Satisfying Criterion (b): The Risk Evaluation

This presentation covers:

- What a Rotterdam Convention Notification and its supporting documents must include in order to satisfy the Convention's Criterion (b), which requires that the notified regulatory action was based on a risk evaluation.

This PowerPoint Presentation is the 7th in a series of 8 presentations on Lead Chromates and the Rotterdam Convention, prepared by IPEN in order to help NGOs, civil society, and government officials better understand the important role a lead chromate listing by the Rotterdam Convention can play in reducing childhood lead exposure and accelerating global lead paint elimination. For other presentations in this series, please visit IPEN's website.

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IPEN's Campaign to List Lead Chromates

IPEN is a network of over 600 NGOs in more than 120 countries working together for a toxics-free future.

- IPEN has been working with NGOs to promote lead paint elimination in low- and middle-income countries for fifteen years.
- Initiatives by governments and these NGOs has led to the adoption of new lead paint regulation in several countries.
- IPEN-affiliated NGOs in countries that recently adopted lead paint control laws are now encouraging their Governments to nominate lead chromates for a Rotterdam Convention listing.

IPEN's Campaign to List Lead Chromates

The Rotterdam Convention is an international treaty that operates a legally binding Prior Informed Consent (PIC) procedure that applies to international trade in the hazardous chemicals listed in its Annex III.

- The lead paint control regulations that many countries recently adopted impose severe restrictions on the use of lead chromate pigments as ingredients in paints.
- These pigments are the predominant source of lead in lead paints.
- Countries that recently adopted lead paint regulations can submit Notifications to the Rotterdam Convention that nominate lead chromates for a Convention listing.
- A decision by the Rotterdam Convention to list lead chromates can help greatly accelerate the global elimination of all lead paints.

IPEN's Campaign to List Lead Chromates

Those interested in submitting Notifications may wish to review two documents that better explain the listing process and its impact.

Controlling Lead Chromate Pigments: The Case for a Rotterdam Convention Listing. What are Lead Chromates; The Lead Chromate Hazard; Uses of Lead Chromates; and the Impact of a Rotterdam Convention Listing.

Preparing a Rotterdam Convention Notification Listing. Why Countries that Recently Adopted Lead Paint Controls Can Nominate Lead Chromates; the Rotterdam Listing Process; Most Recent Regulatory Actions were based on Risk Evaluations; Establishing Controls on Trade in both Lead Chromates and in Paints that Contain them; How to Satisfy the Convention's Listing Criteria.

The Rotterdam Convention's Listing Criteria

The Rotterdam Convention's Annex II specifies four Criteria that a Notification of Final Regulatory Action must satisfy for it to successfully nominate a hazardous chemical (or well-defined family of hazardous chemicals) for an Annex III listing.

- This presentation addresses how a Notification can satisfy **Criterion (b)**.
- A subsequent presentation adresses how a notification can satisfy the other three Listing Criteria:
  - **Criterion (a)**
  - **Criterion (c)**
  - **Criterion (d)**

Satisfying Criterion (b): the Risk Evaluation

Of all the Convention requirements and listing criteria, it typically is most difficult for a Notification to fully satisfy *Criterion (b)*.

The regulatory actions that were taken by most of the countries that recently adopted controls on lead in paints imposed severe restrictions on the use of lead chromate pigments as ingredients in paints.

- The countries that adopted such regulations can notify the Rotterdam Convention of their Final Regulatory Action to severely restrict lead chromates.
- Such Notifications can nominate lead chromates for a Rotterdam Convention listing if they satisfy the Convention's ***Information Requirements*** (as specified in its Annex I) and if they also fully satisfy the Convention's four ***Listing Criteria*** (as specified in its Annex II).

Satisfying Criterion (b): the Risk Evaluation

For the Notification to satisfy Criterion (b),

> **It must demonstrate that the country's decision to take the notified regulatory action was *justified* by a *Risk Evaluation* that reviewed scientific data and information in the context of the *Prevailing Conditions* in the notifying country.**

The remainder of this presentation will discuss how countries can do this.

Satisfying Criterion (b): the Risk Evaluation

The **Convention's Chemical Review Committee** (CRC) reviews all the Notifications it receives to determine whether they fully satisfy the Convention's four ***Listing Criteria.*** In determining whether a Notification has satisfied Criterion (b), the CRC will review:

- **Whether** the country's decision to take the notified regulatory action was ***based on a Risk Evaluation***.
- **Whether** the information that the risk evaluation relied upon was based on data and findings that were generated according to ***Scientifically Recognized*** methods, principles and procedures.
- **Whether** the risk evaluation took appropriately into account the ***Prevailing Conditions*** in the notifying country.

Satisfying Criterion (b): the Risk Evaluation

In most of the low- and middle-income countries that recently adopted regulatory controls on the lead content of paints:

- Some national entity considered available, science-based information and reached the conclusion that allowing the continued use of lead paints would create an unacceptable risk to the country's human health.
- In response to this conclusion, national authorities enacted regulatory controls on the lead content of paints.

The process by which science-based information was considered and by which this conclusion was reached ***can reasonably be called a risk evaluation***.

Satisfying Criterion (b): the Risk Evaluation

To satisfy Criterion (b), the Notification must:

- **State** that the regulatory action to control lead in paint was *taken to protect human health* and was *based on a risk evaluation*.
- **Include** a short *Summary Description* of the risk evaluation that:
  - Identifies the science-based information and findings upon which the risk evaluation was based,
  - Describes how the risk evaluation's conclusion was reached,
  - Explains how the risk evaluation took properly into account the prevailing conditions in the notifying country, and
  - Tells how the risk evaluation's conclusions were transmitted to the relevant national authorities.

Satisfying Criterion (b): the Risk Evaluation

When the Notification is submitted, it should be accompanied by a ***Risk Evaluation Report*** that:

- Describes, in more detail, how the risk evaluation reached its conclusion that allowing the continued use of lead paints would be harmful to human health in the notifying country,
- Provides references to the sources of the scientific data and findings which the risk evaluation relied upon,
- Demonstrates that the data and findings that the risk evaluation relied upon were generated according to generally recognized scientific methods, principles, and procedures, and
- Fully explains how the risk evaluation addressed exposure to lead from lead paint under prevailing conditions in the notifying country.

IPEN can help prepare *Risk Evaluation Reports*

Different low- and middle-income countries (LMICs) evaluated the risk to human health from exposure to lead from lead paint in differing ways.

But the toxicological and exposure-related information that most of their risk evaluations relied upon were often very similar.

- Most countries relied upon the science-based information that was disseminated by the World Health Organization and by other active partners in the Global Alliance to Eliminate Lead Paint.
- Most countries identified young children (typically children under six years of age) as the vulnerable group that is most harmed by exposure to lead from lead paint.

IPEN can help prepare *Risk Evaluation Reports*

IPEN has reviewed the lead paint risk evaluations that were performed by several different LMIC countries, and it has identified the science-based information that most of them relied upon.

Based on this review, IPEN can help provide:

- Documentation and references to the scientific studies and findings that the science-based information that was often used in lead paint risk evaluations relied upon.
- Insights into how a *Risk Evaluation Report* can demonstrate that the risk evaluation appropriately considered the human health effects from exposure to lead from lead paints under the prevailing conditions in the notifying country.

Conclusion

For a Notification to successfully nominate lead chromates for a Rotterdam Convention listing, it must satisfy Criterion (b). To do this, it must:

1. State that the regulatory action was *taken to protect human health*, and that the decision to take the regulatory action was *based on a risk evaluation*.
2. Include a *Summary Description* of the risk evaluation and *supporting documentation* which, together, can demonstrate that the risk evaluation fully satisfies all element of the Convention's Criterion (b).

Many of the low- and middle-income countries that recently adopted lead paint controls should be able to do both.

What Are Lead Chromates and How Do They Cause Harm?

For Additional information and other *Lead Chromates and the Rotterdam Convention* PowerPoint presentations, please visit IPEN's website. (https://ipen.org/site/listing-lead-chromates-under-rotterdam-convention)

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