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REVISED POSITION OF COLOMBIA WITH REGARD TO THE OECD LEGAL INSTRUMENTS IN THE FIELD OF CHEMICALS AS OF 13TH FEBRUARY 2017

This document contains Colombia's Revised Position with regard to the OECD legal instruments in the field of chemicals as of 13 February 2017. On request of the Chemicals Committee, expressed at the meeting of the Committee on 7 November 2016, the Revised Position was updated by Colombia to align the timeframes for implementation and respective action plans included therein with those contained in the National Industrial Chemicals Policy adopted on 5 October 2016.

Contact information:
Rafał BRYKOWSKI, Environmental Policy Analyst
rafal.brykowski@oecd.org; +33 1 45 24 98 81

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COLOMBIA

REVISED POSITION

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13 February 2017

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Position: Acceptance.

Justification:

1. Colombia is in a position to accept data in the assessment of chemicals generated according to the OECD Test Guidelines (TG) and OECD Principles of Good Laboratory Practice (GLP).

2. Regarding environmental and health safety studies in the context of registering or licensing products identified in the scope of OECD GLP Principles, the following legal framework applies:

- Sanitary registry requirements: Decree 677 of 1995 contains the sanitary registry regime applicable to medical drugs, natural-based pharmaceutical preparations, which covers their production, processing, packaging, distribution, import, export and commercialization (Article 1). In most cases, sanitary registration requires a pharmaceutical or technical evaluation (depending on whether the product is produced domestically or imported), and in case of new medical drugs and imported drugs that are not included in pharmacological norms, it requires a pharmacological evaluation as well. The pharmaceutical or technical evaluation intends to establish the technical capacity of the producer, the production process and the product's quality (Article 21). The pharmacological evaluation implies a judgment as to the utility, convenience and safety of a medical drug (Article 27). There are no express restrictions regarding accreditation requirements, test guidelines or GLPs required for the acceptance of data generated in the testing conducted in this context.

- Decree 1545 of 1998 contains sanitary registry regime applicable to hygiene and cleaning products relating production, processing, packaging, distribution, import, export and commercialization (Article 1), and Decree 219 of 1998 regulates the sanitary regime in quality control and surveillance or cosmetic products, relating their production, processing, packaging, distribution, import, export and commercialization (Article 1).

- Cosmetic products and household cleaners: Andean Decisions 516 of 2002 and 706 of 2008 require a mandatory sanitary notification (NSO by its acronym in Spanish) to the competent local authority of the first Andean Community of Nations (CAN by its acronym in Spanish) Member country where the product will be commercialized (Article 5 of both Decisions). For NSO purposes, these Decisions require the submission of general and technical information, the latter including physical-chemical specifications of the finished product and a justification of the benefits and statements accompanying the product that may represent a health problem in case of inaccuracy (Article 7). There are no express restrictions in these Decisions regarding tests guidelines or GLPs required for the acceptance of data generated in the testing conducted in this context. Decision 516 accepts Food and Drug Administration (FDA) of the United States of

America, European Cosmetic Toiletry and Perfumery Association (COLIPA) and European Union Directives ingredient lists to be used in cosmetic products (Article 3).

- Food additives: Decree 2106 of 1983 and Resolution 2606 of 2009 regulate the production and the conditions under which food additives may be used and commercialized. There are no express restrictions in these regulations regarding tests guidelines or GLPs required for the acceptance of data generated in the testing conducted in this context.

- Pesticides: Regarding the use and management of pesticides, Decree 1843 of 1991 requires interested parties to register and to obtain a sanitary permit for the use of pesticides (Articles 10 and 18). In this context, interested parties must submit information regarding the product to allow the competent authority to issue a "determination on toxicological classification and the toxicity risk of the products". The Decree requires that the information be submitted according to the regulations that the Ministry of Health issues specifically to this end, which must include information on the responsible laboratory. The reports must be produced by qualified and/or officially authorized persons (Article 143, Decree 1843 of 1991). There are no express restrictions regarding tests guidelines or GLPs required for data generated in the testing of chemicals in this context.

- Chemical pesticides for agricultural use: These pesticide products are subject to a special regime established in Andean Decision 804 of 2015 (previously Decision 436 of 1998) (regarding guidelines and procedures for the registry and control of chemical pesticides for agricultural use). In order to produce, formulate, import, export, pack, commercialize or distribute a chemical pesticide for agricultural use, the interested party must be previously registered before the competent authority (Article 7, Andean Decision 804). Colombia implemented this Decision nationally through Decree 1071 of 2015[1] (previous Decree 502 of 2003), which designated the Ministry of Agriculture and Rural Development through the Colombian Agricultural Institute (ICA by its acronym in Spanish) as the authority in charge of keeping the register and exercising control over these pesticides, as well as to enforce the Decision, the Technical Manual and national regulations (Article 2.13.8.1.1., Decree 1071). The assessment of chemical pesticides for agriculture use is based on test data on health and environmental effects, as well as exposure analysis provided by the registrant. A Technical Manual was adopted in Andean Resolution 630 of 2002[2], which covers all aspects of pesticide registration, safety assessment, classification and labelling, and contains technical specifications regarding studies to determine toxicity effects and physical and chemical properties. For each of them, the Manual recommends preferred methods, including OECD and EPA guides.

- Chemicals for industrial use: Outside of the legal framework specified above, the registration and assessment of human and environmental hazards and risks of chemicals for industrial use has not yet been implemented in Colombia. Consequently, there is no provision that prohibits accepting data that is in compliance with the Council Decision concerning the Mutual Acceptance of Data. The new legal framework that will set up the Chemicals for Industrial Use Management Programme shall require compliance with these two Decisions regarding the acceptance of non-clinical data generated in accordance with Test Guidelines (TG) and Good Laboratory Practice (GLP).

[1] Decree 1071 of 2015 now contains all executive regulations for the agricultural administrative sector.

[2] According to the third provisional article of Decision 804, Andean Member countries must apply Resolution 630 while new technical manual is developed and adopted.

3. Regarding the Decision-Recommendation C(89)87/FINAL on the Compliance with GLP Principles, this Council Act applies in cases where GLP principles are being carried out, for the purposes of recognition by other member countries of GLP compliance. Colombia is in the process of setting up a GLP compliance monitoring authority with the technical and financial support of the United Nations Industrial Development Organization (UNIDO). The National Accreditation Body (ONAC by its acronym in Spanish) will become the GLP compliance authority in Colombia according to the recently issued Decree 1074 of 2015[3] (Article 2.2.1.7.7.6).

4. In summary, Colombia is willing and able to comply with these Decisions as much as it recognizes and accepts data from OECD Member countries and non-member full adherents to the Council Acts related to the Mutual Acceptance of Data (MAD) that comply with the referred Decisions.

GENERAL PRINCIPLES OF CHEMICALS MANAGEMENT

C(82)196/FINAL – DECISION OF THE COUNCIL CONCERNING THE MINIMUM PRE-MARKETING SET OF DATA IN THE ASSESSMENT OF CHEMICALS

C(77)97/FINAL – RECOMMENDATION OF THE COUNCIL ON GUIDELINES IN RESPECT OF PROCEDURES AND REQUIREMENTS FOR ANTICIPATING THE EFFECTS OF CHEMICALS ON MAN AND THE ENVIRONMENT

C(74)215 – RECOMMENDATION OF THE COUNCIL ON THE ASSESSMENT OF THE POTENTIAL ENVIRONMENTAL EFFECTS OF CHEMICALS

Position: Acceptance of Decision C(82)196/FINAL, with a specific timeframe for implementation (2020). Acceptance of Recommendation C(77)97/FINAL, with a specific timeframe for implementation (2020). Acceptance of Recommendation C(74)215, with a specified timeframe for implementation (2020).

Justification:

Regarding the requirements of the Decision C(82)196:

Information on the properties of new chemicals should be available before they are marketed to ensure that a meaningful assessment of hazard to man and the environment can be carried out

5. Colombia is currently designing a Programme for the Management of Chemicals for Industrial Use. This Programme is structured based on three types of elements: technical, transversal and functional. As part of the technical elements, the Programme includes the hazard and risk assessment of chemicals for industrial use.

6. According to the proposed programme, hazard and risk assessment and information on potential exposures related to new and existent chemicals for industrial use will be requested to manufacturers and importers of these substances.

Minimum pre-marketing set of data (MPD) to assess the potential hazard of chemical to health and the environment

[3] Decree 1074 of 2015 now contains all executive regulations for the trade, industry and tourism administrative sector.

7. Currently, some of the minimum pre-marketing set of data identified in Council Act C(82)196/FINAL are requested in Colombia for pesticides, food additives, cosmetic products, pharmaceutical products and disinfectants for household use, in the context of sanitary registry or notification requirements, operation licenses, use permits and environmental licenses.

8. As an example, the legal and technical framework related with the premarketing assessment of pesticides in Colombia includes:

- Andean Decision 804 (previously Decision 436 of 1998) regulates the Registration and Control of Pesticides for Agricultural Use, and it is regulated in Colombia by Decree 1071 of 2015[4] (previous Decree 502 of 2003 issued by the Ministry of Agriculture and Rural Development, the Ministry of Social Protection (now the Ministry of Health and Social Protection), the Ministry of Commerce, Industry and Tourism, and the Ministry of Environment, Housing and Territorial Development (now the Ministry of Environmental and Sustainable Development).

- Andean Resolution 630 of 2002, which is the Andean Technical Manual for Registration and Control of Pesticides for Agricultural Use within Andean Community of Nations (CAN by its acronym in Spanish). The Technical Manual was developed in compliance with Article 70 of Andean Decision 436 of 1998.

- Resolution 3759 of 2003 issued by the Colombian Institute for Agriculture (ICA by its acronym in Spanish) dictates the provisions for the registry and control of pesticides for agricultural use.

- Decree 1843 of 1991 regulates the use and handling of pesticides used in public health, domestic use, livestock use, bio-pesticides, and natural pesticides. Specifically, Articles 143 to 145 of Decree 1843 include all the requirements for conducting toxicological evaluations for this type of products.

- Resolution 1442 of 2008 issued by the Ministry of Environment, Housing and Territorial Development (today Ministry of Environment and Sustainable Development) establishes the procedure to issue the technical environmental assessment required for the registration of chemical pesticides for agricultural use before the ICA. The assessment summarizes environmental considerations and specifies authorized activities, use conditions and requirements, and any other obligations that the registration applicant must comply with (article 4). The Environmental Licensing Authority (ANLA by its acronym in Spanish) must currently issue this technical report.

- Decree 1076 of 2015, in the chapter that establishes environmental licensing procedures applies to the manufacture of all pesticides and the import of pesticides for agricultural, veterinary, public health, industrial and domestic use. An environmental impact study must be conducted with regards to these substances, although the import of chemical pesticides for agricultural use must follow the procedure established in Andean Decision 804 (paragraph 10, article 2.2.2.3.2.2, Decree 1076 of 2015).

9. According to the current provisions established in the Andean Technical Manual, an evaluation and toxicology classification as well as an environmental risk assessment are carried out in Colombia for: (a) the Technical Grade Active Ingredients (TC) used to produce pesticides; and for (b) the formulated product. It is worth pointing out that Colombia –being a member of the CAN - is required to perform a registration and risk assessment of pesticides for agricultural use prior to their release to the market. The

[4] Decree 1071 of 2015 now contains all executive regulations for the agricultural administrative sector.

registration before pesticides are imported or marketed is mandatory. The assessment is based on test data on toxicological and eco-toxicity data, as well as exposure analyses provided by the registrant. These assessment activities are carried out based on the Technical Grade Active Ingredients (TC) of chemical and biologic origins, whether imported or synthesized in the country.

10. The minimum data required for the environmental assessment of pesticides in Colombia are consistent with the OECD Minimum Pre-Marketing Set of Data that are included in the Annex of the Decision C(82)196/FINAL. The only data in the list of the Annex that is not required for ***environmental assessments*** are the dissociation constant and the particle size. However, these two variables are not included in the mathematical models that support the decision-making process about environmental behaviour of pesticides.

11. The National Health Institute (INS by its acronym in Spanish*)* conducts the toxicological risk assessment of pesticides in the country. The minimum data required for the toxicological evaluation of pesticides in Colombia used for public health, domestic use, livestock use, bio-pesticides and natural pesticides are consistent with the OECD Minimum Pre-Marketing Set of Data of the Annex of the Decision C(82)196/FINAL. The following table shows the details regarding MPD currently required for *Toxicological Risk Assessment of Pesticides*:

MPD required for Toxicological Risk Assessment of Pesticides in Colombia

Table 1. MPD required for Toxicological Risk Assessment of Pesticides in Colombia

Data Components for the OECD Minimum Pre-Marketing		**Is the data used for assessing pesticides for agriculture use[5]**	**Is the data used for assessing pesticides used in public health, domestic, livestock, biopesticides and natural pesticides[6]**
Chemical Identification Data	Name according to agreed international nomenclature	Yes	No
	Other names	Common name accepted by ISO	No
	Structural formula	Yes	No
	CAS-number	No	No
	Spectra ("finger-print spectral" from purified and technical grade product)	No	No
	Degree of purity of technical grade product	Yes	Yes

[5]Data required for toxicological risk assessment according to the provisions established in Andean Resolution 630 of 2002 (Andean Technical Manual for Registration and Control of Pesticides for Agricultural Use) and in Andean Decision 436 of 1998.

[6] Data required for toxicological risk assessment according to the provisions established in Decree 1843 of 1991.

Data Components for the OECD Minimum Pre-Marketing		Is the data used for assessing pesticides for agriculture use[5]	Is the data used for assessing pesticides used in public health, domestic, livestock, biopesticides and natural pesticides[6]
	Known impurities, and their percentage by weight	Yes	Partially: Composition of the technical product, nature and quantity of isomers, name of the determined impurities.
	Essential (for the purposes of marketing) additives and stabilizers and their percentage by weight	Yes	Yes
Production/Use/Disposal Data	Estimated production, tons/year	No	No
	Intended uses	Yes	Yes
	Suggested disposal methods	Yes	Yes
	Expected mode of transportation	Yes	No
Recommended Precautions and Emergency Measures		Yes	No
Analytical Methods		Yes (only for the Technical Grade Active Ingredients)	Yes (for Technical Grade Active Ingredients and the formulated product)
Physical/Chemical Data	Melting point	Yes (only for the Technical Grade Active Ingredients)	Yes (only for the Technical Grade Active Ingredients)
	Boiling point	Yes (only for the Technical Grade Active Ingredients)	Yes (only for the Technical Grade Active Ingredients)
	Density	Yes (only for the Technical Grade Active Ingredients)	Yes (only for the Technical Grade Active Ingredients)
	Vapour pressure	Yes (only for the Technical Grade Active Ingredients)	Yes (only for the Technical Grade Active Ingredients)
	Water solubility	Yes (only for the Technical Grade Active Ingredients)	Yes (only for the Technical Grade Active Ingredients)

Data Components for the OECD Minimum Pre-Marketing		Is the data used for assessing pesticides for agriculture use[5]	Is the data used for assessing pesticides used in public health, domestic, livestock, biopesticides and natural pesticides[6]
	Partition coefficient	Yes (only for the Technical Grade Active Ingredients)	Yes (only for the Technical Grade Active Ingredients)
	Hydrolysis*	No	No
	Spectra	No	No
	Adsorption - Desorption*	No	No
	Dissociation constant	No	No
	Particle size	No	No
Acute Toxicity Data	Acute oral toxicity	Yes (for both the Technical Grade Active Ingredients and the formulated product)	Yes (for both the Technical Grade Active Ingredients and the formulated product)
	Acute dermal toxicity	Yes (for both the Technical Grade Active Ingredients and the formulated product)	Yes (for both the Technical Grade Active Ingredients and the formulated product)
	Acute inhalation toxicity	Yes (for both the Technical Grade Active Ingredients and the formulated product)	Yes (for both the Technical Grade Active Ingredients and the formulated product)
	Skin irritation	Yes (for both the Technical Grade Active Ingredients and the formulated product)	Yes (for both the Technical Grade Active Ingredients and the formulated product)
	Skin sensitization	Yes (for both the Technical Grade Active Ingredients and the formulated product)	Yes (for both the Technical Grade Active Ingredients and the formulated product)
	Eye irritation	Yes (for both the Technical Grade	Yes (for both the Technical Grade Active

Data Components for the OECD Minimum Pre-Marketing		Is the data used for assessing pesticides for agriculture use[5]	Is the data used for assessing pesticides used in public health, domestic, livestock, biopesticides and natural pesticides[6]
		Active Ingredients and the formulated product)	Ingredients and the formulated product)
Repeated Dose Toxicity Data	14-28 days, repeated dose	Sub-chronic toxicity (13 to 90 days) for the Technical Grade Active Ingredients	Information regarding chronic toxicity of the Technical Grade Active Ingredients
Mutagenicity data		Yes)only for the Technical Grade Active Ingredients)	Information regarding chronic toxicity of the Technical Grade Active Ingredients
Degradation/ Accumulation Data	Biodegradation	Yes	No
	Bioaccumulation	Yes	No

12. Based on the previous information, the data required for the toxicological and environmental assessment of pesticides prior to their introduction into the market is consistent with the requirements of this Council Act. Based on the previous information, however, this procedure does not apply to chemicals for industrial use, which is why the Programme for the Management of Chemicals for Industrial Use shall include all the data components for the OECD Minimum Pre-Marketing set of data contained in the Annex of Decision C(82)196/FINAL.

Regarding the requirements of the Recommendation C(77)97:

Establishing new procedures on extending existing procedures for anticipating the effects of chemicals, taking into account the Guidelines contained in Annexes I and II of this Council Act

13. Colombia has relevant processes and requirements related to the methodologies to evaluate the effects of pesticides on man and the environment. In that respect, it can be asserted that the guidelines and the methodological approach described in Annexes I and II of the Recommendation C(77)97/FINAL are consistent with the methodology employed in Colombia to evaluate pesticides, according to the above-stated applicable law.

14. Regarding the guidelines contained in Annex II of the Recommendation C(77)97/FINAL, an equivalent approach is currently being applied for pesticides in Colombia.

- **Initial Assessment- Step one requires the following data:**

Physical and Chemical Properties: As previously mentioned the data required for the toxicological and for the environmental assessments of pesticides prior to their release to the market, is consistent with the data components for the OECD MPD listed in the Annex of Council Act C(82)196/FINAL.

Data relevant to Human Health: As previously mentioned the data relevant to human health is consistent with the data components for the OECD MPD listed in the Annex of Council Act C(82)196/FINAL.

Discharge to the Natural Environment: The national production of all pesticides and the import of pesticides for agricultural[7], public health, industrial, domestic and veterinary use, must obtain an environmental license and conduct an environmental impact studies and formulate an environmental management plan.

The environmental management plan is a tool to prevent, mitigate, correct or compensate a project work or activity´s environmental impacts and includes contingency, follow up and monitoring plans. To this end, environmental impact studies must evaluate potential risks associated to impacts on abiotic, biotic and social media. In this case, data production rates and intended use are requested, as well as an estimate of the amount that could be liberated to the environment, and the processes of dissemination of the possible environmental impacts generated by the operation of a production facility (such as the contingency plan).

- **Initial Assessment - Step two carries out the following activities:** The ANLA abides to the procedures established in the Andean Technical Manual and the terms of reference issued for the import of chemical pesticides for domestic, industrial and public health use and other terms of reference issued by for the formulation of environmental impact studies. According to the Andean Technical Manual for Registration and Control of Chemical Pesticides, the established methods for the environmental study are preferential methods, where the OECD Test Guidelines are the main protocol to be used. Nevertheless, other methods are considered, such as the methods used by the U.S. Environmental Protection Agency (EPA), the Office of Prevention, Pesticides and Toxic Substances (OPPTS), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the European Commission, or other valid method or methods with international endorsement. In order to determine levels of concern, pesticides terms of reference also refer to methodologies such as the Andean Technical Manual, the EPA and the European Union.

The pesticide environmental risk assessment includes:

- The pesticide environmental risk assessment takes into account their persistence in soil, air, and water, as well as the potential for bioaccumulation in fish.

- The pesticide environmental risk assessment takes into account the acute and subacute toxicity, for the technical active ingredient and its metabolites, which also have pesticidal activity.

- The pesticide environmental risk assessment takes into account the worst-case scenario of risk in all environmental components that are assessed.

The pesticide environmental risk assessment does not take into consideration their interaction with atmospheric constituents or other chemicals introduced into the environment (for example, chlorine used in water treatment).

15. Although Colombia has in place procedures that are consistent with the requirements of this Council Acts, Colombia does not apply these procedures to new and existing chemicals for industrial use. Therefore, an action plan is proposed in order incorporate chemicals for industrial use into a framework that will be used to evaluate the effects of these chemicals on human health and the environment.

[7]Except pesticides of biological origin based on extracts of plant origin (article 8.10.2(a), Decree 2041 of 2014).

Regarding the requirements of the Recommendation C(74)215:

16. As mentioned before, Colombia is proposing to set up a Programme for the Management of Chemicals for Industrial Use, described in detail in the corresponding action plan. This program will cover the main aspects of this recommendation, such as: a) keep statistics on the import, manufacturing and sales of chemicals and chemicals products and b) establish procedures to assess the potential effects on man and the environment of chemicals and chemicals products.

17. Regarding the statistics on chemicals, Colombia recently updated the National Inventory on Chemicals, with emphasis on chemicals for industrial use. This update allows a fairly complete inventory of figures of import, export, consumption and production of the chemicals for industrial use in Colombia, for the period 2003-2012. In the future this information will be collected and stored systematically through proposed the National Registry of Chemicals.

18. As for the other two main aspects of the recommendation, the Programme for the Management of Chemicals for Industrial Use will require information of chemicals for industrial use, as described in the action plan below:

- Hazards assessment (identification and characterization);
- Risk assessment (environmental and toxicological);
- Industrial risk management actions.

Hazard and risk assessments will serve as a basis to evaluate the effectiveness of industrial risk reduction actions, and support decision-making processes at a national level for the adoption of additional *risk reduction measures* (RRM) and research programmes.

19. The overarching objective of the Programme for the Management of Chemicals for Industrial Use being developed by Colombia is to protect human health and the environment in the national territory due to the use of industrial chemicals.

20. The proposed Programme focuses primarily on new and existing chemicals for industrial use. The first stage will only cover pure substances and homogeneous mixes and it will not apply to:

a) Radioactive substances;

b) Substances in customs transit, destined for export;

c) Non-insulated intermediate substances (substances that are generated and consumed *in-situ*);

d) Pharmaceutical products for human or veterinary use, food products and additives, as long as they are regulated;

e) Pesticides and other substances within the scope of a specific regulation;

f) Natural substances without chemical processing (e.g. minerals, natural gas);

g) Polymers (excluding monomers).

21. As part of the conceptual design of the Programme, Colombia reviewed the toolbox developed by the Inter-Organization Programme for a Sound Management of Chemicals (IOMC), which helped identify the technical elements, resources and infrastructure required for the implementation of the Programme.

22. The Programme is structured based on three types of elements: technical, transversal and functional, which are described in more detail in the Table below. The *technical* elements constitute the core of the Programme, and are complemented by *transversal* and *functional* elements, which are relevant for the operation of the Programme as a whole, as suggested by the IOMC Toolbox. The four stage priority setting process (compilation, screening, refinement and review) contained in Annex I to Decision-Recommendation on the Systematic Investigation of Existing Chemicals [C(87)90/Final] is also reflected in the technical and functional elements of the Programme.[8]

Technical, functional and transversal elements of the Programme for the Management of Chemicals for Industrial Use adapted from the IOMC Toolbox

Table 2. Elements of the Programme for the Management of Chemicals for Industrial Use

Elements		Description	Responsible Authorities
Technical Elements			
1	Gap Analysis	This element provides an initial outlook of existing chemicals for industrial use in Colombia. To that end, the Government updated the National Inventory on Chemicals, which includes information on production, imports, exports and use these chemicals as well as a prioritization of certain chemicals for industrial use according to the selection criteria in Annex I of Council Act C(87)90/FINAL.	• Ministry of Environment and Sustainable Development
2	Compilation of Information	Capturing information will allow for systematically identifying existing and new chemicals for industrial use imported and manufactured in the country, their quantities, projected use, hazard assessments, risk management actions and parties involved (importers and manufacturers). To this end, the Programme foresees the creation of a national registry to capture this information and systematically update the information contained in the National Inventory on Chemicals of Industrial. The Programme will consider as a new chemical substance of industrial use any such substance that is not registered within a reasonable timeframe after the registry begins to operate in 2018. Until the Registry becomes operational, the basis for decision making will be the National Inventory on Chemicals.	• Ministry of Commerce, Industry and Tourism

[8] The four stage priority setting process is comprised of the following stages: compilation, screening, refinement and review. The compilation stage is covered by the technical element on compilation of information. The screening stage is covered through the technical element on hazard assessment, risk assessment and risk management. The refinement and review process will be carried out through the performance review functional element.

Elements		Description	Responsible Authorities
3	Hazard Assessment	The hazard assessment includes the identification and characterization of the hazardous properties of chemicals for industrial use. In order to do this, the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) will be implemented.	• National Licensing Authority - ANLA • Ministry of Health and Social Protection
4	Risk Assessment	This element implies a health and environmental risk assessment, required only for new chemicals for industrial use, where these do not already have an internationally accepted assessment. Chemical substances which are employed in distinctly new applications, or in considerably increased quantities, or selected because of newly discovered possible harmful effects in human health or the environment, shall also be considered as a new substance subject to a risk assessment.	• National Licensing Authority - ANLA • Ministry of Health and Social Protection
5	Risk Management	The risk management process, applicable to both new and existing substances, includes the following components: • **Risk Treatment:** Manufacturers and importers will be required to submit *industrial risk management actions* (IRMA) based on risk and hazard assessments. • **Risk Communication:** In addition to presenting the previous information, manufacturers and importers will be required to adopt GHS labelling and to provide Safety Data Sheets (SDS) communicating the hazards and risks to all users of chemicals for industrial use. The Programme shall include the development of capacity building sessions and communication tools to achieve an effective risk communication to all stakeholders involved.	• National Licensing Authority - ANLA • Ministry of Health and Social Protection
6	Poison Centres	The events of exposure to chemical substances are identified in Colombia by competent health and labour authorities, where the health sector deals with risks that could affect public health and the labour sector deals with risks related to accidental occupational exposures. The Ministry of Labour and the Ministry of Health and Social Protection are currently working on a strategy to articulate their existing information systems, in order to allow a systematic collection of data and provide specialized technical advice to the general public on	• Ministry of Labour • Ministry of Health and Social Protection

Elements		Description	Responsible Authorities
		the toxicological effects of chemical substances, as part of the surveillance and control process.	
Functional Elements			
1	Monitoring	Covers environmental monitoring over natural resources through the Colombian Environmental Information System (SIAC by its acronym in Spanish) and health monitoring through Poison Centres which report to Integral Social Protection and Health Information System (SISPRO by its acronym in Spanish).	• Regional environmental authorities • Regional Health Directorates • Ministry of Labour
2	Monitoring and enforcement	Once chemicals for industrial sue are commercialized, enforcement authorities will be able to impose sanctions, preventive or compensation measures in cases of non-compliance.	• Ministry of Labour • Ministry of Health and Social Protection • Ministry of Environment and Sustainable Development • Ministry of Commerce, Industry and Tourism
3	Performance Assessment	The Programme will be subject to performance assessments based on information obtained from health monitoring (Toxicological Centres) and environmental monitoring systems (under SIAC, including RETC and other environmental monitoring networks). These will serve as a basis to evaluate the effectiveness of industrial risk reduction actions, and support decision-making processes at a national level for the adoption of additional *risk reduction measures* (RRM) and research programmes. The RRM, which shall be previously submitted to public consultation with the industry, will include measures such as:[9] • Restriction or prohibition of imports, manufacture and/or specific uses; • Gradual elimination plans or other risk reduction programmes; • Promotion of research programmes for substitution of chemical substances through green chemistry and cleaner production processes.	
4	Systematic investigation	Based on the information from the registry and from the competent authorities related to health and environment, the government will further promote systematic investigation programmes to elucidate the potential effects of new and existing chemicals for industrial use, as proposed in the action plan.	• Ministry of Health and Social Protection • Ministry of Environment and Sustainable

[9] Colombia is willing to develop common criteria with other OECD members to determine which chemicals are suitable candidates for risk reduction activities.

Elements		Description	Responsible Authorities
			Development • Administrative Department of Science, Technology and Innovation (Colciencias by its acronym in Spanish) and other Research Institutes. • Public and private universities.
Transversal Elements			
1	Resources	The Colombian Government will need to ensure availability of human, technical and monetary resources required for the implementation of the Programme.	
2	Sensibilisation & Capacity building	The Programme foresees sensibilisation activities for the general public and capacity building activities for government entities.	
3	Dissemination of information	The Registry will capture basic information on manufacturers and importers and will include the Material Safety Data Sheet. In addition, the implementation of GHS will also allow dissemination of risk and hazards of chemical substances throughout the value chain, starting in workplaces and progressively in all sectors. Finally, chemical substances in transport are currently labelled, marked, shipped and packaged according to the "UN Recommendations on the Transport of Dangerous Goods" in Colombia.	

Action Plan

23. The following table contains the action plan for the development of the previously described elements of the Programme for the Management of Chemicals for Industrial Use:[10]

Table 3. Action Plan for the Programme for the Management of Chemicals for Industrial Use

[10] The following OECD instruments were taken into account to design the action plan for the Programme for the Management of Chemicals for Industrial Use: C(82)196/FINAL, C(77)97/FINAL, C(74)215, C(96)41/FINAL, C(90)163/FINAL, C(87)90/FINAL, C(83)98/FINAL, C(83)96/FINAL and C(83)97/FINAL. For more specific information on the interactions between the OECD instruments and the action plan please refer to Report on Colombia´s Industrial Chemicals Management and Chemical Accidents Programmes, presented in the 54th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of 11 February, 2016.

Elements	Time-frame	Objective	Specific Activities	Status
Gap Analysis	2012-II	Obtain initial outlook of existing chemicals for industrial use in Colombia.	National Chemical Substances Profile, 2012.	Done
	2015-II		Update of the National Inventory of chemicals for industrial use (Chapters 2 and 3 of the National Chemical Substances Profile, 2012).	
Compilation of Information	2017-I	Systematically Compile information on imported and manufactured chemicals, their quantities, projected use, hazard assessments, risk management actions and importers and manufacturers.	Digital publication of the preliminary national inventory of chemicals for industrial use.	The Ministry of Commerce, Industry and Tourism will implement the registry and already presented an investment project to the National Development Department to secure future funding. The investment project was approved in July 2016. Colombia already has a preliminary definition of the information requirements to be collected through the registry
	2016-II		Design of the national registry, which includes: - Definition of the institutional framework in charge of the registry. - Definition of information requirements to be collected through the registry.	
	2017		Software development.	
	2017-2018		Dissemination and training for use of the tool.	
	2018-I		Voluntary registration process to pilot test the registry.	
	2018-I		Upload the preliminary national inventory to register.	
	2018-II		Evaluate the information received during the pilot registration process.	Resources will be allocated to the annual budget of the Ministry of Commerce, Industry and Tourism.
	2018-II		Mandatory registration implemented.	
Hazard Assessment	2016-I	Identify and characterize the hazardous properties of chemicals for industrial use based on GHS labelling.	Update the technical guidance of classification and communication of hazards according to GHS, for the industry.	The Ministry of Environment and Sustainable Development (MADS by its acronym in Spanish) already developed and presented an investment project to the National Development Department to secure funding for the activities of 2017 and
	2016-II		Consultation with stakeholders of four priority sectors of the inter-sectorial GHS plan: industrial, workplace, agriculture, transport and consumer products.	
	2017-I		Issue a Decree to adopt the GHS.	
	2017		Develop GHS training material aimed at the industry, government	

Elements	Time-frame	Objective	Specific Activities	Status
			entities and civil society.	2018. The investment project was approved in June, 2016 A draft of the GHS Decree and the inter-sectorial GHS plan were subject to stakeholder consultation during the second semester of 2016 and is expected to be issued in the first quarter of 2017. The technical guidance of classification and communication of hazards according to GHS, for the industry have already been developed and will be shared with relevant stakeholders.
	2017-II		Gradual implementation of GHS.	
Risk Assessment	2018-II	Assess health and environmental risks (required only for new chemicals).	Define terms of reference for the development of risk assessments by manufacturers and importers.	MADS already developed and presented an investment project to the National Development Department to secure funding for the activities of 2017 and 2018. The investment project was approved in June, 2016.
	2017 - 2018		Competent authorities must define procedures, criteria and methods to evaluate risk assessments submitted by manufacturers and importers.	
Risk Management	2018	Establish risk communication mechanisms	Dissemination of risk reduction measures (RRM) adopted by the Government.	Amounts will be defined once the RRM have been established through the Programme.
	2018-2019	Develop and implement risk management measures	Define industrial risk management measures for specific chemicals.	MADS already developed and presented an investment project to the National Development
	2018-2019		Define terms of reference for manufacturers and importers for submission of industrial risk	

Elements	Time-frame	Objective	Specific Activities	Status
			management measures.	Department to secure funding for the activities of 2017 and 2018. The investment project was approved in June, 2016.
	2019-2020		Competent authorities must define procedures, criteria and verification methods to evaluate industrial risk management measures presented by manufacturers and importers.	
	2020		Implement procedures applicable to manufacturers and importers.	
Poison Centres	2018-2020	Obtain systematic collection of toxicological data and provide specialized technical advice to the public on the toxicological effects of chemical substances.	Define mechanisms to capture and analyse toxicological information.	Resources allocated to the annual budget of the Ministry of Health and Social Protection and the Ministry of Labour.
	2018-2020		Strengthen existing mechanisms to provide timely toxicological information and 24-7 assistance.	
	2018-2020		Strengthen capacities of agencies in charge of verifying compliance prior to commercialization (health, environmental and trade).	
Environmental Monitoring	2016-2020	Create and use PRTR as a monitoring tool according to the action plan proposed.	See Action Plan for Recommendation C(96)41 FINAL.	
	2018-2020	Use of Environmental Monitoring. Networks as a monitoring tool.	Adjust monitoring networks of regional environmental authorities to capture information on chemical substances.	
Enforcement	2016-2020	Strengthen enforcement and monitoring mechanisms to ensure compliance of the Programme.	Include in the chemical´s regulatory framework additional enforcement and monitoring mechanisms and competences to be able to impose sanctions and preventive or compensation measures in case of non-compliance.	Enforcement provisions already included in the proposed regulatory framework for chemicals. .
Performance Assessment	2020	Evaluate the performance of the Programme, evaluate the effectiveness of industrial risk reduction actions, and support decision-making processes at a national level for the adoption of additional risk reduction measures (RRM) and research programmes.	Establish risk reduction measures (RRM) and investigation programmes for specific chemicals based on the programme performance.	Amounts will be defined once the investigation programmes and the RRM are defined.

Elements	Time-frame	Objective	Specific Activities	Status
Systematic investigation	2017-2018	Promote systematic investigation programmes related to chemicals for industrial use.	Identify sources of funding for research projects linking chemical substances and its effects on health and the environment together with the Administrative Department of Science, Technology and Innovation (Colciencias by its acronym in Spanish) and other Research Institutes.	Colciencias is already promoting fields of research related to environmental health, with emphasis in hazardous chemicals. To date it has funded research related to the use of mercury and pesticides.
	2019-2020		Establish partnerships with universities in Colombia to contribute to the priority setting of chemicals for health and environmental purposes and perform systematic investigation in this area.	The National University of Colombia has actively participated in defining the priority setting process.
Dissemination & Capacity building	2016-2020	Create awareness among key stakeholders regarding the main aspects of the Programme.	Establish dissemination and capacity building activities for the public and government entities.	A forum was organized in Bogota in February 2016 with the OECD Secretariat to disseminate the Programme with a wide range of stakeholders. At least five workshops were carried out in the first semester of 2016 with the industry and other stakeholders. Four public consultation workshops organized by the Ministry of Environment and Sustainable Development, the Ministry of Labour, the National Business Association and the United Nations Industrial Development Organization - UNIDO will be carried out with the industry in

Elements	Time-frame	Objective	Specific Activities	Status
				September 2016 to disseminate the Programme and its requirements. In addition, the Ministry of Labour will also carry out public consultation workshops with the academia and key private and public stakeholders on the implementation of GHS during 2016.
Legal Framework & National Policy	2016	Develop the necessary legal and policy framework.	Develop a National Policy for the Management of Risk associated with the Use of Chemicals Substances in order to: - Establish long term policy objectives to manage the environmental and health risks associated with the use of chemicals. - Align the efforts of the institutions involved. - Incorporate in the national policy the most relevant aspects of the action plan proposed by Colombia to implement the Programme for the Management of Chemicals for Industrial Use. - Jointly define the resources required to implement the programme and determine the potential sources of funding.	The CONPES 3868 of 2016 adopts the National Policy for the Management of Risk Associated with the Use of Chemical Substances.
	2016 - 2017		Develop a regulatory framework between the main entities involved to: • Establish the functions that public entities must perform to implement the programme.	The draft Decree for the adoption of the Programme for the Management of Chemicals for Industrial Use is ready and expected to be issued in the first

Elements	Time-frame	Objective	Specific Activities	Status
			• Establish obligations for importers and manufacturers. • Create Registry of chemical substances. • Establish the necessary mechanisms for the provision of information to the public. • Promote systematic investigation on chemicals. • Create a framework for the Identification and management of risks and hazards of chemicals. • Specify provisions on mutual acceptance of data. • Determine additional enforcement mechanisms.	semester of 2017. The Presidential Decree was published for stakeholder consultation on January 30th, 2017.
	2017		The Programme for the Management of Chemicals for Industrial Use will be adopted by a Presidential Decree issued by the Ministers of Environment and Sustainable Development, Health and Social Protection, Labour, and Trade, Industry and Tourism.	
	2017-2020		Prepare a draft of additional regulations: • Issue the corresponding resolutions to establish the technical aspects of the Programme (e.g. list of prioritized substances, thresholds, terms of reference for industrial risk management actions). • Establish the registration requirements. • Issue a Decree to adopt the GHS.	

24. The Colombian Government, through the Legal Department of Presidency, analysed the most adequate legal instrument for the implementation of a comprehensive strategy for the management of chemical substances in the country, in order to reduce risks related to the use of these substances to health and the environment, and to prevent accidents. The Programme for the Management of Chemicals for Industrial Use will be adopted by a Presidential Decree issued by the Ministers of Environment and Sustainable Development, Health and Social Protection, Labour, and Trade, Industry and Tourism.

25. As to the institutional arrangements, the Government is considering that health evaluations and related functions be performed by the Ministry of Health and Social Protection. For environmental evaluations, the Government is considering the National Environmental Licensing Authority ANLA as the most appropriate authority to be in charge of the task. The national register on chemicals will be implemented by the Ministry of Commerce, Industry and Tourism.

INVESTIGATION AND RISK REDUCTION OF EXISTING CHEMICALS

C(90)163/FINAL DECISION– RECOMMENDATION OF THE COUNCIL ON THE COOPERATIVE INVESTIGATION AND RISK REDUCTION OF EXISTING CHEMICALS

Position: Acceptance with a specified timeframe for implementation (2020).

Justification:

Cooperative Investigation of Existing Chemicals

26. The National Government is willing to work on cooperative research of high production volume (HPV) chemicals with other OECD member countries in order to identify those that are potentially hazardous to the environment and/or to the health of the general public or workers.

27. Additionally, Colombia will use the existing available information concerning the potential hazards of chemicals in order to conduct the environmental and toxicological risk assessment of the chemicals that will be addressed within the Programme for the Management of Chemicals for Industrial Use.

28. The Programme for the Management of Chemicals for Industrial Use proposed in the action plan described below will be subject to performance assessments that will contribute to prioritize the research programmes in this area. Also, Colombia needs to build its internal technical capacity to be able to generate data in accordance with Test Guidelines and Good Laboratory Practice.

Risk Reduction Programmes of Existing Chemicals

29. In line with Decision-Recommendation C(90)163/FINAL, Colombia currently has national risk reduction programmes in place, aimed at the reduction of risks from existing chemicals to the environment, the health of the general public or workers. Some of these programmes include:

- The Ten Year Plan for Cancer Control.
- Plan for the management of Polychlorinated Byphenyls (PCBs).
- The National Mercury Plan.

30. Additionally, in 2014 Colombia initiated the development of a strategy to implement the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). This is a tool that will facilitate the creation of risk reduction programmes in the future and feed existing ones. The Ministry of Labor has a draft of a Decree to adopt the GHS in the country, which is currently being discussed among the different institutions involved and is expected to be issued between the last quarter of 2016 and the first quarter of 2017.

The GHS will be the basis for the hazard and risk assessment of existing and new chemicals for industrial use, which will allow implementing an adequate risk management system in the Programme for the Management of Industrial Chemicals. Furthermore, the application of the GHS will improve the generation and dissemination of information regarding chemicals hazards throughout the supply chain. Additionally, the GHS classification of hazardous substances will facilitate the identification of hazardous facilities in the Major Accident Prevention Programme also currently under development (see Action Plan for Chemical Accidents, Prevention and Preparedness and Response).

31. The primary components of these risk reduction programs and tools may be summarized as follows:

The Ten Year Plan for Cancer Control (2012 -2021)

32. The Ministry of Health and Social Protection issued Resolution 1383 of 2013, which adopts the *Ten-Year Plan for Cancer Control in Colombia* (2012-2021). This programme is being implemented nationwide. The Plan seeks to support and manage the implementation of the policy and regulatory framework related to cancer in Colombia, supported by the competent authorities. Among the risk control strategies of the Plan are occupational risk control activities. This plan has been constructed to cover and enhance the objectives of previous plans implemented by the National Government[11]. The activities aimed at reducing risks include:

a) Coordinate with the Ministry of Labour that the companies from the formal sector that handle the five principal occupational carcinogens (asbestos, silica, benzene, inorganic lead compound, and ionizing radiation) include preventive actions within the Occupation Health and Safety Management System aimed at decreasing the exposure to these substances.

b) Generate multi-sector actions for the definition of technical guidelines that contribute to the design of control methods, according to the level of risk estimated, to reduce exposure of workers to the five most important carcinogens in Colombia to permissible levels, according to what is established in Law 1562 of 2012. Accordingly, Article 9 of Law 1562 requires that companies that process, manipulate, or work with toxic or carcinogenic substances, must carry out a minimum of preventive activities according to labour and health regulations.

c) Support the development of government policies to regulate the import, production, use and control of carcinogenic agents.

d) Ban and/or restrict the use of occupational carcinogens.

[11]These previous plans include the Occupational Cancer Plan (Plan de Cancer Occupational), developed as part of the strategies to deal with the exposure of workers to carcinogenic compounds. The plan has the objective of protecting the health of the working population exposed to different carcinogenic compounds and of promoting healthy work conditions, reducing the exposure levels and carrying out medical oversight focused on detecting such risk factors. The plan aimed at reducing exposure to asbestos, silica, benzene, ionizing radiation, inorganic lead compound and all the compounds that present carcinogenic risk.

Plan for the Management of Polychlorinated Biphenyls (PCBs)

33. Colombia has mitigated the health and environmental risks associated to the handling of PCBs by prohibiting the production of PCBs and the import of PCBs and of equipment containing them, as well as the use of equipment, elements and substances that contain PCBs, the use of contaminated equipment in new electrical installations and in the modification of existing ones, the import of PCB waste, the dilution of oils with over 50 ppm of PCBs, among others (Article 34, Resolution 222 of 2011).

34. Consequently, Resolution 222 of 2011 established several measures aimed at reducing current risks based on the safe handling of equipment or waste contaminated PCBs. These measures include identification, classification, labelling, safe storage, transport, treatment and final disposal of equipment and waste contaminated with PCBs. These measures are complemented with fish, blood and breast milk monitoring programme for exposed populations and by risk divulgation activities to create awareness regarding the handling of such substances or contaminated equipment. Further details of how this program is being implemented in Colombia can be found below in section regarding C(87)2/FINAL – DECISION-RECOMMENDATION OF THE COUNCIL ON FURTHER MEASURES FOR THE PROTECTION OF THE ENVIRONMENT BY CONTROL OF POLYCHLORINATED BIPHENYLS.

35. Regarding risk reduction of PCBs, the Ministry of Environment and Sustainable Development is conducting a project with the University of the Andes (2015-2016) to develop capacity for the environmentally sound management of PCBs. The project has the following objectives:

- Design and implement a qualitative risk-analysis tool for activities associated with storage, handling, and disposal PCBs.
- Define minimum requirements for contingency plans to be used in environmental licensing of contract facilities involved in the storage and destruction of PCBs.
- Provide expert training for government and industry personnel involved in transport of PCBs.

36. This program can be readily extended to other chemicals in addition to PCBs in the future.

The National Mercury Plan

37. Article 8 of Law 1658 of 2013 set the framework for the National Mercury Plan, officially established in 2014. The objective of the Plan is to take measures regarding each stage of mercury's life cycle, including use, import, production, commercialization, handling, transport, storage and final disposal, and to prevent and manage any undesired mercury release to the environment, in a context where the law proscribed the use of mercury in all industrial and productive processes beginning 10 years from the law's enactment (5 years for mining activities).

38. The Plan contemplates actions aimed at eliminating the use of mercury and to reduce emissions in industrial and mining activities. Initially this elimination would take place in gold mining and then in all other industrial sectors, resulting in a risk reduction for the environment and human health. This elimination process contemplates monitoring and enforcement mechanisms, as well the establishment of an information system regarding the lifecycle stages of mercury and products that contain it and their related health risks.

39. This information system will allow the following:

- Feed the sectorial action plans.

- Maintain up-to-date information regarding exposed geographical areas and population.

- Implement a mercury risk communication system.

- Strengthen diagnosis and response to health issues due to mercury exposure.

40. The implementation of the National Mercury Plan has a timeframe set until 2023 with a milestone on reduction targets in 2018 for the mining industry. Further details regarding the National Mercury Plan may be found in the section regarding C(73)172/FINAL – RECOMMENDATION OF THE COUNCIL ON MEASURES TO REDUCE ALL MAN-MADE EMISSIONS OF MERCURY TO THE ENVIRONMENT.

41. Two mercury risk programmes are currently being developed;

- Ongoing project proposed by the United Nations Industrial Development Organization (UNIDO) and funded by the Global Environment Facility (GEF) for the period 2015- 2017, to facilitate the implementation of the Minamata Convention in Colombia. The project outcomes include: Inter-institutional coordination and capacity building, updating the national inventory on mercury and dissemination of information on mercury to the public and public authorities.

- Project funded by GEF for the period 2016- 2018 to (1) reduce mercury releases from healthcare waste treatment and to assure a sound management of mercury related waste, and (2) prevent and reduce the generation of toxic releases of mercury from the processing of Waste of Electrical and Electronic Equipment (WEEE).

42. Besides the three programmes described above to promote risk reduction from certain chemicals, public authorities in different sectors have other risk prevention tools and safety measures at their disposal. For instance, sanitary authorities have the ability to adopt prevention, control and safety measures in order to guarantee the protection of public health. This includes measures such as the power to ban the use of pesticides when its use constitutes a grave health risk for people, animal or plant health or environmental conservation (Article 22, Decree 1843 of 1991). Furthermore, monitoring and enforcement mechanisms of sanitary authorities, specified in Resolution 1229 of 2013, are conducted through a risk approach (evaluation, management and communication) and a prevention approach (to avoid or reduce sanitary risks). As for environmental authorities, they can impose risk reduction measures in the context of an environmental license related with pesticides (Article 2.2.2.3.6.3(5), Decree 1076 of 2015). Under the Andean regime, Articles 28-38 of Decision 804 authorizes the National Competent Authority to suspend, modify or cancel the registration of a chemical pesticide for agricultural use based on technical and scientific grounds related to agriculture, environment or health.

43. Finally, as mentioned before, Colombia is currently designing a Programme for the Management of Chemicals for Industrial Use proposed in the action specified in paragraph 23. This Programme will be subject to performance assessments based on information obtained from health and environmental monitoring. These, along with hazard and risk assessments will serve as a basis to evaluate the effectiveness of industrial risk reduction actions, and support decision-making processes to promote additional risk reduction activities to the ones mentioned above.

C(87)90/FINAL – DECISION – RECOMMENDATION OF THE COUNCIL ON THE SYSTEMATIC INVESTIGATION OF EXISTING CHEMICALS

Position: Acceptance with a specified timeframe for implementation (2020).

Justification:

44. In 2012, a National Profile of Chemical Substances was developed by the Ministry of Environment and Sustainable Development as a strategic tool to establish a general overview of chemicals management in Colombia. The document´s objective, among others, was to conduct a National Inventory of Chemical Substances focusing on different categories of chemicals for various uses and to identify legal and administrative gaps on management of chemicals. This was performed in the context of Colombia´s commitment to implement the Strategic Approach to International Chemicals Management (SAICM).

45. The Inventory used data from the year 2007 and contains information on the import, export, production, and use of organic and inorganic chemicals, paints, varnishes, dyes, colorants and pigments, pesticides, fertilizers, petroleum and their derivatives.

46. In 2015, the Ministry of Environment and Sustainable Development with the Universidad Nacional de Colombia carried out an update of the National Inventory of Chemicals. The inventory`s main objectives are to establish a baseline of industrial chemical produced, consumed, imported and exported in the period of analysis (2003-2012) and to prioritize these chemicals compounds considering seven components; hazards (physical, environmental and health), internal trade, external trade, chemicals emergencies, chemicals transport presence in geographical regions and use in industrial sectors according to the International Standard Classification of All Economic Activities (ISIC) and the principles and technical guidance summarised in Annexes I and II to Decision/Recommendation on the Systematic Investigation of Existing Chemicals [C(87)90/Final].[12] Regarding the hazardous component the methodology developed is based on the class and categories of the GHS of Classification and Labelling of Chemicals.

47. However, Colombia does not systematically collect information related to existing chemicals, which would allow prioritizing the chemicals subject to investigation to reduce risks to human health and the environment. Therefore, the action plan to implement the Programme for the Management of Chemicals for Industrial Use includes the creation of such a register as a first step to begin a systematic investigation of existing chemicals.

48. Despite the lack of systematic collection of information, the Administrative Department of Science, Technology and Innovation (Colciencias by its acronym in Spanish) promotes nowadays several fields of research related to environmental health, with emphasis in hazardous chemicals. For instance, research projects developed in this topic include the evaluation of effects from mining, pesticides use and other chemicals. Since 2006, Colciencias has financed approximately US$ 7,000.000 for research projects in fields related to environmental health and the effects of chemicals.

49. Please refer to the section on systematic investigation contained in the general action plan for the Programme for the Management of Chemicals for Industrial Use in paragraph 23, which describes the main activities that will be undertaking to foster systematic investigation of existing chemicals in Colombia.

[12] This information was presented in the eChemPortal webinar organized by the OECD Secretariat on July 7th 2016. Further cooperation initiatives are expected to follow with countries such as Canada in order to further refine Colombia`s methodology to prioritize chemical substances according to potential hazards.

CHEMICAL ACCIDENTS, PREVENTION / PREPAREDNES

C(2003)221 – RECOMMENDATION OF THE COUNCIL CONCERNING CHEMICAL ACCIDENT PREVENTION, PREPAREDNESS AND RESPONSE

C(88)85/FINAL – DECISION-RECOMMENDATION OF THE COUNCIL CONCERNING PROVISION OF INFORMATION TO THE PUBLIC AND PUBLIC PARTICIPATION IN DECISION-MAKING PROCESSES RELATED TO THE PREVENTION OF, AND RESPONSE TO, ACCIDENTS INVOLVING HAZARDOUS SUBSTANCES

C(88)84/FINAL – DECISION OF THE COUNCIL ON THE EXCHANGE OF INFORMATION CONCERNING ACCIDENTS CAPABLE OF CAUSING TRANSFRONTIER DAMAGE

Position:

50. Acceptance of Recommendation C(2003)221, with a specified timeframe for implementation (2020). Acceptance of Decision-Recommendation C(88)85/FINAL, with a specified timeframe for implementation (2020). Acceptance of Decision C(88)84/FINAL[13], with a specified timeframe for implementation (2018).

Justification:

51. Colombia has currently three major frameworks that are related with the management of risks associated to major accidents involving hazardous substances that pose risks to public, workers, the environment, infrastructure and society in general. These frameworks are developed in disaster risk management regulations, occupational and health regulations, and environmental regulations.

52. Although each of these frameworks address some of the requirements of Recommendation C(2003)221, none of them establish a specific control framework based on the hazardousness of the installation (i.e. by directly regulating hazardous installations based on a prior definition of hazardous substances and thresholds). Current regulations in Colombia are specific to the type of risk involved, e.g. disaster risk, occupational or health risk, and environmental risk. Below we will describe in more detail the exiting related legal framework as well as the gaps identified in relation with the three recommendations on major chemical accidents.

53. In order to fill the identified gaps Colombia is developing its National Major Accident Prevention Programme[14] based on OECD Guiding Principles for Chemical Accident Prevention, Preparedness and Response, 2nd Ed.), the European Union Directives (Seveso I, II and III), the United Sates Risk Management Program (RMP) (48 CFR 68), the United Kingdom COMAH regulations, the French PPRT, the ILO Convention 174 and its 181 Recommendation, the recommendations of the United States

[13]Although Colombia does not have bordering territories with existing OECD member countries, the country will develop and implement the appropriate policies and mechanisms to encourage information exchange relating to the prevention of accidents capable of causing trans-frontier damage, as well as regarding to risk reduction in case of such accidents.

[14] Colombia has decided to use the term "Major industrial accident", instead of "chemical accident", providing a common term for the requirements of ILO, OECD and other important references such as Seveso. Also, the definition contained in the proposed regulatory framework is coherent with the OECD recommendations on the subject.

Chemical Safety Board (CSB) and the ISO 31000 standard. Furthermore, all on-going and past work has been carried out following the UNEP Flexible Framework format.

Regarding the requirements of the Recommendation C(2003)221:

Develop overall safety objectives related to the prevention of, preparedness for, and response to accidents involving hazardous substances

54. Law 1523 of 2012, issued by Congress, provides a national policy for disaster risk management and establishes the National Disaster Risk Management System. Particularly, Articles 6 and 7 set out disaster risk management objectives and components, covering prevention, preparedness and response actions.

55. Decree 1072 of 2015, issued by the Ministry of Labour, requires employers to establish the appropriate objectives related to the prevention of, preparedness for, and response to emergencies in the work place.

56. Based on the previous information, Colombia identifies that although the previous legal framework elements establish the occupational and disaster risk management objectives, there are no legal frameworks that require identifying major accident scenarios of an operation and building emergency response plans based on them.

Develop and implement control frameworks covering all aspects of accident prevention, emergency preparedness and mitigation of accidents, emergency response, and follow-up to incidents, recognizing appropriate roles of all stakeholders including industry, labour and the public

57. Law 1523 of 2012, (Articles 1 and 4 - 8), provides a national logical framework for disaster risk management and establishes the National Disaster Risk Management System. The System is based on three pillars: knowledge, risk reduction and disaster management, which address the safety continuum of prevention, preparedness and response. Furthermore, Article 42 requires specific risk analysis, mitigation measures, and off-site emergency and contingency plans for certain public service providers and for those who conduct industrial activities that may represent a disaster risk for society. Chapter III establishes a planning framework based on national, regional and local risk management plans and emergency response strategies. Finally, Articles 2, 8 and 44 recognize the roles of all stakeholders (public and private entities and the public), including the monitoring, evaluation and control of disaster risk management obligations, both by the State and through citizen oversight.

58. Decree 1072 of 2015 requires employers to define, build and follow-up on indicators to evaluate the structure, process and results of the Occupational Health and Safety Management System (SG-SST for its acronym in Spanish).

59. Decree 1072 of 2015 (Articles 2.2.4.6.23 to 2.2.4.6.25) covers requirements related to hazard and risk management, prevention and control measures, and emergency prevention, preparedness and response.

60. Based on the previous information, Colombia identifies the following gaps:

- The current legal framework does not define specific requirements to ensure the prevention, preparedness and response to major accidents involving hazardous substances. Additional legal regulations need to be put in place to close this gap.

- Colombia has not clearly defined the responsibilities of public authorities and industry for ensuring the implementation of prevention, preparedness and response measures related to

major accidents involving hazardous substances. An institutional framework needs to be created to close this gap.

Consider the use of safety performance indicators to assess the performance related to the prevention of, preparedness for, and response to chemical accidents

61. Decree 1072 of 2015 (Articles 2.2.4.6.19 to 2.2.4.6.22) establishes the occupational health and occupational safety performance lagging indicators – qualitative and quantitative- to monitor the performance of the SG-SST.

62. Based on the previous information, Colombia identifies the following gap:

- Colombia has not established all the required process safety performance indicators related to the prevention of, preparedness for, and response to chemical accidents. Colombia has to adopt and apply the OECD guidance on safety performance indicators to close this gap.

Encourage and/or facilitate processes in which all stakeholders, including industry, public authorities, communities, and other stakeholders, can take action and help ensure effective communication and co-operation

63. A detailed justification and gap identification regarding access to information and public participation is presented in the next section of this document concerning the Decision C(88)85/FINAL.

Establish arrangements for monitoring safety of hazardous installations and for enforcing any requirements related to the control framework

64. Decree 4108 of 2011 (Articles 2, 27, 28 and 30) establishes monitoring and enforcement functions to achieve compliance of the General Labour Risk System.

65. Decree 3518 of 2006 creates the Public Health Surveillance System that includes enforcement functions to ensure compliance in the health sector.

66. Based on the previous information, Colombia identifies the following gap:

- Decree 4108 of 2011 does not specifically cover within its scope the aspects related to process safety and to the prevention of, preparedness for, and response to chemical accidents. Therefore, Colombia also lacks proper monitoring and enforcement mechanisms to ensure the safety of hazardous installations.

Arrange for the development and implementation of compatible off-site and on-site emergency preparedness plans for hazardous installations

67. Law 1523 of 2012 (Article 42) establishes the need for developing specific risk analysis and emergency and contingency plans (on-site).

68. Law 1523 of 2012 (Article 37) establishes the requirement for local authorities to develop community emergency preparedness plans (off-site).

69. License process: the licensee must report the method used to inform communities in their area.

70. Decree 1076 of 2015 (Article 2.2.2.3.3.3) specifically requires informing the community about the scope of the project, its impacts, and proposed management measures. The comments of the

community should be assessed and incorporated in the Environmental Impact Assessment submitted by the petitioner, when deemed appropriate.

71. Decree 1072 of 2015 (Article 2.2.4.5.25) establishes that the industry must develop emergency plans (on-site) within the SG-SST.

72. Based on the previous information, Colombia identifies the following gaps:

- Colombia identified that there are no legal requirements to include major accident scenarios of an operation and build emergency response plans based on them.

- There are no national guidelines for including the on-site emergency plans in the community emergency preparedness plans (off-site).

Establish appropriate arrangements for siting new hazardous installations and for preventing inappropriate developments near existing hazardous installations in order to mitigate possible off-site effects of an accident involving hazardous substances, recognising also the need to take into account the possibility of accidents which are capable of causing transfrontier damage

73. Law 388 of 1997 (Articles 8.2 and 8.3) establishes that the decision for siting hazardous installations are made at the local level and must be considered within land-use plans.

74. Decree 3600 of 2007 (Article 14) establishes the requirements for the location of industrial uses in rural and suburban areas.

75. Decree 1469 of 2010 requires a land classification that considers environmental impacts as a basic condition for defining industrial uses.

76. Law 1523 of 2015 (Articles 4 and 39 to 41) foresee the need to develop land-use regulations that consider minimum safety requirements or restrictions in areas prone to hazardous events. Specifically, these articles require incorporating disaster risk assessment in the biophysical, economic and social-environmental diagnosis that authorities make for territorial and water-basin planning purposes. Risk management considerations must therefore be incorporated in territorial, land-use and development plans at all governmental levels, according to the guidelines and recommendations of the National Disaster Risk Management Plan. Disaster risk must be treated as a conditional factor for land-use and an environmental determinant, which prevails in matters of territorial planning.

77. Based on the previous information, Colombia identifies the following gap:

- The mechanisms to take into account major accident scenarios within land-use planning decision-making processes have not been defined by the current legal framework.

Share information and experience on accident case histories by reporting past accidents to the Major Accident Reporting System (MARS) scheme

78. Decree 1076 of 2015 (Article 2.2.2.3.9.3) considers that if fires, spills, leaks and/or dumping outside the permitted limits occur or if any other environmental contingency occurs during the execution of projects or activities subject to environmental licensing or environmental management plan, the licensee shall inform the competent environmental authority.

79. Decree 1295 of 1994 (Article 62) establishes the requirement to report all occupational and work-related accidents to the occupational risks insurance.

80. Based on the previous information, Colombia identifies the following gap:

- There is no clear harmonization between the existing reporting and communication system and the requirements of the Major Accident Reporting System (MARS) scheme.

Support and promote related research, including co-operative international activities

81. Colombia has not yet established a formal plan or program to promote research (including co-operative international activities) focused on the prevention of, preparedness for, and response to accidents involving hazardous substances. Nevertheless, Colombia received international cooperation from the Health & Safety Executive (HSE) of the United Kingdom, who evaluated the conceptual framework proposed to implement the Major Accident Prevention Programme (PPAM by its acronym in Spanish). Further research and international cooperation activities are needed.

Regarding the requirements of the Decision C(88)85/FINAL:

Provide the public with specific information on the appropriate behaviour and safety measures they should adopt in the event of an accident involving hazardous substances

82. Colombia has mechanisms that allow the public to request information, such as Article 74 Law 99 of 1993, which recognises the right of any person to directly submit information requests to the authorities regarding potential polluting elements and the hazards that the use of these elements may cause to human health. Additionally, Article 23 of Colombia's Political Constitution of 1991 establishes a general right to request public information.

83. Decree 1076 of 2015 (Article 2.2.5.1.9.3) determines the obligation for the industry to develop emergency response plans that include preparation and response actions.

84. Law 1523 of 2012 (Articles 3 and 6) indicates that public participation is fundamental for developing community emergency response plans and the elements of the territorial risk management processes, which will be based on the on-site emergency response plans.

85. Law 1523 of 2012 (Article 94) guarantees the freedom of press in the risk management process as a useful mechanism for risk communication.

86. Based on the previous information, Colombia identifies the following gaps:

- The mechanisms for the provision of information - without request - to the public have not been clearly defined.

- There is no clear harmonization between the emergency preparedness and response elements required by the Health and the Labour Ministries.

- No effective mechanisms have been developed for the inclusion of major accident scenarios in the development of the community emergency preparedness plans or in the response strategies.

Provide the public with general information on the nature, extent and potential off-site effects on human health or the environment, including property, of possible major accidents at a planned or existing hazardous installation

87. The Colombian information systems that allow the provision of general information are defined by:

- Decree 1076 of 2015 (Article 2.2.2.3.10.3) establishes the Colombian Environmental Information System (SIAC for its acronym in Spanish), which provides environmental information to support decision-making processes.

- CONPES 3550 of 2008 and Decree 2972 of 2010 define the Unified Environmental Health System (SUISA for its acronym in Spanish), which is the main information source for the design, implementation, follow-up and assessment of the National Integrated Health Policy.

- Law 1523 of 2012 adopts the National Policy for the Disaster Risk Management and Article 45 establishes the Disaster Risk Management National System, which is administered by the National Unit for Disaster Risk Management (UNGRD by its acronym in Spanish) and allows Public Authorities to communicate emergencies and public alerts in real-time (http://www.gestiondelriesgo.gov.co/snigrd/index.aspx).

88. Based on the previous information, Colombia identifies the following gaps:

- Colombia has not clearly defined the type of general information on industrial activities that must be communicated to the public authorities without request, nor the appropriate mechanisms to do so.

- Colombia has not defined the type of general information that the public authorities have to communicate to the potentially affected population without request.

- None of the national information systems (SIAC, SUISA, and the National System for Disaster Risk Management) provides information on the nature, extent and potential off-site effects on human health or the environment, including property, of possible major accidents at a planned or existing hazardous installation.

Provide access to such other available information needed to understand the nature of the possible effects of an accident (such as information on hazardous substances capable of causing serious off-site damage) and to be able to contribute effectively, as appropriate, to decisions concerning hazardous installations and the development of community emergency preparedness plans

89. Based on the previous information, Colombia identifies that no mechanism has been clearly established to provide the public with information -without request- to understand the nature of the possible effects of an accident and to be able to contribute effectively, as appropriate, to decisions concerning hazardous installations and the development of community emergency preparedness plans.

Take action to facilitate, as appropriate, opportunities for the public to comment prior to decisions being made by public authorities concerning siting and licensing of hazardous installations and the development of community emergency preparedness plans

90. The two main control frameworks that are applicable to the matter of accident prevention, preparedness and response and to the provision of information to the public and public participation in Colombia, are on one hand, the environmental licensing process and on the other, the national disaster risk management system.

91. Regarding the environmental licensing process, Law 99 of 1993 (Articles 69, 70, 71, 72, 74, 75, 76) and Decree 1076 of 2015 (Articles 2.2.1.2.7.18, 2.2.2.1.5.5, 2.2.2.3.3.3) define the public information and participation mechanisms related to licensed activities. Public information and participation mechanisms include the right to request information, notification of licensing processes and decisions, opportunities to intervene in the licensing process, mandatory socialization requirements during the licensing process, prior consultation with ethnic groups and public environmental hearings.

92. Law 1523 of 2012 regulates all aspects related to the national system of disaster risk management. It includes not only natural events but also unintentional anthropogenic events capable of causing major impacts. General principles of the disaster risk management system include *public participation* of ethnic communities and public interest associations (civil, community, neighbourhood, non-for-profit, volunteer); and *provision of timely information*, which creates an obligation on disaster risk management system authorities (primarily governors and mayors), of keeping the public informed about risk possibilities, disaster management, and rehabilitation actions (articles 3.5 and 3.15, Law 1523).

93. Based on the previous information, Colombia identified that not all of the industrial installations susceptible to major accidents (for example chlorine and ammonia production and storage facilities) are within the scope of an environmental license and its corresponding participation and consultation mechanisms, which is an aspect to be addressed in the proposed action plan.

Regarding the requirements of the Decision C(88)84:

Exchange of Information concerning Accidents capable of causing Transfrontier Damage

94. Colombia currently does not share borders with any OECD Member countries. However, Colombia has a number of cooperation platforms that would facilitate the creation of mechanisms for the implementation of the OECD Decision concerning exchange of information about accidents capable of causing transfrontier damage. Under the ILO Convention 174, Colombia also has an obligation under Article 16(c) to provide information to the member states regarding safety measures and warnings in cases where a major accident could have transfrontier effects, in order to cooperate and coordinate proper arrangements.

95. In terms of cooperation platforms, the Andean Community of Nations (CAN) currently conformed by Peru, Ecuador, Bolivia and Colombia, has formulated an Andean Disaster Prevention and Attention Strategy (CAN Decision 713) and created an Andean Disaster Prevention and Attention Committee (Decision 529). There is also an Andean Committee of Environmental Authorities (Decision 435), which has within its functions to recommend and promote cooperation mechanisms to solve common environmental problems, as well as to promote the fulfillment of international commitments adopted by member countries (CAN Decision 713, Article 3).

96. Colombia has the National IHR Focal Point in the Ministry of Health and Social Protection, which performs the functions of monitoring, evaluating and reporting related to the global public health response to natural occurrences, accidental releases or deliberate use of biological and chemical agents or radio-nuclear material that affect health according to the implementation of the International Health Regulations – IHR/WHO (2005).

97. Notwithstanding the above cooperation mechanisms Colombia identified the absence of an information exchange mechanisms concerning accidents capable of causing transfrontier damage, which is why this aspect will be covered in the proposed action plan below.

98. Based on the previous information, Colombia identifies that in order to comply with the provisions relating to the exchange of information contained in Appendix I to this Council Act, Colombia

would first need to implement the action plan proposed for Council Act C(2003)221 – RECOMMENDATION OF THE COUNCIL CONCERNING CHEMICAL ACCIDENT PREVENTION, PREPAREDNESS AND RESPONSE related to chemical accidents, which would allow for a more cost-effective and consistent implementation of this Decision.

Background on Colombia´s process for designing a Major Accident Prevention Programme

99. Colombia is designing a Major Accident Prevention Programme (PPAM by its acronym in Spanish). The PPAM's objective is to manage major accident risks, which implies preventing, controlling and mitigating potential accidental scenarios in hazardous facilities. In order to do this, the Ministry of Environment and Sustainable Development (has been leading this process and has created the Major Accident Committee (CIAM by its acronym in Spanish).

100. The CIAM is an inter-institutional coordination group that seeks to:

- Identify and define institutional roles and responsibilities.
- Achieve cooperation between government entities.
- Define consultation mechanisms with other stakeholders.
- Design a conceptual framework for the implementation of the PPAM.
- Perform a legal gap analysis.
- Identify legal and technical alternatives for implementation of the PPAM.
- Follow up and assessment of the progress toward the implementation of PPAM.

101. The work being carried out in the CIAM follows the guidelines of *"A Flexible Framework for Addressing Chemical Accident Prevention and Preparedness – A Guidance Document"* (UNEP, 2010), for the diagnostic, assessment, implementation and analysis and review phases required to set up the programme.

102. Additionally, the Ministry of Environment and Sustainable Development presented a preliminary reference document to the CIAM on the "*Conceptual Framework for the Construction of a Major Accident Prevention Programme"*. This document has been used as a basis for the technical discussions of the Committee and is based on the OECD major accident requirements, European Union Directives (Seveso I, II and III), the United States Risk Management Program (RMP) (48 CFR 68), the United Kingdom COMAH regulations, the French PPRT, the ILO Convention 174 and its 181 Recommendation, the recommendations of the United States Chemical Safety Board (CSB) and the ISO 31000 standard.

103. The CIAM has been in touch with the Health and Safety Executive (HSE) of UK, in order to support the design & implementation of the PPAM. The Senior Policy Adviser (for Hazardous Installation) of the Health & Safety Executive (HSE) of the United Kingdom visited Colombia in February of 2016 and evaluated the conceptual framework.

Action Plan

104. The CIAM has been implementing the action plan for the development of a Major Accident Prevention Programme. The activities for the 2016 - 2020 period included in the action plan are presented below:

Table 4. Action Plan for the Major Accident Prevention Programme

OECD Instrument	Time-frame	Objective	Specific Activities	Status
C(2003)221	2015-2017	Design the Major Accident Prevention Programme (PPAM by its acronym in Spanish).	Define the objectives and the conceptual framework for the PPAM, including safety objectives related to the prevention of, preparedness for, and response to accidents involving hazardous substances.	Colombia already defined the overall objective of the PPAM: to manage major accident risks, which implies preparing preventing and responding to potential accidental scenarios involving hazardous substances. Specific safety objectives will be defined between 2016 and 2017.
	2016		Define and develop main technical elements to implement the PPAM.	Eight main elements of the PPAM have already been defined: Compilation of information, Major Accident Prevention Policy, Safety Management System, Emergency Plan, Safety Report, Incident Report, Incident Investigation, and Enforcement.[15]
	2016		According to the Annex I of Seveso III and Annex III of Decision [C(88)84/Final] define the scope of the PPAM based on (a) the Hazardous Substances List and its thresholds and (b) the exclusions from the program,	Colombia already defined a Hazardous Substances List and its thresholds as well as the exclusions in a "*Conceptual Framework for the Construction of a Major Accident Prevention Programme*". The Hazardous Substances List will be subject to public consultation during 2016 with relevant stakeholders.
	2015-2020	Compile information on hazardous	Design and implement a mechanism to compile information on hazardous	In 2015, Colombia developed a preliminary inventory of hazardous installations to have an

[15] Please refer for more detail to the Report Define on Colombia´s Industrial Chemicals Management and Chemical Accidents Programmes, presented in the 54thJoint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of 11 February, 2016, page 25-26.

OECD Instrument	Time-frame	Objective	Specific Activities	Status
		installations.	installations.	initial baseline for decision making. The Ministry of Labour as the coordinating authority will compile this information.
	2017	Generate safety performance indicators to evaluate and monitor PPAM´s performance.	Define safety performance indicators to assess the performance related to the prevention of, preparedness for, and response to chemical accidents. Define guidelines for industry and public authorities.	The Ministry of Labour as the coordinating authority will generate this indicators and provide the funding for this activity.
	2017	Define the technical guidelines for the prevention, preparedness and response to chemical accidents.	Define the maximum individual risk value to develop a risk evaluation process and a guideline to carry it out.	The UNGRD already defined the terms of reference to develop this technical product.
			Define the guidelines and regulation for hazard identification and risk management processes for industry and public authorities.	The CIAM is currently defining the responsible entity for this activity.
			Define the guidelines and regulation for the design and implementation of the safety management system and the major accident policy.	The Ministry of Labour as the coordinating authority will develop this guideline and provide the funding for this activity.
			Define guidelines and regulation for the construction of emergency plans for industry and the public authorities.	The UNGRD will develop this guideline and provide the funding for this activity.
	2019	Establish appropriate arrangements for siting new	Develop guidelines and regulation to incorporate the Major Accident Prevention Program in	The UNGRD and the Ministry of Housing, Cities and Territory will develop this guideline and provide the funding for this

OECD Instrument	Time-frame	Objective	Specific Activities	Status
		hazardous installations and for preventing inappropriate developments near existing hazardous installations in order to mitigate possible off-site effects of an accident involving hazardous substances.	land use planning instruments.	activity.
	2020		Develop a pilot program to incorporate the Major Accident Prevention Program in land use planning processes.	The UNGRD and the Ministry of Housing, Cities and Territory will develop this pilot and provide the funding for this activity.
	2019-2020	Share information and experience on accident case histories by reporting past accidents to the Major Accident Reporting System (MARS) scheme.	Design mechanisms to report and communicate following the MARS scheme. Since December 2016, Colombia has a user account to access the eMARS database.	The Ministry of Labour as the coordinating authority will be responsible for this activity.
	2016 – 2018	Strengthen enforcement mechanisms to ensure compliance of the Programme.	Include in the regulatory framework additional enforcement mechanisms and capacities to be able to impose sanctions and preventive or compensation measures in case of non-compliance.	Enforcement provisions already included in the proposed regulatory framework.
			Strengthen institutional capacities through the use of monitoring networks.	
	2016	Support and promote related research, including co-operative international activities.	Maintain a continuous participation in the OECD Chemical Accidents Working Group meetings and seek opportunities for cooperation with member countries.	
C(88)85	2019-2020	Provide the public with specific information on the	Define a legal mechanism to include Industry emergency response	

OECD Instrument	Time-frame	Objective	Specific Activities	Status
		appropriate behaviour in the event of an accident involving hazardous substances and general information on the nature, extent and potential off-site effects on human health or the environment.	plans (on-site) in the community emergency preparedness plans (off-site) and in their response strategies.	
	2019-2020		Define a legal mechanism to require communication of the community emergency preparedness plans to the potentially affected population.	
	2019-2020		Define the legal instrument that establishes the type of information that Industry must communicate to Public Authorities, and also the appropriate mechanism to do so.	
C(88)85	2019		Establish which of the existing information systems (SIAC, SUISA, and the National System for Disaster Risk Management) will provide this information without request and develop a specific module for that system.	The National System for Disaster Risk Management will provide the platform to inform the public in this regard.
	2018-2019		Define the type of general information that public authorities must communicate to the potentially affected population, with and without request, as	The CIAM will carry out this activity.

OECD Instrument	Time-frame	Objective	Specific Activities	Status
			stipulated in the Annex to C(88)85/Final.	
	2018	Provide participation mechanisms in decisions concerning hazardous installations and the development of emergency plans.	Define a legal mechanism that allows public participation and consultation for decisions being made by public authorities concerning siting and licensing of hazardous installations and the development of community emergency preparedness plans.	
C(88)84	2018	Define and establish mechanisms that allow the exchange of information concerning accidents capable of causing transfrontier damage.	Develop and implement the mechanisms that allow the exchange of information concerning accidents capable of causing transfrontier damage.	
C(2003)221 C(88)85/FINAL C(88)84/FINAL	2016	Issue the policy framework.	Issue the previously mentioned National Policy for the Management of Risk associated with the Use of Chemical Substances, which shall: - Establish long term policy objectives to manage major accidents risks. - Align the efforts of the institutions involved. - Incorporate in the national policy the most relevant aspects of the action plan proposed by Colombia to implement the PPAM.	The CONPES 3868 adopted the National Policy for the Management of Risk associated with the Use of Chemical Substances on October.2016.

OECD Instrument	Time-frame	Objective	Specific Activities	Status
			-Jointly define the resources required to implement the PPAM and determine the potential sources of funding.	
	2017	Issue the regulatory framework	Issue a Presidential Decree between the main entities involved to: - Establish the functions that public entities must perform to implement the programme. - Establish economic instruments - Establish the necessary mechanisms for the provision of information to the public. - Determine additional enforcement and monitoring mechanisms.	The Major Accident Prevention Programme will be adopted by a Presidential Decree issued by the Ministers of Environment, Health and Social Protection, Labour, Housing, Cities and Territory and by the Presidency of the Republic on behalf of the National Unit for Disaster Risk Management. The draft Decree for the adoption of the Programme was published for public consultation on February 6th, 2017 and expected to be issue in the first semester of 2017.
C(2003)221 C(88)85/FINAL C(88)84/FINAL	2016-2018	Strengthen enforcement and monitoring mechanisms to ensure compliance of the PPAM.	Include in the regulatory framework provisions for enforcement and monitoring mechanisms and competences to be able to impose sanctions and preventive or compensation measures in case of non-compliance.	Enforcement provisions already included in the proposed regulatory framework.
C(2003)221 C(88)85/FINAL C(88)84/FINAL	2016-2020	Dissemination & Capacity building.	Establish dissemination and capacity building activities for the public, government entities and industry.	A forum was organized in Bogota in February 2016 with the OECD Secretariat to disseminate the Programme with a wide range of stakeholders. The Ministry of Labour organized in April 2016 an international conference in which the PPAM was presented.

OECD Instrument	Time-frame	Objective	Specific Activities	Status
				At least five workshops were carried out in the first semester of 2016 with Business Associations and other stakeholders. Four public consultation workshops organized by the Ministry of Environment and Sustainable Development, the Ministry of Labour, the National Business Association and the United Nations Industrial Development Organization - UNIDO will be carried out with the industry in September 2016 to disseminate the Programme and its requirements.

105. Regarding the institutional arrangement for the implementation of the PPAM in Colombia, the CIAG has been working on specifying the entities that would perform: 1) coordination, 2) technical guidance and 3) operative and enforcement actions within the Program. Coordination activities are placed in the Ministry of Labour in the current draft of regulatory framework. Technical guidance would be provided by an inter-institutional body represented by experts from all relevant entities (health, labour, disaster risk, territorial development and environment), and operational and enforcement functions would be carried out by health, labour and environmental authorities jointly, as well as territorial authorities.

106. The coordinating authority would be in charge of:

- Lead the process of drafting the corresponding regulation.
- Receive safety reports and emergency plans among other relevant information.
- Coordinate with other entities at the national and local/regional level.
- Promote investigation and international cooperation on chemical accidents.

C(89)88/FINAL – RECOMMENDATION OF THE COUNCIL CONCERNING THE APPLICATION OF THE POLLUTER-PAYS PRINCIPLE TO ACCIDENTAL POLLUTION

Position: Acceptance.

Justification:

107. Colombia agrees with the Guiding Principles Relating to Accidental Pollution set out in the Appendix to OECD Act C(89)88/FINAL (hereinafter "Guiding Principles"). Colombia's legal framework provides appropriate legal tools to allocate the costs of accidental pollution prevention and control in operators of hazardous installations with regards to pollution from those installations. Although there is not just one regime that generally regulates the application of the polluter-pays principle (PPP) specifically to

accidents involving hazardous installations, regulated operators are, as a general rule, charged with bearing the costs of preventing and controlling accidental pollution, as opposed to the State assuming such costs by means of subsidies, tax advantages or other measures.

108. The following provisions in Colombian law are examples of consistency with the PPP, based on the criteria considered in the Guiding Principles.

The PPP as a founding principle of environmental policy in Colombia

109. This subtitle addresses paragraphs 3 and 4 of the Guiding Principles. Article 1 of Law 99 of 1993 (general environmental law issued by Congress) establishes General Environmental Principles that shall guide environmental policy in the country. Among them are: *"The process of economic and social development will be guided by universal principles of sustainable development contained in the Declaration of Rio de Janeiro of June of 1992 on Environment and Development"* (article 1, paragraph 1, Law 99) and *"The State will promote internalization of environmental costs and the use of economic instruments to prevent, correct and restore environmental degradation, and in order to preserve renewable natural resources"* (article 1, paragraph 7, Law 99). Principle 13 of the Rio Declaration is particularly relevant as it requires states to develop laws "*regarding liability and compensation for the victims of pollution and other environmental damage*", as well as to co-operate to develop international laws "*regarding liability and compensation for adverse effects of environmental damage caused by activities within their jurisdiction or control to areas beyond their jurisdiction*."

110. Additionally, article 12 of Law 23 of 1973 (guiding principles of environmental law) requires the Government to create technical evaluation mechanisms in order to require that those who lucratively use environmental resources contribute to the expenses incurred in the protection and renewal of natural resources. Based on this mandate, Law 99 of 1993 established mechanisms to make this contribution effective but without differentiating between lucrative and non-lucrative uses.

Domestic law requiring collection of control costs after an accident

111. With regards to paragraph 5 of the Guiding Principles, article 80 of the Constitution requires the State to prevent and control environmental deterioration factors, as well as to impose legal sanctions and demand compensation for any damages that may have been caused. Additionally, article 31 of Law 99 of 1993 states the functions of Regional Autonomous Corporations (regional environmental authorities), one of which requires the authority to take action, according to applicable regulations, to demand compensation of environmental damages, according to applicable regulations (article 31 # 17, Law 99 of 1993).

Environmental management and contingency plans as mechanisms to allocate costs of accidental pollution prevention and control measures

112. Regarding the types of measures described in paragraphs 6 and 8 of the Guiding Principles, contingency plans involve foreseeing and implementing prevention and control measures such as accident prevention and preparedness, emergency plans and the determination of responsibilities to take prompt action, mitigate effects and conduct clean-up operations following an accident. The development of contingency plans and therefore the performance of these prevention, preparedness and control obligations is, as a general rule, charged to the operator of the installation, understood as the party who intends to carry out a project, work or activity that requires an environmental license or a discharge or emission permit under applicable law (license or permit holders), or industries which according to applicable law expressly require the adoption of a contingency plan.

113. This is consistent with the scope defined in OECD's Council Act C(89)88/FINAL through the definition of "operator" and "hazardous installation", as under Colombian law installations capable of

giving rise to hazards sufficient to warrant the taking of precautions off-site are those for which regulations have required an environmental license or a permit or otherwise a contingency plan. Where an environmental license or permit is not required, environmental authorities may still impose compensatory measures when a violation of environmental regulations or environmental damage occurs. Polluters may also be held liable under general civil liability regimes (in cases of individual damage) and under liability regimes that protect collective rights (in cases of pure ecological damage). These will be explained further below when addressing paragraphs 6 and 11 of the Guiding Principles. The following are contingency plan requirements under applicable law:

1. In activities subject to environmental license: Decree 1076 of 2015 (chapter on environmental licensing regulations)[16] requires the submission of an Environmental Impact Assessment (EIA) for all projects, works or activities subject to an environmental license.[17] The EIA is regarded as the essential decision-making instrument in this context and it must contain an environmental management plan (article 2.2.2.3.5.1 # 7) and a contingency plan (article 2.2.2.3.5.1 # 9). These plans address strategies related to risk prevention, mitigation, compensation and correction, as well as potential threats, the probability of occurrence of emergency scenarios, and the actions to be taken in cases of accidental pollution (both during construction and operation of the project) with a view to reducing risks, mitigating possible consequences and be prepared to execute coordinated response actions[18] (articles 2.2.2.3.1.1—definition of environmental management plan and 2.2.2.3.5.1—EIA requirements). In terms of control cost allocation, article 2.2.2.3.9.3 of Decree 1076 of 2015 regarding environmental contingencies, states, "*Should any fires, spills, leaks, emissions or discharges beyond the permitted limits or any other environmental contingency occur during the execution of the project, work or activity subject to environmental license or environmental management plan, the [license] holder shall execute all actions necessary to stop the environmental contingency and inform the competent environmental authority within twenty four (24) hours. The environmental authority (...) may impose additional measures if necessary.*"

2. In activities involving potential accidental spills of hydrocarbons, its derivatives and harmful substances into lakes, rivers and marine waters: Decree 321 of 1999 adopts the National Contingency Plan (hereinafter the "Plan") against spills of hydrocarbons, their derivatives and harmful substances (hereinafter "harmful substances") in seawaters, rivers and lakes (hereinafter "surface waters"). The general purpose of the Plan is to serve as the main instrument to design and implement activities to prevent, mitigate and correct the effects of oil and harmful substances spills in the national territory. Regarding prevention and control cost allocation, article 5 paragraph 5 of Decree 321 requires local contingency and mutual assistance plans for any public or private, natural or legal person involved in any manner in the handling of harmful substances, or those responsible for controlling and preventing spills in surface waters. In cases of environmental damages caused by a spill that may affect bodies of water, paragraph 8 turns to the person responsible for the installation, operation, owner of the substance or activity where the spill originated, who shall be responsible for comprehensively attending to the spill. The actions

[16] Decree 1076 of 2015 now contains all executive regulations for the environmental administrative sector.

[17] Only projects, works or activities listed under articles 2.2.2.3.2.2 and 2.2.2.3.2.3 of Decree 1076 of 2015 are subject to environmental license. Listing of these projects, works, or activities is based on the recognition that they may cause grave deterioration over renewable natural resources or the environment, or that they may introduce significant or noticeable modifications to landscape (article 2.2.2.3.1.3 of Decree 1076 of 2015).

[18] Detailed criteria and guidelines regarding the contents of EIAs are contained in the Environmental Studies Evaluation Manual published by the Ministry of Environment of Colombia. An official translation into English of relevant parts of this Manual are available for consultation.

to be taken are laid out in the specific contingency plan developed according to the same paragraph 5, article 5 of Decree 321, or other applicable laws and regulations. Should the responsible party fail to comply, this same provision foresees that the entities that become aware of the spill, or those trained to deal with emergencies of this nature and who take over handling of the event, will at no time be held liable for the damages caused by the spill. Although one of the guiding principles of the Plan in article 5, paragraph 6 of Decree 321 contemplates the possibility of providing State support to third parties for any type of emergency, or to provide primary emergency support in cases of spills with yet undefined responsible parties, the same provision states that the costs and expenses derived from spill response actions performed in support of third parties shall be reimbursed by the party responsible for the spill, once the corresponding bills, which shall be approved by the National Plan's Technical Committee, have been submitted (article 5 # 6, Decree 321 of 1999).

3. In activities involving potential accidental spills of hydrocarbons and harmful substances into aquifer-related land and bodies of water: Decree 1076 of 2015 (chapter on general water use and liquid discharges regulations), requires in article 2.2.3.3.4.14 that those users who explore, exploit, manufacture, refine, transform, process, transport or store hydrocarbons or substances harmful to health and hydro biological resources, shall have a contingency and spill control plan in place, which shall be approved by the competent environmental authority. Users are defined in articles 2.2.3.3.13 paragraphs 33 and 34 as "*[a]ny private or public, natural or legal person that holds a discharge permit, a compliance plan, or a sanitary or discharge management plan to dispose of its discharges into surface or marine waters and onto land*" or that "*discharges to the public sewer system*." Additionally, article 2.2.3.3.5.4 of Decree 1076, requires any person (natural or legal, public or private) involved in activities that generate discharges into a body of water or aquifer-related land to develop a Risk Management Plan to manage discharges in situations that limit or prevent their treatment. This plan must include risk analysis, prevention and mitigation measures, emergency and contingency protocols and a rehabilitation and recovery program.

4. In activities involving potential accidental air emissions arising from the handling of hydrocarbons and toxic substances: Decree 1076 of 2015 (chapter on general air protection and quality control regulations), establishes in article 2.2.5.1.9.1 measures that competent environmental authorities shall take in cases where air quality in any given area triggers actions of Prevention, Alert or Emergency. These actions mainly concern the provision of timely information to the public and the authority to restrict, suspend or prohibit activities that may aggravate the event. Regarding allocation of prevention and control costs, article 2.2.5.1.9.3 of Decree 1076 requires those who explore, exploit, manufacture, refine, transform, process, transport or store hydrocarbons or toxic substances that may be harmful for health, renewable natural resources or the environment, to conduct a contingency plan that contemplates a comprehensive safety system, prevention measures, response organization, equipment, trained personnel, and the budgetary resources to prevent and control contaminating emissions and to compensate damages. This Plan is subject to approval by the competent environmental authority. Article 2.2.5.1.9.2 of Decree 1076 also authorizes regional environmental authorities to impose on emitters of stationary sources an obligation to prepare contingency plans that are tailored to the nature of the given activity, and to require proof of the effectiveness of their response systems through periodic verifications.

5. In the context of the handling of hazardous substances under sanitary regulations: Law 9 of 1979 issued by Congress and containing Colombia's main sanitary regulations (also known as Sanitary Code), requires in article 130 that in the import, production, storage, transport, commerce, handling or disposal of hazardous substances, all necessary measures and precautions to prevent

damage to human or animal health or the environment are taken. In terms of allocation of costs of control measures, article 132 states that those responsible for transport, use or disposal activities involving hazardous substances during which damage to public health or the environment occur, shall be responsible for the injuries that may have been caused.

6. In the context of disaster risk management regulations: Law 1523 of 2012 (National Disaster Risk Management System) provides a national policy for disaster risk management and establishes the National Disaster Risk Management System. This law applies broadly to "disasters" or "disaster risks", i.e., natural or non-intentional anthropogenic events capable of causing serious human, material, economic or environmental damages[19] (articles 1 and 4 # 8). Article 42 of Law 1523 requires public services providers or entities involved in activities that may entail a disaster risk for society, either public or private, to conduct a specific risk analysis considering possible effects of natural events over exposed infrastructure, as well as possible impacts derived from the damage caused to such infrastructure in its area of influence, and those resulting from its operation. Based on this risk analysis, the said entities must design and implement mandatory risk mitigation measures as well as emergency and contingency plans. Law 1523 includes several provisions that require the State to take prevention and control measures with regards to disasters. However, in the terms of paragraphs 7, 14 and 15 of the Guiding Principles, because of the nature of the circumstances involved (*see* "disaster" definition), the assumption of the costs of these prevention and control measures by public authorities would not be inconsistent with the PPP.

7. In the context of hazardous waste regulations: Under the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (hereinafter Basel Convention) which Colombia approved through Law 253 of 1996, Colombia acquired commitments to require pollution prevention and control measures from hazardous waste disposal facilities and the persons involved in the management of hazardous wastes (management including disposal of hazardous wastes and after-care of disposal sites) (articles 2.2 and 4.2(c), Basel Convention). In the "responsibility" chapter of Law 1252 of 2008 (hazardous waste regulations) responsibility is attached to the producer, importer or transporter of chemical products or substances with hazardous characteristics for any environmental and health effects resulting from activities such as their transport and storage (article 8, Law 1252).

Licensing fees allocating follow-up costs to license and permit holders

114. This subtitle addresses paragraphs 9, 10 and 13 of the Guiding Principles. Article 28 of Law 344 of 1996 (modified by Law 633 of 2000) (rationalization of public expenditure) establishes a fee in order to charge for evaluation and follow-up services of environmental licenses, permits, concessions, authorizations and any other environmental control and management instrument provided by laws or regulations. These are not specific to certain installations on account of their hazardous nature and they are not adjusted based on certain exceptional prevention measures, but charged based on the value of the project with a maximum limit (article 28, Law 344, article 46 paragraph 11, Law 99 of 1993—general environmental law; article 1, Resolution 1280 of 2010—evaluation and follow-up services fee). However, fees are charged for each service provided by the environmental authority (e.g. a fee for each field visit)

[19] "Disaster" is defined in article 4 # 8 of Law 1523 of 2012 as the result that is unleashed from the manifestation of one or more natural or unintentional anthropogenic events, which coming upon vulnerability conditions among people, goods, infrastructure, means of subsistence, provision of services or environmental resources, causes damages or human, material, economic or environmental losses, generating an intense, grave and extended alteration of the conditions under which society normally functions, and which requires the State and the national system to execute emergency response, rehabilitation and reconstruction actions.

calculated based on the formulas established in article 2 of Resolution 1280. Therefore, for instance, if follow-up services for a given project imply more than one visit (often due to the complexity of the activity involved), the operator will incur the fee for each visit and will end up paying more overall for follow-up services.

115. There are currently no mechanisms in place for pooling financial risks among operators connected with accidents.

Legal mechanisms available to charge to the operator the costs of pollution control measures decided by the authorities following an accident

116. This subtitle addresses paragraphs 6 and 11 of the Guiding Principles. Article 16 of Law 23 of 1973 (guiding principles of environmental law) imposes civil liability for damages caused by private parties or the State to any given person, or to natural resources owned by the State or private parties as the case may be, as a consequence of actions that generate contamination or are detrimental to the environment. This provision reaffirms the application of general liability regimes under Colombian law in an environmental context, both with regards to individuals and to the State (civil or state responsibility).

117. The following paragraphs present the mechanisms available in the legal framework to seek compensation for either pure ecological or individual damages.

- Administrative enforcement mechanisms: environmental administrative action may be taken in two scenarios: (1) in cases of violations of environmental provisions and (2) in cases of environmental damage (causing environmental damage in itself is considered an environmental violation). In both scenarios, environmental authorities may impose "compensatory measures" to compensate or restore the damage or impacts caused (including violations of the terms and conditions of environmental licenses and contingency plans). These measures are contemplated in article 31 of Law 1333 of 2009 (environmental enforcement and sanction regime) and they may be imposed besides any applicable sanctions (paragraph 1, article 40). Their purpose is to achieve recovery, rehabilitation or restoration of ecosystems that have been degraded, damaged or destroyed as a consequence of an environmental violation (pure ecological damage).[20]

- In the context of a violation of environmental provisions, sanctions and compensatory measures may be applied notwithstanding issues concerning the origin of the accident or other liabilities that may be involved under applicable law (paragraph 1, article 40). In cases of environmental damage, a sanction or a compensatory measure may only be imposed once the elements required under tort law for civil wrongs are established (civil liability): damage, fault or intent, and causation. In these cases, paragraph 1, article 5 of Law 1333 establishes a rebuttable presumption of fault or tortious intent from the violator. Being rebuttable, Colombia's Constitutional Court has not interpreted this presumption as constituting objective responsibility. Instead, it treats this as a case of subjective responsibility where the burden of proof is overturned.[21] The imposition of sanctions and compensatory measures are besides any other sanction or remedy for which provision may be made according to applicable law.

- Judicial Mechanisms—Civil and State Responsibility: the judicial mechanism available to public authorities to pursue compensation for damages caused to them by private parties is the "action

[20] Constitutional Court Decision C-632 of August 24 of 2011, Presiding Justice Gabriel Eduardo Mendoza Martelo, at paragraph 8.7.

[21] Colombia Constitutional Court Decision C-595 of July 27 of 2010, Presiding Justice Jorge Iván Palacio Palacio.

for direct compensation" (*acción de reparación directa*), which is brought before administrative law courts according to the procedural requirements of the Colombian Administrative Code (article 140, Law 1437 of 2011—Colombian Administrative Code). The mechanism available to private parties to pursue compensation for damages caused to them by other private parties is a tort claim brought before civil law courts under tort law regulated in Colombia's Civil Code and in the Code of Civil Procedure. Based on articles 2341 and 2356 of the Civil Code, Colombia's Supreme Court has developed a doctrine of liability for dangerous activities that does not require proof of fault.[22]Although there is no definition of dangerous activity in the Civil Code, the Court has defined criteria according to which a dangerous activity takes place, i.e., where it creates risks of such nature that the occurrence of damages becomes imminent, or that alter the balance of forces that people exert with respect to one another in ordinary circumstances.[23] Based on the same notions of responsibility, the State Council has developed a "creation of exceptional risk" doctrine for cases of state responsibility. Exceptional risk is determined based on whether the state objectively created a threat of injury to a person's goods, rights and/or interests.[24]

- In cases where one or more—but less than twenty—plaintiffs have suffered individual damages for the same wrong, they may file a class action lawsuit to recover them from the same plaintiff. Class actions are regulated along with popular actions (see below) in article 46 et. seq. of Law 472 of 1998 (popular and class action regulations).

- Judicial Mechanisms—Popular Action: article 88 of the Colombian Political Constitution created "popular actions" to protect collective rights and interests, including the right to a healthy environment. This action may be brought both to protect collective rights from a threat of injury (as a preventive mechanism) and in cases where an injury has already occurred. Because of the nature of popular actions, i.e. to protect collective rights and interests, legal remedies primarily consist of requests for injunctive relief or restitution as opposed to damages. Damages may only be awarded by a judge in cases where he or she has determined that injunctive relief or restitution is not feasible.[25] Article 34 of Law 472 of 1998 (popular and class action regulations) states that where an award for damages has been entered, payment must be made to the non-guilty public entity responsible for the defence of the collective rights and interests involved. Public entities that exercise functions of control, intervention and monitoring (and other public authorities defined by Law 472) may bring popular actions as long as the threat or injury to the collective rights or interests involved had not originated in the entities own action or omission (article 12, Law 472); so does any natural or legal person, as well as civil and non-for-profit organizations.

- Judicial Mechanisms—*Tutela* Action: article 86 of the National Constitution introduced the *Tutela* Action (writ of protection) exclusively to protect constitutional fundamental rights. Any person may file under this action when no other means of judicial defence are available (except

[22] Colombia State Council (*Consejo de Estado*), Third Division, Decision of February 20 of 2014, Presiding Councillor Ramiro Pazos Guerrero at 36-9 & n. 41 (there is a split between the State Council and the Supreme Court as to whether liability for dangerous activities under the Civil Code may be properly understood as strict liability. They both agree, however, that in cases where dangerous activities are involved, the claimant is not required to prove fault).

[23] Colombia Supreme Court, Civil Chamber (*Sala de Casación Civil*) Decision of 26 of August of 2010, Presiding Justice Ruth Marina Díaz Rueda at paragraph 4.

[24] Colombia State Council (*Consejo de Estado*), Third Division, Decision of February 20 of 2014, Presiding Councillor Ramiro Pazos Guerrero at 39-40.

[25]Colombia Constitutional Court, Decision C-215 of April 14 of 1999, Presiding Justice Martha Victoria Sáchica de Moncaleano.

temporarily to avoid irreversible harm). It involves a preferential and summary proceeding for the immediate protection of these rights when the latter may be or have been violated by the action or omission of a public authority or a private party that provides a public service, or whose conduct may seriously and directly affect the collective interest, or in respect of whom the applicant may find himself/herself in a state of subordination or vulnerability. No more than 10 days may elapse between the filing of the writ of protection and its resolution and it will not proceed if the damage caused by the violation has been consummated unless the violation continues (it is not an action to recover for damages, but an exceptional mechanism for the immediate protection of fundamental human rights).

118. Although enjoyment of a healthy environment is a collective and not a fundamental right under the Constitution, article 6 of Decree 2591 of 1991 (regulates *tutela* actions) allows the protection of fundamental rights in situations where collective rights are compromised, as long as it involves avoidance of an irreversible harm. Accordingly, the Constitutional Court has upheld *tutela* actions in cases where environmental protection is essentially linked to a fundamental right, such as life and freedom, or to other rights linked to life such as health.[26]

119. According to the above, Colombia´s legal framework and control mechanisms are consistent with the OECD Guidelines on the application of the polluter-pays principle to hazardous installations. Additionally, the principles stated in this OECD Recommendation is being considered in the design of the Major Accident Program (PPAG by its acronym in Spanish) that is currently under development as an action plan for the implementation of OECD Acts C(2003)221, C(88)85/FINAL and C(88)84/FINAL.

MANUFACTURED NANOMATERIALS

C(2013)107 – RECOMMENDATION OF THE COUNCIL ON THE SAFETY TESTING AND ASSESSMENT OF MANUFACTURED NANOMATERIALS

Position: Acceptance.

Justification:

120. Currently, there are no specific regulations in Colombia to determine the risks and effects on human health and the environment of manufactured nanomaterials.

121. The Programme for the Management of Chemicals for Industrial Use proposed by Colombia and described in the action plan contained in the section on General Principles of Chemicals Management, will serve for managing the risks and effects on human health and the environment related to manufactured nanomaterials. It should be stressed that the Programme will take into account the OECD Test Guidelines when testing manufactured nanomaterials, as well as the tools listed in the Annex to the Council Act when managing risks of manufactured nanomaterials.

122. Colombia will use the list of twelve (12) nanomaterials presented by the OECD as a base for inclusion in the Programme for the Management of Chemicals for Industrial Use.

[26] *See* Constitutional Court of Colombia, Decision T-154 of 2013 (Morales Ramos v. Drummond), Presiding Justice Nilson Pinilla Pinilla.

123. In 2016, Colombia hosted the Technical Workshop for the Latin American and Caribbean Region on Nanotechnology and Manufactured Nanomaterials: Safety Issues, organized by the United Nations Institute for Training and Research (UNITAR). Participants included representatives from Argentina, Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, Panama, Peru, St. Vincent & the Grenadines and Uruguay.

124. The workshop was a perspective-gathering exercise for the establishment of regional nanosafety requirements. The work will be used to define future actions that institutions and organizations can carry out cooperatively to define a roadmap for nanosafety in Latin America.

125. It was concluded in the workshop that the gap in nanosafety-related issues in Latin America and the Caribbean is significant. The region lacks the infrastructure needed to evaluate physical, health or environmental hazards, based on the particular conditions for the region. Mutual acceptance of data must be supplemented by local skills-building, in order to strengthen decision-making based on informed risk.

EXPORT OF BANNED OR SEVERELY RESTRICTED CHEMICALS

C(84)37/FINAL – RECOMMENDATION OF THE COUNCIL ON INFORMATION EXCHANGE RELATED TO EXPORT OF BANNED OR SEVERELY RESTRICTED CHEMICALS

Position: Acceptance.

Justification:

126. Colombia accepts this Recommendation. The current legal framework includes specific regulations on the subject, such as:

- Law 1159 of 2007 approved the Rotterdam Convention for the application of the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides for International Trade. Specifically, article 11 of Law 1159 establishes obligations related to the export of chemical products listed in Annex III. Article 12 indicates the requirements for export notifications of banned or severely restricted chemicals. Article 13 references information that must be included with chemical products for export, and Article 14 indicates the mechanisms related to the exchange of information regarding the export of banned or severely restricted chemicals.

- Andean Decision 804 of 2015 is the current legal instrument for registration, inspection and control of pesticides for agricultural use. Specifically, Articles 35-36, 65-66 of Andean Decision 436, consolidated in Decision 767, establish measures for the exchange of information related to the export of chemical pesticides for agricultural use and the creation of national systems of information integrated to an Andean System of Information Exchange on Pesticides for Agriculture Use to support the management of the registration and control of pesticides and follow-ups relevant to the Decision.

127. With particular reference to the provisions of the Recommendation, Colombia is working in the implementation of exchanging information related to the export of chemicals which are banned or severely restricted in the country of export, in accordance with the *OECD Guiding Principles on Information Exchange related to Export of Banned or Severely Restricted Chemicals.* The task group dealing with this

subject is made up of professionals of the Ministry of Health and Social Protection, the Ministry of Agriculture and Rural Development, the Ministry of Environment and Sustainable Development, the Ministry of Commerce, Industry and Tourism, the Environmental Licensing Authority (ANLA by its acronym in Spanish), the National Health Institute (INS by its acronym in Spanish), the Colombian Institute of Agriculture (ICA by its acronym in Spanish), and the Directorate of National Taxes and Customs of Colombia (DIAN by its acronym in Spanish).

128. Specifically, the activities in which the National Government must work to achieve full compliance with the Rotterdam Convention include: a) Implementation of the notifications for exports of chemical products and pesticides that have been banned or severely restricted, according to the list of Annex III (Article 12); b) Notify strong regulation measures adopted in the country to ban or severely restrict a chemical product not listed by the Annex III; c) Monitor, gather and inform the status of health incidents occurred due to the Extremely Hazardous Pesticides Formulations, as well as proposing their inclusion in Annex III; d) Strengthen the coordination mechanisms between national authorities to improve chemical products and pesticides imports and exports control; and e) Strengthen the national capacity to perform risk assessments of chemical products and pesticides.

CONFIDENTIALITY AND PROPRIETARY RIGHTS

C(83)98/FINAL – RECOMMENDATION OF THE COUNCIL ON THE OECD LIST OF NON-CONFIDENTIAL DATA ON CHEMICALS

C(83)97/FINAL – RECOMMENDATION OF THE COUNCIL ON THE EXCHANGE OF CONFIDENTIAL DATA ON CHEMICALS

C(83)96/FINAL – RECOMMENDATION OF THE COUNCIL ON THE PROTECTION OF PROPRIETARY RIGHTS TO DATA SUBMITTED IN NOTIFICATIONS OF NEW CHEMICALS

Position: Acceptance of Recommendation C(83)98/FINAL. Acceptance of Recommendation C(83)97/FINAL. Acceptance of Recommendation C(83)96/FINAL, with a specified timeframe for implementation (2018).

Justification:

129. Colombia accepts these instruments and proposes an action plan regarding Council Act C(83)96/FINAL (protection of proprietary rights). Regarding proprietary rights, although Colombia has mechanisms in place for the protection of proprietary data, Colombia's legal framework does not currently specifically require the submission of a certification of the right to use data from the "first notifier" of a new chemical, even though it protects the information submitted by notifiers of new chemicals from unfair use by subsequent notifiers of the same chemical entity. Therefore, an action plan is needed to incorporate this requirement in the legal framework currently regulating notification or authorization requests regarding all new chemicals.

Regarding the requirements of the Recommendation C(83)98/FINAL:

Non-Confidential Data on Chemicals

130. The Constitution protects the public's right to access public documents except in cases expressly established by law. As was explained in the section regarding the Council Act C(88)85/FINAL, Article 74 Law 99 of 1993 (general environmental law of Colombia) also recognises the right of any person to directly submit information requests to the authorities regarding potential polluting elements and the

hazards that the use of these elements may cause to human health. This request must be answered in no more than 10 business days.

131. Recently, Law 1712 of 2014 issued by Congress regulated all matters related to access to public documents and addressed matters of transparency in public administration. The Law defines *public information* as "all information that an obligated person [entities or person bound under the law] generates, obtains, acquires, transforms or controls" (article 6(b), Law 1712).

132. Certain public information may be classified or reserved. Classified public information concerns "information that is under the power or custody of an obligated person in that capacity, which pertains to the own, particular and private or semi-private sphere of a natural or legal person, and as consequence access to such information may be denied or excepted, as long as the legitimacy and necessity circumstances and the private rights recognized in article 18 of this law are involved" (article 6(c), Law 1712).

133. According to article 18 of Law 1712, access may be denied only in cases where access may cause damage to (a) the right to privacy, (b) life, health or safety, and (c) commercial, industrial and professional secrets and information related to investment projects of certain state-owned and private-public enterprises. Importantly, article 18 clarifies that these exceptions shall not be applied "when the natural or legal person has consented to reveal its personal or private data, or when it is clear that the information was submitted as part of such information that shall be covered by the applicable publicity regime" (paragraph, article 18, Law 1712).

134. Regarding the Recommendation C(83)98/FINAL, Colombia is in a position to disclose and exchange data belonging to the OECD List of Non-Confidential Data at the request of an OECD Member country.

135. For chemical pesticides for agricultural use, the list of data considered non-confidential according to articles 57 to 62 of Andean Decision 804 of 2015 is in line with the OECD list of non-confidential data on chemicals. This type of information is also available in resolutions that grant environmental licenses or issue environmental technical reports (for chemical pesticides for agricultural use), which are published in the environmental authority's newsletters contemplated in article 70 of Law 99 of 1993. These are newsletters that environmental authorities are required to publish periodically. Relevant information is also publicly available regarding pharmaceutical, cosmetic, food and cleaning products subject to sanitary registration.

136. We currently meet the requirements of this Act for those chemicals for which we currently have a legal framework in place. Therefore, there is no need to include an implementation plan here for what will be implemented in this regard in the context of chemicals for industrial use (see General Principles of Chemicals Management). The current draft of the regulatory framework incorporates the OECD Recommendation and List of Non-Confidential Data contained in Council Act C(83)98/FINAL, which will be requested to perform the risk assessment of the chemicals for industrial use in the Programme for the Management of Chemicals for Industrial Use.

Regarding the requirements of the Recommendation C(83)97/FINAL:

Exchange of Confidential Information on Chemicals

137. As explained above, information obtained or controlled by a public entity is considered *public information*, which may be classified or reserved in certain cases.

138. Public information may be *classified* when such information (article 6 and 18, Law 1712 of 2014):

- Is under the power or custody of a public entity in that capacity;
- Pertains to the private or semi-private sphere of a natural or legal person; and
- Access to such information may cause damage to:
  a) A person's right to privacy;
  b) Rights to life, health or safety;
  c) Commercial, industrial and professional secrets, and
  d) Information related to investment projects of certain state-owned and private-public enterprises.

139. These exceptions to publicity are:

- Unlimited in time; and
- They shall not be applied when:
  - The natural or legal person has consented to reveal its personal or private data, or
  - It is clear that the information was submitted as part of such information covered by the applicable publicity regime" (paragraph, article 18, Law 1712).

140. Public information may be put under *reserve* when such information (articles 6 and 19, Law 1712):

- Is under the power or custody of a public entity in that capacity;
- Public access is expressly prohibited by law; and
- It is excepted from public access because it may damage public interests in the following circumstances:
  - National defence and security;
  - Public safety;
  - International relations;
  - Crime and disciplinary prevention, investigation and prosecution, to the extent that an arrest has not been executed or charges brought, as the case may be;
  - Due process and party equality in judicial proceedings;
  - Effective administration of justice;

- Infancy and adolescence rights;
- Macroeconomic and financial stability;
- Public health.

141. Information may not be reserved based on these exceptions for more than 15 years (article 22, Law 1712).

142. Specifically with regards to trade secrets, article 261 of Andean Decision 486 de 2000 (Andean Community Intellectual Property Regime) states that "information submitted before any authority by a person in possession of such information, for the purposes of obtaining a license, permit, authorization, registry or any other authority acts, will not be considered to have entered the public domain, or that it should be divulged by virtue of a legal provision or a judicial decision".

143. Article 264 of the same Decision states that "whoever legitimately possesses a trade secret may transmit or authorize its use to a third party. The third party may not disclose the trade secret through any means, except where there is an agreement to the contrary with the person who transmitted or authorized its use". It also states, "Conventions under which technical knowledge or technical assistance is transmitted, or basic or detailed engineering is provided, may establish confidentiality clauses in order to protect trade secrets, as long as they are not contrary to free competition regulations."

144. Finally, article 266 of Andean Decision 486 de 2000 and article 39 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), both provide that[27]:

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort … shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

145. The Stockholm and Rotterdam Conventions, of which Colombia is a party,[28] have also provided for the exchange of information between Parties. Article 9 of the Stockholm Convention on Persistent Organic Pollutants (POPs), states:

1. Each Party shall facilitate or undertake the exchange of information relevant to: (a) The reduction or elimination of the production, use and release of persistent organic pollutants; and (b) Alternatives to persistent organic pollutants, including information relating to their risks as well as to their economic and social costs.

2. For the purposes of this Convention, information on health and safety of humans and the environment shall not be regarded as confidential. Parties that exchange other information pursuant to this Convention shall protect any confidential information as mutually agreed.

[27] Colombia is a Party to the Agreement Establishing the World Trade Organization and the Multilateral Agreements annexed thereto (Law 170 of 1994).

[28] Colombia approved the Rotterdam Convention through Law 1159 of 2007 (entered into force for Colombia March 3, 2009) and the Stockholm Convention through Law 1196 of 2008 (entered into force for Colombia January 20, 2009).

146. Article 14 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, states:

> 1. Each Party shall, as appropriate and in accordance with the objective of this Convention, facilitate: (a) The exchange of scientific, technical, economic and legal information concerning the chemicals within the scope of this Convention, including toxicological, eco-toxicological and safety information;
>
> 3. Parties that exchange information pursuant to this Convention shall protect any confidential information as mutually agreed;
>
> 4. The following information shall not be regarded as confidential for the purposes of this Convention: (a) The information referred to in Annexes I and IV, submitted pursuant to Articles 5 and 6 respectively; (b) The information contained in the safety data sheet referred to in paragraph 4 of Article 13; (c) The expiry date of the chemical; (d) Information on precautionary measures, including hazard classification, the nature of the risk and the relevant safety advice; and (e) The summary results of the toxicological and eco-toxicological tests;
>
> 5. The production date of the chemical shall generally not be considered confidential for the purposes of this Convention.

147. Additionally, Colombia´s Constitutional Court has ruled on the matter of the exchange of confidential information in its review of the Cartagena Protocol on Biosafety. On that occasion, the Court ruled that the State may not undermine its duty to protect confidential information and that, in that sense, other States may access such information solely under the strict terms of the Protocol and where any undue use of such information is compensated according to International Law. The above-stated rules provide a framework within which Colombia may exchange confidential information with OECD Member countries. The framework provided by the Rotterdam and Stockholm Conventions require that where exchange of information takes place, confidential information shall be protected as mutually agreed. The Constitutional Court ruling also requires an agreed basis, mainly the rules set under the international instrument providing for the exchange.

148. In this context, subject to the above-stated requirements, Colombia has an adequate framework in place for the exchange of confidential data on chemicals and therefore will not request a timeframe for implementation of this Council Act. In any case, Colombia is currently considering incorporating a provision in this regard in the legal framework proposed for the Programme for the Management of Chemicals for Industrial Use.

Regarding the requirements of the Recommendation C(83)96/FINAL:

Protection of Proprietary Rights

149. Regarding Recommendation C(83)96/FINAL, Colombia partially complies with the requirements of the Council Act. Protection of proprietary rights is currently conducted through the protection of certain information submitted to the competent authority for registration purposes. The legal framework related to the protection of proprietary rights over data submitted in notifications of new chemicals, for pesticides and pharmaceutical products, includes:

150. Article 266 of Andean Decision 486 de 2000 (common Andean intellectual property regime) and article 39 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), both provide that[29]:

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort shall protect such data against unfair commercial use."

151. Article 2.13.8.1.5 of Decree 1071 of 2015[30] (chapter on Andean Decision 804 regulations), modified by Decree 727 of 2012, both issued by the Ministry for Agriculture and Rural Development, states:

"Protection. When the registration for a chemical pesticide for agricultural use has been issued that contains a new chemical component, a third party may not obtain approval for the same or a similar product based on the non-disclosed information contained in the test protocols accompanying the initial registration request.

Paragraph: it is understood, for the purpose of this Decree, that a new chemical component means the active ingredient of a chemical pesticide for agricultural use that has not previously been registered in the country."

Article 2.13.8.1.6 of Decree 1071 of 2015 establishes exceptions to article 2.13.8.1.5 as follows:

"when the owner of the sales registration of the product that contains the new chemical component has authorized the use of the non-disclosed information to support other registration requests subsequent to its own; b) when it is necessary to protect public interest and c) when the newly registered chemical component has not been commercialized in the country within a year of said registration."

152. Regarding pharmaceutical products, Decree 2085 of 2002, issued by the Ministry of Health (now the Ministry of Health and Social Protection) deals with the protection of proprietary rights on information regarding new chemical substances in these products. It regulates aspects related to the information provided to obtain a sanitary registration for new chemical entities in the medical industry. According to article 2, when the commercialization of a new chemical entity has been approved, the non-disclosed information cannot be used directly or indirectly, as support for the approval of another request of that same chemical entity. Protection of the non-disclosed data is provided when the generation of this information meant a considerable effort for whoever submitted it to the competent sanitary authority.

Specifically, article 3 of Decree 2085 of 2002 establishes:

"The protection on the use of non-disclosed information that is dealt with in this decree will be as follows:

Three (3) years counted from the commercialization approval in Colombia, for those requests submitted during the first year this decree entered into force.

[29] Colombia is a Party to the Agreement Establishing the World Trade Organization and the Multilateral Agreements annexed thereto (Law 170 of 1994)

[30] Decree 1071 of 2015 now contains all executive regulations for the agricultural administrative sector.

Four (4) years counted from the commercialization approval in Colombia, for those requests submitted during the second year from entry into force of this decree.

Five (5) years counted from the commercialization approval in Colombia, for those requests submitted beginning the third year from entry into force of this decree.

Subject to this provision, nothing will prevent carrying out summary proceedings for approval based on bioequivalence or bioavailability studies."

In addition, article 4 of Decree 2085 of 2002 establishes:

"The protection referred to in this Decree does not apply to the following cases:

When the holder of the sanitary registry of the new chemical entity has authorized the use of the non-disclosed information as support for another subsequent request;

When the new chemical entity for which the sanitary registry is requested is similar to another that has been authorized and commercialized in Colombia and the protection period of article 3 has expired;

When necessary to protect the public, as determined by the Ministry of Health (now Ministry of Health and Social Protection);

When the new chemical entity which is subject to sanitary registry has not been commercialized in the country within one year of issuance of the commercialization permit."

Action Plan for Council Act C(83)96/FINAL

153. Although Colombia has some mechanisms in place for the protection of proprietary data, Colombia's legal framework does not currently expressly require the submission of a certificate of the right to use data in cases where the laboratories are not owned or otherwise affiliated with the notifier, unless the information is intended for use as support of a different request. Therefore, Colombia proposes the following action plan:

Table 5. Action Plan for Council Act C(83)96/FINAL

Phase	Implementation (Year)	Objective	Specific Activity
Legal framework	2018	Enact new legal framework to establish the Programme for the Management of Chemicals for Industrial use.	Include a specific provision in the legal framework proposed for the Programme for the Management of Chemicals for Industrial Use, requiring notifiers of new chemicals to comply with the requirements for the protection of proprietary rights according to this Recommendation.

POLLUTANT RELEASE AND TRANSFER REGISTERS (PRTR)

C(96)41/FINAL – RECOMMENDATION OF THE COUNCIL ON IMPLEMENTING POLLUTANT RELEASE AND TRANSFER REGISTERS

Position: Acceptance with a specified timeframe for implementation (2020).

Justification:

154. Colombia accepts this Recommendation. Even though Colombia has already made some progress in regard to the implementation of environmental information systems related to environmental pollutants released at sectorial level, this information system does not currently meet all the requirements of the PRTR system recommended by this OECD Council Act. Therefore, an action plan is required in order to incorporate and integrate those requirements into the environmental information systems currently in place.

155. The environmental information systems currently in place in Colombia are:

The Colombian System of Environmental Information (SIAC)

156. The Colombian System of Environmental Information (SIAC by its acronym in Spanish) constitutes the institutional umbrella for an integrated management of environmental information at the national level. It was articulated in articles 20-24 of the Renewable Natural Resources and Environmental Protection Code of 1974 (hereinafter Natural Resources Code) (Decree-Law 2811 of 1974) and regulated in Decrees 1600 of 1994 and Decree 1200 of 2004.

157. Law 99 of 1993 granted authority to the Ministry of Environment and Sustainable Development to establish the SIAC and made the Hydrology, Meteorology and Environmental Research Institute *(*IDEAM by its acronym in Spanish*)* responsible for leading and coordinating the SIAC, which involves among other tasks, the collection, storage, analysis and dissemination of information, as well as setting the methodologies and standards for data collection, processing, transmission, analysis and dissemination, in order to ensure the availability and quality of environmental information (article 2.2.8.9.1.2, paragraphs 2, 3, 4, and 15, Decree 1076 of 2015 [chapter on environmental information system and environmental research]).

158. Law 99 of 1993 also created a number of scientific research institutes to support MADS and to provide the scientific and technical environmental information that feeds into SIAC. These include the IDEAM, the Institute for Marine and Coastal Research (INVEMAR by its acronym in Spanish), the Research Institute for Biological Resources - Alexander von Humboldt, the Amazon Institute for Scientific Research (SINCHI by its acronym in Spanish) and the Institute of Environmental Research for the Pacific (IIAP) (article 16 et seq., Law 99 of 1993) (see also the regulatory framework for all of these Institutes in the corresponding chapters of Decree 1076 of 2015, which compiled Decrees 1277 of 1994 and 291 of 2004—IDEAM, 1276 of 1994—INVEMAR, 1603 of 1994—Humboldt Institute, SINCHI and IIAP).

159. The SIAC is comprised by several subsystems that provide information on the state and quality of the environment, such as: the Subsystem of Information on the Use of Renewable Natural Resources (SIUR by its acronym in Spanish), the Biodiversity Information System *(*SIB by its acronym in Spanish*)*, the National Forestry Information System *(*SNIF by its acronym in Spanish*)*, Air Quality Information System *(SISAIRE* by its acronym in Spanish*)*, Water Resource Information System (SIRH by its acronym in Spanish*)* and the Coastal Marine Information System (SIAM by its acronym in Spanish). The Registry for Waste Generators and Hazardous Waste (RESPEL by its acronym in Spanish) is also a subsystem of the SIAC.

The Subsystem of Information on the Use of Renewable Natural Resources (SIUR)

160. As mentioned above, SIUR is an integral part of SIAC and comprises the collection, processing and dissemination of information related to environmental pollutants released by the industrial sector. The SIUR scopes is to comprehensively manage environmental information on resource (material) and energy inputs and outputs, water discharges, air emissions, waste, fauna and any other factors that may affect water resources, land, air, climate and biodiversity (article 3, Resolution 941 9F 2009).

161. Resolution 941 of 2009 adopts the Single Environmental Registry (RUA by its acronym in Spanish), which is the register that collects information for SIUR. Currently the register only applies to the manufacturing sector and was originally intended to gradually cover other sectors such as the mining, hydrocarbon and energy sectors. The registry currently collects information from approximately 2,700 companies on the use of natural resources.

162. Resolution 1023 of 2010, issued by the Ministry of Environment, Housing and Territorial Development (today MADS), adopts a monitoring protocol for the manufacturing sector. This resolution, together with other legal instruments, contains aspects related to the OECD Principles set out in this Council Act:

- Information registered through RUA is considered public (Article 11)
- The information obtained must be used by environmental authorities as a tool to support follow up activities, acquire knowledge on the stresses on renewable natural resources, create environmental indicators, and design environmental policies (Article 12).
- The general environmental enforcement regime applies as compliance mechanism (Article 15).
- There is an integration mechanism between RUA and other information sources related with the environmental licensing process (Article 13).

163. Notwithstanding the above, the RUA does not meet all the requirements and principles contained in the OECD Council Act on implementing pollutant release and transfer registers. It is however a significant starting point to establish a more rigorous system to collect and process information on the emission and transfer of pollutants to the environment.

Action Plan

164. Based on the justification above, Colombia proposes the following action plan based on the principals and information set forth in the OECD Guidance to Governments Manual for PRTRs.

Table 6. Action Plan for Council Act C(96)41/FINAL

Phase	Time-frame	Objective	Specific Activities	Status
Phase I	2015	Design a Strategic Plan to put in place the necessary institutional capacity for setting up a PRTR.	The action plan for C(98)67/FINAL – Recommendation of the Council on Environmental Information contains the following specific activity directly related with setting up a PRTR in Colombia: Design and present an investment	The investment project was approved, and 300,000US$ were allocated in 2016 to adjust existing environmental information systems that will host the PRTR system in the future.

Phase	Time-frame	Objective	Specific Activities	Status
			project to the National Planning Department to ensure future funds to consolidate the SIAC (it includes setting up a PRTR system in Colombia).	
	2015	Preliminary development of core elements of the system.	Develop an initial list of chemicals that will be reported.	Preliminary list of chemicals completed
	2015	PRTR capacity building workshops.	Organize capacity building workshops raise awareness on other PRTR systems.	PRTR experts from Canada and the USA provided capacity building workshops for industry and government entities.
Phase II	2016	Strengthen inter-institutional coordination.	Create a technical and a national PRTR coordinating group.	PRTR technical group has already been created.
		Definition of main elements of the system.	Initial diagnosis of the existing information systems (RUA, SIUR) to define how to integrate them with the PRTR (i.e. how the existing requirements of RUA and SIUR will be used as a framework to achieve the PRTR's objectives.	Ongoing consultancy is developing the main elements of the system described.
			Identify the scope, goals and objectives of Colombia´s PRTR.	
			Establish the list of priority chemicals covered and their reporting thresholds.	
			Definition of release estimation techniques.	
			Define data to be collected and reporting formats and frequency for reporting.	
			Define management of confidential information.	
			Specify data quality control and verification procedures.	
			Define sectors to include.	

Phase	Time-frame	Objective	Specific Activities	Status
			Reassess the technical, human and financial resources needed to implement the PRTR.	
Phase III	2016-2020	Development of data collection and data management system (Hardware and Software Design).	Development of digital components to make the PRTR compatible with the current environmental information systems and subsystems.	The Hydrology, Meteorology and Environmental Research Institute – IDEAM will carry out the described activities.
			Web development.	
			Establish the mechanism through which the PRTR data will be made available and disseminated to the public and other interested parties.	
			Training on the use of the system and PRTR reporting.	
	2017	Development of technical elements.	Complete the PRTR´s conceptual model.	The Ministry of Environment and Sustainable Development will carry out these activities.
	2017-2019		Development of technical elements for PRTR regulation and adjustment of main elements of the system.	
	2018		Development of tools and guidelines that support the filling out and reporting of the PRTR.	
	2018	Pilot	PRTR Pilot reporting trial.	
	2019		Results of the pilot reporting trial in used to revise and adjust the main elements of the system	
	2020	Legal Framework.	Development of PRTR regulation.	
			Issue a regulation to set PRTR requirements described in this Council Act to complement or replace the legal framework currently covering RUA and SIUR.	
Phase IV	2020	Implementation phase.	Revision of tools and guidelines that support the filling out and reporting of the PRTR.	

Phase	Time-frame	Objective	Specific Activities	Status
			Prepare document to complete specifications of the national PRTR system.	
			Gradually implement a PRTR starting with a limited scope of prioritized chemicals from the list previously defined.	
			Perform data quality assurance and traceability of information.	
	2016-2020	Dissemination activities.	Dissemination activities with industry and environmental authorities to share the progress on the main elements of the PRTR.	There have been two public consultations with different stockholders and two workshops are planned for the second semester of 2016.

165. The development and implementation of the action plan described above will be led by the Ministry of Environmental and Sustainable Development and the IDEAM.

166. Finally, it is important to mention that the PRTR will be one of the mechanisms available to conduct environmental monitoring into the Programme for the Management of Chemicals for Industrial Use. The environmental and health monitoring will serve as a basis to evaluate the effectiveness of industrial risk reduction actions, and support decision-making processes at a national level for the adoption of additional risk reduction measures and research programmes.

SPECIFIC CHEMICALS

C(73)172/FINAL – RECOMMENDATION OF THE COUNCIL ON MEASURES TO REDUCE ALL MAN-MADE EMISSIONS OF MERCURY TO THE ENVIRONMENT

Position: Acceptance.

Justification:

167. Colombia accepts this Recommendation. Colombia has adopted measures to reduce all man-made emissions of mercury to the environment to the lowest possible levels with particular attention to the elimination of alkyl-mercury compounds and all industrial discharges. Immediate targets include alkyl-mercury compounds in agriculture, pulp and paper industry, mercury-cell chloralkali plants, and mining among others. Accordingly, these measures have already been formally adopted and therefore comply with the requirements of this Council Act. Their implementation, which is being performed progressively, is explained in detail below.

Legal framework for the Reduction of all Man-Made Emissions of Mercury to the Environment

168. With reference to reducing all man-made emissions of mercury in the environment to the lowest possible levels, Law 1658 of 2013 issued by the Congress of the Republic, establishes the regulatory measures to reduce and eliminate the use of mercury in industrial activities.

169. Specifically, Article 1 contains the object of Law 1658, which states that '*in order to protect and safeguard human health and to preserve natural resources and the environment, the use, import, production, sale, handling, transport, storage, final disposal and release into the environment of mercury in all industrial activities, whichever they may be, are to be regulated throughout the entirety of the national territory."*

170. In addition, Article 3 of Law 1658 indicates that the use of mercury must be eliminated within a period not exceeding ten (10) years for all industrial and productive processes and in a maximum period of five (5) years for the mining sector. Environmental, urban, regional and sustainable development authorities, as well as health departments and territorial labour authorities, are required to control and supervise all measures taken by the National Government to regulate the matter.

171. Law 1658 of 2013 also contains a number of provisions related to various aspects such as monitoring and controlling the import and marketing of mercury, cleaner production in industrial and mining activities, and the promotion of research on cleaner technology for the reduction and elimination of mercury.

The National Mercury Plan

172. Article 8 of Law 1658 establishes the obligation in head of various ministries to complete and implement a national mercury plan for the development of activities related to each stage of the life cycle of mercury including use, import, production, marketing, handling, transportation, storage or final disposal.

173. The National Mercury Plan will take into consideration the difficulties regarding the gradual elimination of mercury in certain industries, particularly the use in mercury-cell chloroalkali plants, light bulbs and dental amalgam, within the ten (10) years set out in Law 1658 of 2013, and within the five (5) years set out for artisanal and small-scale gold mining.

174. The structure of this National Mercury Plan was finalised in 2015. The actors included within the Plan are the Ministry of Environment and Sustainable Development, the Ministry of Health and Social Protection, the Ministry of Labour, the Ministry of Mines and Energy, the Ministry of Commerce, Industry and Tourism, the Ministry of Agriculture and Rural Development, the Ministry of Finance and Public Credit, the Administrative Department of Science, Technology and Innovation (Colciencias by its acronym in Spanish), Directorate of National Taxes and Customs of Colombia (DIAN by its acronym in Spanish), the National Apprenticeship Service (SENA by its acronym in Spanish), and the Autonomous Regional Corporations (CARs by its acronym in Spanish).

175. The key components on which the National Mercury Plan will be based include the following:

1. Inter-institutional coordination at national and regional levels, with the environmental, mining, other industry, health and education authorities.

2. Updating the national inventory on mercury.

3. Develop environmental monitoring and control programmes, health and reduction of use, emissions and releases of mercury.

4. Develop regulation and regulatory standards of Law 1658 of 2013. Among the activities considered is the regulation and implementation of a registry of mercury users (RUHg), led by the Ministry of Environment and Sustainable Development. The registration process will initially be implemented in the gold mining sector (Article 4, Law 1658). The objective of the registry is to determine the quantity of mercury used, the quantity emitted to the atmosphere and released into bodies of water and land by the mining sector.

5. Develop the regulation and implementation of control measures and restrictions on the import and trade of mercury and products containing mercury, by creating a registry of importing companies and mercury traders, as well as assigning import quotas. The registry will be managed by the Ministry of Commerce, Industry and Tourism in partnership with the Ministry of Environment and Sustainable Development, the Ministry of Health and Social Protection, and DIAN (Article 5, 1658).

Priority Sectors for the Elimination of Man-Made Emissions of Mercury

176. With particular reference to the provisions of this Recommendation, Colombia has been working towards reducing or eradicating the use of mercury in industrial processes in the following ways:

Agriculture

177. In Colombia Resolution 2189 of 1974, issued by the Colombian Agricultural Institute (ICA by its acronym in Spanish), cancels the registration of fungicide products of agricultural use containing mercury (Article 1). This measure was implemented at the request of the Ministry of Public Health (now the Ministry of Health and Social Protection). Consequently, since 1974, such products cannot be produced, imported or sold in Colombia. The legal effects of this Resolution—cancellation of the registry—took place at the time of issuance and no other administrative act has been passed to reverse them, i.e. no further registration has been granted in Colombia for these types of pesticides.

Pulp and Paper Industry

178. The trade association that represents the pulp and paper industry in Colombia does not use mercury components in its production, in compliance with their official policy. In any case, once the term established in Article 3 paragraph 2 of Law 1658 of 2013ends, the use of mercury in this and all other industrial processes will be effectively forbidden and should have been eliminated in its entirety.

Mercury Cell Chloroalkali Plants

179. There is only one chloralkaliplant in Colombia, and it has already developed a plan of action to eliminate the use of mercury in its sodium chloride electrolysis process. The implementation plan will include the following activities:

1. Phase I: Control of Mercury Emissions: Finalised in September 2013. The results demonstrate a ninety-four percent reduction (94%) in mercury use and consumption within production processes.

2. Phase II: Conversion to Membrane Cells (until October 2016): A cation-exchange membrane is used in place of the porous diaphragm to totally eliminate the use of mercury.

3. Phase III: Disposal of Mercury Waste: Final step to the implementation plan. Currently, this step is under consideration of different alternatives.

180. Other prioritized sectors include:

Lamps and Lightbulb Industry

181. There is only one plant that currently makes lamps and lightbulbs in Colombia. The plant produces compact fluorescent lamps (CFL), halogen lightbulbs, fluorescent tubes and High Intensity Discharge Lightbulb (HID). For the production of fluorescent tubes which use mercury for their production, the industry sector is working in the transitioning from using liquid mercury to mercury on amalgam, which would allow the broad reduction of total mercury use by eighty-five per cent (85%) during the production process for fluorescent tubes.

182. The project had a three (3) year duration, which was completed at the end of 2014 and includes the following activities within the process of technology reconversion:

1. Phase I: Investigation phase and development of viable alternatives for the reduction of mercury use in the process (2011-2012).

2. Phase II: Implementation process of the use of mercury on amalgam (solid form)(2012).

3. Phase III: Installation and improvement of solid mercury use in vertical lines, for the manufacturing of linear fluorescent lamps (2013-2014).

4. Phase IV: Mercury waste disposal in a security cell, authorized by environment authorities. Over 90% of mercury waste has been recollected. Gross figures of such collection are 300 tons in 2012, 540 tons in 2013 and 640 tons in 2014.

Dental Amalgams

183. There exists only one company in Colombia that produces dental amalgams. The amalgams produced contain high levels of copper (Cu), which entails less use of mercury in the mix formulation. This company designed and implemented an eco-efficient way to treat amalgam waste in partnership with the University of Antioquia (*Medellin, Colombia*), with the aim of avoiding inadequate waste disposal that would negatively impact the environment and would allow for the reuse of salvaged metals by reintroducing them into the production chain (mercury life cycle). The phases of the process involve the pyro metallurgical recovery (high temperatures) of mercury in an airtight distiller (Retort), and the hydrometallurgical recovery (aqueous phase) of the rest of the metal components.

Mining

184. The Ministry of Environment and Sustainable Development (MADS for its acronym in Spanish) is working on a National Strategic Plan for the reduction and/or elimination of mercury use in Artisanal and Small Scale Gold Mining (ASGM) in a period of five years (until the end of 2018), establishing goals, targets, programmes and guidelines for projects that will contribute to the reduction of mercury usage in mining processes. The MADS and the Ministry of Mines and Energy are undertaking several actions to support pilot activities and capacity building.

185. The Ministry of Mines and Energy issued Decree 480 of 2014, which regulates the conditions and requirements to conclude and enforce "Mining Formalization Subcontracts", which, within the framework of Article 11 of Law 1658 of 2013, provide an incentive for small scale miners to formalize their mining activities, with a view to eradicate the use of mercury.

186. The latest figures on the total quantities of mercury used in Colombia date back to 2009[31]. The study carried out by the University of Antioquia *(Medellin, Colombia*) indicates that the total national net consumption of mercury in 2009 was 352.3 ton/year, bearing in mind that metal production is the industry that requires the most mercury per year. As previously mentioned, one of the activities to conduct as part of the National Mercury Plan, is to update the national inventory for mercury.[32]

Legal Framework for Current Emissions of Mercury to the Environment

187. Finally, in addition to Law 1658 of 2013, the current legal framework includes some specific regulations on the subject, such as:

- Colombia was one of the first signatories of the Minamata Convention on Mercury (October 2013) and the national government is looking forward to the prompt ratification of this environmental treaty, the process of which has already begun. Under the Colombian legal system, ratification of an international treaty requires Congressional approval by means of a law, as well as constitutional review by the Constitutional Court. The process usually takes up to three (3) years and therefore we expect to become a party by 2017. Meanwhile, Colombia is working to strengthen national capacity and to access international cooperation available for enabling activities.

- Resolution 172 of 2012 issued by the Ministry of Commerce, Industry and Tourism and the Ministry of Environment and Sustainable Development. Paragraph 7.5 of article 7 of this Resolution establishes the maximum permissible levels of mercury, cadmium and lead present in Zinc-Carbon and alkaline batteries imported or produced in the country. For mercury (Hg), the maximum allowed level is 0.0005% by weight, or 5 ppm.

- Resolution 91872 of 2012 issued by the Ministry of Mines and Energy. Article 1 of this Resolution establishes the maximum permissible levels of lead and mercury present in lightning products and street lightning, according to international environmental provisions. Likewise, this Resolution requires manufacturers and importers of these products to comply with applicable regulations on environmental management of waste, including Resolution 1511 of 2010, which establishes selective collection and management standards and requirements for light bulbs.

- Law 1672 of 2012 adopted standards and requirements for e-waste regulations in Colombia under the principle of extended producer responsibility. Among others, the law requires from producers (manufacturers and importers) the establishment of selective collection and management systems for all e-waste based on the categories that the MADS must establish through secondary regulation. MADS is currently advancing on the issuance of a national e-waste policy and on the regulations required to implement this law. In the meantime, the following two resolutions relevant to mercury control are being applied:

    - Resolution 1297 of 2010, issued by the former Ministry of Environment, Housing and Territorial Development (now the Ministry of Environment and Sustainable Development), establishes the Selective Collection Systems and Environmental

[31] Ministerio de Ambiente, Vivienda y Desarrollo Territorial (2010). Cuantificación de Liberaciones Antropogénicas de Mercurio en Colombia. Bogotá.

[32] In compliance with law 1658 of 2013, MADS is developing a GEF project together with UNIDO to come up with a National Plan to implement the Minamata Convention in Colombia. One of the main outcomes of this project is to obtain an updated national inventory on Mercury by 2017.

Management of Battery and/or Accumulator Waste in the country, under the principle of Extended Producer Responsibility (including those containing mercury).

Particularly, Chapter II (Articles 4 to 13) regulates the Selective Collection System and Environmental Management of Batteries and/or Accumulator Waste; Chapter III (Articles 14 to 17) defines the obligations of producers, suppliers, retailers and consumers of batteries and/or accumulators (including those containing mercury) and the support that municipal and environmental authorities must provide to promote the use of less contaminating batteries/accumulators and disseminate information regarding appropriate return mechanisms by consumers; Chapter IV (Article 20), which establishes prohibitions regarding the management and final disposal of waste batteries (including those containing mercury).

- Resolution 1511 of 2010, issued by the former Ministry of Environment, Housing and Territorial Development (now the Ministry of Environment and Sustainable Development), which establishes Systems of Selective Collection and Environmental Management of Light bulb Waste, under the principle of Extended Producer Responsibility. Article 1 specifies the light bulbs covered by the resolution, which include used light bulbs from compact fluorescent technology, tubular fluorescent lamps, halides, sodium vapour and mercury vapour lamps.

  Additionally, Chapter II (Articles 4 to 13) defines the requirements for the Selective Collection System and Environmental Management of Batteries and/or Accumulator Waste; Chapter III (Articles 14 to 17) defines the obligations of producers, suppliers, retailers and consumers of light bulbs (including those containing mercury) and the support that municipal and environmental authorities must provide to promote the use of less contaminating light bulbs and disseminate information regarding appropriate return mechanisms by consumers; Chapter IV (Article 20), establishes prohibitions regarding the management and final disposal of light bulb waste, including waste from fluorescent bulbs and high intensity discharge bulbs used in street lighting batteries (including those containing mercury).

- Decree 1287 of 2014, issued by the Ministry of Housing, City and Territory, establishes criteria for the use of bio-solids generated by municipal wastewater treatment plants. Specifically, Article 5 establishes the maximum values allowed for mercury and other metals according to a use-based classification of bio-solids. Article 6 establishes the limit values for mercury and other metals that may be introduced in the soil while using the bio-solids classified under Article 5.

C(71)83/FINAL – RECOMMENDATION OF THE COUNCIL OF THE DETERMINATION OF THE BIODEGRADABILITY OF ANIONIC SYNTHETIC SURFACE ACTIVE AGENTS

Position: Acceptance.

Justification:

188. Colombia accepts and complies with this Recommendation considering that the Ministry of Health and Social Protection and the Ministry of Environment and Sustainable Development recently issued joint Resolution 0689 of 2016, which establishes the measurement and analysis of biodegradability of detergents according to the OECD Biodegradation Test Methods (OECD Test Methods 301 and 310).

189. Article 6 states that: *"Products object of the present technical regulation shall contain surfactant agents that meet the minimum percentage of final aerobic biodegradability, according to methods 301 and 310 of the Organization for Economic Co-operation and Development - OECD or their equivalent in the European Union (EU) or in ISO standards or in the United States Environmental Protection Agency (USEPA) standards."*

C(87)2/FINAL – DECISION-RECOMMENDATION OF THE COUNCIL ON FURTHER MEASURES FOR THE PROTECTION OF THE ENVIRONMENT BY CONTROL OF POLYCHLORINATED BIPHENYLS

Position: Acceptance.

Justification:

190. Within its legal framework, Colombia has adopted measures to control and reduce risks that could result from exposure to polychlorinated biphenyls (PCBs).

New uses of PCBs and products, articles, or equipment contaminated with PCBs

191. With reference to the uses of PCBs, Colombia prohibited the production of PCBs and the import of PCBs and of equipment containing them, as well as the use of equipment, elements and substances that contain PCBs, the use of contaminated equipment in new electrical installations and in the modification of existing ones, the import of PCB waste, and the dilution of oils with over 50 ppm of PCBs, among others (Article 34, Resolution 222 of 2011).

192. Law 1196 of 2008, which approved the Stockholm Convention on Persistent Organic Pollutants of 22 May 2001, as well as the "Modification to Article 10 of the original text in Spanish" of 21 February 2003, and "Annex G to the Stockholm Convention" of 6 May 2005. This law defines the measures to eliminate PCBs and the equipment that contain PCBs, in accordance with that which is established in Annex A of the Stockholm Convention. Since the signing of the Stockholm Convention, Colombia has made substantial progress to achieve the Convention objectives related to identification, prevention, reduction and elimination of persistent organic pollutants and waste. In support of these objectives, since 2003 the country has developed a series of materials and reports that helped understand and analyse the national situation pertaining to Persistent Organic Pollutants, which was carried out with GEF grant resources as part of the activities contemplated within the implementation of the Convention.

193. Additionally, in July of 2010 the National Implementation Plan (NIP) was completed and submitted to the Convention Secretariat, including some of the following highlights:

- Institutional capacity assessment, available infrastructure and regulatory framework assessment for the management of POPs in Colombia (2005).
- Preliminary inventory of PCBs stocks in the country (2006).
- Design of the outreach strategy and of the community awareness material on POPs and their effects on health and the environment (2006).
- Economic evaluation of impacts on health (public and occupational) associated with POPs (2006).

- Assessment of social and economic implications of the use and reduction of POPs in Colombia (2006).

- Manual assessment and risk management related to POPs (2007).

- Technical Guide for Identification, Assessment and Management of POPs contaminated sites (2008).

- Development of technical and methodological tools for strengthening national capacity to manage POPs contaminated sites (2008).

- Development of training workshops on POPs at regional and national level.

194. Resolution 222 of 2011, issued by the Ministry of Environment and Sustainable Development, establishes the requirements for the comprehensive environmental management of equipment and waste that consist of, contain or are contaminated with toxic polychlorinated biphenyls.

195. Article 34, which sets out the following prohibitions:

1. PCB manufacturing is forbidden in the national territory.

2. Beginning in 2025, the use of equipment, elements or substances that contain PCB is forbidden throughout the national territory.

3. The use of PCB contaminated equipment in new electrical installations and in modifications made to existing ones is forbidden, in compliance with article 41 of the general technical annex Technical Regulations for Electrical Installations (RETIE by its acronym in Spanish), of Resolution 18-1294 of August 6, 2008.

4. The import of PCB or equipment containing PCB is forbidden.

5. The import of PCB waste is forbidden.

6. The export of PCB or equipment containing PCB is forbidden, when such export has a purpose different than the environmentally appropriate management of waste, for which the requirements of the Basel Convention shall be complied with.

7. It is forbidden to dilute oils with a concentration of PCB higher than 50 ppm in any medium of dilution, unless it is part of a decontamination treatment for a project holding the pertinent environmental authorizations.

8. It is forbidden to fill the level of equipment containing PCB by using oils polluted with PCB, or to refill equipment located close to other devices containing PCB with a substitute liquid that has a flammable point lower than 300 degrees Celsius.

196. In relation to the products, articles or equipment contaminated by PCBs, Colombia currently exports equipment and waste with PCB to countries that have the necessary infrastructure to treat and dispose of it. The processes followed to this end are those established by the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal. Any person that wishes to export this type of waste must obtain a permit for transfrontier movement issued by the National Environmental Licensing Authority (ANLA by its acronym in Spanish).

Existing PCBs

197. In relation to existing uses of PCBs, Chapter IV of Resolution 222 of 2011 establishes "measures aimed to the rational environmental management of equipment and waste polluted with polychlorinated biphenyls (PCB." The transport of equipment and waste with PCB is carried out in compliance with the rules set out in Decree 1609 of 2002, issued by the Ministry of Transport, which "establishes technical and safety requirements for the handling and transportation of hazardous merchandise, in order to minimize risks, ensure safety and protect life and the environment, and which follows the guidelines of the United Nations (UN) Recommendations Orange Book on the Transport of Dangerous Goods - Model Regulations, which was developed by the UN Economic and Social Council's expert Committee of Experts on the Transport of Dangerous Goods (current version)."

Disposal of PCBs and Other Wastes Containing PCBs

198. Colombia has established controls over the handling and elimination of PCB waste and contaminated equipment, in order to avoid adversely affecting human health and the environment (Article 2.2.6.2.2.1 of Decree 1076 of 2015 [chapter on hazardous waste management regulations], Articles 27 and 34 of Resolution 222 of 2011).

199. Article 2.2.6.2.2.1 of Decree 1076 of 2015, issued by the Ministry of Environment and Sustainable Development prohibits:

"the import of waste or residues that contain or are constituted of Persistent Organic Pollutants (aldrin, dieldrin, endrin, chlordane, heptachlor, hexachlorobenzene, mirex, toxaphene, polychlorinated biphenyls, DDT); the import of equipment or substances that contain polychlorinated biphenyls (PCB) in a concentration equal or greater than 50mg/kg; the transfer of unused electrical equipment that contain or has contained in the past dielectric oils, via auctions, waste bags, or public or private donations to persons that do not hold the corresponding environmental licenses and without previously informing the competent environmental authorities of the physicochemical characterisations carried out to determine the presence of any PCB contents."

200. Article 27 of Resolution 222, establishes the goal of eliminating PCB-contaminated waste in Colombia. The owners of PCB-contaminated waste shall eliminate such waste in an environmentally appropriate manner, by no later than year 2028 in accordance with the provisions of the Stockholm Convention, in line with the following elimination goals:

1. The total stockpiles and wastes contaminated with PCBs that are identified and labelled by 2016, shall be eliminated in an environmentally safe manner no later than December 31, 2017.

2. The total stockpiles and wastes contaminated with PCBs that are identified and labelled by 2020, shall be eliminated in an environmentally safe manner no later than December 31, 2022.

3. The total stockpiles and wastes contaminated with PCBs that are identified and labelled by 2024, shall be eliminated in an environmentally safe manner no later than December 31, 2028."

Implementation in Colombia

201. With the purpose of facilitating compliance with these obligations by the public and private sectors, Colombia obtained funding from the Global Environment Facility (GEF), through the United Nations Program for Development (UNDP) in 2013 for 3.4 million of dollars, to develop and implement a national project, including strategies for strengthening national capacity in the management and disposal of inventoried PCBs. At the moment, the project, titled "Capability Development for Management and

Appropriate Disposal of PCBs", which is coordinated by the Ministry of Environment and Sustainable Development, is working on the following aspects:

- Strengthening the legal, administrative and regulatory framework for the appropriate management of PCBs. Specifically, Resolution 222 of 2011 will be modified to include the required technical guidelines related to the types of treatments used for equipment and residues that contain PCBs. Furthermore, regulation must be developed to include the technical guidelines to take into account when performing a thermal treatment of hazardous residues, including PCBs incineration facilities.

- Strengthening the MADS and Environmental Sector through the development of the capacity for the management and appropriate disposal of PCBs. The country is currently developing action plans to identify and eliminate any equipment and waste with PCBs. 2028 has been proposed as the deadline to remove all existence of PCBs in the country in accordance with the provisions of the Stockholm Convention on Persistent Organic Pollutants.

- Developing pilot projects to investigate and strengthen national capacity and infrastructure for the management and appropriate disposal of PCBs in the country.

202. Additionally, the National Institute of Food and Drug Oversight (INVIMA by its acronym in Spanish) is designing a plan to monitor PCBs in fish products, which will be held during 2015. The aim of the study is to assess whether the Colombian population is exposed to PCBs through food consumption such as fish products. The National Institute of Health (INS by its acronym in Spanish) will monitor and have close watch of PCBs in bodily fluids (blood and breast milk) in populations that might be potentially exposed to these substances.

203. Finally, in order to fulfil the plan for the disposal of PCBs, Colombia received a grant from the Global Environment Facility (GEF), of $3.4 million dollars, as previously described in paragraph 202. Additionally, the electric sector will provide $ 14.5 million dollars. These resources will be used to identify equipment inventory and waste of PCBs, proper handling of these substances, installation of infrastructure in the country for disposal and monitoring within the population. Also, part of the resources will be used in technical training for environmental and health authorities, in order to perform the tasks required for control and monitoring to ensure the proper disposal of PCBs, thus avoiding environmental pollution.

204. The action plan (2013 – 2017) for developing the PCB disposal project funded by the GEF and the electric sector is structured as follows:

Table 7. Action Plan for Council Act C(87)2/FINAL

Outcome	Elements included	GEF Fund USD	Electric Sector Fund USD
Outcome 1: Strengthening the legal, administrative and regulatory framework for the sound management of PCBs.	A regulatory framework for the environmentally sound management of PCBs. A training program for the local environmental, health, police, transportation, customs control staff and other authorities on the new regulatory framework and the negative impacts	$300,000	$1,500,000

Outcome	Elements included	GEF Fund USD	Electric Sector Fund USD
	of inappropriate PCB management. A labelling system for the identification of PCBs in equipment. An import control system for transformers, capacitors and dielectric oil is to be established and enforced by customs and foreign trade authorities. An information system to consolidate, disseminate and update in an orderly and periodic manner the data related to the inventory and management of PCBs in the country.		
Outcome 2: Development of the national capacity for environmentally sound management and disposal of PCBs.	Quality standards to monitor PCBs and a reference laboratory for PCBs. Protocols for sampling and analysis of PCBs in different matrices (oil, water, soil, air, food, blood and breast milk). Monitoring program for PCB and contaminated sites management plans. Quality standards and accreditation program for laboratories that work with PCBs. Guidelines and standards for environmentally sound management of PCBs (oil and contaminated equipment) during maintenance of equipment, transportation, storage and disposal, including occupational health and safety issues. National training program on the new standards, guidelines and regulations for stakeholders involved in the handling of PCBs (maintenance companies, junkyards and recycling plants, large consumers and industries, retail consumers and industrial users among others). Assessment of the requirements and needs to expand the number of authorized operators for the management of equipment or oils containing PCBs.	$500,000	$2,500,000

Outcome	Elements included	GEF Fund USD	Electric Sector Fund USD
	Technical guidelines for risk assessment of equipment contaminated with PCBs. Strategy for the identification and management of sites contaminated with PCBs.		
Outcome 3: Environmentally sound management and disposal of PCBs through a pilot project	Agreements with PCBs holders to demonstrate the operation, maintenance, storage and disposal of PCBs in accordance with new standards, rules and regulations established. Partnering with at least two interested technology providers to evaluate two alternatives for the decontamination and disposal of equipment contaminated with low concentrations of PCB. Demonstration project for PCB management and disposal of equipment located in high priority areas identified in the country, as established in the Stockholm Convention. Elimination of 600 tons of PCBs through exports and pilot projects.	$2,212,000	$10,500,000
Outcome 4: Monitoring, learning, adaptive feedback & evaluation	Audits and evaluation.	$88,000	
Project management unit	Coordinator	$300,000	

C(96)42/FINAL – DECLARATION ON RISK REDUCTION FOR LEAD

Position: Acceptance.

Justification:

205. Colombia accepts this Declaration on Risk Reduction for Lead. Colombia has adopted measures to reduce risks that could result from exposure to lead.

206. The current legal framework covering aspects discussed in the Declaration includes:

- Decree 1076 of 2015 (chapter on water use and wastewater discharges), specifically, the provisions related to the reduction of lead levels in water resources are: articles 2.2.3.3.4.1,

2.2.3.3.9.3-8, 2.2.3.3.9.10, 2.2.3.3.9.16-17 (except for any limits imposed in Resolution 631 of 2015—see below).[33]

- Resolution 631 of 2015, issued by the Ministry of Environment and Sustainable Development (MADS)[34]which includes maximum permitted limit values of lead for discharges into surface waters from domestic and public sewerage systems (Article 8), non-domestic wastewater sources including agroindustry and livestock activities (Article 9), mining activities (Article 10), hydrocarbon-related activities (Article 11), food and beverage production (Article 12), manufacture of goods (including chemical substances, pesticides, batteries, electrical accumulators, etc.) (Article 13), and provision of services (including power generation, waste treatment and disposal, health-related services, etc.) (Article 14). The lead limits for non-domestic wastewater discharges into public sewerage systems are the same as those applicable to each sector for discharges into surface waters (Article 16).

- Decree 1076 of 2015 (chapter on air protection and quality control regulations), forbids in Article 2.2.5.1.4.5 the use of lead in gasoline in quantities higher than those specified internationally, except for fuel for piston engine aircraft.

- Resolution 909 of 2008, issued by the Ministry of Environment, Housing and Territorial Development (now the Ministry of Environment and Sustainable Development), which establishes accepted norms and standards regarding allowable emissions of pollutants into the atmosphere from stationary sources and dictates other provisions. Specifically, Articles 4, 6, 50, 57 and 93, which limit air emissions from stationary sources, including lead.

- Resolution 610 of 2010, issued by the Ministry of Environment, Housing and Sustainable Development (now the Ministry of Environment and Sustainable Development), which modifies Resolution 601 of 2006, regarding the standard of air quality or allowable levels of emissions for the national territory in reference conditions. Specifically, Article 3 of Resolution 610 of 2010 establishes the maximum contaminant levels for different non-conventional contaminants in air, including lead.

- Resolution 835 of 2013, issued by the Ministry of Health and Social Protection, which establishes technical requirements for materials, objects, containers and equipment made of glassware and glass ceramic to get in contact with food and beverages for human consumption, which are manufactured or imported for marketing in Colombia. Specifically, Articles 5 and 6 of Resolution 835 of 2013 establishes migration limits of lead for these products.

- Resolution 3388 of 2008, issued by the Ministry of Social Protection (now Ministry of Health and Social Protection), which establishes the technical regulations regarding health requirements

[33]Except for articles 20 and 21 of prior Decree 1594 of 1984 (now compiled in Decree 1076 of 2015) was repealed in its entirety by Article 79 of Decree 3930 of 2010 (also compiled in Decree 1076 of 2015) (general water use and liquid discharges regulations). However, according to Article 76 of prior Decree 3930, Articles 37 to 48, 72 to 79 and 155, 156, 158, 160, 161 of Decree 1594 of 1984 are to remain provisionally in force, until the Ministry of Environment and Sustainable Development issues regulations on water use, quality criteria, water discharges into marine waters, public sewerage and soil, as well as a protocol to monitor water discharges into surface and underground waters. On March 17 of 2015, the Ministry of Environment and Sustainable Development issued Resolution 631 of 2015, which establishes parameters and maximum permitted limit values for point discharges into surface waters and public sewerage systems. The parameters and limit values of Decree 1594 will still be applicable unless specifically regulated under the new Resolution 631.

[34]*Id.*

on toys, their components and accessories that are marketed in the national territory. Specifically, Article 5 establishes the maximum permissible levels of lead for these products.

- Resolution 372 of 2009, issued by the Ministry of Environment, Housing and Territorial Development (now the Ministry of Environment and Sustainable Development), which establishes the requirements of selective collection and management of unused lead acid batteries (waste), under the principle of extended producer responsibility.

207. Colombia has been working towards the reduction of human and environmental risks related to lead in accordance with the following provisions of the Declaration on Risk Reduction for Lead, was follows:

National and cooperative actions to reduce risks from exposure to lead

208. Colombia already is considering a series of alternatives and taking specific actions to addresses the risk of exposure to lead, especially in children.

Address the risk of exposure to lead from food and beverages, water, air, occupational exposure and other potential pathways

209. The National Health Institute (INS by its acronym in Spanish) is in charge of monitoring water quality through the Human Consumption Water Oversight Information System. This system includes the measurement of lead in drinking water, in compliance with Article 5 of Resolution 2115 of 2005 (maximum levels of certain substances in drinking water including lead). These results will be included in risk maps, in order to identify risk factors, as well as physical, chemical and microbiological characteristics of the water sources close to the reservoirs for the aqueducts. All of these instruments are intended to protect human health.

210. Regarding risk of exposure to lead from air and water, as mentioned before, maximum permissible levels have been established in Resolution 610 of 2010, Resolution 909 of 2008 (for air) and Decree 1076 of 2015 (chapter on water use and wastewater discharges) and Resolution 631 of 2015 (for water). The major sources of lead emissions in the country are metal smelters, electroplating and production of lead-acid batteries.

Review lead levels in the environment and the exposure of sensitive populations (such as children and pregnant women) and high-risk populations (such as certain groups of workers) to lead.

211. The INS has conducted research related to the exposure level of vulnerable populations and high-risk populations to lead. The last study that was carried out was the assessment of the occupational exposure of workers to lead in battery factories in Cundinamarca (2013).

212. Additionally, the INS has conducted research related to the exposure level of vulnerable populations to lead. The project entitled *"Occupational Exposure to lead of workers in battery factories in Cundinamarca: biomarkers of exposure and effect"* has the objective to determine the degree of exposure to lead in the occupationally exposed workers in the informal sector dedicated to battery recycling in Cundinamarca. The study was conducted in two municipalities of Cundinamarca (Soacha and Fontibón) with vulnerable population exposure to lead. INS is currently working on the data analysis.

Promote and maximise the use of environmentally sound and economically viable recollection and recycling programmes for lead and lead containing products, in order to reduce the release of lead to the environment from waste streams

213. Concerning regulations on selective waste collection, Decree 1076 of 2015 (chapter on hazardous waste regulations) regulates the classification, identification, packaging, labelling, storage and transport of hazardous waste and establishes responsibilities on generators, producers, transporters and waste managers. Decree 1076 of 2015 serves as the basis for the national regulation of the selective collection of waste from unused lead acid batteries, adopted through Resolution 372 of 2009

214. Implementation of Resolution 372 includes the formulation and implementation of selective collection and management plans by producers, which must be submitted for approval to the National Environmental Licensing Authority (ANLA by its acronym in Spanish) (Article 8, Resolution 372). In 2012 more than 13,000 tons of waste was collected, corresponding to an average of more than 900,000 units of used batteries.

Extend cooperative efforts to share, including with non-OECD countries, information about exposures of concern, risk reduction options and environmentally sound and economically viable technologies in order to reduce risks from exposure to lead

215. As part of Colombia´s cooperative efforts in this area a Global Environmental Facility (GEF) project named "Lead Elimination in Paint in the Andean Free Trade Region." has already been submitted. The GEF project would allow making progress in relation with the elimination of lead in paints.

216. The project aims to eliminate the use of lead in paints in the Andean Free Trade Region through joint work between government and industry and to establish limits for lead content in paints. The GEF project, as proposed by the United Nations Industrial Development Organization (UNIDO), has a duration of three (3) years, and would consist of the following outcomes:

1. Validation of national and regional inventory for lead contents in paints and identification of connections to the international paint value chains.

2. Phasing out the production of paints containing lead, demonstrating its application in key industry sectors.

3. Prepare a national legal instrument and the corresponding action plans to eliminate lead content in paints.

4. Achieve regional and national awareness on the implications of lead contents in paint and alternative paints.

5. Project monitoring and evaluation.

Encourage the lead producing and using industries to make best use of their expertise on the management of risks from lead and encourage them to make this expertise available to OECD and non-OECD countries

217. The General Labour Risk System establishes that employers must identify and assess risk in the workplace to protect the health and safety of workers. To do so they must implement an Occupational Health and Safety Management System to manage risk based on the hierarchy of control where the elimination and substitution are the principal measures to prevent adverse effects on the health of workers. This is regulated by Decree 1072 of 2015 and other related regulations.

Work with the lead producer industry to develop its voluntary programme of action to reduce exposure to lead, which will be implemented in co-operation with national authorities in OECD and interested non-OECD countries and encourage user industries to develop similar programmes

218. Although Colombia does not have a specific voluntary programme of action to reduce the risk of occupational exposure to lead, the occupational risks insurance (ARL for its acronym in Spanish), must provide advice and support to companies for reducing, minimizing or eliminating exposure to work hazards (Decree 1295 of 1994, modified by Law 1562 de 2012). Additionally, Colombia has signed ILO Convention 13 on lead, and there are additional regulations on chemical substances (e.g. Laws 9 of 1979 and 55 de 1993, Decree 1843 de 1991 and Resolutions 2844 of 2007 y 1013 of 2008) and the Occupational Health and Safety Management System (Decree 1072 of 2015). This is the legal framework to require companies to implement risk control for lead in the workplace.

Progressively reduce the use of lead in gasoline except where needed for essential or specialised uses for which there are no practical, viable alternatives

219. As mentioned before, with the issuing of Decree 1076 0f 2015 in the country, forbids in Article 2.2.5.1.4.5 the use of lead in gasoline in quantities higher than those specified internationally, except for fuel for piston engine aircraft.

Eliminate exposure of children to lead resulting from products intended for their use (e.g., toys, cribs, crayons)

220. Colombia has in place Resolution 3388 of 2008, which establishes sanitary requirements for all toys for human use, regulates the content of lead in children's toys. However, there is no legal framework in place regarding the elimination of lead in other products intended for use by children such as cribs and crayons.

Eliminate exposure to lead from food packaging (e.g., for cans, by reducing the use of lead solder in existing canning lines, not using lead solder in new canning lines, or where these are not practical, by using functional barriers to prevent lead migration; for wine-bottle capsules, substituting for other materials)

221. The Ministry of Health and Social Protection issued Resolution 683 of 2012, which establishes the technical requirements that must be met by the materials, objects, packaging and equipment intended to come in contact with food and beverages for human consumption.

222. In addition, the following legal framework related to this topic includes:

- Resolution 4142 of 2012, issued by the Ministry of Health and Social Protection, which issues the technical rule for the sanitary requirements of metallic materials, objects, packaging and equipment, intended to come into contact with food and beverages for human consumption in the national territory.

- Resolution 834 of 2013, issued by the Ministry of Health and Social Protection, which issues the technical rule for the sanitary requirements of cellulosic materials, objects, packaging equipment and its additives that are intended to come into contact with food and beverages for human consumption. Specifically, Article 9 establishes the maximum permitted levels of heavy metals (including lead) in these objects, and Article 14 establishes restrictions for elements and substances such as lead in cellulosic materials.

- Resolution 835 of 2013, issued by the Ministry of Health and Social Protection, which issues the technical rule for the sanitary requirements of glass and ceramics materials, objects, packaging and equipment, intended to come into contact with food and beverages for human consumption. Specifically, Article 5 establishes the limits of total migration of cadmium and lead, specifically

for packaging and equipment made out of ceramic, glass, enamelled or vitrified with respect to the face of the material that enters into contact with food and drink, and Article 6 which provides the specific migration limits of lead for glass objects and equipment.

223. It is important to mention that the National Institute of Food and Drug Monitoring (INVIMA by its acronym in Spanish) along with territorial health departments is responsible for verifying compliance with the migration limits after three (3) years from the entry into force of each of the above-mentioned resolutions for each of the regulated materials.

Reduction of lead levels in occupational settings

224. The national legal framework includes Decree 1477 of 2014, issued by the Ministry of Labour and Ministry of Health and Social Protection, which establishes the Table of Occupational Diseases, classified by risk factors in order to promote the prevention of such diseases during work related activities, and groups of diseases which can be detected in affected workers through a medical diagnosis. The work activities in which workers can be exposed to lead are within the risk agents contemplated within Decree 1477.

225. At the same time, the Ministry of Labour and the Ministry of Health and Social Protection are working together to regulate the minimum preventive activities in companies that process, handle or work with toxic or carcinogenic substances or with disease-causing agents included in the Table of Occupational Diseases of Decree 1477 of 2014. The chemical substances referred to in this topic include lead and related toxic agents.

226. Decree 1072 of 2015, issued by the Ministry of Labour. Specifically, Article 2.2.4.6.7 establishes that it is important to identify hazards, assess and evaluate the risks and establish the respective controls as part of the objectives of the Occupational Safety and Health Policy. Additionally, Article 2.2.4.6.8 states that employers must ensure training of workers in health and safety issues at work according to the characteristics of the company, hazard identification, evaluation and risk assessment related to their work.

227. The Occupational Health and Safety National Plan (2013-2020), which establishes as a general objective stimulating the achievement of healthy work and labour places, the welfare and quality of life of the working population, as well as the control of the frequency and consequences of work related accidents and occupational health issues.

Reduce lead levels in drinking water through appropriate measures (e.g. treatment of the water, use of materials in the distribution system which do not release lead into the water)

228. Colombia has in place the following legislation aimed at reducing lead levels in water resources:

- National Policy for Integrated Water Resources Management (2010). The mentioned policy identified the need to perform an update of the regulatory framework related to water resource management in the country.

- Environmental regulations imposing maximum permissible levels (see above).

- Decree 1575 of 2007, issued by the Ministry of Social Protection (now Ministry of Health and Social Protection) and the Ministry of Environment, Housing and Territorial Development (now the Ministry of Environment and Sustainable Development), establishes the System for the Protection and Control of Water Quality for Human Consumption.

- Resolution 2115 of 2007, issued by the Ministry of Social Protection (now Ministry of Health and Social Protection) and the Ministry of Environment, Housing and Territorial Development (now the Ministry of Environment and Sustainable Development), establishes the characteristics, basic tools and frequency of the System for the Protection and Control of Water Quality for Human Consumption. Specifically, Article 5 establishes the maximum permissible levels of substances with known adverse effects on human health, including lead.

- Resolution 1166 of 2006, issued by the Ministry of Environment, Housing and Territorial Development (now the Ministry of Housing City and Territory), establishes minimum technical requirements for water supply and wastewater pipelines and its accessories. Article 5 of Resolution 1166 (modified by Resolution 1127 of 2007), states that pipes and fittings, their internal coatings, paints and other internal protection may not exceed maximum allowable concentrations of chemical compounds (including lead) with recognized adverse effects on human health, which can migrate to water transported through drinking water pipes, as indicated in Decree 1575 of 2007 and its related regulation.

Reduce the use of lead in paints and rustproofing agents except in cases of essential or specialized uses for which there are no practical alternatives

229. Colombia does not currently have a legal framework regarding the use of lead in paint and rustproofing agents.

230. In order to fully comply with the requirements of this Declaration, Colombia will continue to work and take action to phase out the use of lead in paint and eliminate the exposure of children to lead resulting from products intended for use by children.

231. Congress took a step in this direction by presenting for a second time a law proposal in the second semester of 2016, which would contribute to establish a legal framework for those activities using lead that are not currently covered under existing legislation. This law proposal is expected to go through the regular legislative process during 2017. Another regulatory initiative worth mentioning is the joint resolution already drafted and being discussed between the Ministry of Health and Social Protection and the Ministry of Commerce, Industry and Tourism, which will regulate the levels of lead and toxic elements for didactic elements intended for use by children.

232. In addition, the Ministry of the Environment and Sustainable Development drafted a regulatory framework, which would allow the adoption of risk reduction actions concerning different chemicals such as lead. This alternative would open the possibility to restrict or eliminate the use of certain chemicals for environmental and health reasons through governmental actions without having to go through a legislative process for individual substances. The proposed action plan to implement the Program for the Management of Chemicals for Industrial Use specifically mentions the adoption of such Risk Reduction Measures (RRM).

233. Finally, the following measures will be adopted to control and reduce risks that could result from exposure to lead:

1. Regulate the levels of lead and other toxic elements for didactic elements intended for use by children:

    - In 2017, The Ministry of Health and Social Protection, with the cooperation of the Ministry of Commerce, Industry and Tourism will issue a joint Resolution to regulate the levels of lead and other toxic elements for didactic elements intended for use by children.

- A draft of the resolution is already available.

2. Eliminate the use of paint containing lead. The specific activities include:

- To develop an assessment of lead contents in paints (2017).
- To prepare a regulation to establish limits of lead contents in paints and formulate technical and/o economic instruments to assist with eliminating lead from paint formulations (2018-2020).