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**Open-ended Working Group of the International Conference  
on Chemicals Management**

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Item 4(a) of the provisional agenda\*

**Progress towards the achievement of the 2020 overall  
objective of the sound management of chemicals: 2014-  
2016 progress report**

**Proposal by the Organisation for Economic Co-operation  
and Development (OECD) for a new Inter-Organization  
Programme for the Sound Management of Chemicals  
(IOMC) indicator for measuring progress with the sound  
management of chemicals and waste**

**Note by the secretariat**

The secretariat has the honour to circulate, in the annex to the present note, a report received from the Organisation for Economic Co-operation and Development (OECD) on a new Inter-Organization Programme for the Sound Management of Chemicals (IOMC) indicator for measuring progress with the sound management of chemicals and waste. The report is presented in the annex as received from the OECD and has not been edited by the secretariat.

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\* SAICM/OEWG.3/1.

## **Annex**

### **Proposal by the Organisation for Economic Co-operation and Development (OECD) for a new Inter-Organization Programme for the Sound Management of Chemicals (IOMC) indicator for measuring progress with the sound management of chemicals and waste**

Following the publication by the IOMC of a number of simple indicators to measure progress with the implementation of SAICM, the present document outlines a proposal for the OECD to develop and maintain an additional IOMC indicator: number of countries that have legislation in place to manage industrial and consumer chemicals.

## Background

1. Following a proposal made at ICCM4 in 2015, the IOMC has published a number of indicators of progress in implementing SAICM [see [http://www.who.int/iomc/indicators\\_saicm/en/](http://www.who.int/iomc/indicators_saicm/en/)]. These are:

- Number of countries with National Profiles (UNITAR)
- Number of countries with a PRTR (UNITAR)
- Number of countries with Poisons centres (WHO)
- Countries with controls for lead in decorative paint (WHO and UNEP)
- Number of countries that have achieved core capacities for chemicals under the International Health Regulations (WHO)
- Number of parties to the Basel Convention
- Number of parties to the Rotterdam Convention
- Number of parties to the Stockholm Convention
- Number of parties to the Minamata Convention
- Countries which have implemented pesticide legislation based on the FAO/WHO International Code of Conduct (FAO)

2. Work is underway to add further indicators, for example on the GHS. There is currently no IOMC indicator for measuring the progress in countries with setting up management systems specifically dedicated to managing the risks of industrial and consumer chemicals, i.e. chemicals which are not covered by specific legislations such as pesticides or pharmaceuticals<sup>1</sup>. Also the indicators used by the SAICM Secretariat to track progress with SAICM implementation do not specifically address industrial and consumer chemicals. The present document outlines a proposal for developing such an indicator.

### On-going efforts to develop Objectives and Targets/Milestones for the sound management of chemicals beyond 2020

3. In the context of developing a new international framework for the sound management of chemicals and waste, the SAICM Secretariat has proposed objectives and milestones for the [11 basic elements](#) recognized as critical at the national and regional levels to the attainment of sound chemicals and waste management, and in particular for: "(a) Legal frameworks that address the life cycle of chemicals and waste"<sup>2</sup>:

<sup>1</sup> "Industrial" chemicals are defined by default as all chemicals that are NOT managed through legislations dedicated to specific uses, such as pharmaceuticals, pesticides, biocides etc. It also covers consumer uses (such as the use of paints) that are not managed by specialised legislations. To avoid the impression that industrial chemicals are chemicals that are only used in industrial settings, they are called "industrial and consumer chemicals" in the present document.

<sup>2</sup>[http://www.saicm.org/Portals/12/Documents/meetings/IP2/IP\\_2\\_8\\_OBJECTIVES%20AND%20SDG.pdf](http://www.saicm.org/Portals/12/Documents/meetings/IP2/IP_2_8_OBJECTIVES%20AND%20SDG.pdf)

Objective	Related Milestones/Targets
Legal frameworks that address the life cycle of chemicals and waste.	<p>1a. Countries have basic policies and legislation in place to manage chemicals and waste throughout the life-cycle.</p> <p>1b. Countries have developed and are implementing mechanisms to review, update, and strengthen their policy, legislative and regulatory frameworks in light of national priorities and international commitments, with stakeholder involvement.</p> <p>1c. Countries have functional compliance and enforcement mechanisms in place, and are implementing procedures to review, update, and strengthen those mechanisms</p>

4. While this objective and the related Milestones/Targets have not been adopted yet, it is likely that a similar version will emerge during the negotiations<sup>3</sup>.

5. As in the proposal above, “chemicals” covers all types of chemicals, including pesticides, biocides as well as industrial and consumer chemicals, it is likely that different indicators for different types of chemicals will need to be developed. The FAO is already maintaining an indicator for the number of countries that have implemented pesticide legislation based on the FAO/WHO International Code of Conduct. Furthermore, as chemicals management and waste management is usually covered by different legislations in countries, it is likely that separate indicators would need to be developed for measuring the number of countries that have implemented appropriate waste management systems. Further work could also be done in the future on how countries take into consideration the chemicals and waste interface.

#### **Number of countries that have a legislatively mandated system to manage industrial and consumer chemicals**

6. The implementation of the GHS is a very effective measure for reducing the risks from any type of hazardous substances handled at the workplace and/or used by consumers.

7. To complement the impact of the GHS for the reduction of risks from industrial and consumer chemicals, many countries have implemented legislation allowing them to prioritise chemicals for risk management, perform a risk assessment on priority chemicals and implement, if needed, risk reduction measures based on the outcome of the risk assessment. Unfortunately, many countries still lack such legislation for industrial and consumer chemicals and cannot manage the risks of chemicals that have been recognised as needing risk reduction measures in other countries (e.g. chemicals listed on Annex III of the Rotterdam Convention).

8. Recognising the gap in legislation, many countries have started to initiate legislative processes to set up or improve their chemicals management system. To measure worldwide progress with addressing the potential risks from using industrial chemicals it is proposed to develop the following indicator:

- Number of countries that have legislation in place to manage industrial and consumer chemicals

9. Such an indicator would be in line with other IOMC indicators of progress in implementing SAICM and could be one of several indicators measuring progress with meeting milestone 1a proposed by the SAICM Secretariat (see table above)

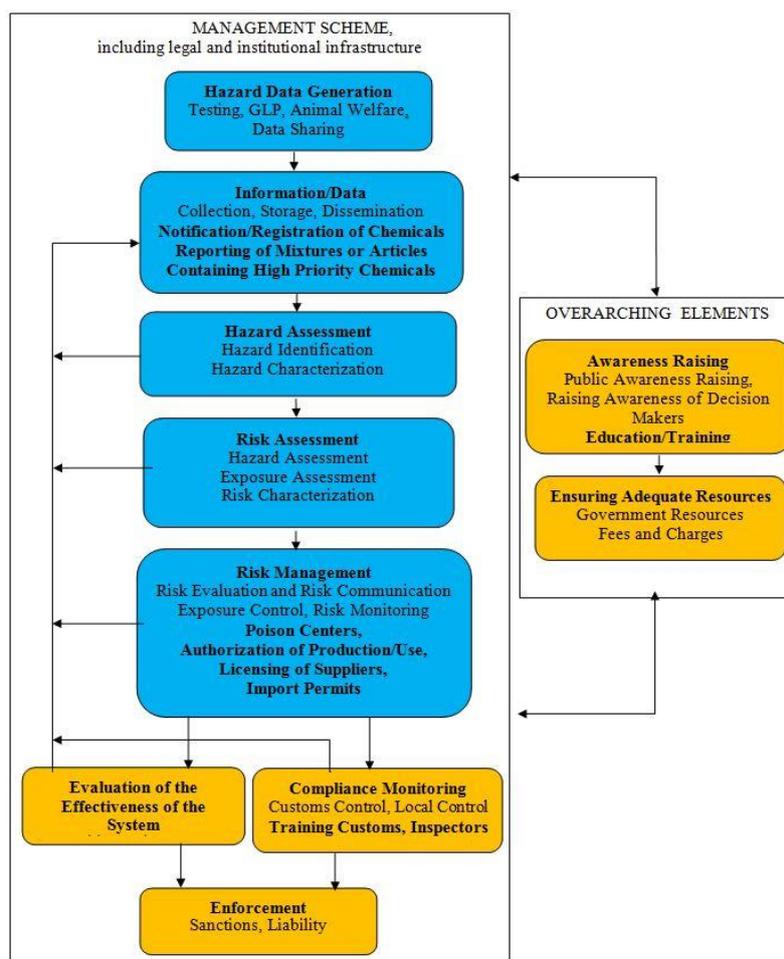
<sup>3</sup> A similar milestone was proposed in a thought starter by the EU: “By 2025, countries have legal frameworks that define responsibilities and address risk reduction and prevention or minimisation of impacts through the life cycle of chemicals and waste and include relevant enforcement and compliance mechanisms.”;

<http://www.saicm.org/Portals/12/documents/meetings/IP2/Draft%20thoughtstarter%20on%20Objectives%20and%20Milestones%20-%20IP2.docx>

## How to qualify as managing industrial and consumer chemicals?

10. The OECD has developed extensive guidance for establishing or improving an industrial and consumer chemicals management system as part of the [IOMC Toolbox for decision-making in chemicals management](#). Such a system is usually made up of a number of elements as outlined in figure 1 [see [ENV/JM/RD\(2014\)2/REV2](#)].

**Figure 1. Relation of the elements of a framework for the management of industrial and consumer chemicals**

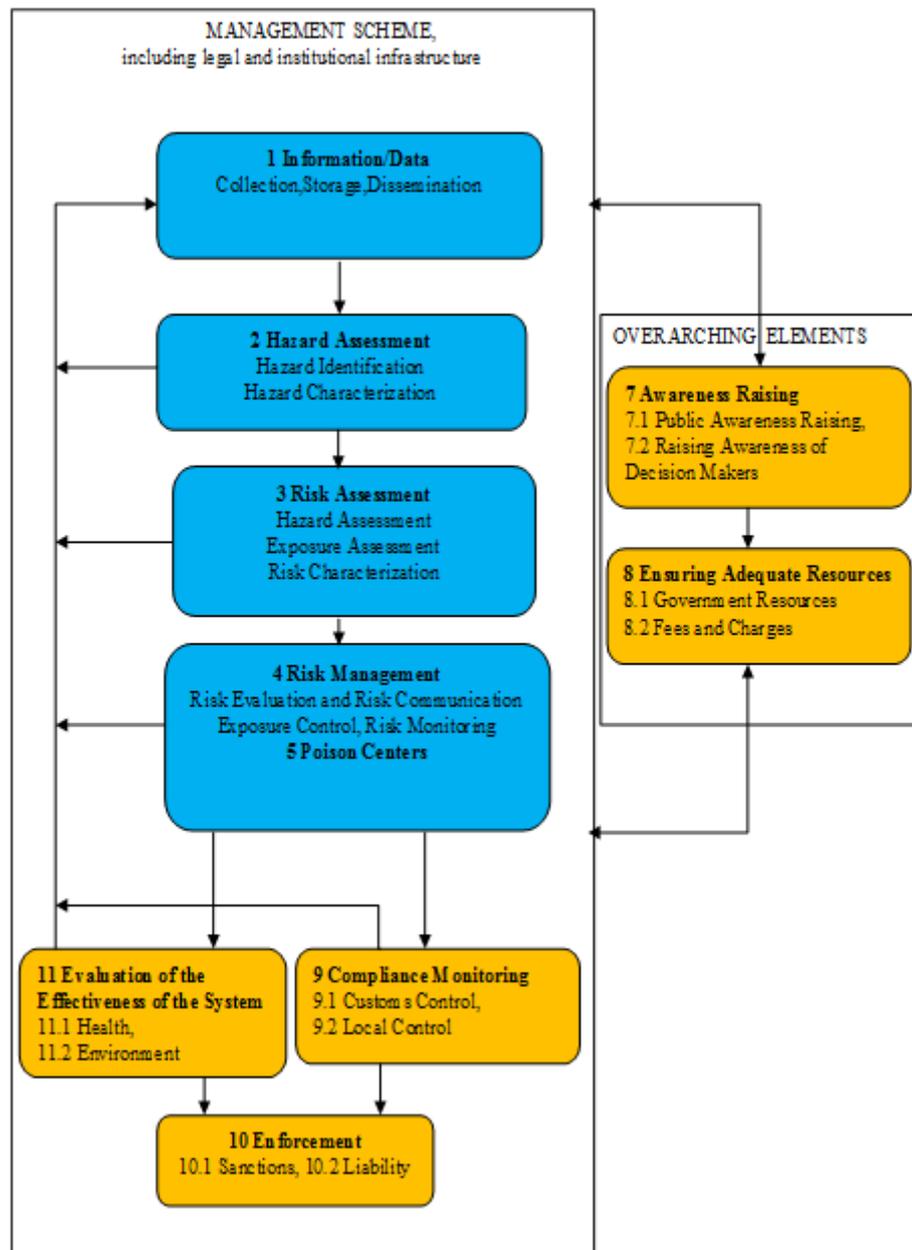


Note: technical elements in blue and functioning elements in orange (bold: elements, normal: sub-elements)

11. More detailed explanations of the different technical and functional elements of this scheme are provided in Annex A. Note that the implementation of the GHS can be considered to be an integral part of a system for managing industrial chemicals, in many countries the implementation of GHS is covered by separate legislation. Hence a separate IOMC indicator is available to measure GHS implementation in countries.

12. As part of this scheme, the IOMC has also defined a “low resource” or “core” framework for a developing country. This low resource framework is a system with the basic key elements that can be implemented with low resources. The relations of the elements of such a core framework are described in Figure 2.

**Figure 2. Relation of the key elements of a core framework for the management of industrial and consumer chemicals**



*Note:* key technical elements 1 - 5 in blue and key functional elements 7 — 11 in orange (bold: elements, normal: sub elements)

13. It is proposed that the indicator counts countries that have implemented a legislatively mandated management system that covers the technical elements of such a core framework. It is clear that the functional elements are very important as well to ensure the operation of the framework. Nevertheless, to keep reporting by countries manageable, it is proposed that, for the time being, the indicator only covers the technical elements. Furthermore, the element on poison centres is already covered by another IOMC indicator maintained by WHO. It is therefore proposed to omit this element from the new proposed indicator. A separate indicator covering the functional elements could be developed in the future. It would be in line with milestone 1c proposed by the SAICM Secretariat (see table above).

14. Developing risk assessments for individual chemicals or groups of chemicals requires considerable expertise and resources. To save resources it is important that countries cooperate and as much as possible and use what has already been performed in other countries. It is therefore proposed that countries also qualify if they implement risk management measures based on:

- risk assessments (fully or partially) performed in other countries;
- screening risk assessments; or
- generic risk assessments (e.g. certain combinations of hazards and uses for which a high probability of risk for human health or the environment is predicted, such as carcinogens in certain consumer preparations).

### **Proposed next steps**

15. This proposal will be submitted to the 3<sup>rd</sup> Open-Ended Working Group of the International Conference on Chemicals Management, which will be held in April 2019.

16. To evaluate whether countries qualify as having a legislatively mandated industrial and consumer chemicals management system in place, national SAICM focal points would be contacted to provide information according to a simple questionnaire and information sheets would be developed and published after approval by national authorities. A draft of the information sheet, together with two examples, is outlined in Annex B. The information sheets could be made available through an interactive map on the internet, similar to the presentation of other IOMC indicators.

17. The establishment of a functioning industrial and consumer chemicals management system is part of the legal instruments developed by the OECD. The OECD could therefore establish and maintain the indicator and periodically report on progress (e.g. once every two years). A baseline report could be presented at the 5<sup>th</sup> International Conference on Chemicals Management in 2020.

*Elements of a framework for the management of industrial chemicals [source: [ENV/JM/RD\(2014\)2/REV2](#), updated following further comments from countries]*

## **Key elements with technical content**

### ***1 Information/Data***

**Description:** Information/Data contains three sub elements – Information/Data Collection, Information/Data Storage and Information/Data Dissemination. It provides the government with information about chemicals production, use, import/export of chemicals as well as other information and data relevant for consumer, worker and environmental safety including GHS classifications and labels, emergency management and safety plans. The information needs to be stored and the access to the information has to be organized in a way that provides access when needed/warranted while also protecting confidential business information from unauthorized disclosure.

**Relation to other elements:** Information on production and use and import/export can be used for Exposure Assessment in **Risk Assessment**, for priority setting in **Risk Assessment** and **Risk Management** and **Compliance Monitoring** of obligations by industry. Information and data relevant for consumer, worker and environmental safety can be used for **Hazard Assessment**, **Risk Assessment** and **Risk Management**, for setting priorities in **Risk Management** and for requesting information through additional elements - **Authorization of Production/Use** or **Licensing of Suppliers** or **Import Permits** for health/environmental reasons as well as for **Raising Awareness of Decision Makers and Public Awareness Raising**, and **Education/Training of the Public and Workers**. Information from **Evaluation of the Effectiveness of the System** could be a basis for reviewing the management system for industrial chemicals. The compliance of industry with reporting obligations needs to be controlled through **Compliance Monitoring** and enforced through **Enforcement**. One could consider requesting fees (**Fees and Charges**) by industry for reporting. Reporting requirements can also be implemented through **Notification/Registration of Chemicals**, **Authorization of Production/Use** and **Licensing of Suppliers** when such elements are selected.

#### ***1.1 Information/Data Collection***

**Description:** Collection of information about chemicals production and use, import and export of chemicals as well as other information and data relevant for consumer, worker and environmental safety. It includes collection of selected available information and data from industry and their associations, government authorities (compliance monitoring, evaluation of the effectiveness of the system), international and regional organisations, academia, scientific and other literature, NGOs, media, projects and studies.

**Relation to other sub elements:** The information and data need to be stored in a way that they are easily accessible for further use in **Hazard Assessment**, **Risk Assessment** and **Risk Management** while ensuring that confidential business information is protected from unauthorized disclosure.

#### ***1.2 Information/Data Storage***

**Description:** The Information/Data collected by government need to be stored for later use. Only up-to-date and quality controlled data should generally be stored, although some historical data on production or import volumes or uses may be useful for time trend analyses. If the information/data contain confidential business information then the

confidentiality should be guaranteed. Information and data could be stored in a National Database.

**Relation to other sub elements:** Information/Data Storage facilitates Information/Data Dissemination.

### *1.3 Information/Data Dissemination*

**Description:** Information/Data Dissemination means that the data collected and stored should be made available to all stakeholders to enable them to fully participate in the management system. Confidential business information will be accessible only by authorized persons. Government officials should have access to all stored information necessary for their work. The public will receive non – confidential information relevant for health and environmental safety.

**Relation to other sub elements:** Effective and appropriate access to the information received and being considered by the government is essential to adequately inform stakeholders and build confidence in the chemical management scheme.

## *2 Hazard Assessment<sup>4</sup>*

**Description:** Hazard Assessment contains two sub elements – Hazard Identification and Hazard Characterization - and is a process to determine the possible adverse effects of a chemical to which an organism, system, or (sub) population could be exposed. Hazard is the inherent property of a chemical that has the potential to cause adverse effects when an organism, system, or (sub) population is exposed to that chemical. Hazard assessment can be done at varying levels, ranging from an initial or “screening” assessment to a comprehensive/detailed assessment.

**Relation to other elements:** Hazard assessment may lead to classification and labeling of chemicals which can be used as a means to communicate hazards along the supply chain from producer to the user. Hence Hazard Assessment is an important input into any **Risk Management** activities to improve environment safety (air, water, soil), public and workers safety, Pollution Release and Transfer Registers, accident prevention, storage, transport and waste management including recycling and waste disposal. Hazard Identification is the basis for Hazard Assessment and together with Hazard Characterization is an important input into **Risk Assessment**. Industry could be requested to classify and label hazardous chemicals according to the GHS and this obligation needs to be controlled and enforced. Information on hazard identification and characterization of (priority) chemicals could be stored in a National Database.

### *2.1 Hazard Identification*

**Description:** Hazard Identification is the identification of the type and nature of adverse effects that a chemical has an inherent capacity to cause to humans or environmental organisms. It should be implemented through the classification according to the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

**Relation to the other sub element:** Hazard Identification is the first step of Hazard Assessment and the basis for hazard characterization.

### *2.2 Hazard Characterization*

**Description:** Hazard Characterization is the qualitative and, wherever possible, quantitative description of the inherent property of a chemical that has the potential to

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<sup>4</sup> Hazard and risk assessment, risk management descriptions are adapted from IPCS RISK ASSESSMENT TERMINOLOGY, WHO, 2004 <http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf>

cause adverse effects. This should, where possible, include a dose response assessment and its uncertainties.

**Relation to the other sub element:** Hazard Characterization is the second step of Hazard Assessment.

### ***3 Risk Assessment***

**Description:** Risk Assessment contains four sub elements - Hazard Assessment including Hazard Identification and Hazard Characterization, Exposure Assessment and Risk Characterization - and is a process intended to calculate or estimate the risk to a given target organism, system, or (sub) population, including the identification of uncertainties, following exposure to a chemical, taking into account the inherent characteristics of the chemical of concern as well as the characteristics of the specific target system. Risk assessment can be done for the whole lifecycle of a chemical, for one or more stage of the lifecycle, for a concrete situation like environmental releases (either generally or for a given site). Risk assessment can be done at an initial (or “screening”) level or at a more detailed/comprehensive level. As detailed/comprehensive risk assessment can be very resource intensive it could be considered to rely on risk assessments carried out in another country or region, if exposure conditions are similar or considered to be covered, or to do such risk assessments only for high priority/selected chemicals.

**Relation to other elements:** Risk Assessment can be used to inform priority setting decisions or to provide an understanding of the need and the basis for **Risk Management** decisions. The information on risk assessments of (priority) chemicals could be stored in a National Database.

The sub elements Hazard Identification and Hazard Characterization are described under **Hazard Assessment**. Exposure Assessment is the estimation or measurement of exposure to the chemical under investigation during its life cycle and is with hazard assessment the basis for risk characterization. The exposure assessment for the lifecycle of a chemical is the main activity in risk assessment and needs input from all sectors involved in industrial chemicals management. Risk Characterization is the qualitative and, wherever possible, quantitative determination, including uncertainties, of the probability of occurrence of known and potential adverse effects of chemical in a given organism, system, or (sub)population under defined exposure conditions.

### ***4 Risk Management***

**Description:** Risk Management contains three sub elements – Risk Evaluation, Socio-Economic Analysis and Risk Communication, Exposure Control and Risk Monitoring - and is a decision-making process involving consideration of relevant risk assessment information relating to the hazards and exposures from a chemical and the socio-economic aspects (political, social, economic, and technical factors) so as to develop, analyze and compare regulatory and non-regulatory control options and to select and implement the appropriate regulatory response to that substance. Precaution can be applied in risk management when there are threats of serious or irreversible damage to man or the environment. In this situation the lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent the damage.

Risk management measures include, for example, labeling of chemicals and mixtures according to the GHS, use of safety data sheets, use of personal protective equipment or bans and restrictions for marketing and use. Other options to anticipate and prevent risks are for example pollution prevention, to reduce the generation of hazardous waste, environmentally sound recovery and recycling, safer alternatives, informed substitution, cleaner production, chemical leasing. If another country has already assessed or acted upon a chemical, information is likely to be available on risk reduction measures that

have been adopted, as well as the background for these measures. This information can be useful for a country starting to assess a chemical.

Risk management measures can be applied to:

- chemicals with unknown properties, e.g. by implementing general exposure minimization measures;
- priority chemicals, e.g. by implementing risk reduction measures depending on the hazard profile and the intended uses;
- high priority chemicals, e.g. through bans or restriction for marketing and use.

**Relation to other elements:** The information on risk management measures of (priority) chemicals could be stored in a National Database. Risk Management provides target levels for Exposure Control as information to **Evaluation of the Effectiveness of the System** and **Compliance Monitoring**. Other elements **Poison Centers, Authorization of Production/Use, Licensing of Suppliers** and **Import Permits** provide measures for risk management.

#### *4.1 Risk Evaluation, Socio-Economic Analysis and Risk Communication*

**Description:** Risk Evaluation and Socio-Economic Analysis involves the establishment of a qualitative or quantitative relationship between risks of exposure to a chemical and the socio-economic benefits (for example, economic or performance) of a chemical, involving the complex process of determining the significance of the identified hazards, exposures, and estimated risks to the system concerned or affected by the exposure, as well as the significance of the benefits brought about by the chemical.

Risk Communication is the exchange of information about (health or environmental) risks among risk assessors, managers, news media, interested groups, and the general public and can be included in Risk Management.

#### *4.2 Exposure Control:*

**Description:** Exposure control are the technical, organisational or legal risk management measures that are expected to decrease the exposure of a chemical to an acceptable level determined in the Risk Evaluation and Socio-Economic Analysis.

#### *4.3 Risk Monitoring:*

**Description:** Risk Monitoring is the process of following up the decisions and actions within risk management in order to ascertain that risk containment or reduction with respect to a particular hazard is occurring.

**Relation of the sub elements:** The content of the Risk Evaluation determines the Exposure Control to manage the identified risks and the effect of the exposure control is evaluated through comparing the results of monitoring the risks with the level of exposure achieved through exposure control.

#### *5 Poison Centers<sup>5</sup>*

**Description:** A poison center is a specialized unit that advises on, and assists with, the prevention, diagnosis and management of poisoning. It 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. In poison centers data on toxic exposures to chemicals

<sup>5</sup> Poison centers adapted from WHO website <http://www.who.int/ipcs/poisons/centre/en/>

and on chemical incidents can be collected. One could consider having a legal obligation for medical doctors to report cases of poisonings on a template to the poison centers.

**Relation to other elements:** A poison centre could contribute to the risk management for health. The information on incidents can be used as a contribution to the **Evaluation of Effectiveness of the System** for health and could be stored in a National Database. If for example a wrongly labeled chemical by a known company was used and that use has led to a poisoning this could be the basis for improving the compliance by the company.

## Key elements relevant for the functioning of the system

### *7 Awareness Raising<sup>6</sup>*

**Description:** Awareness Raising contains two sub elements – Public Awareness Raising and Raising Awareness of Decision Makers. Raising awareness about the problems – hazards, risks - with industrial chemicals in the country, about the gaps and overlaps in the existing sector management systems and how a framework can address the problems and gaps and overlaps, what resources are required and what benefits can be expected from effective risk management measures is essential to get public and political support for the development and implementation of a framework. It is important to communicate adequate understandable information at an appropriate level of detail to the targeted audience. Coordination of the communications from different groups (industry, NGOs, public authorities) should be sought as far as possible in order to avoid that the target group is faced with contradictory information.

**Relation to other elements:** The information for Awareness Raising can come from the result of analysis of gaps and overlaps in the existing management system (e.g., as developed in a National Profile) and from the element **Information/Data** including selected available information and data relevant for health and safety of man or environment collected from industry associations, government authorities (**Compliance Monitoring, Evaluation of the Effectiveness of the System**), international and regional organisations, academia, the scientific and other literature, public NGOs, media, projects and studies. The awareness of the public and decision makers about problems with industrial chemicals provided through **Information/Data** collected by the management system and about the benefits from managing them safely could increase the political support by decision makers **Ensuring Adequate Resources** for the implementation of the management system. Awareness Raising of industry and information on the aim of the framework and of their responsibilities and obligations under the legislation could facilitate that companies comply with the obligations. Companies are more likely to comply if they understand the obligations and their rationale. **Education/Training of the Public and Workers** could complement and strengthen the Awareness Raising activities. The system for classification and labelling (GHS) remain a key instrument in that regard.

#### *7.1 Public Awareness Raising*

**Description:** Public Awareness Raising can be done through information workshops for the public, public awareness campaigns through the media, NGOs, making information publicly available, organizing site visits of industries, laboratories and other events and organizing information sessions in schools. Tools for information could be websites, guidelines and other types of information material like brochures, leaflets or presentations.

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<sup>6</sup>Awareness, fees and charges, compliance monitoring, enforcement, licensing descriptions are adapted from Guidance on the Development of Legal and Institutional Infrastructures for Sound Management of Chemicals and Measures for Recovering Costs of National Administration (LIRA-Guidance), Test version, UNEP Chemicals 2012  
<http://www.unep.org/hazardoussubstances/UNEPsWork/Mainstreaming/UNEPLIRAGuidance/tabid/79269/Default.aspx>

**Relation to other sub element:** It complements the other sub element.

### ***7.2 Raising Awareness of Decision Makers***

**Description:** Raising Awareness of Decision Makers includes raising awareness of the regulated industry as the same type of tools can be used. It can be done through involving industry in the policy making process, information workshops, decision makers and industry, public awareness campaigns through the media, NGOs, organizing site visits of industries, laboratories. Tools for information could be websites, guidelines and other types of information material like brochures, leaflets or presentations.

**Relation to other sub element:** It complements the other sub element.

### ***8 Ensuring Adequate Resources***

**Description:** Ensuring Adequate Resources for the implementation of the system contains two sub elements – Government Resources for the legal and administrative infrastructure of the framework and Fees and Charges which are paid by industry. Resources are an overarching issue as they need to ensure the functioning of all elements that are included in the framework for the management of industrial chemicals. Long term funding will be facilitated by defining the role of the industry and of the administration in the legislation.

**Relation to other elements:** The amount of resources available for the framework depends on the economic situation of the country and the importance of industrial chemicals for the economy. Most countries are not producers but importers of chemicals. Still, all countries use industrial and consumer chemicals to a significant extent. To safeguard economic and social development a management system is therefore of importance to all countries. However, the availability of resources will determine the nature and extent of the management system for industrial chemicals which is to be developed and implemented by a country. The awareness of the public and decision makers about problems with industrial chemicals provided through **Information/Data** collected by the management system and about the benefits from managing them safely could increase the will to provide sufficient resources by decision makers.

#### ***8.1 Government Resources***

**Description:** Resources which are made available to government agencies, departments, or ministries can be used to support staffing and provide needed equipment and training required by the government to develop and implement a management system for industrial and consumer chemicals.

**Relation to other sub element:** Some of the resources by government could be financed by Fees and Charges collected from industry.

#### ***8.2 Fees and Charges:***

**Description:** Fees can be requested from industry for services by the government that complement industry obligations like controlling the quality of submitted information or reviewing assessments with a feedback to industry. Fees could be requested, for example, for enforcement, reporting, notification/registration, licensing, authorization and import permit.

**Relation to other sub element:** Fees and Charges from industry can be a source of resources for an effective chemicals management system, including enforcement.

## ***9 Compliance Monitoring***

**Description:** Compliance Monitoring contains two sub elements - Customs Control and Local Control - and includes steps to ensure that requirements and obligations are being met by industry.

**Relation to other elements:** Compliance Monitoring complements and supports **Enforcement** and, as such, effective inspection systems and reporting requirements are needed to ensure that the regulated companies fulfill their responsibilities and are the bases for sanctions by the authorities for Compliance Monitoring. The **Risk Management** measures that need to be enforced (for example bans and restrictions for marketing and use) will be communicated to customs and the local inspectorates. Relevant information could be found in the information stored for **Information/Data**, for example, in a National Database. **Awareness Raising** of industry and information on the aim of the framework and of their responsibilities and obligations under the legislation could facilitate that companies comply with the obligations. Companies are more likely to comply if they understand and agree with the requirements. The information on Compliance Monitoring can be stored in a National Database while respecting confidentiality of certain company specific information. **Training of Customs Officials and Inspectors** on the obligation of industry for industrial chemicals, how to identify them as such, in mixtures or in articles and on the possible sanctions is important for an effective Compliance Monitoring.

### ***9.1 Customs Control***

**Description:** Customs Control means Compliance Monitoring of obligations of industry from the management system for industrial chemicals by customs officials. This activity is part of the Customs Control of imported goods.

**Relation to other element or sub element:** It complements the sub element Local Control by enforcement at the border to prevent illegal imports of substances. Relying on only customs control is not considered sufficient because it excludes the control of domestic manufacturers. The customs could be supported by a relevant Ministry that issues **Import Permits** on request from the importer implementing obligations from the management system for industrial chemicals. The Ministry could consider having an agreement with customs that specifies their respective roles and tasks.

### ***9.2 Local Control***

**Description:** Local Control means compliance monitoring of obligations of industry from the management system for industrial chemicals by local or national inspectorates.

**Relation to the other sub element:** Inspections within the country complements the Customs Control. Companies could be controlled by different inspectorates under different Ministries for the framework obligations or sector specific management of chemicals. One could consider either to promote a good coordination between the different inspectorates or to centralize some control functions in one inspectorate.

## ***10 Enforcement of obligations***

**Description:** Enforcement of obligations contains two sub elements – Sanctions and Liability. Enforcement of obligations of companies can only be effective if one has a clear and consequent regime.

**Relation to other elements:** Enforcement complements and strengthens **Compliance Monitoring** and an effective inspection systems and reporting requirements are needed to ensure that the regulated companies fulfill their responsibilities. **Evaluation of the Effectiveness of the System** through health and environment monitoring can also be

used as an input to identify possible enforcement priorities. The possibility of applying Sanctions depends on the clarity of the requirements contained in the law.

### ***10.1 Sanctions***

**Description:** Sanctions are generally defined by a list of administrative or criminal offenses – non-compliance with the legal requirements- by companies or government authorities. Sanctions could include monetary sanctions, imposing actions like limitations to or ending of the activities of the company or for serious offences incarceration. Administrative sanctions are based on a decision of a competent authority for Compliance Monitoring. Appeals to this decision should be possible. Sanctions through the legal system are normally based on findings of control authorities.

**Relation to other sub element:** Complements the Enforcement through Liability.

### ***10.2 Liability***

**Description:** Enforcement can also include liability measures. If a causal relationship between an activity of a consumer or worker with a chemical and the damages through poisoning can be demonstrated this can be the basis for a liability for compensating the damage. If a causal relationship between an activity of a company with a chemical and the damages to an area or to an ecosystem through environmental pollution can be demonstrated this can be the basis for the liability for a rehabilitation of the contaminated area or for restoring the ecosystem. Chemical safety would therefore need to be part of a product liability legislation.

**Relation to other sub element:** Complements the Enforcement through Sanctions.

## ***11 Evaluation of the Effectiveness of the System***

**Description:** Evaluation of the positive impact of the management system contains two sub elements - Evaluation of the Effectiveness of the System (human) Health and Evaluation of the Effectiveness of the System (for protecting the) Environment. It can be implemented through health monitoring by Poison Centers or workplace and environmental monitoring, for example through monitoring programs or by using environmental indicators.

**Relation to other elements:** The information from **Poison Centers** or poisoning reporting from industry and hospitals can be used for evaluating the effectiveness of the system for improving human health. Information from biological monitoring of workers or in projects of certain consumer groups can be used for evaluating the effectiveness of the system for protecting human health while environmental monitoring can be used for evaluating the effectiveness of the system for protecting the environment.

### ***11.1 Evaluation of the Effectiveness of the System - Health***

**Description:** Evaluation of the Effectiveness of the System - Health can be implemented as health monitoring like monitoring poisonings of the consumer or worker through reporting by industry, hospitals and/or through reporting by poison centers. Also biological monitoring of workers or of certain consumer groups can be used for evaluation of the effectiveness of the system.

**Relation to other sub element:** Complements the other sub element.

### ***11.2 Evaluation of the Effectiveness of the System - Environment***

**Description:** Evaluation of the Effectiveness of the System - Environment can be implemented through environmental monitoring in the media air, water and soil. .

**Relation to other sub element:** Complements the other sub element.

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 Template for an information sheet on a country's industrial chemicals management system

Country	XXX
Does your country have legislation in place that define responsibilities and address risk reduction and prevention or minimisation of impacts of industrial and consumer chemicals [and include relevant enforcement and compliance]?	Yes / No / In development
Reference of the legislation	XXXX
Year of adoption or last revision	XXXX
Approximate number of industrial chemicals assessed per year (including via the use of risk assessments from other countries)	XX
Protection goals covered by the legislation	Workers/Consumers/Environment
Public availability of risk assessments	Yes / No / NA
URL	XXXX
Recent example of a chemical for which the use of a risk assessment led to risk reduction measures	XXXX
Reference of Risk Assessment	XXXX
Reference of Risk Reduction Measure	XXXX
Other information	XXXX

**Examples:**

Country	United States
Does your country have legislation in place that define responsibilities and address risk reduction and prevention or minimisation of impacts of industrial and consumer chemicals [and include relevant enforcement and compliance ]?	Yes
Reference of the legislation	The Toxic Substances Control Act; <a href="https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act">https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act</a> <a href="https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act">https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act</a>
Year of adoption or last revision	2016
Approximate number of industrial chemicals assessed per year	20 existing chemicals; 500-1000 new chemicals
Protection goals covered by the legislation	Workers/Consumers/Environment
Public availability of risk assessments	Yes
URL	Existing chemicals: <a href="https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca">https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca</a> New chemicals: summaries of risk determinations: <a href="https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices">https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/status-pre-manufacture-notices</a>
Recent example of a chemical for which the use of a risk assessment led to risk reduction measures	Benzidine dyes;
Reference of Risk Assessment	<a href="https://www.epa.gov/sites/production/files/2015-09/documents/dcb_action_plan_06232010.noheader.pdf">https://www.epa.gov/sites/production/files/2015-09/documents/dcb_action_plan_06232010.noheader.pdf</a>
Reference of Risk Reduction Measure	<a href="https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-benzidine-dyes#action">https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-benzidine-dyes#action</a>
Other information	NA

Country	Colombia
Does your country have legislation in place that define responsibilities and address risk reduction and prevention or minimisation of impacts of industrial and consumer chemicals [and include relevant enforcement and compliance ]?	In development
Reference of the legislation	As part of the planned actions, in 2017 Colombia adopted the OECD GLP principles ( <a href="#">Resolution 2507/2017</a> ) and in 2018 the GHS ( <a href="#">Decree 1496/2018</a> ). Also in 2018 Colombia notified its <a href="#">draft decree on industrial chemicals management</a> to WTO.
Year of adoption or last revision	Industrial chemicals programme is predicted to be adopted by 2020
Approximate number of industrial chemicals assessed per year	NA
Protection goals covered by the legislation	Workers/Consumers/Environment
Public availability of risk assessments	NA
URL	NA
Recent example of a chemical for which the use of a risk assessment led to risk reduction measures	NA
Reference of Risk Assessment	NA
Reference of Risk Reduction Measure	NA
Other information	Colombia adopted in October 2016 its <a href="#">National Chemicals Policy</a> . This policy document addresses, <i>inter alia</i> , the development of Colombia's industrial chemicals programme with actions described until the end of 2020.