worldwide registration

knoell
worldwide registration

# Society for Chemical Hazard Communication Spring Meeting

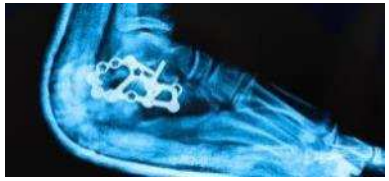
## 28.03.2017, New Orleans | Dr. Christoph Schwarz

# Business Areas

Industrial Chemicals

Biocides

Agrochemicals



Medical Devices

Lab Services

Pharmaceuticals

Veterinary Medicine

Training

Regulatory Software Solutions

# Global Locations

## Germany

Dr. Knoell Consult

knoell academy

## United Kingdom

Dr. Knoell Consult

Cyton Biosciences

## Spain

Knoell Iberia

## Portugal

Knoell Iberia

## Switzerland

Dr. Knoell Consult Schweiz

## the Netherlands

Knoell NL

## France

Knoell France

## USA

Critical Path Services

## China

Dr. Knoell Consult Shanghai

## Thailand

Dr. Knoell Consult Thai

## Japan

Knoell Japan

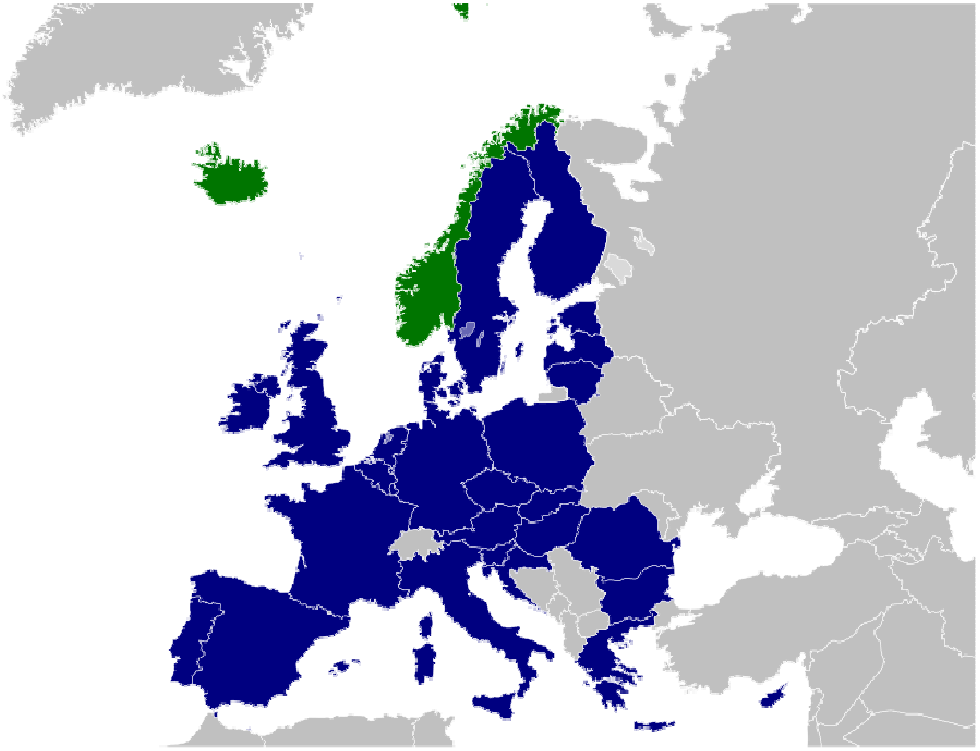
## South Korea

Knoell Korea

# Protecting Trade Secrets Around the World: How to Deal with Confidential Business Information, Part 2, European Union

28.03.2017, New Orleans | Dr. Christoph Schwarz

# European Union (EU) and European Economic Area (EEA)



Source: Wikipedia, image in public domain

**EU**

- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Latvia
- Lithuania
- Luxembourg
- Malta
- Netherlands
- Poland
- Portugal
- Romania
- Slovakia
- Slovenia
- Spain
- Sweden
- United Kingdom

**EEA (EU plus: )**

- Iceland
- Liechtenstein
- Norway

# Intellectual Property Rights and Trade Secrets

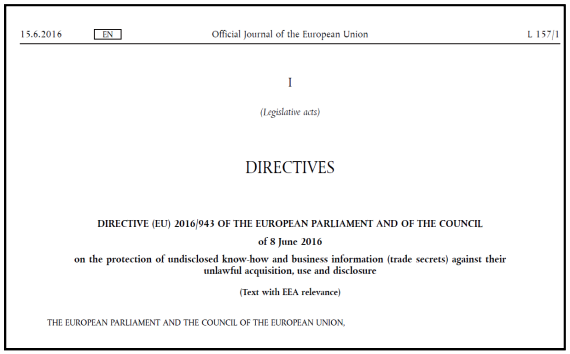
- Intellectual Property Rights (IPR)
  - Patents
  - Trademarks
  - Copyright
  - Industrial design rights

- Trade Secrets
  - No formal government protection granted
  - Companies required to keep own trade secrets secure
  - „Peculiar form of IP“ / soft IP
  - Not “property” like other forms of IP
  - However, should be treated as IPR
  - *[Court of Justice of the European Union in its Microsoft judgment, Case T-201/04, and the European Commission in its Regulation 772/2004, Article 1.1.g, have stated that trade secrets should be treated as equivalent to intellectual property rights.]*

# Trade Secrets Directive (EU) 2016/943 of 8 June 2016

**on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure**.

To be transposed into member state law
by 9 June 2018



15.6.2016 EN Official Journal of the European Union L 157/1

I

*(Legislative acts)*

DIRECTIVES

DIRECTIVE (EU) 2016/943 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 8 June 2016
on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

- harmonises the definitions with existing internationally binding standards
- defines the relevant forms of misappropriation
- clarifies that parallel innovation and reverse engineering must be guaranteed

- Does not establish criminal sanction, but harmonizes civil means for protection
  - stopping unlawful use and further disclosure
  - removal from the market
  - the right to compensation

# Trade Secrets Directive (EU) 2016/943 of 8 June 2016

*Article 2*

**Definitions**

For the purposes of this Directive, the following definitions apply:

(1) 'trade secret' means information which meets all of the following requirements:

(a) it is secret in the sense that **it is not,** as a body or in the precise configuration and assembly of its components, **generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question**;

(b) it has **commercial value because it is secret**;

(c) it **has been subject to reasonable steps** under the circumstances, by the person lawfully in control of the information, **to keep it secret**;

(2) […]

# Trade Secrets Directive (EU) 2016/943 of 8 June 2016

*Article 5*

## Exceptions

Member States shall ensure that an application for the measures, procedures and remedies provided for in this Directive is dismissed where the alleged acquisition, use or disclosure of the trade secret was carried out in any of the following cases:

(a) for exercising the right to **freedom of expression and information** as set out in the Charter, including **respect for the freedom and pluralism of the media;**

(b) for **revealing misconduct, wrongdoing or illegal activity**, provided that the respondent acted for the purpose of **protecting the general public interest**;

(c) disclosure by workers to their representatives as part of the legitimate exercise by those representatives of their functions in accordance with Union or national law, provided that such disclosure was necessary for that exercise;

(d) for the purpose of protecting a legitimate interest recognised by Union or national law.

# CBI in the chemical industry

**Safety relevant data / potential risks must be communicated**

- Public safety
- Worker protection
- Environmental protection

in balance with

**Legitimate business interests of companies**

- Protection of CBI
- Preventing economic disadvantage caused by competitors access to trade secrets

**For European Union:**

- REGULATION (EC) No 1907/2006 (**REACH-Regulation**)

and

- REGULATION (EC) No 1272/2008 (**CLP-Regulation**)

# REACH-Regulation (EC) 1907/2006 and CBI

- No explicit Article in REACH-Regulation about CBI / trade secrets
- Multiple referencing of the CBI-concept

**→ REACH recognizes necessity of CBI protection for some critical data**

# REACH-Regulation (EC) 1907/2006 and CBI

- *Article 11:*
  **Joint submission of data by multiple registrants**

  **[...]**

3. A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:
   […]

(b) submitting the information jointly would lead to **disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment** […]

… the registrant shall submit, along with the dossier, an **explanation** as to why […] disclosure of information was likely to lead to substantial commercial detriment …

# REACH-Regulation (EC) 1907/2006 and CBI

- *Article 118(2):*
  **Access to information**

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 ▸M3 mixture ◂;

(b) without prejudice to Article 7(6) and Article 64(2), the **precise use, function or application of a substance or** ▸M3 **mixture** ◂, including information about its **precise use as an intermediate**;

(c) the **precise tonnage** of the substance or ▸M3 mixture ◂ manufactured or placed on the market;

**(d)** **links between a manufacturer or importer and his distributors or downstream users**.

→ **This Information is never disclosed, unless:**

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.

# REACH-Regulation (EC) 1907/2006 and CBI

- *Article 119(1):*
  **Electronic public access**

**Data made publicly available over the internet:**

- **IUPAC name** if hazard class is
  - Hazard class 2.1 – 2.4, 2.6 2.7,2.8 A+B, 2.9 2.10, 2.12, 2.13 cat 1+2, 2.15 A – F
  - Hazard class 4.1, Hazard class 5.1
- **EINECS name** if applicable
- **Classification and Labelling**
- **Phys-chem data**
- **Toxicol.** and **ecotoxicol. study results**
- **PNEC / DNEL**
- **Guidance on safe use**
- **(analytical methods** (for detection if accidentally discharged)**)**

- *Article 119(2):*

The following information on substances whether on their own, in preparations 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:

# REACH-Regulation (EC) 1907/2006 and CBI

*Article 119(2):* **Data for which confidentiality CAN be requested**

(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 hazardous;

(b) the **total tonnage band** (i.e. 1-10 tonnes, 10-100 tonnes, 100-1000 tonnes or >1000 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;**

# REACH-Regulation (EC) 1907/2006 and CBI

*Article 119(2):* **Data for which confidentiality can be requested**

e) the **trade name(s)** of the substance;

f) subject to Article 24 of Regulation (EC) No 1272/2008, **the name in the IUPAC nomenclature for non-phase-in substances** referred to in paragraph 1(a) of this Article for a period of **six years**;

g) subject to Article 24 of Regulation (EC) No 1272/2008, **the name in the IUPAC nomenclature** for substances referred to in paragraph 1(a) of this Article 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.

# CLP-Regulation (EU) 1272/2008 and CBI

- *Article 24 of CLP-Regulation:*
  **Request for use of an alternative chemical name**

1. The manufacturer, importer or downstream user of a substance in a mixture **may submit a request to the Agency to use an alternative chemical name** which refers to that substance in a mixture either by means of a name that identifies the most important functional chemical groups or by means of an alternative designation, where the substance meets the criteria set out in Part 1 of Annex I and **where he can demonstrate that disclosure** on the label or in the safety data sheet of the chemical identity of that substance **puts the confidential nature of his business**, in particular his **intellectual property rights, at risk**.

2. Any request referred to in paragraph 1 of this Article shall be made in the format referred to in Article 111 of Regulation (EC) No 1907/2006 and **shall be accompanied by a fee**.

   The level of the fees shall be determined by the Commission in accordance with the regulatory procedure referred to in Article 54(2) of this Regulation.

   A **reduced fee shall be set for SMEs**.

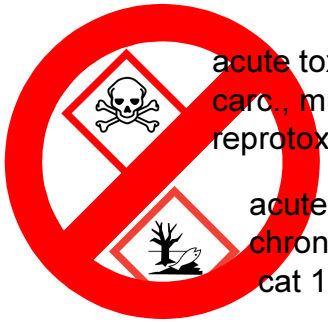
   […]

9. Where the supplier of a **mixture**, **before 1 June 2015, has demonstrated under Article 15 of Directive 1999/45/EC** that the disclosure of the chemical identity of a substance in a mixture puts the confidential nature of his business at risk, **he can continue to use the agreed alternative name** for the purposes of this Regulation.

# CLP-Regulation (EU) 1272/2008 and CBI

An alternative chemical name can only be approved if:

- The substance does **not have an EU based workplace exposure limit (OEL)**
- The use of an alternative chemical name meets the need to **provide enough information to take necessary health and safety precautions at the workplace** and that the risks from handling the mixture can be controlled
- The substance is **only classified in the following hazardous classes** (acc. to 1.4.1 (III), Annex I, EC 1272/2008 (CLP)):
  - *Any of the physico-chemical categories;*
  - *Acute toxicity, category 4;*
  - *Skin Irritation, category 2;*
  - *Eye Irritation, category 2;*
  - *Specific target organ toxicity - single exposure (STOT SE), category 2 or 3;*
  - *Specific target organ toxicity - repeated exposure (STOT RE), category 2;*
  - *Hazardous to the aquatic environment - chronic, category 3 or 4.*



acute tox cat 1-3, carc., muta., reprotox

acute ecotox, chron. Ecotox cat 1, 2

[…]

# REACH-Regulation Article 119(1) and 119(2)

**Note that all of the information listed under REACH Article 119(1) will always be disseminated, regardless of whether a registrant attempts to request this information confidential.**

Hence, any confidentiality requests on this information will be disregarded and no fee will be incurred by such requests.

Additionally, the **information listed under REACH Article 119(2) will also be disseminated unless a confidentiality request has been submitted and accepted as valid, and the relevant fee paid if applicable.**

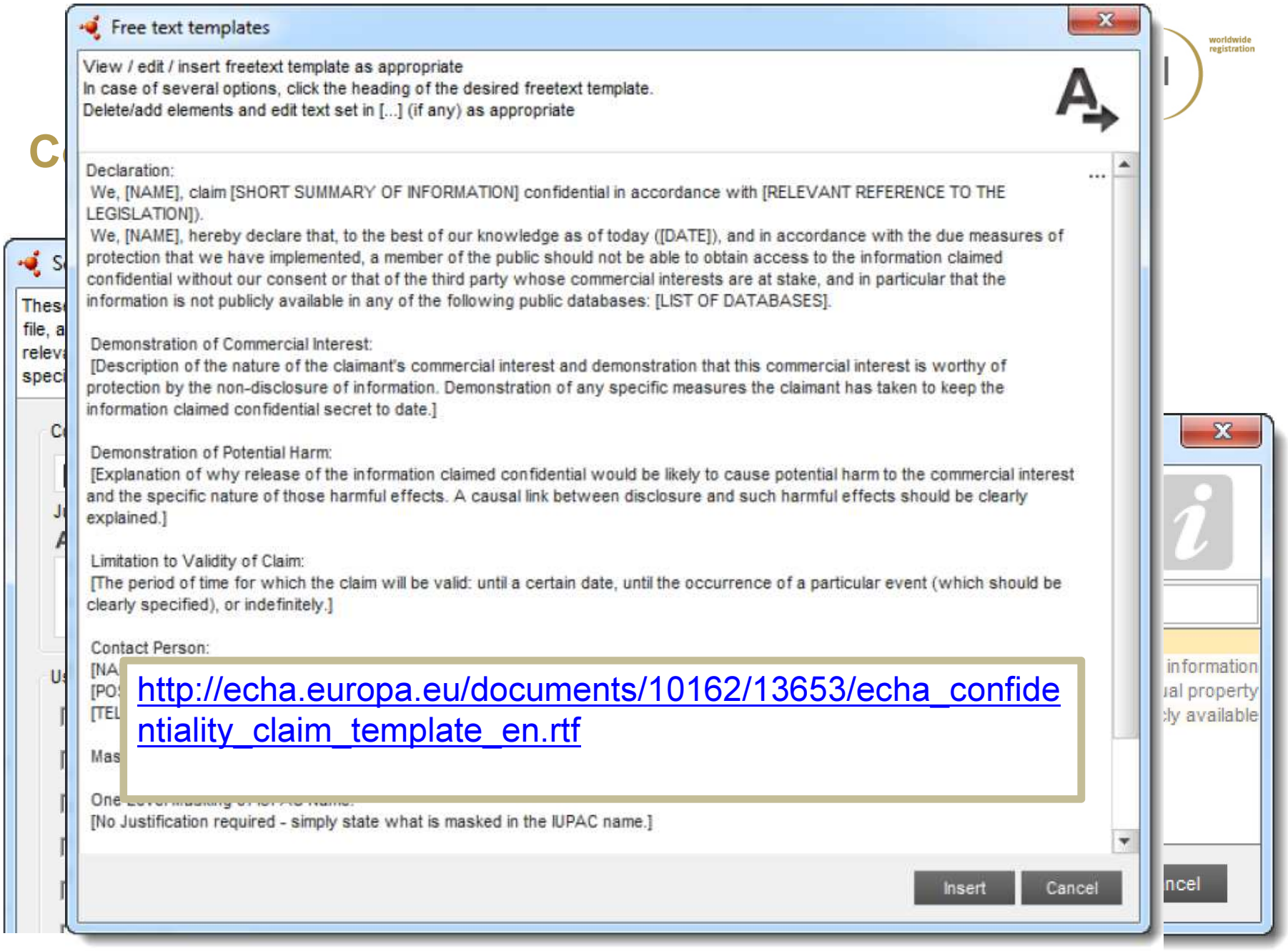
# REACH-Regulation (EU) 1907/2006 and CBI

IUCLID format used for submissions

- **IUCLID-Plugin Dissemination Preview**
  (by default installed with IUCLID 6)

  See, what is likely to be removed before publication over the internet, and which information will be made publicly available.


CAVEAT!
Make sure no information that is deemed / requested confidential is also present in other „public“ fields!
All content of these fields will be disseminated!


Free text templates
View / edit / insert freetext template as appropriate
In case of several options, click the heading of the desired freetext template.
Delete/add elements and edit text set in [...] (if any) as appropriate
Declaration:
We, [NAME], claim [SHORT SUMMARY OF INFORMATION] confidential in accordance with [RELEVANT REFERENCE TO THE LEGISLATION]).
We, [NAME], hereby declare that, to the best of our knowledge as of today ([DATE]), and in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to the information claimed confidential without our consent or that of the third party whose commercial interests are at stake, and in particular that the information is not publicly available in any of the following public databases: [LIST OF DATABASES].
Demonstration of Commercial Interest:
[Description of the nature of the claimant's commercial interest and demonstration that this commercial interest is worthy of protection by the non-disclosure of information. Demonstration of any specific measures the claimant has taken to keep the information claimed confidential secret to date.]
Demonstration of Potential Harm:
[Explanation of why release of the information claimed confidential would be likely to cause potential harm to the commercial interest and the specific nature of those harmful effects. A causal link between disclosure and such harmful effects should be clearly explained.]
Limitation to Validity of Claim:
[The period of time for which the claim will be valid: until a certain date, until the occurrence of a particular event (which should be clearly specified), or indefinitely.]
Contact Person:
http://echa.europa.eu/documents/10162/13653/echa_confidentiality_claim_template_en.rtf
[No Justification required - simply state what is masked in the IUPAC name.]
Insert
Cancel

# Substances already notified under Directive 67/548/EEC

## (Notification Of New Substances (NONS) Directive)

**Information that cannot be requested confidential under NONS was disseminated since November 2012, if not updated to indicate request for confidentiality**

"At some point in the future, the full set of information contained in the NONS dossiers may be disseminated. Before this step, any updates or confidentiality requests should be finalised by registrants.

You are advised to review each of your company's NONS dossiers and ensure that you find it suitable for dissemination."

https://www.echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

# Data from dossiers submitted under Regulation (EU) 1907/2006 (REACH Regulation)

| Information | |
|---|---|
| EINECS name | always published |
| IUPAC name | confid. possible / public name required |
| Legal identity | confid. possible |
| Trade name | confid. possible |
| UN name / number | always published |
| Other identifiers | volunteered |
| Compet. Pers SDS | confid. possible |
| Legal entity composition | confid. possible if IUPAC name confid. |
| Boundary composition | volunteered |
| Precise details of composition | never provided |
| Purity / impurities | confid. possible if not C&L related |

| Information | |
|---|---|
| REACH Reg # | legal entity masking / confid. possible |
| GHS classif&labelling | published (except confid. IUPAC name) |
| DSD / DSP labelling | published (except confid. IUPAC name) |
| PBT assessment | confid. possible for some details |
| Uses advised against | published, unless confid. request accepted by ECHA |
| Phys – chem data | confid. possible |
| Guidance on safe use | always published |
| Total tonnage band | confid. possible |

Source: ECHA Manual - Dissemination and Confidentiality under REACH Regulation

# Case rationales for requesting confidentiality under Article 119(2)

***Article 119(2)(a) -*** Purity – Identity of Impurities

- Possible revelation of production process / purification process that has (not) been used
- Hinting competitors a direction for research efforts
- Identity of possible additives with relevance for substance function

| Supporting Factors | Non-Supporting Factors |
|---|---|
| small / niche markets (particularly SMEs) | high number of registrations with similar purity |

# Case rationales for requesting confidentiality under Article 119(2)

***Article 119(2)(b)* -** Total Tonnage Band

Exact volume always confidential, however:

- If market is relatively small → indication of market size
- Indication about the market share

| Supporting Factors | Non-Supporting Factors |
|---|---|
| only few competitors / few registrants in joint submission | higher number of members in joint submission |
| "relatively precise" tonnage band (1-10 t rather than 100-1000 t) | |

# Case rationales for requesting confidentiality under Article 119(2)

***Article 119(2)(d)* -** Other Information in the SDS

**Uses**

- SDS may contain data intended only for direct customer

| Supporting Factors | Non-Supporting Factors |
|---|---|
| All registrants request same uses confidential | use already published on ECHA website (→ common use, not confidential) |
| related to scientific R&D or PPORD | general description (no info on use, concentr., frequency of application …) |

# Case rationales for requesting confidentiality under Article 119(2)

***Article 119(2)(d)* -** Other Information in the SDS

**Legal entity**

| Supporting Factors | Non-Supporting Factors |
|---|---|
| 3rd party representative appointed | registrant is direct supplier in non-complex supply chain |
| registrant is not direct supplier (e.g. toll manufacturer) | |

# Case rationales for requesting confidentiality under Article 119(2)

***Article 119(2)(d)*** **-** Other Information in the SDS

**REACH Registration Number:**

| Supporting Factors | Non-Supporting Factors |
|---|---|
| not fully available through supply chain (01-0000345678-68-XXXX) | fully available through supply chain (01-0000345678-68-1234) |

# Case rationales for requesting confidentiality under Article 119(2)

***Article 119(2)(e)*** – Trade Name(s)

- May reveal market dealings between manufacturer / supplier and customers

| Supporting Factors | Non-Supporting Factors |
|---|---|
| smaller markets, where connection would be easier to establish | trade names are generally regarded as public |

# Recapitulation:

- Legal basis for harmonized handling of CBI in EU adressed with Trade Secret Directive (EU) 2016/943
  - Does not establish criminal sanctions, but harmonizes civil means of protection
  - Common definitions
  - Journalist- and whistle-blower protection
  - Clarifies that reverse engineering and parallel innovation must be guaranteed
  - To be transposed into national law by June 2018

- CLP Regulation (EU) 1272/2008 (Art. 24)
  - Possibility of masking IUPAC name within certain limits (instead: public name)
- REACH Regulation (EU) 1907/2006(Art. 118, 119)
  - Publication / dissemination through ECHA website / database
  - Possibility for various confidentiality claims where disclosure would be potentially harmful for registrants economic interest
  - Specific justification required and subject to fee
  - Fee depends on company size and number of endpoints that are requested confidential

# Thank you for your attention!

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Christoph Schwarz
cschwarz@knoell.com

# Links

- IUCLID 6 Website
  https://iuclid6.echa.europa.eu/
- ECHA Dissemination Manual:
  https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0
- ECHA Confidentiality Claim template:
  http://echa.europa.eu/documents/10162/13653/echa_confidentiality_claim_template_en.rtf
- ECHA Webinars, instructional and support videos:
  https://www.youtube.com/user/EUchemicals

# List of Databases

Used by ECHA during Assessment of REACH Art 119(2) confidentiality request, to check whether in public domain:

- eChemPortal: http://www.echemportal.org/ (Participating databases: ACToR , CCR , CESAR, CHRIP, GHS-J, HSDB, HSNO CCID, INCHEM, JECDB, OECD HPV, OECD SIDS IUCLID, UK CCRMP Outputs, US EPA IRIS, US EPA SRS)
- Chemical Safety Information from Intergovernmental Organizations (INCHEM): http://www.inchem.org/
- GESTIS-Stoffdatenbank: http://www.dguv.de/ifa/de/gestis/stoffdb/index.jsp
- Institut national de recherche et de sécurité (fiches toxicologiques): http://www.inrs.fr
- NITE - Chemical Risk Information Platform (CHRIP): http://www.safe.nite.go.jp/english/db.html
- Toxnet: http://toxnet.nlm.nih.gov/ (Participating databases: HSDB, TOXLINE, CCRIS, DART, GENETOX, IRIS, ITER, LactMed, Multi-Database, TRI, Haz-Map, Household Products, TOXMAP)

# Abbreviations

| Abbrev. | |
|---|---|
| CLP (Regulation) | Regulation on Classification, Labelling and Packaging, (EC) 1272/2008 |
| ECHA | European Chemicals Agency |
| IPR | Intellectual Property Right |
| NONS | Notification Of New Substances Directive 67/548/EEC |
| PPORD | Product and Process Orientated Research and Development |
| REACH (Regulation) | Regulation on Registration, Evaluation and Authorization of Chemicals (EC) 1907/2006 |
| SIEF | Substance Information Exchange Forum |
| SMEs | Small and medium-sized Enterprises |