Preparing a Rotterdam Convention Notification to List Lead Chromates: *A Reference and Guidance Paper*

Summary

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Introduction

The Rotterdam Convention is an international treaty that operates a legally binding Prior Informed Consent (PIC) procedure that applies to the hazardous chemicals listed in its Annex III. Many countries have recently adopted lead paint control regulations that severely restrict the use of lead chromates as pigments in paints. These pigments are the predominant source of lead in lead paints. And for this reason, IPEN is helping NGOs in several of the countries that recently adopted lead paint controls promote decisions by their governments to nominate lead chromates for a Rotterdam Convention listing.

This is a Summary of a longer document titled: ***Preparing a Rotterdam Convention Notification to List Lead Chromates: A Reference and Guidance Paper.*** The longer paper addresses several challenging issues that governments of the low- or middle-income countries that recently adopted lead paint controls will need to address if they wish to prepare a Notification to the Rotterdam Convention that can successfully nominate lead chromates for a Convention listing.

Topics discussed in that paper and summarized here include:

1. Reasons why many of the countries that recently adopted lead paint controls can submit Notifications that nominate lead chromates for a Rotterdam Convention listing.
2. Many countries that recently adopted regulations to control lead in paint performed risk evaluations that should satisfy the Convention's Criterion (b).
3. If lead chromates are listed, the Convention's PIC procedure should apply not only to their powder form, but also to international trade in paints and masterbatches that contain lead chromate pigments as major constituents.
4. How a Notification can demonstrate that the country's regulatory action imposed a sufficiently severe restriction on lead chromates to justify a Convention decision to list them.
5. The process the convention will use in deciding whether to list lead chromates.

This Summary is an introduction to the above topics. Those considering preparing and submitting a Notification to the Rotterdam Convention to nominate lead chromates for a Convention listing are encouraged to consult guidance documents produced by the Rotterdam Convention as well as the more detailed information contained in the paper that is summarized here.

This Summary assumes a general understanding of issues discussed in an earlier IPEN paper titled Controlling Lead Chromate Pigments: The Case for a Rotterdam Convention Listing. That paper discusses the human health hazards associated with lead chromates, their composition and their uses. It also discusses how a Rotterdam Convention decision to make international trade in lead chromates subject to its Prior Informed Consent procedure will help accelerate global lead paint elimination.

1. Many of the countries that recently adopted lead paint controls can submit Notifications that nominate lead chromates for a Rotterdam Convention listing.

Lead chromates are the predominant source of lead in lead paints. For this reason, many of the low- and middle-income countries that recently adopted legally binding controls that severely restrict the lead content of paints can submit a Notification to the Rotterdam Convention of a "*final regulatory action to severely restrict lead chromates*."

The Rotterdam Convention defines the term "*Final Regulatory Action*" to mean "*an action taken by a Party … the purpose of which is to ban or severely restrict a chemical*." And the Convention's Article 5 states that "*Each Party that has adopted a final regulatory action **shall** notify the Secretariat in writing of such action*."

When the Rotterdam Convention receives and reviews Notifications that nominate lead chromates for a Convention listing, we can expect it will follow an important precedent that was established in 2004 when the Convention listed tetraethyl lead (TEL) and tetramethyl lead (TML) in its Annex III. This decision was based on Notifications submitted by Canada and the EU of the regulatory actions they took to establish a maximum allowable limit on the total lead content of automotive fuels in order to protect human health. And in doing this, they imposed a severe restriction on the use of TEL and TML.

The regulatory actions taken by Canada and the EU to control the lead content of automotive fuels were very similar to the more recent regulatory actions taken by many low- and middle-income countries to control the lead content of paints. In both cases:

- The government took a regulatory action because it recognized that lead in the product (in one case automotive fuel; in the other case paint) is a significant source of human exposure to lead.
- The regulatory action the government took established a maximum allowable limit on the total lead content of the product (maximum milligrams of total lead per liter in the fuel; maximum parts per million total lead in the dry paint film).
- The regulatory action did not ban all uses of the targeted hazardous chemicals. It allowed some significant uses to continue. (The use of TEL and TML was still permitted in aviation fuels and some others; lead chromates are still allowed for use as colorants in plastics.)

When it decided to list TEL and TML based on the regulatory actions taken by Canada and the EU, the Convention established a precedent that should also apply to lead chromates. If the Convention was able to agree (in 2004) that a *purpose* to Canada's and the EU's regulatory actions was to severely restrict TEL and TML, it should also be able to agree that a *purpose* of a country's regulatory actions to control lead in paint was to severely restrict lead chromates (the predominant source of lead in paints).

It is, therefore, valid and appropriate for many of the countries that recently enacted lead paint control laws to prepare and submit a Rotterdam Convention Notification of *Final Regulatory Action to Severely Restrict Lead Chromates.*

*For a more detailed discussion on this topic, please see the full paper's **Chapter 1: Can countries that adopted lead paint controls state that they took a final regulatory action to severely restrict lead chromates.***

2. Many countries that recently adopted regulations to control lead in paint performed risk evaluations that should satisfy the Convention's Criterion (b).

Notification Form. A country can nominate a hazardous chemical for a Rotterdam Convention listing by completing and submitting a standard *Notification Form* that details the *Final Regulatory Action* that it took to ban or severely restrict that chemical. When submitting the completed *Notification Form,* the country must also submit all necessary supporting documentation.

The *Notification Form* asks, among other things: "*Was the final regulatory action based on a risk or hazard evaluation*?" For it to satisfy the Convention's Criterion (b), the Notification must state that the final regulatory action *was based on a* ***risk evaluation****.*

The *Notification Form* additionally asks the notifying government to provide:

- A "*summary description"* of the risk evaluation, and
- References or a copy of "*relevant documentation*" *which describes the risk evaluation.*

Satisfying the Convention's Information Requirements. Almost all the low- and middle-income countries that recently adopted regulatory controls on the lead content of paints did so based on their government's understanding that, in the absence of regulatory controls, sales and use of lead paints would continue, and this would likely result in significant harm to the country's human health.

In most cases, governments reached this understanding based on a process in which some national entity considered available, science-based information; reached the conclusion that exposure to lead from lead paint poses an unacceptable risk to the country's human health; and conveyed this conclusion to those who had the necessary, regulatory decision-making authority. *The process by which the evidence was considered and the conclusion reached can reasonably be called a "risk evaluation."*

Most governments that recently adopted lead paint controls, therefore, should be able to prepare and submit a Rotterdam Convention Notification which validly states that the regulatory action it took was based on a risk evaluation. Additionally:

- If the Notification includes a summary description of how the risk to human health from exposure to lead from lead paint was evaluated, and how the government reached the conclusion that regulatory action was needed, and
- If the Notification is accompanied by a report that includes a more detailed description of the risk evaluation and that also includes documentation of the science-based information the risk evaluation relied upon,

then, the Convention's Secretariat should be able to verify that the Notification satisfies the Convention's Information Requirements (specified in Annex I of the Convention).

Satisfying Listing Criterion (b). After the Convention's Secretariat verifies that a country's Notification satisfies the Convention's Information Requirements, the Notification will be sent to the Convention's Chemical Review Committee (CRC) for its review.

The CRC will evaluate whether the Notification also satisfies all the Convention's Listing Criterion (as these are specified in its Annex II). One of these criteria, Criterion (b), applies to the risk evaluation that the country performed to justify its decision to take the notified regulatory action.

When the CRC reviews whether the Notification satisfies Criterion (b), it must determine whether:

- The final regulatory action was taken as a consequence of a risk evaluation,
- The risk evaluation was based on a review of scientific data in the context of the conditions prevailing in the notifying country, and
- The data and findings the risk evaluation relied upon were generated and documented according to generally recognized scientific methods, principles, and procedures.

The Notifications Governments prepare and submit to nominate lead chromates for a Convention listing must provide sufficient information – in the Notification's *summary description of the risk evaluation*, and in its *relevant documentation* – to enable the CRC to determine that all the elements of Criterion (b) have been satisfied.

The Notification's *Summary Description* of the risk evaluation will need to:

- Identify the toxicological, exposure-related, and other science-based information that the risk evaluation relied upon,
- Describe how those who evaluated the risk used this science-based information to reach the conclusion that continued sales and use of lead paints would create an unacceptable risk to the country's human health under the prevailing conditions in the notifying country, and
- Explain how the risk evaluation's conclusion was transmitted to the relevant regulatory authorities.

The Relevant Documentation should include:

- A more complete description of the risk evaluation,
- References to the scientific/medical studies and findings upon which the science-based information that the risk evaluation relied upon was based,
- Documentation to demonstrate that these studies and findings were in conformance with scientifically recognized methods, principles, and procedures, and
- A full explanation of how the risk evaluation properly took into account the human health effects from exposures to lead from lead paint under the prevailing conditions in the notifying country.

Preparing the Summary Description and Relevant Documentation. The specifics of how different low- and middle-income countries evaluated the human health risk from exposure to lead from lead paint differed one from another. But the toxicological and exposure-related information their risk evaluations relied upon were often very similar.

In almost all cases, countries that recently adopted regulatory controls on lead in paint were guided by information that was disseminated by the World Health Organization and by other active members of the Global Alliance to Eliminate Lead Paint. For this reason, many of the risk evaluations identified young children (typically children under six years of age and the developing fetus) as the vulnerable group that is most harmed by exposure to lead from lead paint.

Additionally, IPEN, in cooperation with NGOs from a number of the countries that recently adopted lead paint controls, has reviewed the lead paint risk evaluations that several countries performed, and it has compared their commonalities and their differences. Based on this review, IPEN is preparing a report that provides information and documentation that should be useful to those responsible for preparing Notifications of *Final Regulatory Action to Severely Restrict Lead Chromates* that can satisfy all elements of Criterion (b).

The new IPEN report will:

- Identify scientific/medical studies and findings that were the basis for toxicological and exposure-related information that many lead paint risk evaluations relied upon,
- Present evidence that these studies and findings conformed to scientifically recognized methods, principles, and procedures,
- Give special attention to the ways many of the risk evaluations considered the prevailing conditions in the notifying country, and
- Discuss Rotterdam Convention precedents and past practices that can provide insights on how to prepare a Notification and supporting documentation that can satisfy sub-paragraph (iii) of Criterion (b) which requires that the risk evaluation took prevailing conditions within the notifying country appropriately into account.

For a more detailed discussion on this topic, including how the Rotterdam Convention interprets "risk evaluation" and how the risk evaluations counties conducted in developing their regulation will satisfy Criterion (b), please see the full paper's ***Chapter 3: Many countries that adopted lead paint controls performed risk evaluations that can satisfy Criterion (b).***

3. The Convention's PIC procedure should apply not only to lead chromates in their powder form, but also to international trade in paints and masterbatches that contain lead chromate pigments.

Lead chromates are traded, sold, and used not only in their powder form, but also as primary constituents in paints, and in masterbatches used to colorize plastics.

The Rotterdam Convention states that "*for the purposes of this Convention"* the term "*Chemical"* should be understood to mean *"a substance whether by itself or in a mixture."* This should mean that if lead chromates are listed by the Convention, its PIC procedure should apply not only to international trade in lead chromate pigment powders, but also to trade in lead chromates when they are present as major constituents in mixtures, and specifically, when they are present as major constituents in paints and masterbatches (which are mixtures).

Masterbatches. Lead chromates in powder form can be mixed directly into molten plastic. Increasingly, however, producers of plastic products prefer to colorize plastic using color masterbatches. These consist of a polymer or some other solid matrix into which concentrated pigments or other additives have been mixed.

Lead chromates that are destined for use in colorizing plastics are traded as pigment powders and as major constituents in color masterbatches. If the PIC procedure were applied to one but not to the other, those who currently export lead chromates in powder form for use in colorizing plastics could easily evade the Rotterdam Convention's PIC procedure by, instead, producing and exporting color masterbatches that contain lead chromates as major constituents. In that case, even if a country were to deny consent to imports of lead chromates, in their powder form, for colorizing plastics, it would not have the right to deny consent to imports of color masterbatches that contain lead chromates as major constituents for the very same use.

Paints. Pigments are the essential ingredient in almost all paint products. The primary use of the other two major paint constituents – binders and solvents – is as vehicles for adhering the pigments to surfaces. Paints are generally considered, and regulated, as mixtures (of pigments, binders, solvents, and addititives).

For the above reasons, and because the Convention states that the term "*chemical"* should be understood to mean *"a substance whether by itself or in a mixture,"* if the Rotterdam Convention adds lead chromates to its Annex III list of hazardous ***chemicals***, all of the Convention provisions that apply to lead chromates in their powder form should also apply when lead chromates are contained as major constituents in paints and in materbatches.

For a more detailed discussion of why the Rotterdam Convention's PIC procedure should apply to paints and masterbatches that contain lead chromates as major constituents, and for a discussion of how to prepare a Notification that helps ensure this happens, see the full paper's: ***Chapter 4: Will the convention's PIC procedure address international trade in paints that contain lead chromates?***

4. How a Notification can demonstrate that the country's regulatory action sufficiently restricted lead chromates to justify a Convention decision to list them.

The Rotterdam Convention's (Annex II) Listing Criterion (c) requires that the Chemical Review Committee *"Consider whether the final regulatory action provides a sufficiently broad basis to merit listing of the chemical in Annex III."*

In determining whether Criterion (c) has been satisfied, the CRC will review relevant information contained in the Notification and its supporting documents, and it will use this information to answer two questions:

> 1. *"Whether the final regulatory action led, or would be expected to lead, to a significant decrease in the quantity of the chemical used or the number of its uses", and*
>
> 2. *"Whether the final regulatory action led to an actual reduction of risk or would be expected to result in a significant reduction of risk for human health or the environment of the Party that submitted the notification."*

The Notification can only satisfy Criterion (c) if the CRC's answer to the two above questions is *yes*. And if the CRC's answer is *yes*, it will – in effect – have determined that the restriction the regulatory action imposed on lead chromates was sufficiently severe to justify a decision to list them in Annex III.

Answering Question #1. The Notification Form's Section 2.3 calls for information about the ***uses*** of lead chromates. (Providing use information is mandatory.) Section 2.5.1 calls for information about the ***quantities*** of lead chromates that were used. (Providing information about the quantities used is optional.)

The information countries provide in the Notification Form's Sections 2.3 (on uses) will likely indicate that prior to the regulatory action there were **two** significant uses of lead chromates in the country: lead chromates were used as pigments in paints and as colorants in plastics.

1. **In Paints.** In most cases, countries that recently decided to severely restrict the lead content of paints effectively prohibited the use of lead chromates as ingredients in paints; and they also effectively prohibited the import, sale, and use of paints that contain lead chromates as major constituents.

2. **In Plastics.** In most of the countries that recently adopted lead paint controls, producers of plastic-containing products import lead chromates (in powder form or in masterbatches) for use in colorizing the plastics and other syntheric polymers (rubber, leather, etc.) that go into their products. And few countries have taken regulatory action to prevent this use.

When answering the portion of question 1 relating to the "*number of uses*" of lead chromates, therefore, most countries will likely respond that following their regulatory action, the number of significant uses of lead chromates was reduced from two to one. This ***does not*** make a strong case that the regulatory action led to a significant decrease in the **number** of uses of lead chromates.

Therefore, to enable the CRC to answer *yes* to Question 1 as a whole, it is important for the Notification to make the case that the regulatory action did result in a significant decrease in the **quantity** of lead chromates that were used.

To do this, the Notification can use section 2.5.1 of the Notification Form to provide data and/or good estimates that enable a comparison between the quantity of lead chromates that were used in the country prior to the notified regulatory action and the quantity used after the regulatory action fully entered into force.[1] In almost all cases, good estimates will show that the quantity of lead chromates in legal use after entry into force of the country's lead paint control law was relatively quite small as compared to the quantity that was in use before national paint producers and sellers began phasing out the manufacture, import and sales of lead paint.

Answering Question #2. The information that a country provides in the Notification's summary description of the country's risk evaluation, and in the accompanying supporting documents should be sufficient to make the case that the regulatory action can be expected to result in a significant reduction of risk to human health in the notifying country.

The World Health Organization, the United Nations Environment Programme, and other authoritative international voices have – for more than a decade – been consistently informing governments and others that effective regulatory action to control the lead content of paints is needed, and it will result in a significant reduction of risk to human health. Information that supports this conclusion will be presented in the Notification's discussion of the country's risk evaluation. The Rotterdam Convention's CRC and/or its Conference of the Parties is unlikely to disagree.

For a more detailed discussion on this topic, including how a country might prepare good estimates of the significant decrease in the quantity of lead chromate used following regulatory action, see the summarized paper's ***Chapter 5: How Countries Can Demonstrate That the Restriction's They Imposed on Lead Chromates Was Sufficiently Severe to Justify a Listing.***

[1] Chapter 5 of the paper that is summarized here discusses how a one might obtain the necessary data, and how to prepare and present good estimates which demonstrate that the regulatory action resulted in a **significant decrease in the quantity** of lead chromates that were used.

5. The Convention's process for deciding whether to list lead chromates

The process by which the Rotterdam Convention considers and decides whether to list a hazardous chemical in its Annex III (and make its international trade subject to the Convention's PIC procedure) begins when Convention Parties submit Notifications of final regulatory action to ban or severely restrict the hazardous chemical for human health and/or environmental reasons. The Rotterdam Convention's listing process has the following steps:

Notification. Parties to the Rotterdam Convention are expected to notify the Convention when they take a final regulatory action that bans or severely restricts a hazardous chemical for health and/or environmental reasons. They do this using the Convention's standard *Notification Form* accompanied with relevant supporting documentation.

Verification. When the Convention's Secretariat receives a Notification of *Final Regulatory Action*, it reviews the Notification to verify that it contains all required information (as specified in the Convention's Annex I). If the Secretariat *verifies* that Notifications of Final Regulatory Action that ban or severely restrict the same chemical (or family of chemicals) have been submitted by at least one country from each of at least two regions and satisfy all the Convention's Information Requirements, it will forward the verified Notifications to the Convention's Chemical Review Committee (CRC) for its review.

Inter-sessional CRC Activities. The Secretariat circulates verified Notifications and their supporting documents to the CRC's members prior to the CRC meetings. And it offers them an opportunity to comment, in writing. The Secretariat may additionally establish inter-sessional Task Groups to review written comments about Notifications that nominate the same hazardous chemical (or family of chemicals). The Task Groups prepare reports with recommendations for consideration by the CRC as a whole.

CRC Review. The CRC reviews the Notifications it receives, and it considers the written comments and the reports of the Task Groups. For each Notification, the CRC will go through the Convention's four listing criteria, one by one, to determine whether the Notification has fully satisfied each of them.

CRC Recommendation. If the CRC determines that at least one Notification from each of at least two regions satisfies all the elements of all four Listing Criteria, it will recommend to the Convention's Conference of the Parties (COP) that the chemical (or family of chemicals) in question be listed in Annex III. The CRC will also prepare a draft *Decision Guide Document (DGD)* for the COP to consider.

COP Decision. If the CRC decides to recommend a hazardous chemical be listed, both its recommendation and the draft DGD will be placed on the agenda of the next meeting of the Rotterdam Convention's Conference of the Parties (COP) for its consideration and decision. If the COP decides in favor of listing, it will also adopt a Decision Guidance Document. And when this happens, international trade in the hazardous chemical will become subject to the Convention's PIC procedure.

For a more detailed discussion on this topic, including information on the Convention's Criteria and on how Rotterdam Convention Process works, please see the summarized paper's ***Chapter 2: The Convention's Process for Deciding Whether to List Lead Chromates.***