

Guidance on national chemicals control

**Access to information on primary suppliers
and chemicals on the market**

GUIDANCE 1/19



The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

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Preface

Chemicals contribute in many ways to improving our standard of living, but some of them are hazardous and can have serious adverse effects on human health and the environment. It is therefore necessary to use different means to protect human health and the environment from adverse effects emanating from exposure to hazardous chemicals.

This guidance, is part of a series of guidance documents developed by the Swedish Chemicals Agency. The series forms a complement to the UNEP Guidance on the Development of Legal and Institutional Infrastructures and Measures for Recovering Costs of National Administration (LIRA guidance) by giving more detailed guidance in different areas. This guidance document gives further guidance on how to find information on which the primary suppliers of chemicals are in a country and which chemicals they place on the market.

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Summary

The aim of the present document is to give guidance to countries (governments and authorities) in their efforts to set up an efficient system for the sound management of chemicals with a special focus on how to find information on companies producing and/or importing chemicals on the domestic market as well as identifying those chemicals.

In setting up systems for chemicals management and in developing and implementing legislation on chemicals placed on the market, there are a number of tasks that are to be carried out by the government or its authorities that benefit from knowledge on which producers and importers, i.e. primary suppliers, are active on the market and which chemicals these companies produce or import. This information is needed, for instance, in the development, implementation, and enforcement of legislation and in giving targeted information to companies as well as for possible systems for cost recovery. This document gives guidance to governments on how to obtain such information.

Because resources for chemicals control can be rather limited and finding data can be very resource-demanding, it is very important to be clear on the purpose of searching for such data not to take on a workload that is out of proportion to the actual needs. Further, the needs must be defined regarding the kind of information to be collected, how often it needs to be updated, its coverage, and the responsibility for the completeness and correctness of the information.

There are different ways in acquiring necessary information on companies in countries as well as on the chemicals they place on the market, and some different methods are discussed. Some are only useful for finding companies and some for finding chemicals, whereas some are useful for both.

When planning the information gathering, a first step can be to explore if other authorities, such as environmental and health authorities, poisons centres, or customs have information that can be used as a starting point for identifying companies and chemicals. Contacts with regional and local authorities as well as with trade organisations might also be helpful. Other sources are publications and advertisements from companies, openly available literature and information from other countries. One simple way to find out the occurrence of a limited number of chemicals could be to send a questionnaire asking companies, once their identities are known, to send information on the chemicals they produce or import.

If these methods will not fulfil the needs of the authority for chemicals control and it is deemed that more comprehensive information is needed, mandatory reporting from companies can be considered, either once to create an inventory or on a regular basis to form a regularly updated register. A decision that an authority should require information on companies and the chemicals they produce or import needs to be reflected in relevant legislation, i.e. a clear mandate should be given to the authority to collect such information as well as to keep it in an ordered way. There is also a need for legislation to make it clear to companies what they need to report, how, and when.

The result of the collection of information on companies and chemicals normally generates quite an extensive amount of data. To be able use the obtained information for different purposes, a structured system for storing the data is required. When deciding how to structure the collected information, it is important to consider the scope of the data collected at present and if it is planned to expand the scope in the future, the type of information that should be possible to extract from the collected data, and how often data extraction is needed. The more data that are gathered, the greater the demands on the structure will be.

Depending on the needs, the choice of technical solution for structuring the collected data might vary considerably, ranging from simple lists of names and addresses of companies to complex computerized systems with extensive information and data on both companies and the chemicals they produce and/or import. The way to collect and structure the incoming information and how comprehensive the information is will affect the levels of resources needed, both during the set-up phase and for long-term maintenance.

The collected information might also be useful for other functions of the government. The primary users are of course the authorities responsible for chemicals control, but the information could also be of use for other authorities such as poison centres, environmental and health authorities, customs, and the authority responsible for national statistics.

Definitions and acronyms

Chemicals (or chemical products) are usually defined and understood as chemical **substances** and **mixtures** of chemical substances.

Many chemical products are incorporated in finished products, or **articles**. Examples could be painted and lacquered furniture, polymers and metals in electric and electronic products, dyes in textiles, flame retardants and plasticizers in plastic products etc. Articles may pose a risk due to their chemical contents. In some countries specific substances have been regulated in specific groups of articles, but in general they are to a large extent unregulated with regards to their chemical contents.

GHS uses the following definitions of substance and mixture:

Substance means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities derived from the process used, but excluding any solvent, which may be separated without affecting the stability of the substance or changing its composition.

Mixture means a mixture or solution composed of two or more substances in which they do not react.

The following definition of article is used in the EU Reach regulation:

Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

In this guidance, the following additional definitions are used¹:

Placing on the market means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.

Producer means any natural or legal person producing chemicals.

Importer means any natural or legal person responsible for import, i.e. the physical introduction of chemicals into the territory of the country.

Primary supplier means producers and importers of substances and mixtures.

Retailer means any natural or legal person in the country who only stores and places on the market a chemical for third parties.

Downstream user means any natural or legal person who uses a substance, either on its own or in a mixture, in the course of his or her industrial or professional activities.

Transporter means any natural or legal person who facilitates the physical transfer of products, whether on land, sea, or by air. Loading, unloading, storage, and other handling as part of the transfer are also included.

¹ Similar definitions are used in the EU Reach regulation

Acronym	Explanation
CAS	Chemical Abstracts Service. A CAS number, is a registration number for chemicals. It functions as an international identification number for chemical substances.
CBI	Confidential Business Information
CLP	EU Regulation on Classification and Labelling of Substances and Mixtures (No. 1272/2008)
CMR	Carcinogenic, mutagenic and reprotoxic substances,
ECHA	European Chemicals Agency
EU	European Union
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HS	The Harmonized Commodity Description and Coding System
ISIC	International Standard Industrial Classification of All Economic Activities
IUPAC	International Union of Pure and Applied Chemistry is the recognized world authority in developing standards for the naming of the chemical elements and compounds
OECD	Organisation for Economic Co-operation and Development
PBT, vPvB	Persistent, Bioaccumulating and Toxic, very Persistent and very Bioaccumulating
PRTR	Pollutant Release and Transfer Register
REACH	EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (No. 1907/2006)
UN	United Nations
UNEP	United Nations Environment Programme (UN Environment)
WCO	World Customs Organization
WHO	World Health Organization

1 Introduction and scope

In order to achieve the international goal of sound management of chemicals and several of the Sustainable Development Goals adopted by the UN in 2015, the establishment of national legal frameworks and related institutional infrastructure is essential. There are numerous chemicals produced, sold, and used in every society, and these need to be handled as safely as possible in order to avoid harm to humans and the environment. There are a number of positive effects for society from improved chemicals management, and as reported by UN Environment² the costs due to the mismanagement of chemicals can be very substantial. This guidance is aimed for countries that develop national chemicals management according to principles in LIRA³ and the Swedish Chemicals Agency's Guidance documents on national chemicals control for other countries⁴. In setting up systems for chemicals management, basic or more advanced information will be needed on who the producers and importers, i.e. the primary suppliers, of chemicals are and what chemicals they place on the national market. This document gives guidance to governments on how to get such information.

Concerning information on the chemicals, this guidance focuses on information on the occurrence on the market and the intended usages of chemicals, information that can be used, e.g. in an exposure assessment. The guide does not cover gathering data on the intrinsic properties (the health and environmental hazards) of substances. This information can many times be found in internationally available sources such as the databases at the European Chemicals Agency (ECHA)⁵ and the OECD Global portal to information on chemicals, the eChemPortal⁶, with an exception for substances that are only produced nationally and for which countries need to consider the introduction of registration of the intrinsic properties on a national basis.

1.1 Substances, mixtures, and articles

A chemical substance can be placed on the market in a country as such, in a mixture, or incorporated in an article. To get a picture of the occurrence of a substance in a country, this needs to be taken into account. Searching for information on the occurrence of a substance placed on the market only by looking at the pure substance would be very narrow and have limited effect because most substances placed on the market are parts of mixtures. Therefore, it is advisable to cover both pure substances and mixtures.

This guidance will primarily focus on the government's overview of substances as such and in mixtures and the companies placing them on the market.

To get the full picture of substances occurring on the market in a country, especially when risks emanating from them need to be reduced, substances in articles also need to be taken into account to a certain extent. Given the great number of articles on the market, it is a

² UNEP Cost of Inaction Report <https://www.unenvironment.org/resources/report/costs-inaction-initiative>

³ UNEP Guidance on the Development of Legal and Institutional Infrastructures and Measures for Recovering Costs of National Administration, 2015 <https://www.unenvironment.org/resources/report/lira-guidance>

⁴ See the series of guidance documents at <https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries>

⁵ ECHA Information on Chemicals https://echa.europa.eu/information-on-chemicals/registered-substances?p_p_id=dissregisteredsubstances_WAR_dissregsubportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&dissregisteredsubstances_WAR_dissregsubportlet_javax.portlet.action=dissRegisteredSubstancesAction and <https://echa.europa.eu/regulations/clp/cl-inventory>.

⁶ eChemPortal <https://www.echemportal.org/echemportal/index.action>

difficult and resource-demanding task to get detailed knowledge about the use of chemicals in articles. Such information therefore normally needs to be sought on a case-by case basis. For further discussion, see section 4.5.

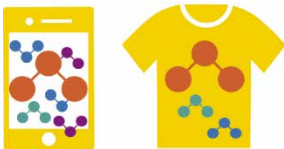
		
Substance	Mixture	Article
For example, citric acid or pentachlorophenol	For example, a can containing paint	For example, a mobile phone or a T-shirt

Figure 1 A substance can be used as such, in a mixture, or in an article.

1.2 Producers and importers

This guidance covers the primary supplies of chemicals, e.g. producers and importers of substances and mixtures. A producer of substances produces pure substances. An importer of substances imports pure substances. A producer of a mixture might import substances or buy them on the domestic market and then produce chemical mixtures that are placed on the market. An importer of mixtures import mixtures of substances. The substances and mixtures can be used by producers of articles or used as such by the end-users.

When trying to get knowledge on chemicals appearing on the market, it is advisable to concentrate on the companies that produce and/or import the chemicals as the number of companies are much fewer than the users further down in the supply chain. When it comes to import, focusing on the importer as the legal entity having the responsibility for the import also makes it possible to get aggregated information on the number and volumes of chemicals imported by that entity over a period of time, for example one year. This is much less resource-demanding than requiring reporting on each batch passing the border. See also chapter 3 in the Swedish Chemicals Agency Guidance 4/18 Enforcement of legislation on chemicals placed on the market.

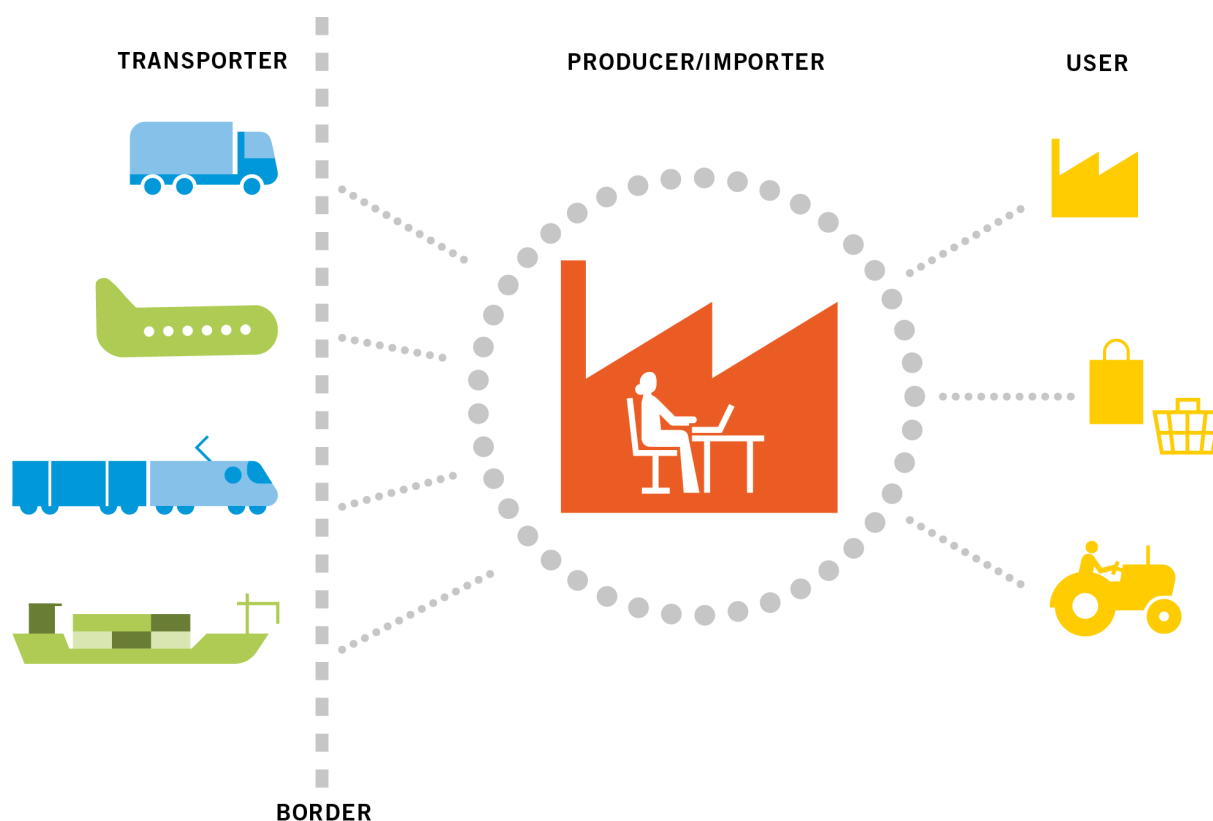


Figure 2. The legal entities producing and importing chemicals are normally much fewer than the shipments over the border and the users of the chemicals.

1.3 Structure of the guidance document

In chapter 2 some different situations are described in which information on primary suppliers and the chemicals they place on the market is needed or beneficial. Because it can be very resource-demanding and costly to gather comprehensive information on the occurrence of chemicals on the market, it is necessary to be very clear regarding the purpose of collecting such information. In chapter 3 more reasoning on defining the actual needs of a country is given. In chapter 4 various methods for gathering information is presented, and in chapter 5 ways to organise the information is discussed. Chapter 6 describes how the information gathered also can be of use for other actors.

2 Information on importers, producers, and chemicals is a key element for chemicals control

National chemicals legislation as described in the LIRA guidance⁷ and in the Swedish Chemicals Agency Guidance 3/18 on Legislation on chemicals placed on the market⁸ lays specific responsibilities on producers and importers of chemicals to ensure a sound chemicals

⁷ UNEP Guidance on the Development of Legal and Institutional Infrastructures and Measures for Recovering Costs of National Administration, 2015 <https://www.unenvironment.org/resources/report/lira-guidance>

⁸ <https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries>

management, and the main role for the government is to ensure that they fulfil their obligations. When developing and implementing such legislation, there are a number of tasks that are to be carried out by the government and/or its authorities that benefit from knowledge on which companies are active on the market and which chemicals these companies produce or import. This information is needed for instance in the development, implementation, and enforcement of legislation and for giving targeted information to companies.

This chapter gives examples on when and how information on producers and importers of chemicals and on the chemicals they place on the market is needed.

2.1 Development of new legislation

When developing new legislation, a transparent process with possibilities for companies to engage in the process makes it easier for them to understand and comply with the legislation. Compliance with the legislation normally increases if companies have been consulted in the process of its development. Because primary suppliers, producers and importers of chemicals to the market have a key role in the national legislation, it is advisable to try to reach out to these actors already when forming the primary law so that they can contribute with their viewpoints. Sometimes the primary suppliers are organised in a way that allows the government to invite comments by contacting their sector organisations. Consultation processes could also take place on the Internet, allowing everyone who so wishes to take part in the consultation.

Once the legislation is in place, well-established contact with the companies increases the chances of successful implementation of the legislation, because relevant guidance, tools etc., can be developed in dialogue with them and distributed in an efficient way.

It is also valuable to have continuous contact with companies after the primary legislation has been adopted in order to further develop subsequent legislation. For development of further relevant legislation, e.g. bans and restrictions to reduce risks, information on which chemicals are available on the market in the country and how they are used is normally of importance. Therefore, it might be necessary not only to collect information on which companies are placing chemicals on the market, but also to collect information from them on which chemicals they import or produce. Further, it might be necessary to get information on the volumes, intended uses, etc. The producers and importers are the ones who have specific knowledge on the chemicals they place on the market.

2.2 Implementing international conventions and agreements

For countries that have signed and ratified⁹ conventions, it is an obligation to implement the agreed decisions in their legislation. The legislation might need to be continuously updated due to new decisions in the conventions. The implementation needs to be carried out in a manner that is coherent with the aim of the agreement, such as introducing bans or restrictions on the production and use of specific chemicals. Examples of international conventions with such demands are the Stockholm Convention on Persistent Organic Pollutants, the Minamata Convention on Mercury, and the Montreal Protocol on Substances that Deplete the Ozone Layer.

In order to prepare national implementation plans, there is a need to know how the substances are used within the country. For countries that have ratified conventions related to the sound

⁹ Ratification means signing or giving formal consent to a treaty, contract, or agreement making it formally valid. In many countries, this requires the adoption of a legal act by the parliament.

management of chemicals or that take part in the work with voluntary agreements, country reporting is normally a requirement. From this point of view, it is also necessary to have good knowledge on the domestic market and the use of certain chemicals.

2.3 Prioritising chemicals for assessment

In addition to the obligations for implementing conventions after ratifying them, it is necessary for a country to consider the need for introducing further risk reduction measures for other chemicals not covered by the conventions but that nevertheless pose risks to human health or the environment on the national level.

Altogether, there is quite a high number of chemicals on the global market, and the chemical production capacity of 2.3 billion tonnes in 2017 is projected to double by 2030 according to UN Environment¹⁰. Countries need strategies for prioritising those chemicals that could cause the largest problems to human health and/or the environment. In the Swedish Chemicals Agency Guidance 2/18 on risk reduction of chemicals¹¹, various ways of prioritising are described. Prioritisation can be hazard based or risk based. Especially when prioritising chemicals based on potential risk, information about their occurrence is needed early in the process. When performing a risk assessment, it is necessary to have information both on the hazard of the substance (the intrinsic properties) and the potential exposure to the substance in the country because risk is a function of *hazard and exposure*. These parameters therefore also form the basis for the prioritisation.

The following information should be taken into account when setting the priorities:

- Degree of severe intrinsic properties
- Exposure
 - Volume of the substance produced and imported used as a proxy for potential exposure, and/or
 - use pattern (e.g. whether the product is likely to be used by a vulnerable part of the population such as children, pregnant women, illiterate persons, etc.), and/or
 - widespread and/or well-known exposure from, for example, monitoring studies or surveillance projects (this includes if there is a large number of producers and/or users or if the chemical is available to the general public).

The exposure parameter needs to be based on available data, and the simplest method is to base it on the volume of the substance on the market. If more refined data exist, this information should be added or used instead.

Prioritisation is normally a stepwise procedure and a broader group of substances might be prioritised based on basic information. For these, more refined data are searched for, and when more detailed data become available the prioritisation is gradually improved to finally target the substances with the greatest potential risks.

¹⁰ The Global Chemicals Outlook II – From Legacies to Innovative Solutions: Implementing the 2030 Agenda for Sustainable Development <https://www.unenvironment.org/resources/report/global-chemicals-outlook-ii-legacies-innovative-solutions>

¹¹ <https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries>

Adopting a national chemicals policy pointing to the types of substances that should be prioritised for action can support the subsequent legislative work of the government. For example, chemicals meeting chosen specific criteria could be subject to, or be candidates for, certain risk-management measures. Having access to relevant information on which substances are available on the domestic market and that are used in the country is necessary for identifying where substances meeting the chosen criteria can be found in order to be able to introduce relevant risk reduction measures.

2.4 Risk assessment

As mentioned in section 2.3, when performing a risk assessment, it is necessary to have information both on the hazard of the substance (the intrinsic properties) and the potential exposure to the substance in the country. Normally, the first step when carrying out a risk assessment of a substance is to assess the intrinsic properties of the substance – to make the hazard assessment. The intrinsic properties of any substance are always the same and thus available and reliable hazard data and assessments from other countries, organisations, and science can be used as the basis for the risk assessment. The exposure of the environment and the population to a substance might, however, vary from country to country. In cases where the use of a substance can be assumed to be very similar to the use in other countries, it might be relevant to make use of risk assessments that are available in order to save resources and time. On the other hand, if it is clear that the use pattern or the volume of the substance differs significantly, it is necessary to undertake a national risk assessment taking into account the national exposure¹². For assessing the exposure, information is needed on where and how a chemical is used. The more refined the data, the more refined the exposure assessment can be.

2.5 Risk reduction

When the result of a risk assessment shows that there is a need to reduce the exposure to a chemical in the environment or in humans, it is necessary for the government and/or its authorities to introduce one or more risk reduction measures. There are a number of different instruments that can be used. Risk reduction instruments can be administrative (e.g. bans and restrictions), economic and/or informative as described in Swedish Chemicals Agency Guidance 2/18 Risk reduction of chemicals¹³. When considering how to most effectively reduce the exposure and thus the risk of a chemical, it is necessary to look into where the highest exposure occurs and what is giving rise to this exposure.

When the hazard is very high measures might be taken without doing a full risk assessment. This can be the case, for example, for substances with persistent, bio-accumulating, and toxic properties (PBT) or very persistent and very bioaccumulating properties (vPvB) or substances that are carcinogenic, mutagenic, or toxic to reproduction (CMR). In such cases, the preferred risk reduction measure many times can be a total ban. However, for other substances risk assessments are needed before deciding on the risk reduction method.

Information on the producers and importers and the chemicals they place on the market is essential for all types of risk reduction measures. Both administrative and economic instruments must be based on legal requirements. Therefore, knowledge on which companies that will be affected is valuable to have beforehand in order to be able to invite them in

¹² Swedish Chemicals Agency, *Guidance on Hazard Assessment and Risk Assessment of Chemicals – an introduction*, (to be published)

¹³ <https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries>

consultations when drafting the legislation. The information is also valuable for enforcement as described further in section 2.6. For informative instruments, it is essential to know which companies to target with specific information in order to be efficient.

In the case of introducing bans and restrictions, it has to be remembered that the substance to be regulated might also enter the country through the import of articles in which the substance is incorporated. It might therefore be relevant to find out in which kind of articles the substance might appear. The companies importing articles are normally not the same as the companies importing or producing chemicals.

2.6 Enforcement

Any country introducing legal requirements in different areas will need to consider how these requirements shall be controlled. Provisions for enforcement should therefore be established in legislation and be effectively implemented. The goal with enforcement is to ensure compliance with legislation, see the Swedish Chemicals Agency Guidance 4/18 Enforcement of legislation on chemicals placed on the market¹⁴.

The main task of the enforcement authority, whether an independent authority or as a part of a ministry or a chemicals authority, is thus to ensure legal compliance by carrying out inspections of companies that are subject to the legislation. Having a good overview and knowledge of the companies in the country is crucial for effective enforcement of the legislation on chemicals.

Usually countries have limited resources in terms of staff and/or financing for chemicals control. Therefore, there needs to be a prioritisation between possible enforcement activities. A number of factors should be taken into consideration when prioritising enforcement activities, all of which requires a simple way to identify target groups for inspections.

The prioritisation of target groups for inspections should be based on a structured and documented approach. This gives transparency and makes it possible to evaluate and improve the methodology. Factors to take into consideration in such prioritisation are for example those who place chemicals on the market that could cause the highest risks, those who are known to frequently not comply with the legislation or more practical aspects such as identifying all primary suppliers in a specific geographical area to be visited. Specific legislation could be controlled as well as specific groups of chemicals.

If the legal requirements are not enforced, the compliance might be poor and hence the legislation will not fulfil its purpose.

2.7 Cost recovery

When setting up institutional capacity for chemicals control, countries need to consider how to finance such functions. In the Swedish Chemicals Agency Guidance 1/18 Sustainable financing of institutional capacity for chemicals control¹⁵ various ways of financing institutional capacity for chemicals control are discussed. One option is to use cost recovery fees, which can finance tasks that can be defined as services to those paying the fees. In a system with annual fees, all companies placing chemicals on the market in a country are obliged to pay an annual fee. If a country chooses this option, the country needs to issue

¹⁴ <https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries>

¹⁵ <https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries>

legislation to define such fees. An annual fee can be used to cover different government tasks during a full year, for example:

- performing a number of inspections of producers and importers of chemicals,
- carrying out a number of assessments of specific chemicals,
- maintaining a process for granting exemptions,
- providing a helpdesk service and other guiding and supportive material to companies,
- issuing licenses, and/or
- maintaining registers of producers and importers of chemicals and the chemicals that they place on the market.

A prerequisite for annual fees is that information on, for example, the volume of chemicals and the number of chemical products that each company is producing or importing, in addition to the name and address of the company, is kept as a basis for charging the fees (see also table 3). This information must be updated on a regular basis. The more differentiated a fee is the more accurate it could be in covering the actual costs of national administration. Thus the fee could be seen as fairer by those paying the fee. However, highly differentiated fees require a lot more work for the authorities and does not perform well when it comes to administrative feasibility.

2.8 Official statistics

In some countries, the task to collect statistical information on the production and import of chemicals falls on the authority responsible for the chemicals control. If such a task exists, it is necessary for the authority to have knowledge about the production and import of chemicals in the country. To be useful and serve its purpose it should be possible to follow up changes over time, and to do this the responsible authority needs to have a structured system for gathering and storing the data.

3 What needs does your country have?

In chapter 2 various examples have been presented of when information on primary suppliers and/or chemicals on the market is useful or necessary to have. Because resources for chemicals control can be rather limited and finding data can be very resource-demanding, it is very important to be clear on the purpose of searching for such data and not to take on a workload that is out of proportion to the actual needs. It is important to save resources within authorities for other tasks and it is also important not to ask for information from companies that is not necessary. Reporting requirements from the authorities will generate additional administration and costs for them, and it is therefore important that you can motivate all such demands. Therefore it is necessary to decide which cases are relevant to your country before you decide which information to gather, at what frequency to gather it, and by which methods. This will be discussed in this chapter, by giving a few examples. The various methods for finding information on primary suppliers and information on chemicals on the market will be described further in chapter 4.

Some questions to reflect on before deciding on methods for collecting data are:

- What is the **purpose** of collecting the information? What do you want to use the information for?
- What **kind of information** do you need?

- How **often** do you need the information?
- Is it important that the information is **updated** regularly?
- Is it important that the information has a full **coverage**, i.e. that all companies producing and/or importing chemical products in the country and all their products are covered?
- Who should be **responsible** for the completeness and correctness of the information?

After having considered these questions you can decide on the most efficient model for finding data that fulfil the needs that you have.

Examples of cases and the level of information needed are presented in table 1. Concerning the responsibility for the completeness and correctness of the information, it has to be remembered that when a general obligation to report to the authorities is placed on the companies, the legal responsibility that this is carried out in the correct way lies on companies. On the other hand, if the authority is the one who undertakes the search for information, the responsibility for the coverage and correctness rests upon the authority. If the intention is to cover all relevant companies in the country in a register and to make it obligatory for them to register with the authorities, then it is necessary that such requirements are legally binding. This is especially important when a level playing field is necessary to ensure the trust in the system, e.g. in relation to charging fees. All companies obliged to pay fees should report their existence and the required data for calculation of the fees to the authority. The authority may use enforcement to get corrections if some companies do not comply with the legal reporting requirements.

Table 1. Examples of cases when the authority needs different kinds of information on companies and chemicals.

	Purpose	Kind of information	How often?	Need for updating	Need for full coverage?
Case 1	Perform risk assessment of a specific substance and decide on need for risk reduction	Occurrence of the substance in chemical products and articles.	Once (plus possible follow-up)	No	Sufficient coverage for making a risk assessment relevant for the country.
Case 2	General prioritisation for risk assessment based on intrinsic properties and volumes	Occurrence of a wider group of substances as - defined by criteria on intrinsic properties - in chemical products and articles.	Once or several times depending on how often this kind of prioritisation is foreseen to take place	Depends on how often this kind of prioritisation is foreseen to take place	Sufficient coverage for making a first assessment on possible volumes. Stepwise refinements are possible.
Case 3	General or specific information and communication	Which companies place chemical products on the market	Repeatedly	Yes	Normally not
Case 4	Information on specific chemicals for reporting to global conventions	Occurrence of specific substances according to conventions	Once or at regular intervals depending on the convention	Yes, for these substances	Yes, for these substances
Case 5	Enforcement	Which companies place products covered by the chemicals legislation on the market. Additional information can make more refined prioritisation possible.	Repeatedly	Yes	Yes
Case 6	Charge annual fees	Which companies place the categories of products that the fee is based upon, on the market. Additional information might be needed depending on the level of differentiation, see table 2	Yearly updated information	Yes	Yes

By clearly defining the purpose of gathering data on primary suppliers and/or the chemicals they place on the market at the start, different methods for collection of the data will turn out to be more or less effective. In reality there might be more than one purpose for gathering data and in the case that more comprehensive data are gathered for one purpose, such data should of course as far as possible also be used for other purposes. For example, there is no need to set up regular reporting requirements to a register for filling the needs in case 1, but if a register of chemical products exists to fulfil other purposes the information from the register should of course be used when searching for information also in case 1.

Comments on the cases and which methods that might be most useful.

Case 1:

When making a risk assessment for a specific substance that the country has identified as being a potential risk, sufficient information for making an assessment of the exposure is needed. Openly available sources might give a picture of the main uses of the substance and exposure assessments from other countries might give an idea for what the major sources of exposure are. For example, if exposure from chemical products or articles is a relevant source, then production and trade statistics could be used to determine to what extent these products or articles are used in your country.

If already existing sources are not enough, asking for reporting from companies on a case-by-case basis normally is sufficient. This could cover suppliers both of chemical products and articles.

Case 2:

If prioritisation of substances for risk assessment is going to be done more systematically in your country, broader data are needed than in case 1. Normally various proxies for exposure, like volume on the market, are used for the initial screening. In this case an inventory of the primary suppliers and chemicals they place on the market and in what volumes is most likely needed. The gathering of the data should be done as close in time to the use of the data as possible.

Case 3:

Information can be used as a risk reduction measure in itself and it can be used to communicate information about other measures, for example, pending legislation. Because information on risk reduction either is intended to lead to a voluntary change in behaviour or is intended to help those who should comply with, for example, new legislation to know about and understand the legislation, it is beneficial to have a broad coverage of the target group although this is not totally necessary. If a register of primary suppliers exists, it will constitute a good basis for sending information, but if not, then general information published on a website might be sufficient. To further facilitate reaching companies that produce, import or use chemicals with more targeted information and invitations to information meetings, an invitation to register contact details could be posted on the website of the relevant authority and information could be sent out to those who voluntarily sign up for receiving information.

Case 4:

When international reporting requirements exists in conventions and agreements that your country is a party to, you need to consider how to best gather the information needed. This depends on the number of substances, the number of uses of these substances and the frequency of the reporting. Either a case-by-case method could be used, similar to case 1, or a smaller register could be kept for these specific substances. The latter might be especially useful if regularly repeated reporting is required.

Case 5:

If general legal requirements are placed on primary suppliers of chemicals, it is of importance that they can easily be found for those inspecting the compliance with the legislation. For that purpose, a register of the primary suppliers would be very useful. Because inspections take place over time, it is important that this information is regularly updated. To ensure a level playing field it is reasonable to place an obligation on the primary suppliers to report to the authorities that they produce or import chemicals – rather than placing the responsibility on the authorities to try to find them by other means. A register of the primary suppliers could be complemented with some information on the chemicals they place on the market in order to make it easier to plan enforcement activities.

Case 6:

To finance the work done by authorities various cost-recovery models can be considered. If a model with yearly fees is chosen, it will be necessary to have legally binding requirements on companies for regular reporting to a register, which will serve as the basis for calculating and charging the fees. The calculation can be more or less elaborated but the more parameters that are used to get the fees as fair as possible the more data will be needed. This is illustrated in table 2.

Table 2. Financing structures with fees, the required additional data needed, and the capacity needed by national authorities. This table is relevant only for the cases in which it is decided to introduce a cost recovery system.

Fees based upon	Requires that the authority has access to	What needs to be established and maintained in the country?	Degree of resources required
One level for all importers and producers	Contact details of importers and producers	Register of importers and producers of chemicals that is updated annually.	Limited, a register of enterprises is also often central for other purposes.
Size of the importers and producers (e.g. number of employees or annual turnover)	Information about number of employees and annual turnover per company	More detailed register of importers and producers of chemicals that is updated annually. Competence to retrieve, store, and analyse information about the importers and producers.	Low
Volume of produced/imported chemicals per company and year	Detailed information about volumes produced or imported per company	Register of producers, importers, and chemical products. Competence to annually retrieve, store, and analyse information about the importers and producers and the volume of various chemicals.	Medium
Number of chemicals produced/imported per company and year	Detailed information about the number of chemicals produced or imported per company	Register of producers, importers, and chemical products. Competence to retrieve, store, and analyse information about the importers and producers and the number of various chemicals.	Medium
A combination of volume and number of chemicals per company and year	Detailed information about volumes and numbers of chemicals produced or imported	Register of producers, importers, and chemical products. Competence to retrieve, store, and analyse information about the importers and producers, the volume of various chemicals, and the number of products.	Medium-high
The hazardous properties of the produced/imported chemicals per company and year	Data on hazardous properties	Register of producers, importers, and chemical products. Competence to retrieve data on hazardous properties and to assess the data against criteria for all substances/products imported or produced.	Very high

4 How to find information on importers and producers of chemicals and the chemicals they produce and/or import

As shown in chapter 3, knowing which companies are active in the area of import and production of chemicals is necessary or at least beneficial in many cases. Not only having knowledge on companies active on the market in the country, but also on the chemicals these companies produce or import and for what purposes they are used, in what volumes, etc., is necessary for some tasks that the government might want to include in the system for chemicals control. There are different ways of acquiring necessary information on companies in countries as well as on the chemicals they place on the market, and some different methods will be discussed in this chapter. Some are only useful for finding companies and some for finding chemicals, whereas some are useful for both. At the end of the chapter how to find information on chemicals in articles will also briefly be discussed.

4.1 Information already available to the government

When planning the information gathering, a first step can be to explore whether other authorities have information on companies that can be used as a starting point for finding companies that produce or import chemicals. Dialogue and cooperation with such authorities prevents double work, saves resources, and opens up for national harmonisation and sharing of contacts and data.

Authorities in the country might have access to information on the identities of companies producing or importing chemicals, in for example, an address register. How far this information might be used by the authority responsible for chemicals control depends on the reliability of the data and the purpose for which it is intended to be used. If the purpose is to send out general information, this could be sufficient. If the purpose is to reach all companies, the requirements on reliability becomes greater. A prerequisite is that the legal provisions allow use by another authority.

In some cases not only the information on the primary suppliers, but also the chemicals they place on the market can be found in registers that other authorities keep.

It could be appropriate for the authority responsible for chemicals control to cooperate with authorities such as:

- Environmental and health authorities
- Poisons centres¹⁶
- Customs
- Companies Registration Office
- Tax authorities
- Bureaus of statistics.

4.1.1 *Environmental and health authorities*

The sources described here might be based on tasks carried out by the authority responsible for chemicals control. In such cases, the information will already be available within the authority. If not, another authority in the field of environment and health might be engaged with these tasks and cooperation with them might give access to valuable information.

¹⁶ Poisons centres were available in 46% of the WHO member states in 2017.

4.1.1.1 The Rotterdam Convention

An important step in getting information on the occurrence of substances regulated in other countries is to use information from the Rotterdam Convention. Annex III to the Convention lists substances, including pesticides and industrial chemicals that are banned or severely restricted in at least two of the five UN regions. For all substances listed in Annex III, a Decision Guidance Document is available that contains valuable background information on the substance and its properties. Information on further national restrictions can be found through information¹⁷ sent to the Rotterdam Convention Secretariat because parties to the Convention have an obligation to inform the secretariat about their national or regional bans and severe restrictions on chemicals that are not (yet) covered by any international conventions or agreements. Some background information is also available for these substances. Such notifications give the importing country and others valuable information about the occurrence and use of a substance as well as the decisions of other countries to ban or restrict the substance, and it gives them an opportunity to consider the need to introduce similar measures in their country.

When parties to the convention import or export a chemical that is covered by the Rotterdam Convention, the import as well as the export has to be notified to the responsible authority both in the importing and the exporting country, and consent is needed in the importing country for the import. In these cases, the exporting and the importing company is known, which gives a route of information for identification of these companies to the authorities and thus should be a help in identifying relevant companies in the country. The Rotterdam Convention requirements not only support the identification of some importing companies, but also which chemicals these companies import because an informed consent is required before the import is allowed.

4.1.1.2 Authorisations

Many countries have systems for authorisation of specific types of chemicals, such as pesticides, cosmetics, pharmaceuticals and food additives, that are produced in or imported in the country. This type of system normally requires that responsible authorities keep records of the companies and their products because the system is likely to require companies to supply the authorities with quite detailed information. Information on these products and the primary suppliers of these products is thus available in the authorisation systems.

The information gathered through the authorisation of specific chemicals can be useful also when searching for producers and importers of other chemicals because some companies provide a broad range of products, covering both those that require authorisations and other chemicals.

4.1.1.3 Concessions

In many countries, each company producing chemicals has to get a license or a concession for their activities from a national, regional, or local authority. Companies that have been granted a concession for such activities would thus be known to the authorities and could be used as an information source for identifying such companies.

4.1.1.4 Import licencing

As mentioned in section 1.2 it is advisable to request reporting from producers and importers of chemicals on total amounts, for example on a yearly basis. However, some countries

¹⁷ <http://www.pic.int/Implementation/PICCircular/tabid/1168/language/en-US/Default.aspx>; see annex V.

require companies to get a license for each chemical they import, in some cases even for every single batch that is imported. If such a system exists the information that it generates should be used. In these cases, not only the company should be known to the authority but also the chemicals they import. If this information is available in a structured form, the system can be used for purposes covered in this guidance and if the authority trust that such a licensing system covers all necessary data it would not have to restructure or reorganise the information. If the information is not stored in a structured and easily searchable way, the authorities still can benefit from the availability of the data but need to restructure it for it to become available in a more easily accessible way for its new use.

4.1.1.5 Pollutant Release and Transfer Register

A Pollutant Release and Transfer Register (PRTR) is an environmental database or inventory of potentially hazardous chemical substances and/or pollutants released to air, water and soil from both point sources as well as diffuse sources. When a PRTR is available in the country and followed up continuously, companies producing or using certain chemicals sometimes can be identified depending on the level of details in the system.

4.1.1.6 Monitoring

At authorities for environmental protection there might also be other information, for example, from environmental monitoring or monitoring in human tissue, as well as, for example, analysis of the contents in sludge from sewage treatment plants, that could indirectly signal that a specific substance is used in the country. However, the occurrence in different media could also be due to long-range transport or legacies from the past. Further, such data are normally only available for a few substances.

If a substance is found through monitoring at levels that give rise to an exposure that might lead to a risk, the sources should be searched for. This could be done by applying other methods described in this guidance.

4.1.2 Poisons centres

If a poisons centre, (see box 1), is available in the country, it could be quite a useful entity to cooperate with because much of the information on importers, producers, and chemical products that is necessary for such a centre is the same as needed by the authority responsible for the chemicals control. A common need is contact information for the importer and producers as well as chemical identifiers. However, there are also differences regarding the need of information. The information gathered by the poison centre is primarily focused on the health effects of chemicals and substances with other properties such as adverse effects on the environment is normally not covered. Therefore, the poison information centre might provide only partial information on primary suppliers and chemicals in general.

Box 1. Poisons centres**What is a poisons centre?**

A poisons centre is a specialized unit that gives advice on, and assists with, the prevention, diagnosis and management of poisoning. The structure and function of poisons centres varies around the world, however, at a minimum a poisons centre is an information service. Some poisons centres may also include a toxicology laboratory and/or a clinical treatment unit.

What does a poisons centre do?

A poisons centre answers enquiries about exposure to chemical agents, including products, pharmaceuticals, natural toxins, pesticides and industrial chemicals. It provides an assessment of whether a particular exposure is hazardous, and information on the need for treatment and the kind of treatment that should be given. Poisons centres aim to promote the evidence-based, cost-effective management of poisoning and to ensure that unnecessary or ineffective treatment is avoided.

Source: WHO: <https://www.who.int/ipcs/poisons/centre/en/>

4.1.3 Companies Registration Offices

Some countries have requirements for companies to register with a companies registration office. The registers they keep might contain comprehensive information on which companies that exist in the country, their registration numbers, contact details, type of company, main area of activities, and/or annual reports from the companies.

4.1.4 Tax authorities

If taxes are charged on companies in the country, the tax authorities would need to have information on the companies that are subject to the tax system. Depending on the level of detail in registering the companies' main activities, if done at all, companies in the chemicals sector might be possible to identify.

4.1.5 Customs

Collaborating with the customs might also be quite useful in relation to the types of imported chemicals and importing companies. Customs worldwide use the international customs tariff chapters, i.e. the Harmonized System, the so-called HS system, (see box 2), and these can be used to identify which types of chemicals are imported. However, the customs cannot provide information on producers in the country, so therefore use of data from the customs need to be combined with other sources if the intention is to identify all primary suppliers.

Box 2. The Harmonized Commodity Description and Coding System:

- is generally referred to as the Harmonized System or HS,
- is governed by The International Convention on the Harmonized Commodity Description and Coding System,
- is used by more than 200 countries, territories, or customs or economic unions,
- acts as a basis for customs tariffs and the collection of international trade statistics,
- divides commodities into about 5,000 groups identified by a 6-digit code,
- is available through the World Customs Organisation (WCO).

Source: WCO: <http://www.wcoomd.org/en/topics/nomenclature/overview/what-is-the-harmonized-system.aspx>

4.1.6 Bureau of Statistics

Most countries in the world have a government statistics office or bureau. These are normally charged with supplying official statistics for general information, investigation, and research. Such statistics should be objective and made available to the public. Sometimes they rely on reporting from the authority for chemicals control when it comes to background information for statistics on specific chemicals, but if they use other sources these might be of interest also to the authority for chemicals control. Statistics on trade and industrial production can be valuable, also when identifying the flow of articles and materials that can contain specific substances.

4.1.7 Regional and local authorities

Regional and/or local authorities quite often have extensive local knowledge on companies in their part of the country. Sometimes they are the ones issuing licences for industrial facilities. It will thus be valuable to have a good cooperation with authorities both at the central, regional, and local level.

4.2 Openly available sources**4.2.1 Information that companies make available**

When searching for information on suppliers of chemicals general information sources, such as the Internet, catalogues, and other publications as well as advertisements in trade magazines and similar, can help in identifying these actors. Through these channels some basic information on chemicals on the national market can also be found.

4.2.2 Literature

In the open literature general information on the typical chemical composition of different types of products can be found. This can be helpful in determining whether it is likely that a substance is used in the country. However, in most cases this information will not be enough in itself, but can be used as a starting point, e.g. for directing specific questions to a subset of the total number of all suppliers as described in section 4.3.

4.2.3 Data on usage from other countries

A relevant and useful source on the use of chemicals is information from other countries. This kind of information is similar to what can be found in the literature, but might be even more up to date and relevant. One of the most useful sources can be information from neighbouring

countries, especially if the use patterns of the products are expected to be similar to the use on the domestic market.

General information, such as the use in broad products groups as plastic products, textiles etc., can be found in the REACH database¹⁸ at ECHA. This database contains information on more than 20,000 different chemicals to date, which among other types of information covers general use categories. To a limited extent, information on use categories can be found in other publically available databases such as the OECD eChemPortal.¹⁹ In some cases there might be information on the occurrence of specific chemicals in different kinds of materials, such as textiles or plastic products in reports from countries, organisations and academia (see for example the publication series from the Swedish Chemicals Agency²⁰).

4.3 Inquiries and questionnaires to companies and trade organisations

One simple way to find out which chemicals are imported to or produced within the country could be sending an inquiry or questionnaire asking companies, once you know their identities, to send information regarding the chemicals they produce or import. Relevant companies can be found through different means as outlined and suggested above. This method does not require that legal requirements are introduced but the response rate might be higher if it is mandatory to send in the information asked for by the authorities.

This method is primarily useful when searching for information on the occurrence of one or a few substances. The method is quite burdensome if many companies and/or chemicals are to be covered.

Questions could also be directed to those who place articles on the market if detailed information on the actual use of specific chemical is needed. This makes the method quite flexible in actually capturing the needs of the authority.

Another route to acquire relevant information could be through different trade or sector organisations, if available, because they might have useful information within their remit and can thus be helpful in identifying relevant companies and information on what types of chemicals their members produce or import. They might also be helpful in retrieving information from their members. Especially small and medium-sized companies might, however, be difficult to find this way because they are not always members of a trade organisation.

4.4 Placing reporting requirements on companies

If the sources in sections 4.1–4.3 will not fulfil the needs of the authority for chemicals control and it is deemed that more comprehensive information is needed, it can be considered to place legal requirements on companies to report without specific requests from the authorities. Before placing reporting requirements on companies, there is a need for the authorities to decide if a “snapshot” of the situation at a specific point in time would be sufficient or if it is essential to be able to follow the development and changes of the

¹⁸ ECHA information on substances https://echa.europa.eu/information-on-chemicals/registered-substances?p_p_id=dissregisteredsubstances_WAR_dissregsubportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&dissregisteredsubstances_WAR_dissregsubportlet_javax.portlet.action=dissRegisteredSubstancesAction

¹⁹ eChemPortal <https://www.echemportal.org/echemportal/index.action>

²⁰ Swedish Chemicals Agency, Publications: <https://www.kemi.se/en/publications>

companies acting on the market and their chemicals over time. The decision on what type of market overview is preferred will affect the reporting requirements.

Irrespective of the method chosen for determining which chemicals are available on the national market, based on the analysis of the government's needs, it should be considered if the stocktaking should cover all chemicals placed on the market or only a subset of the total number, for example, the ones of highest concern, such as chemicals meeting specified criteria on intrinsic properties (e.g. based on the Globally Harmonized System of Classification and Labelling of Chemicals, the GHS) or those with the largest volumes.

It is also wise to carefully consider how much details the required information needs to contain. If too much information is required, this creates an unnecessary burden on the authority as well as on the companies.

Even a limited amount of information considered most important for the authorities can be very resource-demanding to keep in order. It is therefore advisable to start on a small scale, then, if needed, require further information step-wise and clearly define the purpose of all new requirements.

When there is a mandatory obligation to report to the authority, the responsibility that this is carried out lies with the companies that have this obligation. Clear legal requirements make the request for data more transparent and avoids arbitrariness. That this obligation is fulfilled then needs to be enforced by the authorities, similarly to any other legislation on chemicals, (see section 4.4.3).

Normally, reporting to an inventory or a register kept by the authority does not imply any kind of authorisation or other explicit decision on acceptance of registered chemicals by the authorities. If an inventory or register is set up with the purpose of getting information on the occurrence of primary suppliers and the chemicals they place on the market it is important to keep this in mind. The authorities can confirm the receipt of the information but it should be clear that this is not an approval of the chemical. Approvals or authorisations of chemicals is a resource-demanding task that requires a process which not is discussed in this guidance. More information on authorisation as a tool for risk reduction can be found in Swedish Chemicals Agency Guidance 2/18 Risk reduction of chemicals²¹.

If an inventory or register on companies and their chemicals is planned, the sources of information in sections 4.1–4.3 could still be useful for identifying companies that information could be sent to, regarding coming legislation and reporting requirements. They could also be invited to participate in consultative processes when the legislation is being developed. The viewpoint of the companies might be helpful in designing a system that will function as smoothly as possible both for the authority and for the reporting companies. It is also beneficial to get input from the reporting companies to find out what might facilitate or help their reporting. Thus, it is necessary to reserve time for meetings and the development of tools for those who are to report and to take their views and possible experience into consideration. It is also advisable, when registration has started, to take time to explain to data providers how to report correctly at the registration occasion and possibly introduce a helpdesk for further support. This saves time in the long run, enhances the quality of the data and offers input for improvements.

²¹ <https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries>

4.4.1 Reporting once or on a regular basis

4.4.1.1 Reporting once to form an inventory

If it is decided to go for the “snapshot” scenario, the situation at a specific point in time can be identified by making an inventory of companies, possibly in combination with the chemicals they produce or import at the same time or asking for further information at a later stage when the identity of the companies is known. In this case, the companies will only report each kind of information once.

However, an inventory can of course be repeated after some years and comparisons can be made between the different occasions to see if the market is still the same or if there are different chemicals available or changes in volumes.

The forms for reporting and the level of the information that the companies should give must be decided on. The requirements should not cover more than what actually is needed, and they should not be unnecessarily resource-demanding for either the authority or the companies.

4.4.1.2 Reporting on a regular basis

Companies might come and go fairly quickly and the number of chemicals as well as the type of chemicals on the national market can also change over time. Import and production volumes are adapted in relation to the demand of the products. Thus, failure to update information quickly might make the data out-dated and unreliable for the authorities.

As pointed out in chapter 3, for some purposes there is a need for regularly updated information where the information should come directly from the primary suppliers. If this is the case, a system with regular reporting should be designed. To really be able to make use of the reported data, it needs to be maintained in an ordered way by the authority receiving the data. This is described further in chapter 5. However it is important to take this into account already when designing the reporting requirements. Keeping some form of register needs to be regarded as a continuous activity or an on-going process. A register cannot be kept running on project funding or on other short-term financing because it is supposed to exist and be updated over a long time.

The forms for reporting and the level of the information that the companies should provide must be decided. The requirements should not cover more than what is actually needed and should not to be unnecessarily resource-demanding for either the authority or the companies.

Irrespective of the level of details in the requirements on reporting, it is advisable to form a system that can be updated regularly and expanded in an easy way in case further needs arise in the future. However, countries have to be aware of the fact that every extension of reporting requirements and related registry functions at the authority means increased work for the companies and for the authority for registering and controlling the data. The more information that is required, the more complicated it is to update it.

4.4.2 Legal requirements

A decision that an authority should require information on companies and the chemicals they produce or import needs to be reflected in the relevant legislation, i.e. a clear mandate should be given to the authority to collect such information as well as to maintain it in an ordered way. Together with this mandate, there could also be a delegation to form more detailed information requirements on the companies and on chemicals. In principle, whatever level of information is required, there is also a need for a legislation to make it clear to companies

what they need to report and how. The legislation should preferably be part of a legislation covering various legal aspects of chemicals placed on the market. See also Swedish Chemicals Agency Guidance 3/18 Legislation on chemicals placed on the market²².

4.4.2.1 Contents of the legislation

General

There are some general aspects that need to be covered by the legislation, such as definitions, exemptions (if any), which companies have reporting obligations, sanctions, and when the law enters into force.

Definitions of words that are used in the legislation, such as substances, mixtures, articles, producers, importers etc., needs to be provided. If the legislation is part of a broader legislation on chemicals these definitions might already exist.

If some types of chemicals are covered by other national legislation with reporting requirements they should preferably be exempted in this legislation on registration. This could apply to chemicals such as pharmaceuticals, cosmetics, food additives, radioactive substances and/or pesticides. It is in any case important to make sure that chemicals are not unnecessarily double registered in accordance with several different pieces of legislation.

Clear definitions in the legislation pointing out, which companies have to report based on the type of products they produce or import are needed. This can be done in combination with defining which chemicals that should be covered. When defining which companies have an obligation to report, it can be necessary to include companies that pack, repack, or change the name of a chemical that was produced or imported by another company in the country. The reason is that it is necessary to find a product that is marketed under a different name than the original.

Thus, the legislation could cover those who professionally produce, import, change the name, or pack or repack any of those chemicals that are listed in the legislation. Identifying relevant chemicals could be carried out by identifying them via specific customs tariff chapters or groups according to HS²³, (see box 2). In this system, chemicals and certain types of products are designated with specific codes that are internationally agreed upon and commonly used worldwide. The selection of codes might then be used to clearly state in the legislation, which companies have an obligation to report to the authorities. This could be done with a narrow or broad scope. Even if the idea is to have a broad coverage of chemicals, these must still be defined. Either all chemicals that fall under the general definitions of substances and mixtures could be included, or they could be identified by HS codes. The difference between a narrow and broad coverage would then be the number of codes included.

The legislation should be written in such a way that it is easy to enforce. In addition, sanctions for non-compliance to the regulations need to be included in the chemicals legislation or in a specific regulation also covering other types of non-compliance.

The date when the legislation comes into force should be specified.

²² <https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries>

²³ The Harmonized Commodity Description and Coding System, usually called the Harmonized system or the HS.

Provisions should at least cover:

- definitions,
- exemptions for chemicals covered by other legislation (e.g. pharmaceuticals, food additives),
- who should comply with the legislation (for example, professional importers/producers/packers/repackers or those that change names of defined chemicals),
- sanctions for non-compliance to the regulations and
- the date when the legislation comes into force.

Forms for reporting

The forms for reporting must be clear to the companies and it has to be clear from the legislation what is the latest date for reporting data to the register for the first time. It must also be clear when a new company needs to report the data after having started its business and also how soon a chemical that is produced or imported for the first time should be registered. Because the reason for keeping a register with information on companies is to ensure that all relevant companies in the country are known to the government, it is recommended that the importers and producers should be obliged to report to the register as soon they start their production and/or import. If it is decided that the information should be updated regularly, this should take place at a specific time (e.g. a specific date each year) for all companies that are still active.

By providing standardised forms for the companies to fill in, the authorities can save significant resources. This is especially true if standardised electronic forms can be used, that can be transferred directly to an electronic register, with as few manual steps in between as possible. The details concerning accepted ways for reporting could preferably be placed in secondary legislation, possibly in combination with further guidance to the companies.

The method for reporting to the responsible authority depends on the amount of data to be reported and the technical solution for storing the incoming data. Possible options are:

- Reporting on paper, preferably in a format and structure chosen by the authority;
- Reporting in a data file in a format and structure chosen by the authority;
- Direct reporting to a database in a specified format with specific log-in for each company.

These forms could also be mixed. Thus larger companies in a country might be able to submit their information electronically, while smaller companies can still give in their information on paper. Then the authorities would still need to transfer some information to a computerised format, but the workload will be less than if all information was provided on paper.

Provisions should at least cover:

- when by the latest the reporting shall be done the first time,
- when by the latest a new company shall report after having started its business and how soon a chemical that is produced or imported for the first time should be registered,
- when updates of reporting shall be done (e.g. a specific date each year),
- name of the authority to receive the reporting and
- accepted ways for reporting.

Reporting information on companies

Knowing which companies are active in the area of import and production of chemicals is a prerequisite for acquiring information on the chemicals present on the domestic market. The process thus needs to start with registering relevant companies and requiring companies to register information defined in the legislation.

It is necessary to include in the legislation clear information on what data are required from industry when supplying general company data.

Obligations for companies to register should at least cover:

- the company's name and address,
- tax authority number or similar official identification number,
- name and contact details of the person responsible for reporting,
- type of business activity (whether the company is producing or importing chemicals, etc.).

Reporting information on the chemical products

If including reporting on chemicals, based on the analysis of the government's needs, the chemicals that should be covered by reporting requirements must be defined and the information about them that should be reported needs to be stated.

As mentioned above, identifying the companies that have reporting obligations could be done by stating that all suppliers of substances and mixtures or the suppliers of chemicals with specific customs tariff chapters or groups according to the HS²⁴ are covered by the legislation. The same system could also preferably be used for identifying relevant chemicals to be reported. The companies could be obliged to report all chemical products according to the general definition of substances and mixtures, those covered by HS-codes listed or a subset of codes. In the latter case, some companies will not have to give in any information about the chemicals they produce or import.

If only information about a limited number of chemicals is needed for the purpose for which the information is collected, then the legislation should be designed to capture only this information. This could be done in different ways depending on the needs of the authority. If only some specific groups of chemicals are of interest to a country, such as paints, glues, lubricants etc., then these can be defined by the HS-codes. Others might want to focus on chemicals that contain substances with specific intrinsic properties. In this case, references needs to be done to some criteria or list of substances that can be included in the legislation. Then all chemicals covered by specific HS-codes that contain these substances above certain concentrations will be covered by reporting requirements.

A lowest quantity limit for reporting the chemicals should also be set. The reason for this is that in the case of an obligation to report all chemicals placed on the market, the number of chemicals to be registered might be unnecessarily large. The limit could be set at a rather high volume if the chemicals of the highest volumes are those of the highest interest to start with. The reporting requirements could then gradually expand to lower limits (e.g. 1 tonne/year or less) over time. Very small amounts of chemicals for use in, for example, laboratories might not need to be reported at all unless the chemical is of certain interest and the government explicitly requires registration.

²⁴ The Harmonized Commodity Description and Coding System, usually called the Harmonized system or the HS.

It is necessary to include in the legislation clear information on what data are required by industry when supplying data on the chemicals the companies produce or import. This could include amounts (quantities) of the chemical produced/imported per year, either exactly or in intervals. If reporting in intervals is sufficient, the legislation needs to define which intervals to apply (e.g. 1–10 tonnes, 10–100 tonnes, etc.). It also has to be defined if the amount to be given is the anticipated amount for the coming year or if the amount should be the factual amount produced or imported for the previous year.

Further information that could be useful is the intended use of the chemical and such information could be easier to search for if it is given in a standardised format. However, there is no international standard for such information, but as an example a set of codes are harmonised in the Nordic countries as “Use Categories Nordic”²⁵. It might also be relevant to get information on intended user categories – to start with, whether the intended use is for professionals and/or consumers (households). Industrial users could be further specified by a code according to a choice of codes in a common standard like the International Standard Industrial Classification of All Economic Activities (ISIC)²⁶.

Depending on the intended use of the information gathered, it might not be enough to simply know which chemical products are placed on the market, and in some cases, it might also be necessary to know the contents of the chemical product if it is a mixture, i.e. which substances the product contains and in what concentrations. How detailed these figures need to be can depend on the intended use. Either all substances present in the product should be reported or only those that are present above certain limits or those that are hazardous. This then needs to be defined further. If GHS has been introduced in the country, more detailed information could be required for those products that are classified as hazardous and especially for the substances that give rise to the classification.

The chemical identity of the substances in the product could preferably be reported by using internationally agreed upon or recognised names e.g. IUPAC names and/or CAS-numbers²⁷. The concentration (weight-%) of the substances also needs to be reported as such or in intervals.

If requirements on reporting information on the chemical products placed on the market should be included, the provisions should cover:

- chemicals to be reported, e.g. by pointing out the customs tariff number according to the harmonized system (HS-numbers) and
- limits (i.e. tonnage per year) of the chemical produced or imported per year above which the registration obligation should apply and
- requirements for identification of the imported or produced chemical by its trade name or other designation on the national market.

For the chemical products that are covered the following data might also be required:

- amounts (quantities) produced/imported per year (actual amounts during the previous year or planned amounts for the coming year) and

²⁵ <http://195.215.202.233/DotNetNuke/Portals/0/DNNPortal-Download/Funktionskoder-eng%20htm.htm>

²⁶ https://unstats.un.org/unsd/publication/seriesM/seriesm_4rev4e.pdf

²⁷ A CAS number, Chemical Abstracts Service number, is a registration number for chemicals. It functions as an international identification number for chemical substances. International Union of Pure and Applied Chemistry is the recognized world authority in developing standards for the naming of the chemical elements and compounds.

- intended use and
- intended users (consumers or professionals, and in the latter case in which sector), and
- the chemical identity of all or some of the substances in the product by using internationally agreed upon or recognised names e.g. IUPAC names and/or CAS-numbers that can be used as identification for substances and the concentration (weight-%) of the components.

4.4.2.1 Confidentiality of data

When placing reporting requirements on companies, it is important to consider that some data might rightfully be claimed to be confidential business information (CBI). This could for example be the case if detailed information about the contents of specific products is requested. In order for the authority to build trust among companies, this needs to be recognised. The identification of potential CBI should as far as possible build on existing national legislation, such as the national secrecy legislation as well as competition law. In case no such legislation exists, further specifications on how to deal with data protection should be considered.

4.4.3 Enforcement needed

If a country places legal obligations to report to registries, inventories or similar on producers and importers, then compliance with these obligations must be controlled. This control is important to ensure that the inventory or register is a good basis for the activities that it is meant for, such as risk management measures, enforcement or charging fees.

Because an important function of a register might be to serve as a basis for identifying companies to inspect, it is essential to make sure that all actors fulfil their reporting requirements. If an actor does not comply with reporting requirements it should not mean that the actor avoids inspections. Therefore, for the purpose of controlling requirements to report to registers, the basis for finding those to inspect must be broader than the register itself, see Swedish Chemicals Agency guidance 4/2018 on Enforcement on chemicals placed on the market²⁸.

Use of general information, such as discussions with sector organisations, searches of suppliers on the Internet, and articles and advertisements in trade magazines can help in identifying actors with potential reporting obligations. Controls of importers' compliance with reporting obligations can also be done via comparison of import statistics and reporting to the register. Controls of producers' compliance with reporting obligations can be done in connection with other forms of inspections on other requirements. It can also be done by following a product up the supply chain, for example if a safety data sheet is controlled at the user level it can be followed up by checking if the supplier named in the safety data sheet has reporting obligations and complies with them. This might require cooperation between different enforcement authorities.

4.5 How to find information on chemicals in articles

In some cases it is not sufficient to have access to information on chemical products produced in or imported to the country in order to get the full picture of the substances occurring in the country. To get the full picture of substances occurring on the market in a country, especially

²⁸ <https://www.kemi.se/en/publications/guidance-on-national-chemicals-control-for-other-countries>

when risks emanating from them need to be reduced, substances in articles also need to be taken into account. A substance can be spread during the use of the article. A chemical, in a textile for example, can be released into the environment during its use when in contact with human skin or during washing. Substances can also be released when the article becomes waste. When considering the need for bans and restrictions of specific chemicals, it is normally therefore necessary to investigate in what kind of articles these chemicals might be present.

Given the large number of actors on the market producing and importing articles containing chemicals, the rapid changes on the market, and the fact that the number of articles is many times higher than the number of chemicals, it is a difficult and resource-demanding task to get detailed knowledge about articles' occurrence, contents, and use. A register of all articles and their contents is not feasible to create or maintain due to the huge number of articles and the limited information on the contents of the articles in the supply chains. To a limited extent information on occurrence in articles produced nationally can be retrieved via a register of chemicals but only if such a register contains information on the industrial categories, functions or types of article the chemicals are used in within the country. For articles there is therefore always a need to use further sources of information. This could, for example, take a case-by case approach, through sending questionnaires to companies likely to introduce articles containing the specific chemical to the market, as described in section 4.3

5 How to structure the information received

Irrespective of how the information on primary suppliers and the chemicals they place on the market is collected there is a need to maintain the information in a structured way. The more data that are gathered, the greater the demands on this will be. Unstructured data are seldom useful, and it requires a lot of resources to try to bring order to a material that is kept in a way that does not allow information to be searched for in an easy way. In this chapter, some different ways of structuring data will be discussed, with an emphasis on setting up IT-based registers.

5.1 Different models for structuring data

Collecting information on companies producing or importing chemicals in the country as well as the chemicals produced or imported, normally generates quite an extensive amount of data. To be able to use the obtained information for different purposes, a structured system for storing the data is required. The issues below should be considered when deciding how to structure the collected information.

How to most efficiently structure the information collected on companies and the chemicals they produce and import depends on:

- the scope of the data collected at present and if it is planned to expand the scope in the future and
- the type of information that you want to extract from the collected data and
- how often extraction of data is needed – the more often, the greater the demand for a structure that makes extractions easy to process.

5.1.1 Technical solutions

The choice of technical solution for structuring the collected data might vary considerably with regards to the level of ambition and complexity. There might be simple lists of names and addresses of companies, and there might be complex computerised systems with extensive information and data on both companies and the chemicals they produce and/or import. Some different options, depending on the amount of collected information and the needs, are described below.

- The simplest way of arranging the information is just to keep the incoming documentation in a physical archive, for example, in alphabetical order or any other suitable way to make it possible to retrieve the information on companies and the chemicals they produce or import. Compiling any larger amount of information from an archive like this is, however, quite resource-demanding and not easily achievable.
- A somewhat more advanced solution is to insert the information in a data file or a simple database. A commercially available software could in many cases do for this purpose. Using such software, allows data to be sorted in a rather easy way but does not allow for automated processing of data.
- Another option is to set up a more advanced IT-based system with a data base where different types of information can be searched for in an easy way and where data can be compiled in different ways to meet the needs of different data users. Such a database facilitates easy access and use of the registered data for different purposes, and should be an easy way, for example, to find companies within a specific area or to find companies that produce or import a specific chemical that might be of concern. It would also be possible to find out, with the support of a register in the form of such a database, if a chemical is produced or imported by many different companies and/or for many different uses and thus can potentially give rise to a wide-spread exposure.

It needs to be taken into consideration as well whether, the information required will be updated over time either regularly or at least on a couple of occasions. If so, the last option above will be the most practical, but the second option might be sufficient to a certain extent, especially if the data collected are limited. Furthermore, if future expansions are planned, these need to be taken into account when designing the system for keeping the information.

5.1.2 Linking, storing and reporting formats

In chapter 4.4.2.1 methods for reporting to the responsible authority were discussed, it is advisable to consider reporting formats and storage of the information at the same time. The formats for reporting should as far as possible be designed in such a way that the information provided needs as little work as possible before being fed into the system for storage of the information.

5.1.3 Clearly identifiable sources

If there are several different ways of collecting data make sure not to mix them. As discussed in chapter 3, it might be necessary to have responsibilities for the completeness and correctness of the information made clear in the legislation. If primary suppliers report data they should be kept separate from data that are gathered by the authority through other means.

Otherwise it will not be possible to hold the reporting companies responsible for the quality of the data.

5.1.4 Quality control

Quality control of the submitted information and comparisons between different reporting occasions will mainly be most convenient when a database is used, even if the other options also might allow for such control and comparison in a more restricted manner. Quality control is necessary, and an easy form of control might be by comparing the figures from one year with those of other years. If there are large deviations between the years, this should be checked further. With a computerised system such checks could be done automatically.

It is also useful to compare the supplied information with others, especially neighbouring countries, having similar registers in order to compare the content and to ensure that the reported data contain comparable information.

5.2 Setting up IT-based registers

As described in section 5.1, more or less advanced systems could be used for storing data. The more advanced solutions need more planning and considerations, and a number of practical issues have to be considered, such as technical solutions, competence of staff and financing for the system. Therefore, searchable databases will be further discussed in this section.

5.2.1 A stepwise building

To build a register in the form of a database through a step-by-step approach is advisable because resources for the management of chemicals are normally quite scarce in most countries, especially in low- and middle-income countries, and this needs to be taken into account. Once implemented, the requirements could then be gradually expanded. Starting with a limited amount of information would also make it possible for the competent authority to gain experience in building up a register with a smaller amount of data and not be overwhelmed by piles of information that potentially could block the whole creation of the register. This would also make it possible to assess how well the system works and if it fulfils the needs and expectations of the authority.

If found necessary, the reporting requirements and thus the register can be expanded to cover more substance groups or lower volumes produced or imported every year over time, or to cover more data and information on the substances already being registered. However, as mentioned in chapter 4, the more information that is asked for, the more complicated and resource-demanding it will be to keep the register up-to-date and reporting requirements should not cover more information than what is actually needed.

5.2.2 Cooperation with other countries

Cooperation with other countries, especially with neighbouring countries and regionally, could be useful and resource saving. To study how registers have been set up in other countries and learn from these countries' experiences is recommended. Regional cooperation with neighbouring countries having a similar structure in terms of industry and that are also in the process of setting up registers would be quite beneficial. If the same type of format for reporting is chosen in neighbouring countries, this facilitates reporting for companies that are active in several countries as well as for the users of the information because it will facilitate comparisons of the information received by the authorities in the different countries.

5.2.3 Competences and costs for keeping a register

Depending on the way the incoming information is collected and structured and how comprehensive the information is, different competences and levels of resources will be needed, both during the set-up phase and also for long term maintenance.

Establishing an IT-based register might demand new competences at the responsible authority. During the phase of establishment and periods of large-scale expansion or reorganisation, more personnel and financial resources are needed.

When running a register resources are needed for maintenance, update, quality checks of the register's contents, guidance to the importers/producers and for responding to requests for information from the register, including the compilation and presentation of search results, and the possible production of statistics on chemicals. The necessary personnel resources vary with the kind of information that is collected and the number of reporting producers and importers. The number of staff required might vary from only one or two persons, if only information on the producers and importers is required, to a rather large group of people if detailed information on the chemicals is to be handled. The size of the country and the number of primary suppliers of course also influences the total workload for the authority. As an example, some seven to eight annual employees are required for the Swedish Products Register including resources for production of statistics, and compilation and presentation of search results from the register. These include a team leader, an administrator, some chemists, and an IT object manager. The scope of the register is approximately 2500 companies and 100 000 chemicals imported/produced every year, and its information is updated annually. The register is kept as a database, into which most importers and producers annually report electronically. In addition, the basic services such as functions for communication and information, IT, economy, law and human resources are provided by the Swedish Chemicals Agency, which is the authority keeping the register.

As pointed out in section 4.4.1.2 it is necessary to secure financing for setting up a register, but also for running it in the long term. Ways of financing national chemicals control, including financing for registers is discussed in Swedish Chemicals Agency Guidance 1/18 on Sustainable financing of institutional capacity for chemicals control^[1].

5.3 Legal aspects

5.3.1 Mandate to the responsible authority

As pointed out in section 4.4.2, there is a need to include in the legislation a mandate to the responsible authority to keep a register and to require that relevant companies supply the authority with information as defined in the legislation.

5.3.2 Confidentiality of data

When receiving and storing information from the companies, it is important to do this in a way that assures them that CBI can be protected and not is disclosed to unauthorised persons or organisations. As discussed in section 4.4.2.2 existing national legislation should be referred to in order to decide what information should be considered as CBI. In some countries, a competition law can require that certain business information not should be revealed to competitors or others. If this is the case, this has to be taken into consideration when deciding and setting up systems for keeping company information and deciding what data can be made publically available.

However, confidentiality should not apply to basic information or for aggregated information. If information from several companies is put together, there will be no risk that confidential information, e.g. in the form of specific recipes, from one single company or product will be revealed. Therefore, it should be possible for the authority to publish information, for example, on the total volume placed on the market of a substance with several primary suppliers. In addition, information needed for the protection of health and the environment should not be kept secret. The GHS system stresses that provisions for the protection of CBI should not compromise the health and safety of human health or the environment (see the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Seventh revised edition, part 1, section 1.4.8.²⁹). Generally, companies should not have the right to claim that this type of information should be kept confidential by authorities. Authorities might have legitimate reasons to also make public other information if needed for the protection of health and the environment.

If someone requests access to information from the register, a decision on whether data can be handed out or not needs to be taken by the authority. Confidentiality assessments thus shall be made and decided on by the authority to ensure secure and equal treatment. If principles for handling such cases are developed in advance, this will be helpful. This is also discussed in chapter 6.

6 Making information available for other tasks of the government

If information is gathered for the control of chemicals, as described in this guidance document, this information might also be useful for other functions of the government. In section 4.1, some functions in the national, regional and local administration that could be useful to cooperate with have been mentioned, with a focus on how the information that they keep can be useful for the authority responsible for chemicals control. Vice versa, these authorities may also benefit from getting information from the authority responsible for chemicals control.

If a register is established the primary users are of course the authorities responsible for chemicals management. However, if possible, when building a register considerations could be given to benefits for other authorities of having access to data from the register. In such a case it has to be considered what information from the register can be supplied to other authorities without compromising any CBI and how this should be done. Normally, to give aggregated figures based on information from several companies would not be a problem. There has to be enough companies though, so that it is not possible to identify recipes, etc., from one single company or product. More detailed information could also be given, if the authority that receive the information is covered by the same kind of secrecy legislation or policies as the authority that keep the register.

The most important users outside the responsible authority could be:

- poison information centres,
- environmental and health authorities,
- customs,

²⁹ https://www.unece.org/trans/danger/publi/ghs/ghs_rev07/07files_e.html#c61353

- the authority responsible for the national statistics.

Information from a chemical products register could be available to other authorities, institutions, organisations and the public, for example in the form of published statistics, published summarised information or information compiled in responses to direct inquiries. In table 3 below there are examples from Sweden for how information in the Swedish Products' register is made available for publically available statistics, for tasks carried out by other agencies, and as a basis for researchers.

6.1 Publicly available statistics

In several countries, according to law there must be official statistics for general information, investigation, and research. For example, the Swedish Chemical Agency is appointed by the Government to take responsibility for the official statistics in the field of Environmental Accounts and Sustainable Development; Sales and Use of Chemicals.

Based on information from the Swedish products register, statistics on chemicals are published annually as an “overview”, consisting of 24 tables showing statistics on chemicals on the national market. The flow analyses are also part of the official statistics. These show the national use patterns of chemicals substances for which such information is commonly requested to a large extent, for example some phthalates, nonylphenoethoxylates and bisphenol A.

6.2 Publicly available summary tables and diagrams

Besides the official statistics, short summaries showing facts of public interest can be regularly published on the authority's website in order to show the current situation and trends in the use of chemicals. The summaries should be easy to understand, and the information should be fairly simple to reuse for those who need it and it can obviously not cover CBI.

6.3 Direct inquiries

There can also be a possibility for different types of stakeholders to ask for and get access to specific data from a register. Of all external inquiries to the Swedish Products Register more than 50 % are by central authorities, local authorities and universities. Information from the product register can facilitate their tasks through the compilation of facts on the chemicals or contact information for importers and producers. Some examples are given in the table below.

The rest of the inquiries are made by various organisations, representing for instance, professional organisations, media, technical consultants, or businesses.

Table 3. This table shows examples of requests for information to the Swedish Products Register

Other organisations/authorities requesting information	Information asked for from the products register
Police	
Police investigation	A company's reported products in a certain year
Governmental commission	
Investigation on economic instruments	Import of plant protection products and mineral fertilizers
Parliament	
Information on current situation	Import and export of VOC (Volatile Organic Compounds)
Regional authorities / County administration	
For the protection of fresh water sources, information on the annual use of PFOS over the last two decades	Quantities of PFOS imported and produced each year
Local authorities	
Causes of emission into sewage of a chemical substance	Quantities per industrial category and function
Inspections	Reported products of a certain importer/producer
Follow up of "A non toxic environment"	Locally based importers and producers of CMR-substances
Universities	
Content of chemical substances in cosmetics	Import and production of specific substances
Chemical substances in flame retardants and fire-extinguishing agents	Chemical substance, type of product, year
Occupational exposure to two chemical substances	Importers and producers of chemicals containing the chemical substance

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