

Legislative briefing

Information dissemination in the context of the REACH procedure for the authorisation of dangerous substances

[September 2011]

Executive Summary

1. This briefing discusses the legal framework applying to the disclosure of information on dangerous chemicals and on the limits to disclosure in the context of the procedure for authorisation. under REACH.¹
2. The briefing recommends a methodology for ECHA's selection of the information to be disclosed in order to guarantee the openness of the authorisation procedure and to make effective the consultation foreseen under Article 64(2) of REACH that aims to identify alternative substances or technologies that are not harmful for humans or the environment.
3. Under the Aarhus Convention, information on substances is environmental information. ECHA must take into account the obligations deriving from the fact that the EU is a party to the Aarhus Convention. Environmental information has to be actively and systematically disseminated to the public. The grounds that allow environmental information to be withheld have to be interpreted in a restrictive manner.
4. From the analysis of the legal framework and of the case law of the European Court of Justice, the following hierarchy must be considered when assessing the information to be disclosed by ECHA:
 - a. The EU Treaties;
 - b. The Aarhus Convention;

¹ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), (OJ L 396, 30.12.2006, p. 1)

- c. Regulation 1367/2006 and Regulation 1049/2001;
 - d. REACH provisions on access and disclosure.
5. ECHA has a certain amount of discretion in deciding what information to make available to the public in the authorisation phase. However, the information that ECHA decides not to publish, remains accessible to the public through access requests. The limits to the access to this information depends on the existence of exceptions to the right of access according to legislation applicable to environmental information.
6. According to the analysis of the regulatory framework, ECHA can and should disseminate all the information it holds with the exception of the information listed under Article 118(2) and Article 119(2),² unless an overriding public interest in disclosure is identified by ECHA. However, when the information relates to an emission into the environment, an overriding public interest is always deemed to exist and it always prevails over the private interest of a company.
7. For the purpose of the authorisation procedure, this briefing maintains that all the information that may be relevant to the decision-making process on granting the authorisation for the use of chemicals is made available on ECHA's website. As a minimum, ECHA should make available:
 - a. the analysis of alternatives submitted by the applicant;
 - b. broad information on the use(s) applied for;
 - c. exposure scenarios for the use applied for;
 - d. the opinions from the Risk Assessment Committee and from the Socio-Economic Committee.
8. The broad information on the uses should include far more details than those which are submitted by the registrants in the Chemical Safety Report. Details on function of the substance, on the life cycle of the product in which the substance is incorporated or of the process in which the substance is used should be disclosed. Through disclosure, a wider picture is available to the parties involved in the authorisation process on the need to allow the use of SVHC, despite their recognised harmful effects on human health or on the environment.
9. In order to guarantee certainty, ECHA should clarify the information that it intends to disclose during the authorisation procedure through its rules on

² Information listed in Article 119(2) could be withheld when a request from a registrant of a chemical substance pursuant to Article 10(a)(xi) is accepted as valid by ECHA.

transparency pursuant to Article 109. These rules should aim at ensuring the availability to the public of regulatory, scientific or technical information concerning the safety of substances on their own, in mixtures or in articles

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1. Introduction

10. Regulation (EC) 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) was approved to address the concern caused by the lack of knowledge on the impact of many chemicals on human health and the environment. EU chemicals policy must ensure a high level of protection of human health and the environment as enshrined in the EU Treaties.
11. REACH is based on the principle *"no data, no market"*. Without making available required information on chemicals, importers and manufacturers are not allowed to place the substance on the market.
12. Further, REACH aims at incentivising innovation in the market by promoting the substitution of hazardous chemicals with safe alternatives. Therefore, substances with certain hazardous properties that give rise to very high concern will need to be given use-specific permission before they can be employed in particular uses.
13. REACH's goal is to increase the knowledge of the public about the properties of chemical substances in order to phase out those that pose the highest concern. Further, the public should be able to access information about the chemicals to which they are exposed and have the opportunity to choose to avoid products containing dangerous substances.
14. The right of the public to obtain information on chemicals has to be balanced with the right of companies to the protection of commercially sensitive data. REACH, in this regard, operates in the context of the Treaty on European Union (TEU) and of the Treaty on the Functioning of the European Union (TFEU) which enshrine fundamental principles on transparency and access to information. Further, REACH has to interact with the provisions of the Aarhus Convention on the Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.
15. The first part of this briefing discusses the principles of EU law on disclosure of information held by EU institutions, in general, and ECHA, in particular. The second part discusses the obligations and limits in the discretion that the European Chemicals Agency (ECHA) has when processing a request for the authorisation of the use for a specific application of a substance of very high concern (SVHC) included in Annex XIV of REACH.
16. Authorisation is one of the pillars of REACH which provides for the Registration, Evaluation, Authorisation and Restriction of Chemicals. Through authorisation, substances that are very dangerous for humans and for the environment may remain on the market only for a limited time and purpose when alternative

substances or processes do not exist or when the risk deriving from their use can be adequately controlled.

17. Manufacturers and importers of chemicals must register a substance when it is placed on the market in quantities over one tonne per year per manufacturer or importer.
18. By registering, companies submit data on the properties of the substance concerned and on the hazard in relation to its use. REACH reverses the burden of proof: it is for the company to prove that the substance it places on the market is safe. Therefore, the authorisation to place on the market an SVHC for a particular use is granted only when the applicant company can prove that either, the risks arising from that use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.
19. When a substance is identified as an SVHC, the substance can be no longer placed on the market for any use or used by the manufacturer. Although manufacturing is not specifically forbidden, the following activities cannot be carried out: storing, keeping, filling into containers, transferring from one container to another.³
20. If an alternative does not exist, authorisation can only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance, whilst also taking into account the risks posed by the use of the substance and the effectiveness of the risk management measures proposed.
21. The authorisation procedure is open to inputs from the general public. Therefore, access to the same amount of information should be ensured to all parties involved in the decision-making process. Otherwise, the public participation foreseen by REACH would not be effectively achieved.
22. ECHA has an important role in making the authorisation process run efficiently by publishing information on the substance in question so that sufficient information is available to allow third parties to contribute to finding possible alternative substances for the use for which authorisation is sought.
23. Several provisions of REACH make ECHA subject to a number of obligations to make certain information publicly available either by disseminating it or upon

³ Pursuant to Article 3(24) "use" means *"any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization."*

request. However, it is recognized that there are limited circumstances in which non-disclosure may be justified. These provisions have to be read in the light of EU and international law applicable to all EU institutions, including agencies, such as ECHA. Consequently, the EU treaties, the Regulations on Access to information and the Aarhus Convention must be taken into account.

24. Tension and potential conflict may arise between restrictions which ECHA seeks to place on information disclosure and the ability of stakeholders to obtain sufficient information in order to participate fully in the authorisation process. However, as suggested by the EU Treaties, a closed decision-making process would lack of legitimacy. This paper provides suggestions to minimize conflicts with stakeholders on access to the data.

2. Authorisation of Substances of Very High Concern (SVHC)

25. This paragraph outlines the authorisation process and is followed by a detailed description of the information held by ECHA on the substances subject to authorisation. Title VII REACH includes provisions whereby substances of very high concern (SVHC), which are included in Annex XIV REACH, may be authorised for placing on the market and use.
26. Article 56 of REACH states that a manufacturer or importer cannot place a substance on the market for a use or use it himself if that substance is included in Annex XIV.
27. Article 57 REACH sets out six groups of substances which may be included in Annex XIV REACH. The criteria for three of those groups - carcinogenic category 1 or 2, mutagenic category 1 or 2, toxic for reproduction category 1 or 2 (CMRs) - are already specified;⁴ Annex XIII REACH sets out criteria for two additional groups: those which are persistent, bioaccumulative and toxic (PBT) and those which are very persistent and very bioaccumulative (vPvB). The final group of substances are those for which there is *"scientific evidence of probable serious effects to human health and environment that give rise to an equivalent level of concern"* to those with the properties of the other substances falling within Article 57. These substances are to be identified on a case-by-case basis pursuant to Article 59.
28. After identification as an SVHC (in accordance with Article 59), a substance can be included in Annex XIV REACH through the procedure set out in Article 58. A

⁴ The criteria for the classification of carcinogenic, mutagenic and toxic for reproduction substances (CMRs) are set by Regulation (EC) 1272/2008 on the Classification, Labelling and Packaging of Chemicals which repealed and replaced the corresponding provisions of Directive 67/548/EEC.

so-called “sunset date” will be specified for each identified substance. After that date, the substance cannot be placed on the market, or used, unless one or more specific uses have either been authorised⁵ or are exempt⁶ from authorisation

29. The authorisation procedure is operated by way of exception in that it allows the time-limited placing on the market of substances that will have to be phased out.⁷ For that reason, an analysis of alternatives and a substitution plan is required by the applicant when applying for authorisation. The analysis and plan are essential in order to provide the European Commission with the necessary background and basis on which it may take an informed decision on whether or not to grant an authorisation.⁸

2.1 Information held by ECHA on substances

30. The primary source of information held by ECHA on substances derives from the obligation, starting from 1 December 2008, to submit a registration dossier for each substance manufactured or imported in quantities over one tonne per year per manufacturer/importer. Manufacturers and importers of phase-in⁹ substances have to register by different deadlines depending on the quantities and the properties of the substances placed on the market.¹⁰
31. The information to be submitted for the purpose of registration is listed in Article 10 of REACH and further explained in Annex VI. The information includes, on one hand, a technical dossier describing the identity of the manufacturer/importer, the identity of the substance and all the identified uses of that substance. On the other, if a substance is manufactured/imported in quantities over 10 tonnes, a

5 Article 56(1)(a).

6 Article 56(1)(b).

7 REACH Recital 22 reads “Authorisations for the placing on the market and use should be granted only if the risks arising from their use are adequately controlled, where this is possible, or the use can be justified for socio-economic reasons and no suitable alternatives are available, which are economically and technically viable.” .

8 According to the interpretation given by the Legal service of the European Commission, the substitution plan is required only for applications for authorisation when an alternative exists and the risks from the substances can be adequately controlled (Adequate Control route). However the Commissioners responsible for REACH announced in March 2010 that an amendment will be introduced not later than 2012 to include the obligation of a substitution plan also when substitutes do not exist but the socio-economic benefits of the use outweigh the risks (Socio Economic route)

9 Phase in substances are substances already on the market when REACH came into force. Phase-in substance is defined by Article 3(20).

10 The three delayed deadlines for the registration of phase-in substances as set by Article 23 are 30 November 2010, 30 May 2013 and 30 May 2018. Manufacturers and importers of chemical substances can benefit from these delays only if they have pre-registered the substances pursuant to Article 28 of REACH.

chemical safety report (CSR) must be submitted. The CSR includes information on the risks arising from the manufacture and/or use of a substance and information on how the risks are adequately controlled.¹¹

32. The applicant for authorisation must provide the following information:¹²

- a. the identity of the substance(s), as referred to in Section 2 of Annex VI;*
- b. the name and contact details of the person or persons making the application;*
- c. a request for authorisation, specifying for which use(s) the authorisation is sought and covering the use of the substance in mixtures and/or the incorporation of the substance in articles, where this is relevant;*
- d. unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;¹³*
- e. an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate, information about any relevant research and development activities by the applicant;*
- f. where the analysis referred to in point (e) shows that suitable alternatives are available, taking into account the elements in Article 60(5), a substitution plan including a timetable for proposed actions by the applicant.*

33. The applicant may provide the following information pursuant to Article 62(5):

- a. a socio-economic analysis conducted in accordance with Annex XVI;
- b. a justification for not considering risks to human health and the environment arising either from:

¹¹ The CSR is prepared in accordance with Article 14 and Annex I of REACH.

¹² Article 62(4)

¹³ In two cases the chemical safety report could not have been already submitted when an application for authorization is made: pursuant to Article 14, if the applicant manufactures or imports the substance in quantities between one and ten tonnes; or if the deadline for submitting the registration dossier is 2013 or 2018.

- i. emissions of a substance from an installation for which a permit was granted in accordance with Directive 2010/75/EC on industrial emissions (integrated pollution prevention and control);¹⁴ or
 - ii. discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC¹⁵ and legislation adopted under Article 16 of that Directive.
34. In addition, two ECHA committees have to evaluate the application for authorisation and each formulate a draft opinion. Pursuant to Article 64(4), this includes:
- a. *By the Committee for Risk Assessment: an assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;*
 - b. *By the Committee for Socio-economic Analysis: an assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under paragraph 2 of this Article.*

35. The information on substances held by ECHA, including the information listed above, is environmental information as defined by the Aarhus Convention and by Regulation 1367/2006.¹⁶ Article 2(3) (b) of the Aarhus Convention¹⁷ provides that:

"environmental information" means any information in written, visual, aural, electronic or any other material form on:

¹⁴ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control), (OJ L 334/1, 17.12.2010)

¹⁵ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327/1, 22.12.2000).

¹⁶ Regulation 1367/2006 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, OJ 2006, L 264 p.13.

¹⁷ Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in environmental Matters. The EU adhered to this convention with Decision 2005/370, OJ 2005, L 124 p.1. The Aarhus Convention is reproduced in the annex to this Decision.

(a) The state of elements of the environment, such as air and atmosphere, water, soil, land, landscape and natural sites, biological diversity and its components, including genetically modified organisms, and the interaction among these elements(b) factors, such as substances, ...including administrative measures, affecting or likely to affect the elements of the environment within the scope of subparagraph (a) above... ”.

Article 2(1)(d) of Regulation 1367/2006 has the same definition.

36. Therefore, information on substances, affecting or likely to affect the environment, should be treated as environmental information. This is particularly true for substances that are recognized as causing adverse effects to human health and the environment. The substances that are subject to authorisation are Carcinogenic, Mutagenic, or Toxic for Reproduction (CMRs), Persistent, Bioaccumulative and Toxic (PBTs) or very Persistent and very Bioaccumulative (vPvBs) or substances that pose an equivalent level of concern.
37. It follows that ECHA holds a great deal of environmental information on the chemicals that may be the subject of an authorisation request for specific uses. All the substances which are the subject of authorisation are proven to be extremely harmful to human health or the environment. Therefore, this (environmental) information should be disseminated in the greatest extent possible in order to make sure that the consultation on possible substitutes for that substances has a meaningful outcome. Further, dissemination would allow citizens to know about the uses of these harmful substances and make the decisions on authorisation as open as possible as required by the Treaties of the European Union.

3. General EU law requirements on disclosure of information

38. There are several regulatory instruments that have to be taken into account in order to understand to what extent the information held by EU institutions and ECHA can or cannot be made available to the public.
39. With regard to the disclosure of the information held by EU institutions, Article 1(2) TEU establishes a fundamental objective of the EU, stating: “*This Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen.*” In the same vein, Article 11(2) TEU provides: “*The institutions shall maintain an open, transparent and regular dialogue with representative associations and civil society*”. Article 11(3) TEU stipulates that the Union’s actions shall be “*coherent and transparent.*”

40. The Treaty on the Functioning of the European Union (TFEU) takes up these basic orientations, requiring in Article 15(1): *"In order to promote good governance and ensure the participation of civil society, the Union institutions, bodies, offices and agencies shall conduct their work as openly as possible."* Further, Article 15(3) TFEU lays down the governing principle of access to information: *"Any citizen of the Union, and any natural or legal person residing or having its registered office in a Member State, shall have a right of access to documents of the Union institutions, bodies, offices and agencies, whatever their medium, subject to the principles and the conditions to be defined in accordance with this paragraph"*.
41. The general principles enshrined in the Treaty are taken up by Regulation (EC) 1049/2001 which regulates the access to documents held by EU institutions:
- "The second subparagraph of Article 1 of the Treaty on European Union enshrines the concept of openness, stating that the Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen. Openness enables citizens to participate more closely in the decision-making process and guarantees that the administration enjoys greater legitimacy and is more effective and accountable to the citizen in a democratic system. Openness contributes to strengthening the principles of democracy and respect for fundamental rights as laid down in Article 6 of the EU Treaty and in the Charter of fundamental Rights of the European Union."*¹⁸
42. The Court of Justice expressly referred to these recitals at the beginning of one of its landmark decisions concerning access to information.¹⁹ Thus, any interpretation of EU legislation on access to information must be based on these principles.
43. Therefore, the basic principles which govern the issues of access to information are openness and transparency, and the objective of granting access to information as widely as possible.
44. In addition to the general principles on access to information held by EU institutions, because the information on substances held by ECHA is environmental information, the *Aarhus Convention* should also be taken into

¹⁸ Regulation 1049/2001, Recitals 1 and 2.

¹⁹ Court of Justice, joined cases C-39/05P and C-52/05P, Sweden and Turco v. Council, ECR 2008, p.I-4723, paragraph 34. See also Court of Justice, case C-64/05P (n.15, above), paragraph 54; case C-28/08P, Commission v. the Bavarian Lager, judgment of 29 June 2010, paragraphs 53 and 54 .

account. The provisions of the Aarhus Convention were transposed into the EU legal framework through the provisions of Regulation 1367/2006.

45. However, Aarhus Convention is part of EU law. By its conclusion, the European Union committed itself to the other Contracting Parties of the Convention, to make sure that the Convention's provisions as regards access to environmental information²⁰ are respected within the European Union.
46. Where EU law on access to information contradicts a provision of the Aarhus Convention or is not compatible with such a provision, the provision of the Aarhus Convention prevails.²¹
47. Administrations and courts within the European Union are, therefore, obliged to set aside the provisions of secondary EU law (regulations, directives, decisions) and apply the provisions of the Aarhus Convention, where there is a contradiction between the two pieces of legislation. Regulation 1049/2001 explicitly recognises this priority, while indicating, at the same time, that, in the case of conflict between Regulation 1049/2001 and Regulation 1367/2006, the provisions of Regulation 1367/2006 prevail.²²
48. Therefore, the provisions of the Aarhus Convention that are not compatible with EU law, including REACH, prevail. Information on substances is environmental information according to Regulation 1367/2006 and to the Aarhus Convention. The following hierarchy of provisions of access to environmental information should be observed by ECHA:
 - a. The EU Treaties;
 - b. The Aarhus Convention;
 - c. Regulation 1367/2006 in combination with Regulation 1049/2001;

20 These observations do not refer to the Aarhus Convention as a whole, as there are legal doubts, if and to what extent for example Article 9(3) of the Convention which deals with access to justice, is – in the absence of EU legislation on access to justice in environmental matters – part of EU law. Such doubts do not exist, though, in the area of access to environmental information.

21 Court of Justice, case C-344/04, IATA and ELFAA, ECR 2006, p.I-403, paragraph 35: *“Article 300(7) EC [now Article 216(2) TFEU] provides that 'agreements concluded under the conditions set out in this Article shall be binding on the institutions of the Community and on Member States'. In accordance with the Court's case law, those agreements prevail over secondary Community law”*; see also cases C-61/96, Commission v. Germany, ECR 1996, p.I-3989, paragraph 52; C-286/02 Bellio Fratelli, ECR 2004, p.I-3465, paragraph 33.

22 Regulation 1049/2001, Article 2(6): *“This Regulation shall be without prejudice to rights of public access to documents held by the institutions which might follow from instruments of international law or acts of the institutions implementing them.”*

d. The provisions on access to the information held by ECHA established by the REACH Regulation.

49. In summary, ECHA should apply the provisions of REACH taking into account the general provisions on access to documents and the provisions from the Aarhus Convention in relation to the information on substances which should be considered environmental information.

4. Limits to the right to access environmental information

50. Although the general rule in respect to information held by EU institutions is disclosure, and there is a general obligation to disseminate environmental information,²³ there are specific exceptions that may justify the withholding of environmental information. Article 4 of Regulation 1049/2001 lays down the provisions under which access to information may be refused. As exceptions to the general objective to grant the “widest possible access” to information²⁴, they must be interpreted narrowly.²⁵

51. Article 4 of Regulation 1049/2001 enumerates several grounds for refusal to grant access to information which, according to Regulation 1049/2001, would lead, in all cases, to a rejection of an application. These include: privacy and the integrity of the individual,²⁶ the commercial interests of a natural or legal person,²⁷ the purpose of inspections, investigations and audits,²⁸ and when disclosure of a document would seriously undermine the decision-making process of a public institution.²⁹

52. However, the provisions of Article 4 of Regulation 1049/2001 have to be integrated with those of Article 6 of Regulation 1367/2006 which provides for the application of exceptions concerning requests for access to environmental information. According to Article 6 of Regulation 1367/2006, each of the

23 See Art. 4, Regulation 1367/2006.

24 Regulation 1049/2001, Article 1(a). See also the general objectives laid down in Article 1 TEU and 15 TFEU.

25 See Court of Justice, case C-39/05P, Sweden v. Council, ECR 2008, p.I-4723, paragraph 36: “*In view of the objectives pursued by Regulation 1049/2001, [the] exceptions must be interpreted and applied strictly.*” See also case C-64/05P, Sweden and Turco v. Council, ECR 2007, p.I-11389. This interpretation rule is also laid down in Article 4(4), last subparagraph of the Aarhus Convention and in Regulation 1367/2006, Article 6(1).

26 Article 4(1)(b), Regulation 1049/2001.

27 Article 4(2) first indent, Regulation 1049/2001.

28 Article 4(2) third indent, Regulation 1049/2001.

29 Article 4(3), Regulation 1049/2001.

exceptions of Article 4 of Regulation 1049/2001 must be weighed against *"the public interest served by disclosure and whether the information requested relates to emissions into the environment."*³⁰ The reason for this obligation to weigh the different interests in all cases lies in the fact that there is a public interest in ensuring that information on the environment is publicly available; because the environment is the interest of all, not only of a group of persons. In this regard, the Aarhus Convention states that *"public authorities hold environmental information in the public interest."*³¹

53. Particularly relevant in the REACH context is the provision that protects the commercial interest in the information held. Article 4(2) of Regulation 1049/2001 requires that the EU institutions refuse access to information where disclosure would undermine *"the protection of commercial interests of a natural or legal person, including intellectual property."* The interest in seeing information on such issues not to be disclosed has to be weighed against the *"overriding public interest in disclosure."*³² In each individual case, the EU institution shall thus have to balance the diverging interests against each other.
54. This provision must also be read in conjunction with Article 4(4)(d) of the Aarhus Convention which provides for the possibility to refuse access to environmental information on grounds of protection of commercial interest, but only when *"such confidentiality is protected by law in order to protect a legitimate economic interest"*. It is, therefore, necessary that the confidentiality of the information protecting the economic interest in question is foreseen by law.
55. Even where a law protects the confidentiality of information that could undermine commercial interests, disclosure must be granted, where an overriding public interest³³ in disclosure exists. The interest in question must be "public". The personal or private interest of the applicant is, therefore, normally not sufficient. A public interest may exist where the information is of interest to a large number

30 Regulation 1367/2006, Article 6(1).

31 Aarhus Convention, Recital 18.

32 Regulation 1049/2001, Article 4(2).

33 In EU law, the term "overriding public interest" is used in Article 6(4) of Directive 92/43 on the conservation of natural habitats and wild fauna and flora, OJ 1992, L 206 p.7. In that provision, it is used to allow the balancing of interests in the conservation of a habitat against the realisation of a plan or project which would significantly affect that habitat.

of persons, or where it concerns aspects of importance for the society, such as the protection of human health or the environment.³⁴

56. Moreover, "*information on emissions which is relevant for the protection of the environment, shall be disclosed.*"³⁵ The term "emissions into the environment" is not defined. Regulation 1367/2006 enumerates as factors which form part of environmental information "*emissions, discharges and other releases into the environment*".
57. With regard to such emissions, disclosure of information may not be refused in order to protect commercial or industrial interests, even where such interests are protected by a law because both the Aarhus Convention and Regulation (EC) 1367/2006 provide for the existence of an overriding public interest in disclosure where the information requested relates to emissions into the environment.³⁶
58. It follows that the principle of disclosure of information held by public institutions enjoys of a higher degree of protection when the information concerns the environment. In order to refuse disclosure of environmental information for the protection of the commercial interest of a natural or legal person, there must be a legally effective provision recognizing that such information must be protected and that no overriding public interest in disclosure exists.

5. Information disclosure under REACH

59. Articles 118 and 119 of REACH set out the basis for access to, and the public availability of, information held by the European Chemicals Agency ("ECHA"), including the possibility of restrictions on disclosure.
60. In principle, all the information held by ECHA is publicly accessible. Article 1(1)(b) of Regulation 1367/2006 on access to environmental information aims at ensuring that environmental information is progressively made available and disseminated to the public in order to achieve its widest possible systematic availability and dissemination.
61. According to Article 118 of REACH, all the information held by ECHA is subject to the provisions of Regulation (EC) 1049/2001. As indicated above, this Regulation

34 There is not yet jurisdiction of EU courts on this question. A UK court considered it to be of overriding public interest that the UK public be informed of the localisation of masts for mobile telephones, as there was a potential risk for persons of the electromagnetic waves emanating from these masts, see *Office of Communication v. The Information Commissioner*, (2009) EWCA Civ.90.

35 Aarhus Convention, Article 4(4.d).

36 See Article 6(1) of Regulation 1367/2006 and Article 4(4)(d) of the Aarhus Convention.

provides for the right of EU citizens to access information contained in documents held by EU institutions. This includes information written on paper or stored in electronic form or as a sound, visual or audiovisual recording.

62. The right of citizens to access documents is subject to certain limitations which are provided by Article 4 of Regulation 1049/2001 discussed above. Among the reasons listed in Article 4 that justify non-disclosure, is the refusal of access to documents where disclosure would *"undermine the protection of commercial interests of a natural or legal person, including intellectual property"*.
63. REACH, in line with Article 4(4)(d) of the Aarhus Convention provides for a information that is protected from disclosure as it may undermine the commercial interest of the physical or legal person that owns that information.
64. Article 118(2) list the following as *"normally deemed to undermine the protection of commercial interest"* if disclosed:
- a. *details of the full composition of a mixture;*
 - b. *without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or mixture including information about its precise use as an intermediate;*
 - c. *the precise tonnage of the substance or mixture manufactured or placed on the market;*
 - d. *links between a manufacturer or importer and his distributors or downstream users.*

65. Article 119 of REACH lists the information to be made publicly available by ECHA over the internet. Article 119(1) identifies information from the registration dossiers which must disseminated, without any exception. Article 119(2) sets out a list of information to be published, unless ECHA accepts as valid a justification by the registrant of the information that publication would be harmful for its commercial interest or that of any other party concerned.³⁷

66. When claiming the confidentiality of specific information, ECHA checks that the following conditions are fulfilled:³⁸

37 Other provisions protecting a commercial interest in information are contained in Articles 9 and 11 of REACH. Pursuant to Article 9, this includes information on substances manufactured or imported for the purpose of product and process oriented research and development (PPORD); and Article 11 contemplates the possibility that a registrant may submit information separately when he considers that a joint submission would cause him substantial commercial detriment. In this case, an explanation must be provided, but there is no evaluation by ECHA of the existence of the commercial interest.

38 REACH-IT Data Submission Manual, Part 16 - Confidentiality Claims (ECHA-10-B-31-EN).

- a. *The information is known only to a limited number of persons, i.e. it must not be in the public domain or general knowledge of the industry. Typically the registrant or third party would have undertaken specific measures to keep the information secret;*
- b. *Claims must be properly reasoned rather than being simple statements;*
- c. *The existence of a commercial interest must be demonstrated (the information must have some commercial value or a legitimate commercial interest needs to be at stake);*
- d. *Disclosure of the information must potentially harm a registrant's or a third party's commercial interest and there must be a causal link between publication of the information and the potential harm.*

67. It follows that, in order to justify the withholding of environmental information, it must be shown that the confidentiality of the data must be protected (and recognised) by a specific law, that no overriding public interest exists and that the information does not relate to emissions in the environment. Article 118(2) and Article 119(2) are examples of information where the possibility of keeping data confidential is recognized by law but only provided that no overriding public interest exists which would support its disclosure.³⁹

5.1 Authorisation specific requirements on information disclosure

68. Article 64(2) provides for ECHA to *"make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information, for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties."*

69. Article 64(6) of REACH provides for ECHA to *"determine in accordance with Articles 118 and 119 which parts of its opinions and parts of any attachments thereto should be made publicly available on its website."*

70. Finally, after the decision on authorisation is taken through a Commission decision, Article 64(9) provides that ECHA shall establish a database which includes summaries of Commission decisions, including the authorisation number and the reasons for the decision, particularly when suitable alternatives exist.

³⁹ Further provisions on the protection of specific data submitted to ECHA are included in Article 9(9) of REACH which provides for the confidentiality of the information submitted on substances manufactured or imported for the purposes of product and process orientated research and development (PPORD).

Moreover, ECHA has to keep a register which includes all the notifications from downstream users that use the authorised substance as provided by Article 66(2) of REACH.

6. Information to be disseminated

71. Both Article 64(2) and Article 64(6) provide for the dissemination of the information to be carried out, taking into account the provisions of Article 118 and Article 119 of REACH. As explained above, it must also be noted that the Aarhus Convention, Regulation 1367/2006 and Regulation 1049/2001 apply.
72. From the legal framework described above, it is argued that REACH gives a mandate to ECHA to select and disseminate the information related to the substances and their uses in order to achieve the goals and objectives of the Authorisation process: namely, to *"assure that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced with suitable alternative substances or technologies where these are economically and technically viable"*⁴⁰.
73. ECHA has a fair amount of discretion in deciding what information to make available to the public in the authorisation phase, however the information that is not protected under other laws remains accessible through access to documents requests. ECHA should take into account that:
 - a. the authorisation of a SVHC is exceptional and can be justified only when the benefits to society outweigh the risk of continued use;
 - b. all measures have been taken to minimize the risks from the use of the substance;
 - c. the analysis of alternatives has to be accurate and take into account a wide range of factors which may justify the disclosure of information that is normally deemed confidential.
 - d. REACH provides for the participation of the public in the authorisation procedure and that citizens have the right to know about the use of SVHC.

⁴⁰ Article 55 of REACH

- e. without information on the chemical for which authorisation is sought, the decisions of ECHA would not be open and transparent as provided by Article 1 of the Treaty on European Union.⁴¹

74. Therefore, the first step to be undertaken by ECHA is the filtering of the information it holds on the chemical for which authorisation is sought for a specific use; taking account of Article 118(2) which provides for information that, if disclosed, is deemed to undermine the commercial interest of a company.
75. Article 118(2)(b) deems that there may exist a commercial interest related to the *precise use, function or application* of a substance. However, the presumption applies without prejudice to Article 64(2). Because this provision requires ECHA to disseminate broad information on uses, it follows that, in case of authorisation of uses applied for, the protection that REACH grants to a deemed commercial interest in the precise use, function or application of a substance, should not apply.
76. The second step would be to filter the information which ECHA holds through the requests by an applicant not to disseminate the information listed under Article 119(2). The information included in Article 119(2) includes, among others: the total tonnage band within which the substance was registered; information from safety data sheets, the trade name(s) of the substance. The possibility to request non-publication is foreseen by Article 10(a)(xi) as part of the technical dossier for registration.
77. Since the request from the registrant is valid only when ECHA has evaluated and accepted the request as valid, the assessment of these requests should be concluded before the authorisation phase is open. However, since ECHA does not perform an assessment on the existence of a public interest in disclosure at this stage, ECHA must, nevertheless, recognise that the information may be disclosed in the course of the authorisation procedure or through an access to information request.
78. Unless other laws are identified which provide for the confidentiality of the data, at this stage, ECHA, in addition to the information published on its website pursuant to Article 119 would have to publish the information submitted by the applicant under Article 62(4), the broad information on the uses applied for and the opinion of the RAC and SEAC filtered through Article 118(2) and Article 119(2).

⁴¹ Article 1(2) TEU establishes a fundamental objective of the EU, stating: “*This Treaty marks a new stage in the process of creating an ever closer union among the peoples of Europe, in which decisions are taken as openly as possible and as closely as possible to the citizen.*”

79. The third step which ECHA should take would be to assess whether there is an overriding public interest in also disseminating information, the disclosure of which, is normally deemed to undermine the commercial interest of the company; in particular, whether the information provided relates to emissions into the environment.
80. The public interest to be derived from the aim of the Authorisation title of REACH, namely, to progressively replace SVHC and to guarantee the right of citizens to know about the substances they are exposed to and that the decision-making process is as open as possible.⁴² For example, it may be that, without the full composition of a preparation, it is impossible to understand if an alternative process, substance, material or technology may exist. Further, the environmental release category of the use applied for may cause concern in respect to the quantities of the substance that would be authorised in relation to that use, so that the precise tonnage may need to be disclosed.

Specific information to be disseminated

6.1 Information on uses

81. Article 3(24), 3(25) and 3(26) provide for the definition of use,⁴³ registrant's own use⁴⁴ and identified use.⁴⁵ Article 64(2) of REACH, in the context of authorisation refers to "broad information on uses". Further Article 118(2) provides for information on the precise use, function or application of a substance to normally undermine the commercial interest of the person concerned if disclosed, without prejudice to the dissemination of "broad information on uses" under Article 64(2).
82. Therefore, it is necessary to clarify the exact meaning of "*broad information on uses*" which does not seem to correspond to any of the other concepts of use that are mentioned in REACH. "*Broad information on uses*" has to be read in the light of the aim of the authorisation process. For this purpose, the legislator foresaw no limits in the right of ECHA to disseminate information on the use, not even when the information is normally deemed to undermine the commercial

42 Article 130 of REACH provides for the competent authorities, the Agency and the Commission to state the reasons for all decisions they take under the Regulation.

43 Use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

44 Registrant's own use: means an industrial or professional use by the registrant.

45 Identified use: means a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user.

interest of the applicant through disclosure of the precise use, function or application.

83. Article 62(4)(c) requires the applicant to specify the "*use(s) the authorisation is sought for*". Article 64(2) provides for the obligation of ECHA to make available on its website "*broad information on uses*" for which an application for authorisation has been received with a deadline by which interested parties can provide information on alternative substances and technologies.
84. The use described in the CSR, although useful information, may not be sufficient to guarantee the availability of appropriate information on the use.
85. The CSR includes the description of the uses derived from the Guidance on information requirements and chemical safety assessment - Chapter R. 12. This use descriptor system provides for a generic approach to the description of the use.⁴⁶ Therefore, when applying for authorisation, the information on the use applied for has to be much more detailed because it has to identify uses for which alternatives either do not exist or are not economically viable, rather than providing a general idea on the use of the substance.
86. The use descriptor system comprises five separate descriptor lists which are combined to form a brief description of the identified uses of a substance The five lists are:
 - a. The sector of use category (SU) (e.g.: industrial use, consumer use);
 - b. The chemical product category (PC) (e.g. intermediate, semiconductor, explosive);
 - c. The process category (PROC) (e.g. used in closed process, no likelihood of exposure; industrial spraying);
 - d. The environmental release category (ERC) (formulation of mixtures, industrial use of substances in closed systems);
 - e. The article category (AC) (e.g. vehicles, plastic articles, scented eraser).
87. Further, the descriptor system does not address the functional use of the substance (what it actually does) which is essential to understand if the analysis of alternatives is accurate and whether alternative substances or technologies are available.

⁴⁶ Guidance on information requirements and chemical safety assessment - Chapter R.12: Use descriptor system (ECHA-2010-G-05-EN).

88. However the functional use of the substance has to be described in the Safety Data Sheet (SDS). Paragraph 1.2 of Annex II of REACH provides for the SDS to *"Indicate the uses of the substance or mixture as far as they are known. Where there are many possible uses, only the most important or common uses need to be listed. This shall include a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc."*.
89. For this purpose, the use descriptor system developed by ECHA includes a list of 50 technical functions which a substance may have in a chemical mixture or article (e.g. anti-condensation agent, solvent, stabilizer).⁴⁷
90. The focus on the function of the substance recognizes the fact that the chemical substance serves a purpose in the production. Without knowledge of the function of the substance, it would not be possible to identify safe alternatives or processes that could perform the necessary function. Further, it would not be possible to establish if the substance plays an essential role in society so that the benefits from its presence outweigh the risks related to it.
91. Furthermore, all the information above may not be broad enough to understand if an alternative exists since the analysis of alternatives and the public consultation aim not only at finding possible less harmful substances but also alternative processes that would avoid the use of SVHCs.
92. Therefore, the legislator calls, in Article 64(2), for broader information on the uses which should also include details on the life cycle of the product in which the SVHC is used. Only by having a full picture of the production process it can be possible to identify the best solution that avoids the use of SVHCs and is also effective.

6.2 Exposure scenarios and other information in SDSs

93. The exposure scenario is the *"set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or*

⁴⁷ This list has been derived by combining the list of function categories applied under previous system for notification of new substances in the EU (TGD for completion of summary notification dossier for a new chemical substance utilizing the structured notification interchange format (SNIF), Annex 3; http://ecb.jrc.ec.europa.eu/DOCUMENTS/NewChemicals/SNIF_Guidance.pdf) and the list of industrial functions in appendix E of the Instructions for Reporting for the 2006 Partial Updating of the TSCA Chemical Inventory Database (www.epa.gov/iur/pubs/2006_inst_tsca_cheminv.pdf).

*use or several processes or uses as appropriate;*⁴⁸ The exposure scenarios for the use applied for are essential information to be made public by ECHA in order to have a significant public consultation that may reveal the existence of alternative substances or processes.

94. Knowing the operational conditions of use of the substance enables third parties to understand the technical and economic feasibility of an alternative for the use for which the applicant has applied
95. Further, knowing what risk management measures are applied would allow third parties to understand whether a possible alternative substance or technology is suitable which would have lower risk from a health and environmental perspective.
96. A legal basis to disseminate the exposure scenario exists pursuant to Article 119(2)(d) and Article 31(7) of REACH.
97. Article 119(2)(d) provides for ECHA's obligation to disseminate, on its website, *"information, other than that listed in paragraph 1, contained in the safety data sheet"*. While Article 31(7) provides:

"Any actor in the supply chain who is required to prepare a chemical safety report according to Articles 14 or 37 shall place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI."

98. It follows that the exposure scenario that is included in the CSR is part of the safety data sheet and, unless there is a request pursuant to Article 10(a)(xi) not to publish it that ECHA accepts as valid, it has to be published in ECHA's website.

7. Recommendations to ECHA

99. In order to fulfil the aim of the Authorisation title to phase out by progressively substituting SVHC, the quality of the information provided by the applicant and the dissemination of the information by ECHA is crucial.
100. ECHA has to publish the broad information on the use of the substance for which the applicant requests an authorisation. This has to be done in connection with the analysis of alternatives in order to give the general public the opportunity to assess whether the analysis of alternatives is reliable and whether alternative substances or processes are available for that function.

⁴⁸ Article 3(37) of REACH.

101. Apart from dissemination of information, ECHA should consider making available for public consultation a summary of all the relevant information that may lead to the public consultation provided in Article 64(2) to obtain meaningful results that can lead to a decreased use of SVHC. A template, to develop with all relevant stakeholders is suggested.
102. The restriction provided by Article 118(2), according to which the access to information on the precise use of the substance is deemed to normally undermine the protection of the commercial interest of the company, should never apply in case of "*uses applied for*" in the authorisation context.
103. Finally, ECHA must publish the opinion from its committees on the authorisation request filtered through the provisions of Article 118, 119 and taking into account the public interest related to the publication of the information. Particularly, ECHA should take into account that information on emissions into the environment must always be disclosed.
104. Moreover, after the decision is taken by the Commission, ECHA should publish a summary of the authorisation decision including, as a minimum, the authorisation number, the precise uses for which authorisation was granted, the grounds for the decision and the analysis of the alternatives, including the outcome of the public consultation, particularly when suitable alternatives exist.
105. It is also recommended that ECHA keep an up-to-date database with alternatives for the uses relating to substances included in Annex XIV or contributes to existing databases⁴⁹ established for the purpose of promoting substitution of dangerous chemicals with safer alternatives. Updated information on alternatives can lead, at any time, pursuant to Article 61(1) of REACH to the review of an authorisation already granted.
106. All the information to be published should be included in the rules on transparency provided by Article 109 of REACH.⁵⁰ These rules aim at ensuring the availability to the public of regulatory, scientific or technical information concerning the safety of the substances. However, these rules mainly collate the dissemination obligations already prescribed in other parts of REACH and do not address the wider availability of information on substances, particularly in the procedure for the authorisation of dangerous substances.

49 See for example the website of the SUBSPORT project, a project co-financed by the EU:
<http://www.subsport.eu/>

50 See "Rules on transparency regarding safety of substances" (MB/61/2008).

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ClientEarth is funded by the generous support of philanthropic foundations and engaged individuals and with operational support from the European Commission's Life+ programme.

ClientEarth

Brussels

4^{ème} Etage
36 Avenue de Tervueren
Bruxelles 1040
Belgium

London

274 Richmond Road
London E8 3QW
UK

Warsaw

Aleje Ujazdowskie 39/4
00-540 Warszawa
Poland

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www.clientearth.org
September 2011

For further information, please contact:

Vito A. Buonsante

Health and Environment Lawyer
t. +32(0)2 808 34 72
e. vbuonsante@clientearth.org