**Version 13 March 2015**

**European Union reply to the questionnaire of the UN Special Rapporteur on the implications for human rights of the environmentally sound management and disposal of hazardous substances and wastes**

The Special Rapporteur seeks to explore the importance of the right of access to information in the field of hazardous substances and wastes. He is interested in examining the legal framework, identifying information gaps, and analyzing how this right is implemented at various levels (e.g., at the national, local and municipal levels) and by different government bodies (e.g., Ministries of environment, health, labour, etc.) in practice. He also intends to identify barriers to realizing the right of access to information, with the aim of mitigating the adverse impacts of hazardous substances and wastes on human rights.

The common reply of the European Union (EU) has been drafted from the input of the European Commission and its Member States and contains information on the overall framework which exists in the EU on this subject. Aspects which are related to the national circumstances of the EU Member States are to be submitted separately to the Rapporteur by those who decided to do so.

1. ***What obligations does your Government have to ensure the right of access to information under international, regional and national laws? Please provide, in detail, the relevant legislation that guarantees the right of access to information on hazardous substances and wastes, as well as the mechanisms, including grievance mechanisms, which may be used by individuals and groups.***

* ***Directive 2003/4****/EC* ***on public access to environmental information***

The EU and all Member States are parties to the ***Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental matters*** (Arhus Convention), signed in Aarhus, Denmark, on 25 June 1998 by 39 European countries, as well as by the European Community itself within the framework of UN-Economic Commission for Europe. It came into force on 30 October 2001 and 46 countries and the European Union are currently Parties to the Convention.

The first pillar of the convention is access to environmental information in a double perspective: access upon request (Article 4) and active dissemination, in particular through electronic means (Article 5). The convention does not attempt to define 'environmental information' in an exhaustive manner but rather breaks down its scope into three categories. Within each category an illustrative list is envisaged. It goes without saying that hazardous substances and waste are included in the notion of environmental information.

The Aarhus Convention establishes a number of rights of the public (individuals and their associations) with regard to the environment. The Parties to the Convention are required to make the necessary provisions so that public authorities (at national, regional or local level) will contribute to these rights to become effective. The Convention provides for:

* the right of everyone to receive environmental information that is held by public authorities ("access to environmental information"). This can include information on the state of the environment, but also on policies or measures taken, or on the state of human health and safety where this can be affected by the state of the environment. Applicants are entitled to obtain this information within one month of the request and without having to say why they require it. In addition, public authorities are obliged, under the Convention, to actively disseminate environmental information in their possession;
* the right to participate in environmental decision-making. Arrangements are to be made by public authorities to enable the public affected and environmental non-governmental organisations to comment on, for example, proposals for projects affecting the environment, or plans and programmes relating to the environment, these comments to be taken into due account in decision-making, and information to be provided on the final decisions and the reasons for it ("public participation in environmental decision-making");
* the right to review procedures to challenge public decisions that have been made without respecting the two aforementioned rights or environmental law in general ("access to justice").

The EU had to adapt its legislation in order to fully comply with the principles of the Convention, inter alia in this subject. Therefore, ***Directive 2003/4****/****EC******on public access to environmental information*** was adopted to ensure common rules for the national legal orders. The provisions of Directive 2003/4/EC are transposed in national legal acts in all EU member states.

For the EU institutions and bodies ***Regulation 1367/2006/EU*** ***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***was approved to amend the rules provided for in ***Regulation 1049/2011*** ***regarding public access to European Parliament, Council and Commission documents***. These laws constitute the general framework in the matter, applicable unless specific provisions are envisaged in a sectoral domain.

The general philosophy is that Governments in the European Union must ensure the broadest transparency concerning their policies and actions, therefore also environmental information should be made available to each natural or legal person, unless one or more limited grounds for refusal are applicable to a specific request. These grounds are exhaustively envisaged in Article 4 of the Directive. They have to be interpreted restrictively, taking into account for each particular case the public interest served by disclosure to be weighed against the interest served by the refusal. If a ground for refusal is applicable only to a part of information, the remaining part has to be disclosed. Against the refusal, access to justice has to be guaranteed.

***Aarhus convention implementation reports:***

In addition, the Convention collectively requires the Parties to keep under continuous review the implementation of the Convention. This is achieved through a reporting mechanism whereby each Party is requested to submit a report to each meeting of the Parties on the legislative, regulatory and other measures taken to implement the Convention, and their practical implementation.

The Aarhus convention national implementation reports are available in following link - <http://www.unece.org/env/pp/reports_trc_implementation_2014.html>.

* ***Regulation 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register***[[1]](#footnote-1)

Concerning information on pollutant releases and transfers (incl. waste) from industrial activities, the European Pollutant Release and Transfer register (E-PRTR) provides easy public access to key environmental data from large industrial installations in the EU and in Iceland, Liechtenstein, Norway, Serbia and Switzerland.

The legal basis of the E-PRTR is **Regulation (EC) 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register**(E-PRTR Regulation) which implements the EU obligations under the UNECE Protocol on Pollutant Release and Transfer Registers[[2]](#footnote-2) to the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters.

The Protocol on Pollutant Release and Transfer Registers (PRTR Protocol) was signed in May 2003 in Kiev. On 8 October 2009, the PRTR Protocol entered into force. On 13 March 2015, it counted 38 signatories and 33 ratifications. PRTR Protocol requires parties to establish a register of information on releases of 91 substances to air, water and land and also on off-site waste transfers.

***PRTR Protocol implementation reports:***

PRTR Protocol national implementation reports are available in following link <http://www.unece.org/env/pp/prtr_reports_implementation_2014.html>.

* **Chemicals legislation**

According to the EU Regulation on public access to documents (“freedom of information”), every citizen or legal entity may request access to documents and information held by the European Chemicals Agency (ECHA). ECHA will provide this information unless it is covered by a specific exception foreseen in the law. If an exception applies, ECHA will grant partly access, if this is possible. Any decision by the Agency refusing the full access can be appealed. This is explained on a [specific page](http://echa.europa.eu/web/guest/about-us/the-way-we-work/procedures-and-policies/access-to-documents)[[3]](#footnote-3) on the ECHA website.

In addition, ECHA has the duty to proactively disseminate a substantial body of information on chemicals on the Internet in line with the four pieces of EU chemicals legislation under its responsibility, as tabulated below.

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| **REACH (Regulation No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals)** | **Articles** |
| ECHA to make information on substances publicly available over the internet, free of charge  Brief Profiles of hazardous properties, labelling requirements and Community legislation available to citizens | 77(2)(e) 123, 118 & 119  *Recital 117* |
| **Biocidal  products (BPR)** |  |
| ECHA to make publicly and easily available, free of charge, information on active substances, biocidal products, and non-confidential parts of assessment reports | 66, 67 & 76  *Recital 61* |
| **Classification, Labelling & Packaging (CLP)** |  |
| ECHA to make publicly accessible the C&L inventory | 42 |
| **Export & Import of Hazardous chemicals (PIC)** |  |
| ECHA to make publicly available on its website the database on export and import of hazardous chemicals | 6 |

Moreover, art. 123 of Regulation (EC) No 1907/2006 (REACH) foresees that “the competent authorities of the Member States shall inform the general public about the risk arising from substances where this is considered necessary for the protection of human health or the environment”.

The obligation to ensure the right of access to information is also included in other EU legal acts (e.g. Directive 2010/75/EU on industrial emissions, Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances and Directive 2011/92/EU on the assessment of the effects of certain public and private projects on the environment).

1. ***Please provide, in detail, the scope and characteristics of hazardous substances and wastes-related information that is or may be accessible to the public? More specifically, please explain what type(s) of information is produced, by whom, based on what criteria, and the time frame/frequency of data production including whether data collected is disaggregated by gender, age, disability status, etc.***

* ***Chemicals:***

Sharing information is key to safe use of chemicals from manufacturing down to consumer use. The tool used to reinforce public’s trust and make industry’s efforts towards compliant risk management visible for the public is dissemination. Dissemination brings also efficiency in the global context: as authorities, industry and the general public worldwide have access to information.

Companies in the EU have the responsibility of collecting information on the properties and the uses of substances that they manufacture or import at or above one tonne per year. They also have to make an assessment of the hazards and potential risks presented by the substance and submit this data to the European Chemicals Agency (ECHA) in a registration dossier (REACH Article 10). Under REACH they have also the obligation to update their registration without undue delay when relevant new information is available (Article 22). ECHA compiles data from all registrations for a substance and publishes non-confidential information on its dissemination portal. This data can be consulted free of charge but it cannot be used for regulatory purposes without data owners’ permission. For further information please see the [legal notice](http://echa.europa.eu/en/web/guest/legal-notice).[[4]](#footnote-4) ECHA publishes also information on chemicals in line with the CLP, Biocides and PIC Regulations.

Confidential information is filtered out of data provided by industry before the dissemination takes place.

REACH established the setting up of a [candidate list](http://echa.europa.eu/web/guest/candidate-list-table) of "substances of very high concern", to which substances are being added regularly. A substance of very high concern can be carcinogenic, mutagenic, toxic for reproduction, persistent, bioaccumulative and toxic in the environment). The candidate list signals to industry that these substances will eventually be phased out of the market, and intends to encourage companies to look for safer alternatives.

Consumers can play an active role in the process by taking an interest in the safety of the products they buy. Therefore REACH introduced in article 33 the "consumer right to know". Companies are obliged to answer a consumer inquiry about the presence of a substance of very high concern in an article, within 45 days.

Information for consumer’s access is on the ECHA data base - <http://www.echa.europa.eu/web/guest/information-on-chemicals>.

* **E-PRTR:**

The European Pollutant Release and Transfer register[[5]](#footnote-5) contains data reported annually since 2007 by more than 30,000 industrial facilities covering 65 economic activities across Europe. For each facility information is provided concerning the amounts of pollutant releases (91 key pollutants including classic air pollutants, heavy metals, greenhouse gases, pesticides and dioxins) to air, water and land as well as off-site transfers of waste and of pollutants in waste water. Information has to be made available by operators if certain thresholds (capacity, amounts of pollutants/waste) are exceeded.

There are also available links to national PRTR registers - <http://prtr.ec.europa.eu/pgLinksNationalRegisters.aspx>.

1. ***Please explain, in detail, how the information on hazardous substances and wastes is made available to the general public. In addition, what actions does the Government take to disseminate this information and to raise awareness about the adverse impacts of hazardous substances and wastes on human rights? How is this information tailored to the different constituencies?***

* ***Directive 2003/4****/****EC******on public access to environmental information***

The Aarhus Convention and EU Directive 2003/4/EC state that the public administrations must make available two "types" of public information channels to allow everyone easy access to all information and official documents concerning the environment.

* Firstly, administrations must respond to any requests made. This is known as "passive" information.
* Secondly, in addition to this, they must provide a certain amount of basic essential public information, preferably using electronic means (for example through websites). This is called "active" information.

"Active information" does not mean actively giving out all the information held by the public authorities, but rather information considered to be essential for the public, namely:

* basic information for understanding the phenomena and measures implemented (texts of international treaties and conventions, federal, regional and local legislation, policies, plans and programmes, implementation and follow-up reports, data or summaries of data collected, etc.)
* in addition to this, any necessary information that may be required in the event of an imminent threat to the environment or human health, to allow the public to take measures to prevent or limit the damage linked to a particular threat.
* ***Chemicals:***

All information published or disseminated by the European Chemicals Agency (ECHA) is available on the ECHA’s website which is a unique source of information on chemicals manufactured and imported in Europe. The public version of information in ECHA’s databases covers a wealth of information regarding chemical substances including their hazardous properties, classification and labelling, and information on how to use them safely. This information is a valuable resource for advancing the safe use of chemicals and for the replacement of the most hazardous ones by safer alternatives. The information disseminated under REACH, CLP, BPR and PIC can be easily accessed via the “Information on Chemicals” section on the [ECHA website](http://echa.europa.eu/information-on-chemicals).[[6]](#footnote-6) Furthermore ECHA dissemination website continues to contribute to the information accessible via OECD eChemPortal.

**REACH and CLP Regulations**

In addition, ECHA publishes information on chemicals undergoing regulatory processes at EU level - inclusion of substances in the authorisation (REACH), restriction (REACH) and harmonised classification and labelling (CLP) - processes. This information can be accessed via the “Addressing Chemicals of Concern” section of the [ECHA website](http://echa.europa.eu/addressing-chemicals-of-concern). Information is available for example on:

* ECHA’s Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) opinions on proposals for Restriction of substances and Applications for Authorisation;
* RAC opinions on proposals for harmonised classification and labelling;
* Support documents for the identification of Substances of Very High Concern (REACH Article 57)
* Substances of potential concern that may require risk management.

**Biocidal Product Regulation**

The Biocidal Products Regulation (BPR) requires ECHA to disseminate information on approved biocidal active substances and on approved national and European biocidal product authorisations. Information is disseminated on the [active substances](http://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances) and the [biocidal products](file:///C:/Users/EP/Downloads/:%20http:/echa.europa.eu/web/guest/information-on-chemicals/biocidal-products).

Information that needs to be disseminated concern for example for active substances results of toxicological and ecotoxicological studies, acceptable exposure levels or predicted no-effect concentrations. For biocidal products the summaries of the biocidal product characteristics need to be provided, the trade names and the assessment report.

ECHA publishes also the list of active [substance suppliers](http://echa.europa.eu/web/guest/information-on-chemicals/active-substance-suppliers) as required by the legislation to ensure equal treatment of persons placing active substances on the market.

Due to the transition of implementing the Biocidal Product Regulation the accessibility of the information will be improved and in 2016 information will be added specifically on biocidal products.

**Prior Informed Consent Regulation**

The PIC Regulation[[7]](#footnote-7) places obligations on ECHA to make certain information publicly available on its website. In order to comply with this obligation, ECHA has essentially made the same information available as was previously published by the JRC via the dedicated EDEXIM website and, additionally, has provided more advanced search functionality which means that the data are more easily accessible.

**News**

It is worth noting that all information ECHA publishes is available free of charge. The Agency publishes also news and a weekly e-News to inform its stakeholders on any significant development regarding its work. Currently there are over 17,000 e-News subscribers globally.

* ***E-PRTR***

Information is made available on a publicly accessible website (<http://prtr.ec.europa.eu>).

On average around 600 people visit the E-PRTR website per day. The annual reporting is usually accompanied by press releases. Furthermore, there are a wide range of users disseminating information of the E-PRTR, e.g. by scientific reports etc.

1. ***Please provide examples of how information on hazardous substances and wastes has***

***been used to:***

* ***monitor human rights affected by hazardous substances and wastes (e.g., rights to health, safe and healthy working conditions, water and sanitation, healthy environment, etc.);***
* ***protect the human rights of individuals and groups from the adverse impacts of hazardous substances and wastes;***
* ***promote other human rights (e.g., rights to health, safe and healthy working conditions, water and sanitation, healthy environment, etc.);***
* ***prevent potential human rights violations caused by the improper management of hazardous substances and wastes; and***
* ***hold perpetrators accountable and seek remedy for victims.***
* ***E-PRTR***

The role of the European Commission has been to establish and maintain the E-PRTR. There may be many ways in which the information contained in the E-PRTR can be used in practical terms. The fact that this type of information is made publicly available should lead to increased awareness and decreased impacts on the environment and human health. The European Commission does not hold details on how the information of the E-PRTR has been used in single cases.

* ***Chemicals***

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| Rights to health, safe and healthy working conditions, water and sanitation, healthy environment, etc.); | Regulatory authorities and industry in the EU as well as in other regulatory areas (e.g. Australia and Canada) use data published by ECHA when they carry out assessment of chemicals. The general public may access the data e.g. to better understand the properties of a particular chemical. |
| Prevent potential human rights violations caused by the improper management of hazardous substances and wastes; | The PIC Regulation that implements the Rotterdam Convention promotes shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm; and to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. |

1. ***Which businesses are required to provide information on hazardous substances and wastes (e.g., size, sector, operational context, ownership and structure)? Please explain, in detail, the obligations of these businesses, have with regard to the type of information they are obliged to provide, to whom the information is made available, and what measures may be taken if businesses fail to meet these obligations.***

* ***E-PRTR***

The register contains annual data covering installations operating in the following industrial sectors: energy; production and processing of metals; mineral industry; chemical industry; waste and waste water management; paper and wood production and processing; intensive livestock production and aquaculture; animal and vegetable products from the food and beverage sector and some other activities. The information as described in reply to question 2 has to be reported by the operators of the facilities to the competent authorities (CAs). The CAs check the quality and completeness of the information and pass the information on to the European Environment Agency. In order to ensure compliance with the E-PRTR Regulation, Member States have to lay down rules on penalties which are effective, proportionate and dissuasive.

* ***Chemicals***

***REACH***

The REACH Regulation (EC) No 1907/2006 is the EU legislation on Registration, Evaluation, Authorisation and Restriction of chemical substances under which companies have the responsibility of collecting information on the properties and the uses of substances that they manufacture or import at or above one tonne per year. They also have to make an assessment of the hazards and potential risks presented by the substance.

This information is communicated to ECHA through a registration dossier containing the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled.

Registration applies to substances on their own, substances in mixtures and certain cases of substances in articles. Chemical substances that are already regulated by other legislations such as medicines, or radioactive substances are partially or completely exempted from REACH requirements.

Registration is based on the "one substance, one registration" principle. This means that manufacturers and importers of the same substance have the obligation to submit their registration jointly. The analytical and spectral information provided should be consistent and sufficient to confirm the substance identity.

The enforcement of legislation in the EU is the sole responsibility of the Member States and the infringement penalties are defined at national level. The [Forum](http://echa.europa.eu/web/guest/about-us/who-we-are/enforcement-forum)[[8]](#footnote-8)for Exchange of Information on Enforcement within the Agency coordinates that for example spread good practice and highlights problems at Community level and proposes, coordinate and evaluate harmonised enforcement projects and joint inspections.

***CLP Regulation***

The CLP Regulation (EC) No 1272/2008 is the new EU legislation on Classification, Labelling and Packaging of substances and mixtures. It integrates the classification criteria of the United Nations Globally Harmonised System (GHS) into EU law. The CLP Regulation stipulates that all substances must be classified and labelled according to the CLP criteria from 1 December 2010 onwards and that all mixtures must be classified and labelled according to the CLP criteria from 1 June 2015. Detailed information on the requirements is available in the [CLP section](http://echa.europa.eu/web/guest/regulations/clp)[[9]](#footnote-9) of the ECHA website.

The CLP Regulation ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. Before placing chemicals on the market, the industry must establish the potential risks to human health and the environment of such substances and mixtures, classifying them in line with the identified hazards. The hazardous chemicals also have to be labelled according to a standardised system so that workers and consumers know about their effects before they handle them.

Articles 39 to 42 of the CLP Regulation deal with notification to the Classification and Labelling Inventory maintained by ECHA. In general, notification under the CLP Regulation means that manufacturers and importers submit certain classification and labelling information of substances they are placing on the market to the Classification & Labelling Inventory held by ECHA (see Chapter 3 for practical details). The Inventory is a new database. Notification under the CLP Regulation applies to all hazardous substances of all tonnages and also to all non-hazardous substances subject to registration under REACH whenever they are placed on the market in the EU. Notification under the CLP Regulation is due within six months of placing the substance on the market.

Information submitted in notifications is collected in a database called the Classification & Labelling Inventory. The database also contains information from REACH registration dossiers and on substances having a harmonised classification and labelling, i.e. the substances listed in Part 3 of Annex VI to the CLP Regulation. Some information from the notifications is made available in the Public Classification and Labelling Inventory. The Public Classification and Labelling Inventory is a central source of information on the classification and labelling of substances for all users of chemicals.

The public version of the Classification and Labelling Inventory includes substance identifiers referred to in Article 119(1) of the REACH Regulation, the classification and labelling elements and any relevant specific concentration limit (SCL) or multiplying factor (M-factor) for each substance.

**Biocidal Product Regulation**

The Biocidal Product Regulation (EU) No 528/2012 concerns the placing on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms, like pests or bacteria, by the action of the active substances contained in the biocidal product. Detailed information is available in the [Biocide Section](http://echa.europa.eu/regulations/biocidal-products-regulation) of the ECHA website.

Active substances need to be approved before an authorisation for a biocidal product containing them can be granted. The active substances are first assessed by an evaluating Member State competent authority and the results of these evaluations are forwarded to ECHA's Biocidal Products Committee, which prepares an opinion within 270 days. The opinion serves as the basis for the decision on approval which is adopted by the European Commission. The approval of an active substance is granted for a defined number of years, not exceeding 10 years and is renewable.

After approval of the active substances all biocidal products that include these substances are subject to an authorization procedure at a national level. Some products may also be authorized at the EU level.

**Prior Informed Consent Regulation**

The Prior Informed Consent Regulation (EU) No 649/2012 administers the import and export of certain hazardous chemicals and places obligations on companies who wish to export these chemicals to non-EU countries. It implements, within the European Union, the Rotterdam Convention on prior informed consent procedure for certain hazardous chemicals and pesticides in international trade. Detailed information is available in the [PIC section](http://echa.europa.eu/regulations/prior-informed-consent-regulation)[[10]](#footnote-10) of the ECHA website.

Exporters based in an EU Member State have to notify their intentions to export certain chemicals to a non-EU country. This applies to the chemicals listed in Annex I to the PIC Regulation. Exporters have to notify the designated national authority of the country from which the export will originate before the first yearly export takes place, as well as before the first export in each subsequent calendar year.

Each export notification is assigned a unique identifier, called a reference identification number. This is used, for example, to facilitate customs control of the exports of chemicals listed in Annex I.

1. ***When does the Government limit the right of access to information on hazardous substances and wastes? Are these criteria on limitation provided by law? Who has the authority to make decisions on the disclosure/non-disclosure of such information?***

* ***Directive 2003/4****/****EC******on public access to environmental information***

As a matter of principle, information is to be provided but this constitutional rule is not absolute: there are certain limits to this transparency.

The Convention, the Directive and the internal regulations envisage certain exceptions to limit the right of access to information. They include, in general, the following:

* a request that is too general or abusive may be refused, but the public authority must first invite the applicant to clarify their request.
* other requests could concern more delicate matters, such as international relations, national security, confidentiality of public procedures, commercial secrecy covered by law, personal data, or may refer to documents still being drafted, or incomplete, or to internal communications. These do not have to be communicated. It will then be up to the administrations to weigh up the interests on a case-by-case basis to assess what best serves the public interest, and only refuse to give out certain information when the public interest would best be served by maintaining confidentiality.
* information concerning the exercise of judicial and legislative powers is considered to be outside the scope of the Convention.
* whenever information is refused, the applicant must be given a reason why.
* the procedure to be followed when the public authority does not have the requested information. If it knows that the requested information is held by another public authority, it will either send on the request to that other public authority and inform the applicant, or it will refer the applicant directly to the other public authority.
* ***Chemicals:***

The dissemination on information on chemical substances is carried out in line with the regulatory requirements in REACH, CLP, BPR and PIC. For details on access to information please refer to Art. 118 of the REACH:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20140822>

* ***E-PRTR***

The European Commission does not limit the right of access to information contained in the E-PRTR but Member States have the possibility to withhold certain information deemed confidential, subject to explaining the reasons for doing so, in line with the exceptions that are foreseen under the Aarhus Convention and its PRTR Protocol.

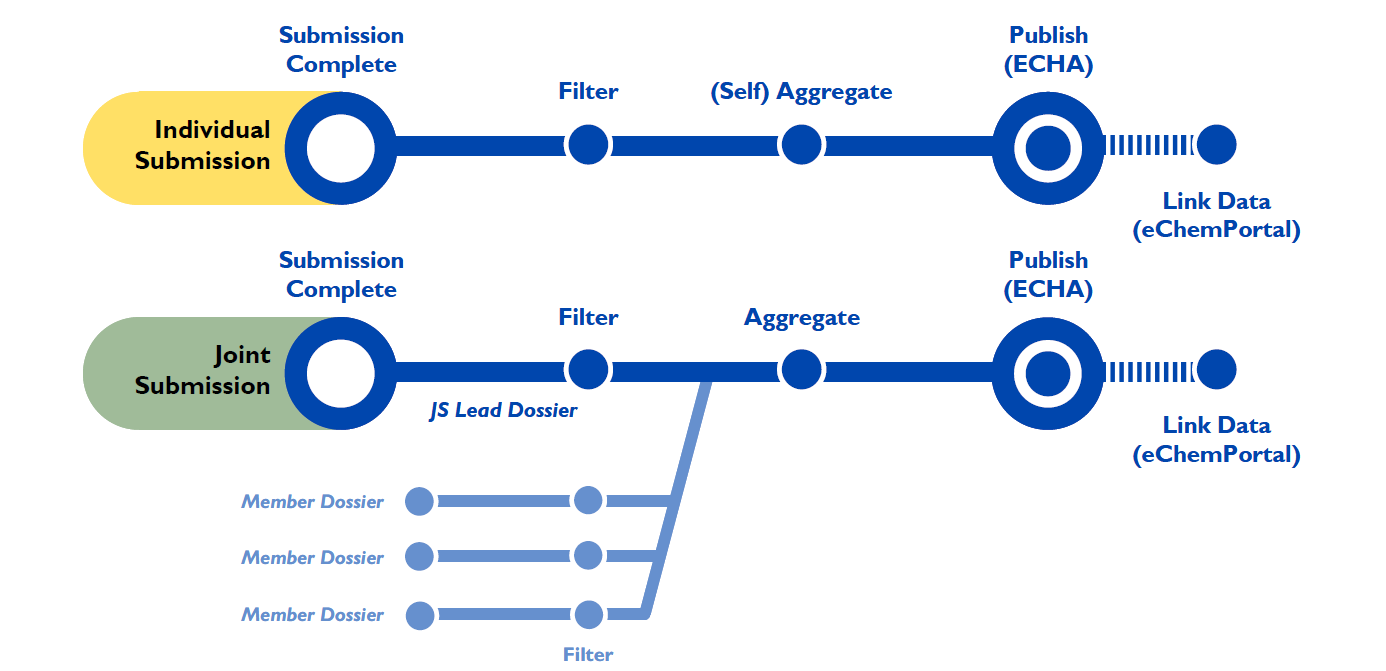
1. ***How does the Government ensure that the right of access to this information is fulfilled while also respecting the confidentiality of business information? If available, please indicate relevant cases and attach copies of relevant judgements.***

* ***Chemicals:***

***REACH***

Under REACH, data from registration dossiers is grouped in three categories: (i) always published, (ii) by default not published, and (iii) information for which registrant may make a confidentiality claim.

For detailed information, please refer to ECHA’s Data submission manual 15: Dissemination.[[11]](#footnote-11)



In broad terms, information not disclosed includes details of the full composition of the substance, its precise use and precise tonnage, as well as the links between manufacturers and their downstream users.

Information for which confidentiality can be requested (under certain conditions and duly justified) includes degree of purity of the substance, IUPAC name for hazardous non-phase-in substances (6 years confidentiality), IUPAC name for hazardous intermediates and R&D substances, trade names, study summaries or robust study summaries, total tonnage band under which the substance has been registered and other information in the SDS such as company name, uses and uses advised against, PBT assessment and whether a CSA was performed.

Information always disseminated (REACH Article 119 (1) includes: IUPAC name for Hazardous substances (exceptions possible), EINECS name, C&L, phys-chem data, pathways and fate, result of each toxicological / ecotoxicological study, DNEL’s, PNEC’s and guidance on safe use.

ECHA validates all confidentiality claims. According to the Data Submission Manual 16: How to write justifications for confidentiality claims, ECHA only accepts confidentiality claims when they fulfil the following criteria:

* The information must not yet be publicly known (this is demonstrated by a corresponding declaration made by the registrant in the justification)
* The registrant must plausibly explain what the commercial interest at stake is and this must be a legitimate commercial interest (“worthy of protection”).
* The registrant must plausibly explain how the commercial interest would be harmed by the disclosure.

The practical checks are carried out by ECHA to ascertain that the justification meets the requirements and can be accepted as valid are the following:

* ECHA double-checks whether the information claimed confidential is not yet in the public domain (i.e. by googling a non-confidential substance name or trade name)
* ECHA reads the justification and ascertains whether the registrant has indeed a legitimate commercial interest and would suffer harm by the disclosure. Some plausibility checks of statements made are also carried out (e.g. if the registrants claims so, whether a third party representative was really appointed). In practice, it can be observed that for specific types of claims, the same lines of argumentation are frequently repeated and thus need to be treated in the same manner.

Should both checks have a positive result (i.e. not in public domain and justification plausible and legitimate) ECHA accepts the confidentiality request.

Should one of the checks return a negative result (e.g. information found in public domain), ECHA gives the registrant one more chance to update the justification (“update request”) and to come back with an explanation. This allows clarification of eventual misunderstanding. If the registrant fails to come back with a satisfactory update of the justification within 2 months, ECHA will reject the claim.

For tests on the registered substances the REACH regulation defines that ECHA receives robust study summaries and not full study reports. The early years of REACH have demonstrated that companies make only low number of confidentiality claims (a fee is levied) and these are mainly on new substances. Therefore, around 98% of all information the legislation would allow to be disseminated is published. Published information on a registered substance does not include Chemical Safety Report (CSR). However, certain information usually contained in the CSR is published. If companies would like to protect the name of the substance that is possible. The rules are explained in Data Submission Manual 17: How to derive a Public Name for a substance for use under REACH Regulation. If confidentiality is requested on the robust study summary, and the request is accepted, then a minimum set of data is published (so-called results).

**Classification, Labelling and Packaging Regulation**

The public version of the Classification and Labelling Inventory does not include the identity of the notifier. The same applies to the IUPAC name of certain substances where a corresponding confidentiality flag has been set.

**Biocidal Product Regulation**

The information to be disseminated on the active substances and the biocidal products are specified in the Article 66 “Confidentiality” and Article 67 “Electronic public access” of the Biocidal Product Regulation.

**Links**

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| **Information on Chemicals** | <http://echa.europa.eu/information-on-chemicals> |
| **Registered substances** | <http://echa.europa.eu/information-on-chemicals/registered-substances> |
| **How ECHA publishes information from dossiers** | <http://echa.europa.eu/regulations/reach/substance-registration/publishing-information-from-dossiers> |
| **Data submission manual 15: Dissemination** | <http://echa.europa.eu/documents/10162/13653/dsm_15_dissemination_manual_en.pdf> |
| **Data Submission Manual 16: Confidentiality Claims** | <http://echa.europa.eu/documents/10162/13653/dsm_16_confidentiality_claims_en.pdf> |
| **Data Submission Manual 17: How to derive a Public Name for a substance for use under the REACH Regulation** - | <http://echa.europa.eu/documents/10162/13653/dsm17_public_name_en.pdf> |
| **Classification and labelling inventory** | <http://echa.europa.eu/information-on-chemicals/cl-inventory-database> |
| **SVHC Roadmap to 2020** | <http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern> |

* ***E-PRTR***

In accordance with Article 4 of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and with Article 11 of the E-PRTR Regulation, Member States have to indicate separately for each industrial facility the type of information that has been withheld for reasons of confidentiality and explain these reasons.

1. Regulation (EC) 166/2006 – at <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1424874948964&uri=CELEX:32006R0166> . [↑](#footnote-ref-1)
2. At <http://www.unece.org/env/pp/prtr/docs/prtrtext.html> [↑](#footnote-ref-2)
3. <http://echa.europa.eu/web/guest/about-us/the-way-we-work/procedures-and-policies/access-to-documents> [↑](#footnote-ref-3)
4. <http://echa.europa.eu/en/web/guest/legal-notice> [↑](#footnote-ref-4)
5. At <http://prtr.ec.europa.eu/> . [↑](#footnote-ref-5)
6. <http://echa.europa.eu/information-on-chemicals> [↑](#footnote-ref-6)
7. This Regulation incorporates the requirements of the Rotterdam Convention. [↑](#footnote-ref-7)
8. <http://echa.europa.eu/web/guest/about-us/who-we-are/enforcement-forum> [↑](#footnote-ref-8)
9. <http://echa.europa.eu/web/guest/regulations/clp> [↑](#footnote-ref-9)
10. <http://echa.europa.eu/regulations/prior-informed-consent-regulation> [↑](#footnote-ref-10)
11. <http://echa.europa.eu/documents/10162/13653/dsm_15_dissemination_manual_en.pdf> [↑](#footnote-ref-11)