

The importance of dissemination

Stakeholder's Day
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Overview

- Legislator's motivation for dissemination
- Legal framework for dissemination under REACH
- Involvement of the ECHA Management Board
- Conclusions

Motivation

Recital 117 to REACH:

EU citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. A transparent means of achieving this is to grant them free and easy access to basic data held in the Agency's database, including brief profiles of hazardous properties, labelling requirements and relevant Community legislation including authorised uses and risk management measures.

Legal framework

Article 77 of REACH: *Tasks*

2. The Secretariat shall undertake the following tasks:

(e) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list established in accordance with Regulation (EC) No 1272/2008.

It shall make the information identified in **Article 119(1) and (2)** in the database(s) publicly available, free of charge, over the Internet, except where a request made under **Article 10(a)(xi)** is considered justified.

Legal framework

Article 35 of REACH: ***Access to information for workers***

Workers and their representatives shall be granted access by their employer to the information provided in accordance with Articles 31 and 32 in relation to substances or mixtures that they use or may be exposed to in the course of their work.

Legal framework

Article 118 of REACH: ***Access to information***

1. Regulation (EC) No 1049/2001 shall apply to documents held by the Agency.
2. Disclosure of the **following information shall normally be deemed to undermine** the protection of the commercial interests of the concerned person:
 - (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.

Where **urgent action** is essential to protect human health, safety or the environment, such as **emergency situations**, the Agency may disclose the information referred to in this paragraph.

Legal framework

Article 10 of REACH: *Information to be submitted for general registration purposes*

A registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:

(a) a technical dossier including:

(xi) **a request as to which of the information in Article 119(2) the manufacturer or importer considers should not be made available on the Internet** in accordance with Article 77(2)(e), **including a justification** as to why publication could be **harmful** for his or any other concerned party's commercial interests.

Legal framework

Article 119 of REACH: *Electronic public access*

1. The following information held by the Agency on substances whether on their own, in mixtures or in articles, shall be made **publicly available, free of charge**, over the Internet in accordance with Article 77(2)(e):

- (a) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC, without prejudice to paragraph 2(f) and (g);
- (b) if applicable, the name of the substance as given in EINECS;
- (c) the classification and labelling of the substance;
- (d) physicochemical data concerning the substance and on pathways and environmental fate;

Legal framework

Article 119 of REACH: ***Electronic public access*** (cont'd)

- (e) the result of each toxicological and ecotoxicological study;
- (f) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;
- (g) the guidance on safe use provided in accordance with Sections 4 and 5 of Annex VI;
- (h) analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

Legal framework

Article 119 of REACH: ***Electronic public access*** (cont'd)

2. The following information on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) **except** where a party submitting the information submits a justification in accordance with Article 10(a)(xi), **accepted as valid by the Agency**, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

Legal framework

Article 119 of REACH: ***Electronic public access*** (cont'd)

- (a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;
- (b) the total tonnage band (i.e. 1 to 10 tonnes, 10 to 100 tonnes, 100 to 1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;
- (c) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);
- (d) information, other than that listed in paragraph 1, contained in the safety data sheet;
- (e) the trade name(s) of the substance;

Legal framework

Article 119 of REACH: ***Electronic public access*** (cont'd)

- (f) the name in the IUPAC Nomenclature for non-phase-in substances which are dangerous within the meaning of Directive 67/548/EEC for a period of six years;
- (g) the name in the IUPAC Nomenclature for dangerous substances within the meaning of Directive 67/548/EEC that are only used as one or more of the following:
 - (i) as an intermediate;
 - (ii) in scientific research and development;
 - (iii) in product and process orientated research and development.

Involvement of the Management Board

- Board considers dissemination as a cornerstone of REACH and vital for achieving the REACH goals
- MB Decision for reviewing a partial or full rejection of a confidentiality claim, adopted in April 2008 (in accordance with Article 118(3))
- Roadmap for Dissemination presented at the MB meetings in June and September 2009
- creation of a Management Board Advisory Group on Dissemination (September 2009)

Mandate of the Advisory Group

- Monitor the progress of the ECHA dissemination project
- Provide strategic advice to the ECHA management
- Act as “ambassadors” to civil society, in particular by reporting back to their respective stakeholders, and raising awareness
- Report to the Management Board

Progress and advice

Meetings in November 2009, February and April 2010:

- Update on the Dissemination project
- Discussions on handling confidentiality claims
- Communication activities

Progress and advice

Legal Framework

a.General principles in European law governing transparency and the protection of confidential information

i.Principle of transparency and free access to information

ii.Principle of protection of confidential information and business secrecy

iii.Protection of confidential information versus public interest

b.Analysis of Articles 118 and 119 of the REACH Regulation

i.The regulatory framework set by Articles 118 and 119

ii.Relevance of the general principles of European law for the application of Article 119(2)

c.Definition of “confidential information”

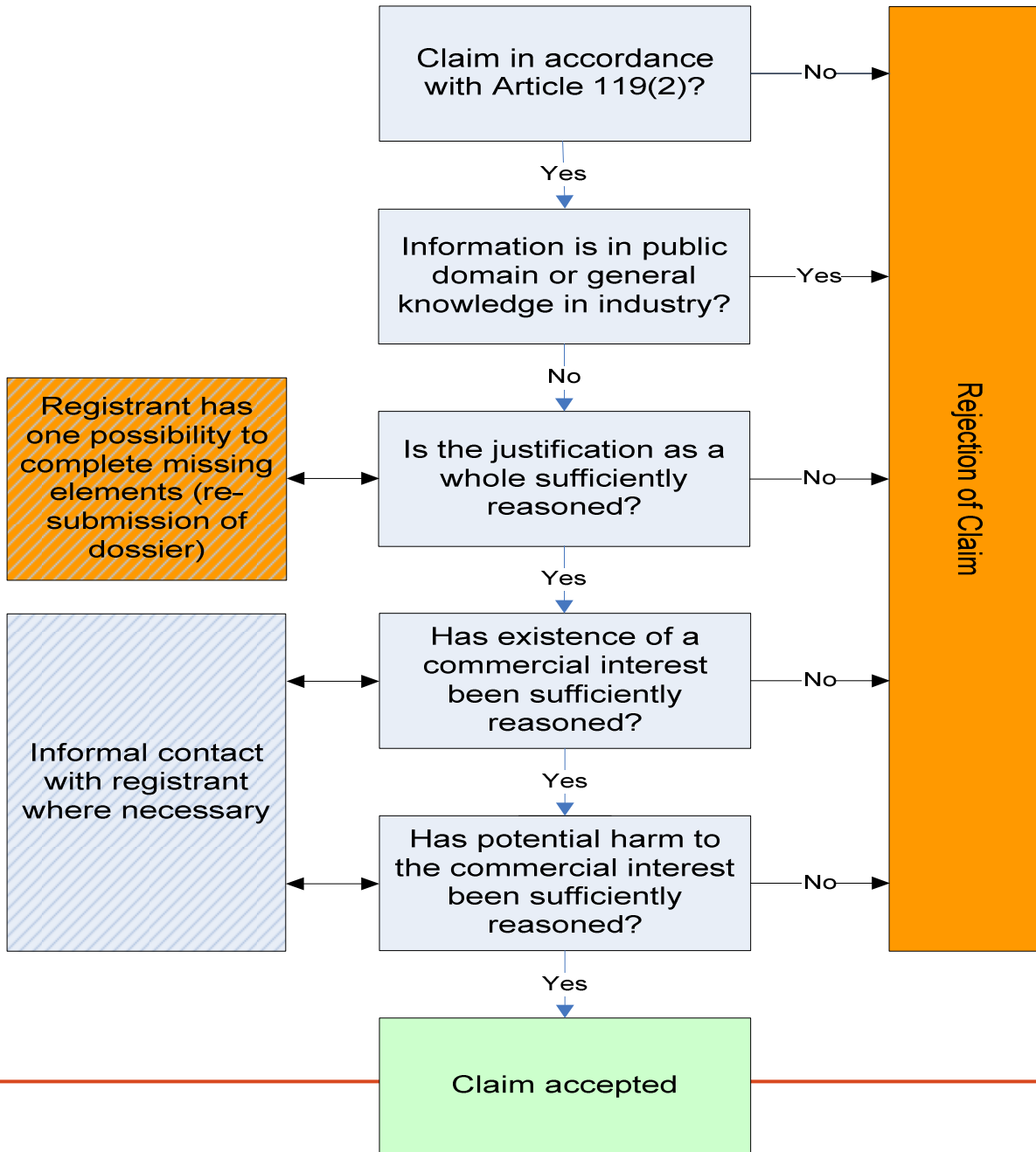
i.Definitions of confidential information applied in international trade law and by other European bodies/institutions

ii.Relevance of the definition of confidential information in the context of Article 119(2)

Common principles governing the assessment of the validity of claims

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WORKFLOW EXAMPLE!



Stakeholder consultations initiated

- Round table of 6 July 2009 on the principles of dissemination
 - Participation: 22 representatives from industry, NGOs, trade unions, OECD, EU Commission, EU Parliament and Commission
 - Outcome: input taken into account in defining filter rules
- 8 April 2010 Technical meeting on confidentiality claims
 - Participation: 16 participants from industry, NGOs, trade unions, competent authorities (Belgium, Sweden, Italy) and Commission
 - Outcome: input taken into account in establishing principles of assessing confidentiality claims and requirements for writing justifications

Conclusions

- the Advisory Group has an active interest in dissemination of information over the internet under REACH
- the Advisory Group is interested in your experiences and concerns about dissemination:
 - Ethel Forsberg (SE - Chair),
Antonello Lapalorcia (IT), Helmut De Vos (BE)
 - Tony Musu (ETUC)
 - Hubert Mandery (CEFIC)
 - Martin Führ (NGOs)
 - Guus Borchardt (Commission)

Conclusions

State-of-play (By December 2009)

- Pilot project on line (<http://apps.echa.europa.eu/registered/registered-sub.aspx>)
- Public consultation via web (<https://comments.echa.europa.eu/Comments/DisseminationFeedback.aspx>)

Conclusions

Questions raised in Advisory Group:

1. Timing
2. Procedure
3. Aarhus Convention related aspects
4. Special considerations for SMEs ?
5. ???

Thank you



<http://echa.europa.eu>

CLP