (hence the reference of the authorization)** are particularly needed in that regard. This information should be systematically disclosed.

3) 'the data relating to the effects of those emissions into the environment' aka **information on the effects of the emission:**[20]

Information sent by downstream users have an important role to play in the understanding of the effects of the emissions. This is particularly the case for the **number of staff involved, the annual quantity and any monitoring information.** They should be made public by default as they are needed to obtain a full picture of the population directly and indirectly exposed, the impact on the environment and thus the magnitude of the risk associated with the use. The number of staff involved should ideally be given per company, or at least as an aggregated number.

3.3 The need to change the approach to data required by the authorisation decision

ECHA cannot approach the confidentiality of all data that DUs have to send in application of the authorisation decision in a similar way as this information can widely vary. It can relate to biomonitoring, substitution efforts, measures applied to control the risk, etc.

ECHA cannot make this information a category in itself, as the fact that it is required by the authorisation has no bearing on the nature of the information (of commercial interest, related to emissions into the environment, etc.), which is the only thing which matters in the assessment of whether EU law requires its disclosure or not. To comply with EU Regulations on Access to Information, it is indispensable to distinguish between the type of information required and treat them accordingly.

Recommendations

- Should always be published, as planned: country of site, substance name, current status as planned
- Should always be published, contrary to what is planned: name of downstream user, address of site, Use name, quantity or precise range for annual quantity, number of staff involved or aggregated number, description of use, conditions of use.
- Can be made claim dependent: Involvement in substitutions activities and contact details
- Need to be defined more precisely: data required in authorization decision, name of authorisation holder

[20] Case C-673/13 P, Para. 80.

4 The treatment of confidentiality claims and dissemination

ECHA currently proposes (page 6) to have in the IT platform a dedicated step for setting confidentiality flags during the online submission process. The document states that companies must provide a clear justification along with any confidentiality claim. We welcome this process.

However, four additions (see recommendations below) are necessary to ensure that:

- In compliance with the EU Regulation 1049/2001 on Access to Documents and with Article 15 TFEU, the principle is full disclosure, and confidentiality the exception. This means that a case-by-case evaluation of confidentiality claims is needed. This process would be eased if ECHA follows our recommendation to make most information systematically public. In any case, it is hoped that this would not lead to extra workload of ECHA officials, since we presume that they actively read each and every notification received;
- ECHA has a clear and simple system to enable it to correctly state the reasons for its decision to grant confidentiality to avoid 'failures to state reasons';
- The process is inclusive and transparent.

Another question relevant to the treatment of the claims is raised by ECHA, which seeks advice on whether the Authorisation Holders should always be consulted before starting publication from the downstream users. We welcome the decision of ECHA to consult on the matter. The answer to this question must be found in the EU Regulations on Access to Information. Under these Regulations, third parties do not have the right to be consulted on the disclosure of information that belongs to, and are sent to ECHA by, another person. **Downstream users are the only persons to be consulted on the disclosure of their notifications.** ECHA should use its limited resources to enforce existing laws, rather than for time consuming process which are neither foreseen, required or allowed by the applicable regulation.

Recommendations

- Authorisation holders must not be consulted on the disclosure of information notified by downstream users;
- ECHA needs to commit to consult stakeholders on the guidance which will be provided to companies to decide on and formulate their confidentiality claims;
- Each confidentiality claim will be analysed, aka that the claim will not be automatically considered by the IT tool as legitimate when the justification box has content, whatever its content is;
- The on-line system should have two confidentiality claim boxes. One for the companies to use to give a summary of the reason why confidentiality is sought, not containing itself sensitive information but able to inform the general public of why the decision to maintain confidentiality is legitimate. A second one for detailed justification, for ECHA, which may contain sensitive information and therefore not automatically made public.
- ECHA needs to explain the way in which ECHA will make the information public (access to the online platform? Report? Searchable database? other means).

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