Guidance and Model Law for Regulating Lead Paint DRAFT FOR COMMENTS BY 10 JULY 2017

The Global Alliance to Eliminate Lead Paint (Lead Paint Alliance) is a multi-stakeholder partnership convened by the UN Environment and World Health Organization (WHO) to enhance the global efforts to eliminate the use of lead in paint to protect human health and the environment. One of the goals of the Alliance is to have legal limits to lead in paint in all countries by 2020.

UN Environment, in cooperation with WHO, United States Environment Protection Agency and other partners, has developed a draft guidance document and a model law in order to assist countries in establishing and implementing regulation on lead paint. This draft is made available in the Alliance's website (http://www.unep.org/noleadinpaint) for comments.

Any stakeholder interested in the draft guidance is encouraged to review the draft and submit comments to <u>lead-cadmium.chemicals@unep.org</u> by Monday 10 July 2017. UN Environment will finalize the document taking into account the comments received by this date. Please note that UN Environment will not be able to individually respond to specific comments.

Guidance and Model Law for Regulating Lead Paint

Introduction

This document provides guidance to countries drafting new laws to establish legal limits on lead content in paints in order to protect human health and the environment. It can also be a useful tool for countries interested in modifying their existing laws. It was developed by the United Nations Environment Programme (UN Environment) in support of the Global Alliance to Eliminate Lead Paint (Lead Paint Alliance). "Lead paint" is paint or similar surface-coatings to which one or more lead compounds have been added. The primary goal of the Lead Paint Alliance is to prevent children's exposure to lead from paints containing lead and to minimize occupational exposures to lead paint. To help achieve that goal, the Lead Paint Alliance's broad objective is to promote a phase-out of the manufacture and sale of lead paint and eventually to eliminate the risks that such paints pose.

To achieve this global objective, it is necessary for all countries to eliminate the use of lead additives in new paints by establishing and enforcing lead paint laws. An important strategic goal of the Lead Paint Alliance is for all countries to have lead paint laws in place by 2020.¹ As of February 2017, only 65 countries had confirmed to the Lead Paint Alliance that they have legally binding controls on lead paint, 67 stated that they do not, and information was unavailable for the remaining 63 countries.² Thus there are many countries where lead paint is allowed to be used in homes and schools and on toys, creating a significant risk of children's exposure to lead. Countries that have not yet done so are encouraged to enact and enforce effective national legislation, regulations and/or standards to stop the manufacture, sale and import of lead paints.

Countries that have enacted laws to limit the lead content in paint have generally used one of two approaches: (1) establish a set of chemical-specific regulatory limits based on the risks of individual lead compounds that are used as additives in paint (currently used in the European Union REACH regulation³), or (2) establish a single regulatory limit on the total concentration of lead in paint from all sources (currently used in 34 countries).⁴ Both approaches have been effective in limiting the lead content in paint, but the chemical-specific approach requires risk assessments of individual lead compounds that may be beyond the capacity of many developing countries. In contrast, a single regulatory limit on total lead content does not require extensive risk assessments, and is much simpler for governments to implement and enforce. Manufacturers can achieve a low legal limit on total lead

² WHO, *Regulations and Controls on Lead Paint*, Global Health Observatory, World Health Organization, available at <u>http://www.who.int/gho/phe/chemical_safety/lead_paint_regulations/en/</u>.

³ <u>https://echa.europa.eu/regulations/reach</u>

¹ The Lead Paint Alliance was formed under the auspices of the Strategic Approach to International Chemicals Management (SAICM), pursuant to SAICM Resolution II/4 B. SAICM provides a policy framework to achieve the goal that, by 2020, chemicals will be produced and used in ways that minimize significant adverse impacts on the environment and human health. The strategic goals for the Lead Paint Alliance are included in its 2012 Business Plan, available at http://web.unep.org/chemicalsandwaste/leadpaintalliance/resources/publications.

⁴ UNEP (2016), *Global Report on the Status of Legal Limits on Lead in Paint*, United Nations Environment Programme, available at <u>http://web.unep.org/chemicalsandwaste/sites/unep.org.chemicalsandwaste/files/Status%20of%20Limits-Lead-Paint-2016%20Report-Final.pdf</u>.

content in paint by developing formulations that do not intentionally use any lead additives and that take into account potential residual lead content in raw material ingredients.

Purpose and Scope

The purpose of this guidance is to assist countries interested in enacting new laws that establish a single regulatory limit on the total lead content in paints. This guidance can also assist countries in modifying their existing laws. The guidance describes the key elements of effective and enforceable legal requirements, and provides a model law that incorporates the key elements and reflects the best approaches that are currently found in lead paint laws around the world. Countries may use the model law to help develop their own laws, considering the individual countries' existing legal frameworks and other national circumstances. For example, some countries use consumer protection laws that establish a limit on lead content in consumer paints (e.g. the United States of America), whereas other countries establish limits on lead in paints through a regulation or legal order under a chemicals management law (e.g. the Philippines) or as part of an environmental protection law (e.g. Nepal). Still other countries have established lead limits through governmental standards-setting processes (e.g. Kenya). Accordingly, the model law can be adapted so that it fits appropriately within a country's legal framework but should retain the key aspects described in this guidance.

For efficiency, this guidance uses the term "Agency" to refer to the relevant government entity that will be responsible for implementing the lead paint law. In different countries, the relevant government entity may be, for example, the environment ministry/agency, the health ministry/agency, or the standards-setting bureau. Where different ministries, agencies or bureaus will be responsible for implementing different parts of a lead paint law, it will be important for those ministries, agencies or bureaus to meet at the outset of the drafting process to agree on and establish clear lines of responsibility.

As countries draft new laws to limit the lead content in paint, it is recommended that they provide public access to information about the new laws and opportunities for public input and engagement, such as the opportunity to provide public comments. The regulated community and other stakeholders can provide valuable input and suggestions for effective laws. Many countries that have been successful in enacting effective lead paint laws have actively engaged stakeholders such as paint manufacturers and civil society by establishing working groups or similar mechanisms for input and discussion.

Finally, while this guidance and model law focus on establishing a regulatory limit on the total lead content in new paint and similar surface-coating materials, consumer exposure to lead from paint already applied to products may need stricter control. Accordingly, countries may wish to review their existing consumer products safety laws, and consider prohibiting the import and manufacture of consumer products coated with lead paint, especially products intended for use by children.

Method of Development

A proposed draft of this guidance document was developed by a working group of representatives from UN Environment, the World Health Organization and the US Environmental Protection Agency. The working group looked at examples of existing laws and regulations pertaining to lead paint from several countries and reviewed information compiled in the *Global Report on the Status of Legal Limits on Lead*

in Paint published by UN Environment in 2016. The group also consulted with government bodies responsible for consumer protection and standard setting.

The proposed draft was reviewed by the Advisory Group of the Lead Paint Alliance. The Advisory Group is comprised of representatives from governments, industry, environmental and health NGOs and international organizations. Following review and comment by the Advisory Group, a final draft was provided for review by partners of the Alliance and the general public via the Lead Paint Alliance web site. Comments from this secondary review were considered when the guidance was finalized. [At the completion of the review process, this description may be updated as needed.]

Background on Lead Paint

Paint is typically a mixture of resins, pigments, fillers, solvents, and other additives. Historically, lead compounds have been intentionally added to paint to give it certain properties, such as color, reduced corrosion on metal surfaces, or faster drying time. For the same reasons, lead compounds may be present in other types of coatings, including varnishes, lacquers, stains, enamels, glazes, and primers. Lead additives are most commonly used in solvent-based paint due to their specific chemical properties, and such solvent-based lead paints and coatings are still widely available and used in many countries. Water-based, or latex, paints, rarely contain intentionally added lead compounds.⁵

Paints may also include ingredients that are added and unintentionally contain lead. For example, paints may include natural clays and other raw materials that may contain residual lead content. This is why it is not technically feasible to set a "zero" limit for lead content in paint. However, when a paint manufacturer does not intentionally add lead compounds to its paints and takes into account the residual lead content in raw materials, the lead content of the paints will be low.⁶

In countries without legal limits on lead in paint, uses for lead paint can include decoration of interior and exterior surfaces in homes and public buildings, on roads, bridges and industrial equipment, and on toys, furniture and playground equipment. On the other hand, non-leaded pigments, driers and anticorrosive ingredients for use in solvent-based paints are also widely available and are used by manufacturers to produce high-quality paints in all regions of the world. Increasingly, paint producers around the world are publicly stating that it is feasible to eliminate the use of intentionally added lead compounds in all paints.

The Case for Legal Limits

The weathering, peeling or chipping of lead paint releases lead into dust and soil in and around homes, schools and other locations. Lead-containing dust can also be brought into the home on the clothes of those who work in industries where such dust is generated, including paint factories where lead continues to be used. Lead-contaminated soil and dust are easily ingested and absorbed, particularly by young children when they play on the floor or outdoors and put their hands or other objects in their

⁵ IPEN (2016), *Global Lead Paint Elimination Report*, available at <u>http://ipen.org/documents/global-lead-paint-report-2016</u>.

⁶ IPEN (2016) *Global Lead Paint Elimination Report*.

mouths. Children also ingest lead if they mouth and chew toys painted with lead paint. Additionally, children and adults can be exposed to lead during the manufacture, use and stripping of lead paint.

The negative health effects from exposure to lead have been known for many years, and include effects on multiple body systems. Lead can cause permanent damage to the brain and nervous system, resulting in decreased IQ and behavioural problems. It can also cause anaemia, increase the risk of kidney damage and hypertension, and impair reproductive function.

Children under 6 years of age and pregnant women (whose developing fetus can be exposed) are especially vulnerable to the adverse effects of lead. Even relatively low levels of exposure can cause serious and, in some cases, irreversible neurological damage. There is no known level of lead exposure that is considered safe.

The negative impacts on children's developing brains resulting from exposure to lead has staggering economic costs that are borne by the affected children, their families and societies at large. These include health care costs, productivity losses and intellectual disability. The Institute for Health Metrics and Evaluation has estimated that, based on 2015 data, lead exposures from all sources accounts for 12.4% of cases of idiopathic intellectual disability (i.e., intellectual disability without another known cause).⁷ The largest economic burden of lead exposure is borne by low and middle income countries. Estimated annual costs (in international dollars) of lead exposure by global region, based on loss of IQ, include the following: Africa - \$134.7 billion; Latin America and Caribbean - \$142.3 billion; and Asia - \$699.9 billion.⁸ In addition, the cost of removing existing lead paint from surfaces in homes, schools and other buildings can be substantial.⁹ It makes economic sense for countries to enact laws that prevent future removal costs by establishing a legal limit on lead content that will result in lead paint no longer being used in such buildings.

By contrast, the economic cost of eliminating the use of lead compounds in many paints is known to be low, with many manufacturers already successfully reformulating paint products that avoid the intentional addition of lead. According to a paint industry spokesman, "the reformulation of residential and decorative paints to eliminate lead additives is feasible, and the technical and cost impacts are manageable."¹⁰

Lead released into the environment from any source, including lead paint, is also toxic to plants, animals and micro-organisms. In all studied animals, lead has been shown to cause adverse effects in several organs and organ systems, including blood, central nervous, kidney, reproductive and immune systems.

⁷ Institute for Health Metrics and Evaluation (2016), *GBD Compare Data Visualization*. Seattle, WA: IHME, University of Washington, available at <u>http://vizhub.healthdata.org/gbd-compare</u>.

⁸ Attina and Trasande (2013), *Economic Costs of Childhood Lead Exposure in Low- and Middle-Income Countries*. Report and map available from <u>http://www.med.nyu.edu/pediatrics/research/environmentalpediatrics/leadexposure</u>.

⁹ For example, the cost of removing lead paint from homes most in need of remediation in the United States has been estimated at between \$1.2 billion and \$11.0 billion. Gould (2009), *Childhood Lead Poisoning: Conservative Estimates of the Social and Economic Benefits of Lead Hazard Control*, 117 Environmental Health Perspectives 1162.

¹⁰ IPPIC (2016), Presentation to The World Bank on March 15, 2016: *Practical Sustainability Interventions: Protecting Public Health and Promoting Economic Development through Legal Limits on Lead in Paint*, The International Paint and Printing Ink Council, Washington D.C.

It bio-accumulates in most organisms, with environmental exposures occurring through multiple sources and pathways.

The elimination of lead exposure at its source is the single most effective action to protect people from the harmful effects of lead. The removal of lead from gasoline has produced dramatic reductions in airborne emissions and associated exposures and public health impacts around the globe. Similarly, most industrialized countries adopted laws or regulations to control the lead content of residential and decorative paints in the 1970s and 1980s, based on clear findings that lead-containing paint is a major source of lead exposure in children. The continued use of lead in paint in many parts of the world, however, remains an unaddressed environmental source of human exposure. Laws, regulations or enforceable standards are needed in every country to stop the manufacture, sale and import of lead-containing paints.

The global paint and coatings industry is an expanding, worldwide industry. The growth of the paint and coatings industry is closely correlated with the economic development of countries around the world. Therefore, unless the practice of manufacturing and selling paints with added lead is eliminated, the risks of lead exposure will also increase. The growing demand for paints, especially for residential and decorative uses in developing countries, should be met with paints that are not formulated with added lead compounds. Establishing lead paint laws will help countries ensure that not only domestic production but also imported paint and similar surface-coating materials will not include lead above the national legal limit.

By producing or using paints without added lead compounds, paint manufacturers and commercial paint users (such as toy manufacturers) can ensure their continued access to markets where lead content in paint is already restricted, and can also reduce potential commercial risks, including health risks to workers and customers, compliance and liability claims, and industry reputation.

Objectives and Key Elements of Effective Lead Paint Laws

The objectives of legal limits on lead in paint, established through lead paint legislation and/or regulation (hereinafter described as "lead paint law"), include the following: (1) prevention of the manufacture, sale and import of paint that contains lead above an established legal limit; (2) development of a system with effective means of compliance and enforcement; and (3) establishment of institutional responsibilities and arrangements for the management and enforcement of the lead paint law.

In accordance with these objectives, the key elements of a lead paint law include the following:

- A. Defining key terms and ensuring that the scope of the law is clear:
 - a. Persons and activities that are regulated (e.g., manufacture, sale and import)
 - b. Types of paint applications that are regulated (e.g., all paint applications, or certain applications, such as residential, decorative, etc.)
- B. Establishing a clear legal limit on total lead content in paint
- C. Setting the effective dates of the new requirements
- D. Providing methods for ensuring compliance and enforcement
- E. Specifying consequences of non-compliance
- F. Providing any necessary general provisions

This section of the guidance provides explanations and drafting notes for the key elements of a lead paint law. A model law reflecting these key elements is provided in Appendix I.

Key Element A: Define key terms and ensure that the scope of the law is clear

Lead paint laws should clearly define key terms used throughout the law. Key terms may include, for example, "manufacturer," "paint," and "total lead content." The model law in Appendix I provides definitions of key terms (See Appendix I, section A).

An effective lead paint law will specify the activities and persons that are regulated. The model law in Appendix I prohibits the sale, offer for sale, manufacture for sale, distribution into commerce and import of paint that exceeds the established legal limit (see Appendix I, sections B and F). The model law places specific requirements (e.g., testing and declarations of conformity) on manufacturers and importers of paint. (See Appendix I, section D).

The law should also specify the types of paint that are regulated. Countries should decide whether to apply the legal limit to all paints or to allow exemptions from the limit for certain paints for specific purposes. It is entirely possible to restrict the use of lead in all paints, and some countries have done so.¹¹ This has the benefit of protecting the whole population from lead exposure from paint, especially in countries where both household paint and industrial paint are frequently sold side by side in retail markets. The model law provided in Appendix I applies the total lead limit to <u>all</u> paints (e.g., household, industrial, agricultural, etc.). (See Appendix I, section B).

If a country chooses to exempt certain paints from the total lead limit, it should require such paints to bear precautionary labeling so that consumers are aware of the health hazards involved with using such paint. Sample language for a labeling requirement, as well as sample language for the label, is as follows:

- Manufacturers and importers of paint and similar surface-coating materials that are not subject to the ban set forth in [insert section] and contain lead or lead compounds in which the lead content (calculated as lead metal) is in excess of 90 ppm of the weight of the total nonvolatile content of the paint or the weight of the dried paint film shall:
 - Include on the label of each paint or similar surface-coating product a warning stating: "DANGER: CONTAINS LEAD. DO NOT APPLY TO SURFACES ACCESSIBLE TO CHILDREN OR PREGNANT WOMEN."
 - Failure to include such a label shall subject the manufacturer or importer to penalties as set forth in [insert penalties section].

Key Element B: Establish a clear legal limit on the total lead content in new paint

¹¹ See supra note 3.

As discussed in the Introduction, the purpose of this document is to assist countries interested in establishing a single regulatory limit on the total concentration of lead in paint from all sources. Setting a specific legal limit on total lead content helps the regulated community understand the rules and ensures that the law is more easily enforceable. It is necessary to specify a quantitative limit for lead in paint and to specify a valid method that will be used to measure the quantity of lead in paint.

The lowest and most protective maximum regulatory limit that has been set in countries for lead in residential and decorative paints is 90 parts per million (ppm) total lead content, based on the weight of the total non-volatile content of the paint or the weight of the dried paint film. (This specific limit can also be measured and expressed in a law or standard as 0.009 percent or 90 mg/kg of total lead, based on the dry weight of the paint film.) The 90 ppm limit is technically feasible for manufacturers to achieve by avoiding the addition of lead compounds and taking into account residual (unintentional) lead content in certain paint ingredients. Paint testing conducted by environmental groups in numerous developing countries shows that while high levels of lead are often found, in those same countries levels below 90 ppm are also achievable.¹² Countries that have set a legal limit of 90 ppm total lead content are: Canada, India, Kenya, Nepal, the Philippines, Tanzania and the United States of America. Several other countries are also considering adoption of the 90 ppm total lead regulatory standard. Switzerland and Thailand have limits of 100 ppm total lead, while some other countries have adopted a limit of 600 ppm total lead content: Argentina, Brazil, Chile, Costa Rica, Dominica, Guyana, Jordan, Mexico, Oman, Panama, South Africa, Sri Lanka and Uruguay.^{13,} The model law in Appendix I uses 90 ppm as the total lead limit because it is the lowest limit reflected in existing laws and thus provides the best available health protection, and is technically feasible. (See Appendix I, section B).

It is important to specify that the legal limit should be defined as "total lead" content rather than "soluble lead" content in paint. ¹⁴ Currently a few countries regulate paint on toys using a limit on soluble lead, which is the amount of lead that can be extracted using a standard acid treatment test method. Measuring soluble lead is intended to simulate the amount of lead that is bioavailable for absorption by children, such as when a child chews on a toy coated with lead paint. Recent research suggests, however, that soluble lead is not the predominant form of exposure for children, and that particulate (insoluble) lead found in dust, soil and paint chips is a more significant contributor to chronic and acute exposure.¹⁵ Deferred maintenance of painted surfaces, as well as weathering and aging, generate paint chips and dust that contaminate house dust and outdoor soils, thus increasing the potential for exposures to lead. Thus all the lead contained in paint, whether soluble or insoluble in a lab test, has the potential to be available for exposure through inhalation or ingestion, especially by young children who crawl and play on the floor and outside on soil. While there is no safe level of lead exposure, a regulatory limit based on total lead will be more protective of health than a limit based only

¹² IPEN Global Lead Paint Elimination Report, October 2016, http://ipen.org/sites/default/files/documents/IPEN-global-lead-report-final-Oct-2016-en.pdf.

¹³ See supra note 3; WHO (2016), Countries with legally-binding controls on lead paint, as of 17 February 2017. World Health Organization.

¹⁴ For an overview of analytical methods for measuring lead in paint, see WHO (2011) *Brief guide to analytical methods for measuring lead in paint, available* <u>http://www.who.int/ipcs/assessment/public_health/lead_paint.pdf</u>.

¹⁵ Deshommes E., et al (2012), *Experimental Determination of the Oral Bioavailability and Bioaccessibility of Lead Particles*; Chemistry Central Journal; Vol. 6, p. 138.

on soluble lead. The model law in Appendix I therefore uses a regulatory approach based on limiting the total lead content in paint. (See Appendix I, section B).

Key Element C: Set effective dates of the new requirements

Lead paint laws should specify effective dates for requirements set out in the law, such as dates on which prohibitions on the manufacture, sale and import of paint containing lead above the total lead limit will come into force. In establishing such dates, countries may wish to work with industry to determine a reasonable amount of time needed to source and procure alternative materials, to alter product formulations and processes, and to sell or dispose of existing stocks of paint containing lead above the total lead limit. Countries should encourage in-country laboratories to acquire the necessary equipment, expertise, and accreditation to perform the required testing of lead paint. Current lack of in-country laboratory capacity need not be an impediment to a lead paint law going into effect, as industry can still comply with the law by sending paint samples to laboratories in other countries that are qualified to perform the required testing.

One way to allow time for industry to change its practices and come into compliance with the total lead limit is to provide a reasonably delayed effective date for the 90 ppm total lead limit, applicable to all paints covered by the law. Most lead paint laws that limit lead to 90 ppm or 100 ppm have required compliance within one year of passage of the law.¹⁶ (For sample language for a delayed effective date, see Appendix I, section C, option 1).

As an alternative to a broadly applicable delayed effective date for the 90 ppm limit, countries may wish to provide phased effective dates, depending on the type of paint. This approach is designed to take into account the different uses and performance requirements of paints and the relative harms posed by such uses. For example, a law could allow somewhat more time for industrial paints to come into compliance with the total lead limit but less time for decorative paints intended for household use or other applications most likely to contribute to childhood lead exposure. (For sample language for a phased effective date, see Appendix I, section C, option 2).

Key Element D: Establish mechanisms to promote compliance with, and enforcement of, the total lead limit

Effective lead paint laws promote compliance and provide mechanisms for enforcing the legal limit. They also assign clear responsibilities for the various actions required by the new law or regulation. Mechanisms for promoting compliance with, and enforcement of, the legal limit should include: (1) requiring third party testing of paint and similar surface-coating materials and mandatory declarations of conformity by manufacturers and importers of their compliance with the total lead limit based on such testing; and (2) authorizing government inspections and testing to ensure compliance with the total lead limit.

¹⁶ Countries limiting lead in paint to 90 ppm that required compliance within one year include: Canada, India, Kenya, Nepal, Tanzania and the United States. Thailand limits lead to 100 ppm and required compliance within one year. Switzerland limits lead to 100 ppm and required compliance within one years for compliance for architectural, decorative and household applications, and six years for industrial applications.

i) Testing and Mandatory Declarations of Conformity by Manufacturers and Importers

The model law requires manufacturers and importers to submit sufficient samples of paint or similar surface-coating materials to a third party laboratory accredited under international standards for testing for compliance with the 90 ppm total lead limit. "Sufficient samples" is defined as the number of samples the Agency determines necessary to provide a high degree of assurance that the tests conducted accurately demonstrate the paint or similar surface-coating materials' compliance with the 90 ppm total lead limit. Recognizing that an essential part of setting a regulatory limit is specifying the analytical testing methods that will be used to determine whether a product is in compliance with the limit, the model law requires manufacturers, importers and laboratories to use internationally recognized sampling and testing methods. A number of existing methods for the preparation of samples and the analysis of lead in paint are available and are summarized in the World Health Organization's "Brief guide to analytical methods for measuring lead in paint." This WHO guide is available in English, Chinese, French, and Spanish at http://www.who.int/ipcs/assessment/public_health/lead/en/. In addition, internationally recognized sampling and testing methods relating to lead in paint are referenced in the model law (see Appendix I, section D) and are listed in Appendix II.

The model law requires manufacturers and importers to submit sufficient samples of their first production batch or lot for third party testing. The testing of the first production batch or lot will suffice unless a material change occurs in the production process. In the event of a material change in the production process, the model law requires new testing to be conducted and new declarations of conformity to be issued. In order to ensure that testing is not unduly burdensome and duplicative, the model law allows importers to rely on a foreign manufacturer's test results to issue the importer's declaration of conformity, as long as the importer exercises due care to ensure that the manufacturer's test results meet the requirements of the law, and the importer maintains appropriate records of the test methodology and results.

The model law requires manufacturers and importers to issue declarations of conformity based on the third party testing described above in order to certify that their paint products and similar surfacecoating materials comply with the 90 ppm total lead limit. Declarations of conformity are a type of "conformity assessment" procedure, which is an internationally used term that covers activities used to provide confidence in a product supplier's compliance with safety, health, environmental and fair commerce requirements.¹⁷ Conformity assessment systems come in many types, which have varying degrees of complexity and resource intensity. This guidance focuses on mandatory declarations of conformity as the most appropriate approach for lead paint laws and regulations.¹⁸ The model law specifies who must provide the declaration of conformity, to whom it must be provided, and describes the required content of the declaration. As indicated above, an importer may rely on a foreign manufacturer's testing under specified circumstances, but the importer must issue its own declaration of conformity based on the foreign manufacture's testing. (See Appendix I, section D).

¹⁷ ISO/IEC Guide 2 provides definitions for various types of conformity assessment.

¹⁸ See "Conformity assessment – Supplier's Declaration of Conformity," ISO/IEC 17050-1 for more detail regarding supplier's declarations of conformity.

ii) Government Inspections and Testing

Inspections and testing by the relevant government agency are critical to ensuring that paints are manufactured and imported in conformity with the country's total lead limit. The model law authorizes government agents to enter a location at reasonable times to inspect and test paint or similar surface-coating materials as long as the agents first present appropriate credentials to the owners, operators or agents of the location. The model law does not require government agents to test samples in compliance with the third party testing requirements applicable to manufacturers and importers of paint and similar surface-coating materials. Rather, the government agents are required to test in a reasonable manner in order to assess compliance with the law. (See Appendix I, section E).

Key Element E: Specify clear, transparent consequences for non-compliance

Effective lead paint laws clearly articulate prohibited acts. (See Appendix I, section F). They also dictate the consequences of non-compliance, including providing for specific and meaningful penalties. Where a country already has general legal provisions relating to civil penalties and criminal sanctions for offences, it may wish to refer to those provisions of its parent legislation in its lead paint law. (See Appendix I, section G, option 1). If a country does not already have parent legislation relating to penalties or sanctions, or wishes to incorporate independent, specific civil and criminal penalty provisions within its lead paint law, the model law provides sample language. (See Appendix I, section G, option 2). The lead paint law may also provide for criminal fines and imprisonment for knowing and willful violations of the law. (See Appendix I, section H).

In addition to specifying meaningful penalties for non-compliance, effective lead paint laws identify remedies such as injunctive relief and seizure or recall of paints that do not comply with the total lead limit. (See Appendix I, section I). The lead paint law may also include provisions to enable citizens and other "persons" to bring actions to enforce the law. (See Appendix I, section J). The model law defines "person" to include an individual, partnership, corporation, association, or non-profit. (See Appendix I, section A).

Key Element F: General Provisions

In drafting lead paint laws, countries may find they need to reference provisions from other, existing laws that relate to the manufacture and import of paints and help ensure that lead paint is being handled appropriately. For example, countries may wish to refer to applicable waste management laws to address the transport, treatment, storage and disposal of lead paint. (See Appendix I, section K).

<u>Appendix I</u>

Model Lead Paint Law

The text below is intended solely as guidance for governments interested in developing a new national law to limit the total lead content in paints. It does not constitute a legal interpretation or binding obligation in relation to any international Convention. The model law can be adapted so that it fits appropriately within a country's legal framework, but should retain the key elements of effective and enforceable legal requirements, as described in this guidance.

A. Definitions (examples)

"Disposal" means treatment, temporary storage and systematic destruction of lead and lead compounds' wastes in accordance with the applicable provisions of the law regulating hazardous wastes.

"Importer" means any person that undertakes the entry of a product into the country.

"Lead paint" means paint containing lead or lead compounds and in which the lead content (calculated as lead metal) is in excess of 90 ppm by weight of the total nonvolatile content of the paint or the weight of the dried paint film.

"Manufacturer" means any person who undertakes the physical or chemical transformation of substances into a new product performed either by power-driven machines or by hand and markets it under his/her name or trademark or private label.

"Paint" means varnishes, lacquers, stains, enamels, glazes, primers or other similar surface-coating materials used for any purpose; and is typically a mixture of resins, pigments, fillers, solvents, and other additives that constitutes a finished product. Paint does not include materials which become part of the substrate, or materials which are actually bonded to the substrate, such as by electroplating or ceramic glazing.

"Person" means an individual, partnership, corporation, association, or non-profit.

"Total lead content" is defined as a weight percentage of the total non-volatile portion of the paint or as a percentage of the weight of the dried paint film.

B. Legal limits on total lead content

Paint and similar surface-coating materials must not contain lead content (calculated as lead metal) in excess of 90 ppm of the weight of the total nonvolatile content of the paint or the weight of the dried paint film.

C. Effective dates

Option 1: Delayed Effective Date

• Lead content above the 90 ppm total lead limit in [section] is allowed in the paint and similar surface-coating materials surface-coating until, and not after, one (1) year from the passage of this law [or insert date].

Option 2: Phased Effective Dates

• The use of lead and lead compounds is allowed in paints and similar surface-coating materials with more than 90 ppm limit for one (1) year of the date of promulgation of this law for architectural, decorative, household applications, and for three (3) years of the date of promulgation of this law for industrial applications.

D. Declaration of Conformity based on Testing by Third Party Laboratory

- Declaration of Conformity
 - Before distributing in commerce or importing for consumption any paint or similar surface-coating materials a manufacturer or importer shall:
 - Submit sufficient samples of the first production batch paint to a third party laboratory accredited under [see below] to be tested for compliance with the 90 ppm total lead limit in [cite to section], and
 - Based on such testing, issue a declaration of conformity that certifies that such products comply with the 90 ppm total lead limit in [cite to section].
 - Manufacturers and importers shall maintain records of declarations of conformity and test results and attestations supporting such declarations of conformity for a period of at least [5 years].
 - An importer of paint may rely on a foreign manufacturer's test results to issue its own declaration of conformity provided that the importer exercises due care to ensure the manufacturer's test results meet the requirements of this law, and that the importer has records of the test results and attestations regarding how the testing was conducted.
- "Sufficient Samples" as used in [section above] means the number of samples of paint or similar surface-coating materials that the Agency determines is sufficient to provide a high degree of assurance that the tests conducted for declaration of conformity purposes accurately demonstrate the ability of such products to meet the X ppm total lead limit in [cite to section].
- New Declaration of Conformity after Material Change
 - "Material Change" means a change that the manufacturer or importer makes to the design, manufacturing process, or the source of component parts, for the paint or similar surface-coating material, which a manufacturer or importer, exercising due care, knows, or should know, could affect compliance with the 90 ppm total lead limit in [section].
 - In the event of a "material change," a manufacturer or importer must:

- submit sufficient samples of the paint or similar surface-coating material to a third party laboratory accredited under [see below] to be tested for compliance with the 90 ppm total lead limit in [cite to section], and
- Based on such testing, issue a new declaration of conformity that certifies that such paint or similar surface-coating material complies with the 90 ppm total lead limit in [cite to section].
- Who must issue the declaration of conformity
 - In the case of paint or similar surface-coating material manufactured in [X country], the manufacturer must issue the declaration of conformity pursuant to [section].
 - In the case of paint or similar surface-coating material manufactured outside [X country], the importer must issue the declaration of conformity pursuant to [section].
- To whom must the declaration of conformity be given -
 - Manufacturers and importers of paint or similar surface-coating materials must:
 - Provide the declaration of conformity to distributors and retailers.
 - Provide the declaration of conformity to [Agency] upon request.
- Content of declaration of conformity Each declaration of conformity shall include:
 - Identification of the paint or similar surface-coating material covered by the declaration;
 - Identification (name, contact address) of the manufacturer or importer certifying compliance with the 90 ppm total lead limit;
 - Identification of the object of the declaration of conformity (e.g., name, type, date of production or model number of a product, description of a process, management system, person or body, and/or other relevant supplementary information);
 - A sworn affidavit signed by the manufacturer or importer stating that the paint or similar surface-coating material is in compliance with the 90 ppm total lead limit, and
 - Contact information for the individual maintaining records of test results.
- Accreditation of third party laboratory
 - "Third party laboratory" means an independent laboratory that has no interest in the transaction between the manufacturer or importer and the distributor or retailer, and that has been accredited under ISO/IEC 17025 by a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA), or one of its recognized regional bodies: Inter American Accreditation Cooperation (IAAC), European co-operation for Accreditation (EA), Asia Pacific Laboratory Accreditation Incorporated (APLAC).
 - For its accreditation to be accepted to test for the 90 ppm total lead limit for declaration of conformity purposes, a third party laboratory shall be accredited for and use [specify sampling and testing methods here – e.g., ASTM, ISO standards and provide for updating, perhaps via Agency website, to account for test methods changing/improving over time. See Appendix II for recommended methods.]

E. Government Inspections

- For purposes of implementing this law, officers or employees of [Agency], upon presenting appropriate credentials to the owner, operator or agent in charge, are authorized:
 - To enter, at reasonable times, any factory, warehouse, or establishment in which paint or similar surface-coating materials are manufactured or held; and
 - To inspect and test, at reasonable times and in a reasonable manner, such paint and similar surface-coating materials to assess compliance with this law.

F. Prohibited Acts

- It shall be unlawful for any person to:
 - Sell, offer for sale, manufacture for sale, distribute in commerce, import into [X country], any paint or similar surface-coating material that contains lead or lead compounds and in which the lead content (calculated as lead metal) is in excess of 90 ppm of the weight of the total nonvolatile content of the paint or the weight of the dried paint film;
 - Fail or refuse to permit entry or inspection and testing pursuant to Section E;
 - Fail to furnish a declaration of conformity required by [cite section] or issue a false declaration of conformity if such person in the exercise of due care has reason to know that the declaration of conformity is false or misleading in any material respect;
 - Exercise, or attempt to exercise, undue influence on a third party laboratory with respect to the testing, or reporting of the results of testing of any product.

G. Penalties

Option 1:

• Any person who violates the requirements specified in this [Act/Regulation/ Order] shall be liable thereof to the applicable administrative and criminal sanctions as provided for under Sections of [insert the general penalty provision of the parent legislation].

Option 2:

- Any person who violates section [Prohibited Acts] shall be subject to a civil penalty not to exceed [amount] for each such violation.
- A violation of section [Prohibited Acts] shall constitute a separate offense with respect to each paint or similar surface-coating material product involved, except that the maximum civil penalty shall not exceed [amount].
- The maximum penalty amounts authorized in [cite section above] shall be adjusted for inflation [as reflected in applicable regulations or tied to specified index].
- Relevant factors in determining the amount of the penalty
 - The [Agency or applicable court] shall consider the nature, circumstances, extent, and gravity of the violation, including the severity of the risk of injury, the number of paints or similar surface-coating materials which were distributed, the appropriateness of the penalty in relation to the size of the

business of the person charged, including how to mitigate undue adverse economic impacts on small business, and other such factors as appropriate.

H. Criminal Penalties

- A violation of section [Prohibited Acts] is punishable by:
 - Imprisonment for not more than [X years] for a knowing and willful violation of that section;
 - A penalty of [X amount]; or
 - o Both.
- Any individual director, officer, or agent of a corporation who knowingly and willfully authorizes, orders or performs a violation of section [Prohibited Acts] shall be subject to penalties under this section without regard to any penalties to which that corporation may be subject under [above section].
- In addition to the penalties provided by [above section], the penalty for a criminal violation of this law may include the forfeiture of assets associated with the violation.

I. Injunctive Relief and Seizure

• The [applicable courts of X country] shall have jurisdiction to restrain any violation of section [Prohibited Acts] and to authorize seizure or order the recall of the paint or similar surface coating material that do not comply with the 90 ppm total lead limit, and/or other appropriate relief.

J. Citizen Suits

- Any person may bring an action in any [applicable court of X country] to enforce [section], to obtain appropriate injunctive relief, and to apply any appropriate civil penalties under [section], payable to [government of country X].
- A court with jurisdiction over a citizen suit under this provision may order the defendant to pay the attorney's fees and reasonable litigation costs of the plaintiff bringing a good faith citizen suit under this provision.

K. General Provisions

Transport, Treatment, Storage and Disposal Requirements

 Manufacturers and importers of paints and similar surface-coating materials must comply with the Globally Harmonized System procedures and applicable provisions of the [applicable waste management law] and those to be prescribed by the [environment protection agency or competent authority] for the transport and treatment, storage and disposal of lead wastes and contaminated equipment off-site.

Appendix II

Recommended International Standards

Recommended International Standards for Sample Preparation:

ISO 1513, Paints and varnishes – Examination and preparation of test samples;

ISO 1514, Paints and varnishes - Standard panels for testing;

ASTM E1645-01, Practice for Preparation of Dried Paint Samples by Hotplate or Microwave Digestion for Subsequent Lead Analysis; or

ASTM E1979-12, Practice for Ultrasonic Extraction of Paint, Dust, Soil, and Air Samples for Subsequent Determination of Lead.

Recommended International Standards for Test Methods:

ISO 6503, Paints and varnishes - Determination of total lead - flame atomic absorption spectrometric method;

ASTM E1645-01, Practice for Preparation of Dried Paint Samples by Hotplate or Microwave Digestion for Subsequent Lead Analysis;

ASTM D3335-85a (2014), Standard test method for low concentrations of lead, cadmium, and cobalt in paint by atomic absorption; or

ASTM E1613-12, Standard Test Method for Determination of Lead by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES), Flame Atomic Absorption Spectrometry (FAAS), or Graphite Furnace Atomic Absorption Spectrometry (GFAAS) Techniques