Late-Breaking Webinar:

OECD'S Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives

Monday, April 12, 2021
11:00 AM - 12:00 PM ET

WELCOME!

Today's A4 webinar:

OECD'S Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives

Objectives for today:

- Learn about the origins and goals of the guidance
- Understand key elements of the guidance
- Share perspectives about its utility given increased attention on the need for criteria to assist with determining whether an alternative to a chemical of concern is in fact safer

Today's facilitators

Meg Whittaker
ToxServices
A4 Program Committee Co-Chair

Lauren Heine
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Webinar Logistics

- Due to the number of participants on the webinar, all lines are muted
- If you wish to ask a question, please raise your hand or type a question in the Q&A box located in the drop down control panel at the top of the screen
- Questions will be answered to the extent possible during the facilitated discussion
- The webinar is being recorded and will be posted with the slide deck on the A4 website: www.saferalternatives.org
- At the end of the webinar, we will launch a short evaluation survey to help us with future webinars

Introducing the OECD Guidance

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GUIDANCE ON KEY CONSIDERATIONS FOR THE IDENTIFICATION AND SELECTION OF SAFER CHEMICAL ALTERNATIVES

12 April 2021

Eeva Leinala (OECD) and Emily Connor (Abt Associates)

Outline

- Background and Goals of the Guidance
- Main Components of the Guidance
  - Comparative Hazard Assessment
  - Comparative Exposure Assessment
  - Integrating Hazard and Exposure
  - Navigating Tradeoffs and Selecting a Safer Alternative
- Conclusions

OECD ENVIRONMENT, HEALTH AND SAFETY (EHS) PROGRAMME

37 Member countries, many partner countries and other stakeholders work together to develop and co-ordinate activities on chemical safety and biosafety on an international basis. One of the core aspects of the work relates to the Mutual Acceptance of Data.

The main objectives of the Programme are to:

•Assist OECD Member countries' efforts to protect human health and the environment through improving chemical safety and biosafety

•Make chemical control policies more transparent and efficient and save resources for government and industry; and

•Prevent unnecessary distortions in the trade of chemicals, chemical products and products of modern biotechnology.

http://www.oecd.org/chemicalsafety/

Substitution of
Harmful Chemicals

Sustainable Chemistry

OECD RISK REDUCTION Programme

OECD/UNEP Global PFC Group

Working Party on Risk Management

OECD Work on Substitution of Harmful Chemicals

- Goal: Furthering tools and approaches to support decision-making for the substitution of hazardous chemicals

- Outputs:
  - Development of a toolbox to support substitution of hazardous chemicals (launched in January 2015 and ongoing improvement) **www.oecdsaatoolbox.org**
  - Synthesis report from OECD Workshop on Approaches to Support Substitution and Alternatives Assessment (2019)
    - approaches used to support alternative assessments and substitution; the strengths of the approaches and challenges to design and implementation, the link between innovation and progress in substitution and alternatives assessment; and initiatives to facilitate data sharing and other collaborative efforts
  - A Cross Country Analysis of Approaches to Support Alternatives Assessment and Substitution of Chemicals of Concern (2019)
    - describes and gives a list of approaches developed across countries and by different stakeholders to support alternatives assessment and substitution of chemicals of concern.

http://www.oecd.org/env/ehs/risk-management/substitution-of-hazardous-chemicals.htm

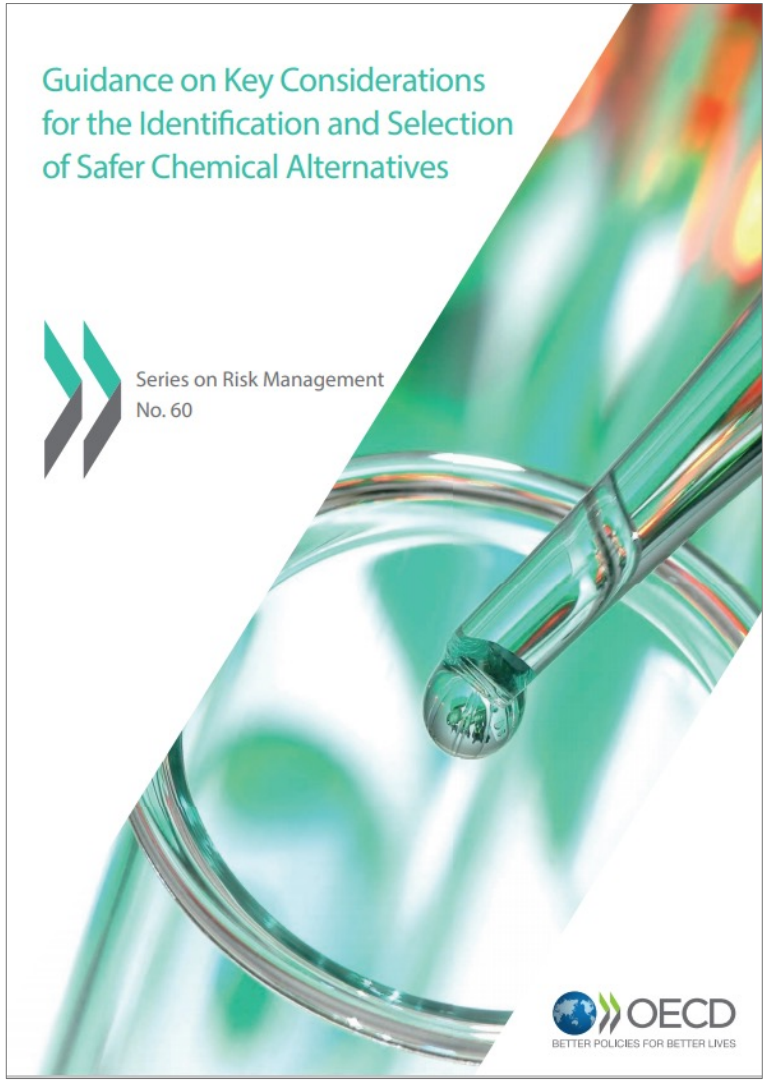
Guidance on what constitutes a ‘safer’ alternative

Guidance on Key Considerations for the Identification and Selection of Safer Chemical Alternatives

Goals of the guidance:

- Define “safer” chemicals in the context of alternatives assessments
- Advance a consistent understanding of the minimum requirements needed to determine whether an alternative is safer

PUBLISHED in March 2021



Guidance Overview

- Section 1: Background
- Section 2: Purpose and Key Principles and Definitions
- Section 3: Minimum Criteria and Recommended Assessment Practices for Safer to Support Substitution Processes
- Section 4: Self-Assessment Checklist
- Section 5: Beyond Safer to More Sustainable Substitution

Purpose and Scope

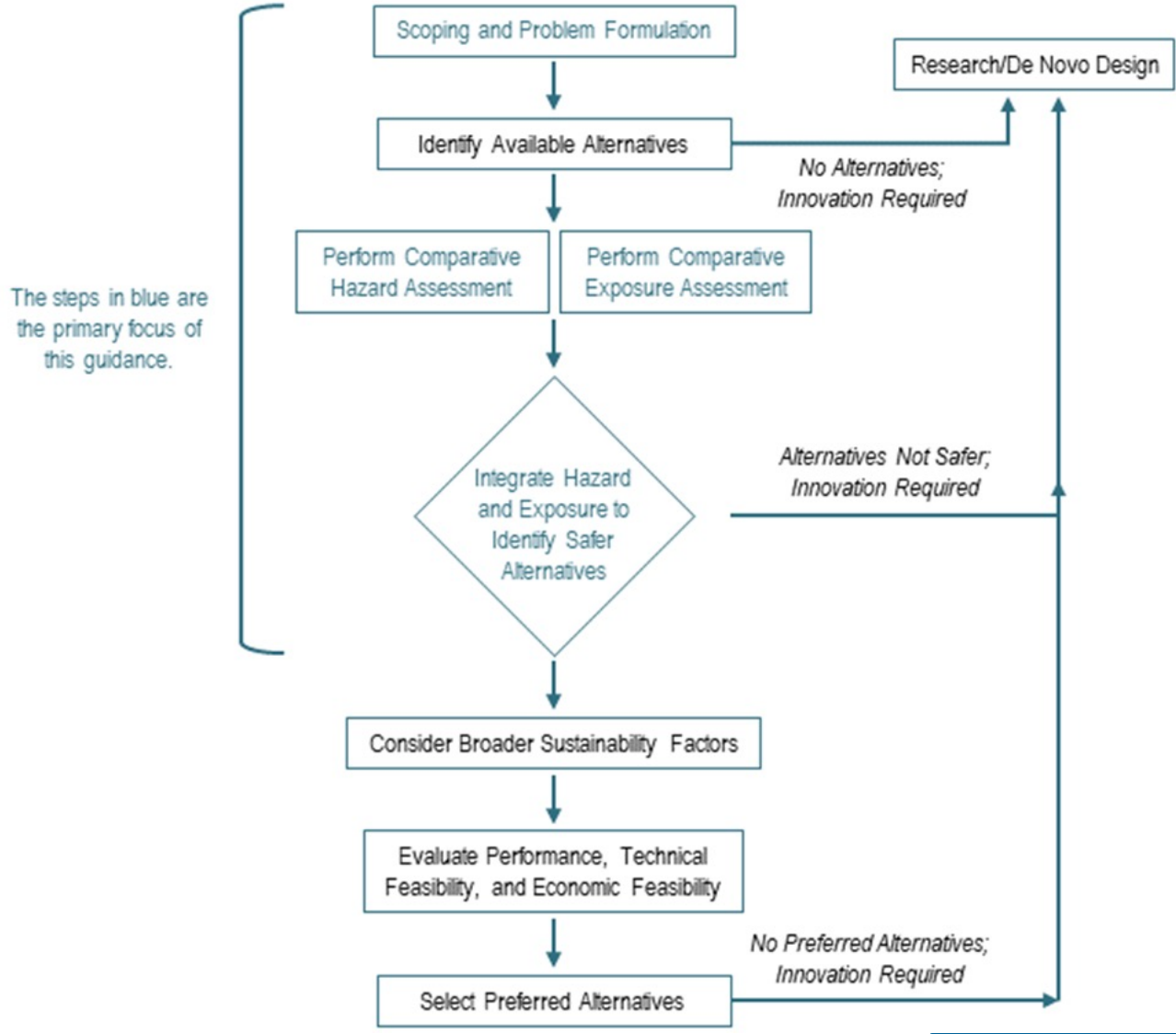
- The Guidance is aimed at establishing and advancing ***minimum requirements (both criteria and assessment practices)*** for safer determinations in four core areas:
  1. Determining the assessment's scope
  2. Comparative hazard assessment
  3. Comparative exposure assessment
  4. Integrating hazard and exposure to select a safer alternative

- In each of these four areas, the Guidance includes recommendations for ***moving beyond these minimum requirements.***

Spectrum of Safer Criteria for the Selection of Alternatives to Priority Substances

Caveats

- Performance, cost and commercial availability are critical assessment components but are not the focus of the guidance
- This guidance does not define or establish criteria for the broader suite of sustainability considerations
- Focus is primarily on single chemical substitution, not “functional substitution” where the alternative could include technology, product or service changes
- Designed to complement any AA framework or decision-making context – i.e., no step-wise process to perform an AA is prescribed



Minimum requirements for:

Determining the Assessment Scope

What are the goals, principles, and decision rules to guide the assessment?

Determining the Assessment Scope

Recommended assessment practice:

- **At a minimum, include stakeholder input and concerns**. Establish an understanding of stakeholder concerns through informal discussions, conducting research (literature and document reviews), attending conferences and listening to stakeholder presentations.
- **Use stakeholder input to help bound the assessment** by including those assessment criteria that are most relevant.
- **Clarify goals, associated principles, assessment criteria and decision rules** to focus the scope of the assessment using stakeholder input to the extent possible.

Minimum requirements for:

Comparative Hazard Assessment

Do specific alternatives present a higher or lower hazard to human health and/or the environment considering an array of human and environmental health endpoints/criteria?

Minimum Requirements for a Comparative Hazard Assessment

A. Use Authoritative Lists to quickly screen out problematic alternatives from consideration before a full hazard evaluation is performed;
B. Select endpoints and apply criteria/thresholds using the Globally Harmonized System (GHS) of Classification and Labeling of Chemicals;
C. Establish transparent decision rules to organize and prioritize information; and
D. Consider data gaps and uncertainty.

A. Use Authoritative Lists

- At a minimum, screen out unacceptable alternatives using authoritative lists

MINIMUM CRITERIA: Use the following Authoritative Lists to screen out unacceptable alternatives based on environmental and human health concerns.	
Montreal Protocol	• List of Controlled Ozone-depleting Substances
Stockholm Convention	• List of Persistent Organic Pollutants (POPs)
World Health Organization's International Agency for Research on Cancer	• List of Classified Carcinogens
Canada	• Toxic Substances List and the Virtual Elimination List
European Chemicals Agency (ECHA)	• Candidate List of Substances of Very High Concern for Authorization • Substances classified as CMR 1a or 1b under Annex VI of CLP
U.S. Environmental Protection Agency	• Toxics Release Inventory's Persistent, Bioaccumulative and Toxic (PBT) Chemicals List and PBT Chemicals under the Toxic Substances Control Act (TSCA) Section 6(h)
U.S. National Toxicology Program	• Report on Carcinogens
State of California	• Proposition 65 List

MOVING BEYOND THE MINIMUM: Consult additional lists as resources allow and as they align with your goals. Example sources of such lists include authorities, NGOs, industry sectors, and academic reviews. There are 200+ restrictive substance lists.

B. Select Endpoints and Apply GHS Criteria

- At a minimum, evaluate the 10 endpoints shown below using GHS criteria

MINIMUM CRITERIA: Evaluate endpoints shown below, using GHS criteria to ascribe level of concern/classification for a given hazard.[1]

Human Health Hazards	Environmental Hazards	Physical Hazards
• Carcinogenicity • Germ cell mutagenicity • Reproductive toxicity[2] • Acute toxicity • Specific target organ toxicity – repeated exposure[3]	• Acute aquatic toxicity • Chronic aquatic toxicity • Bioaccumulation potential • Biodegradability[4]	• Flammability

Notes:

[1]An assessor may need to go beyond traditional sources and types of data, such as in-vitro and in-vivo testing compiled in government databases or scientific journals to using read across, structure activity, and high-throughput data to inform a weight-of-evidence-based decision.

[2]Considers the potential for developmental toxicity

[3]Referred to as Repeated Dose Toxicity in this paper

[4]Referred to as Persistence in this paper

Please see UNECE, 2019 for GHS classification criteria for the above endpoints.

MOVING BEYOND THE MINIMUM: Consider additional GHS and other priority endpoints based on stakeholder engagement, expertise, and data availability.

Human Health Hazards	Environmental Hazards	Physical Hazards
• Neurotoxicity • Specific target organ toxicity – single exposure • Skin corrosion/irritation • Serious eye damage/eye irritation • Respiratory or skin sensitization • Aspiration hazard • Endocrine disruption*	• Mobility • Wildlife toxicity* • Eutrophication* • Greenhouse gas emissions, ozone depletion potential, waste generation, and other sustainability endpoints**	• Corrosivity • Explosivity • Oxidizing properties • Pyrophoric properties • Self-reactivity • Self-heating properties • Emission of flammable gases in contact with water • Other physical hazards: aerosols, gases under pressure, organic peroxides, ergonomics, vibration, noise

**Not included in GHS criteria*

***Please see Section 5 for more discussion on sustainability considerations.*

C. Establish Decision Rules to Select a Safer Alternative

- At a minimum, exclude alternatives classified as "High" concern based on GHS criteria.

MINIMUM CRITERIA
Exclude alternatives that are classified as **"High" concern** based on GHS criteria for: • Carcinogenicity • Germ Cell Mutagenicity • Reproductive/Developmental Toxicity • PBT • vPvB
Please see UNECE, 2019 for classification criteria for the above endpoints.

MOVING BEYOND THE MINIMUM
Level 1: **Exclude** alternatives with a classification of **"High" concern** for the remaining minimum endpoints in Exhibit 6 based on the results of a hazard evaluation using GHS criteria for: • Acute mammalian toxicity • Specific target organ toxicity from repeated exposure • Flammability Level 2: **Exclude** alternatives with **"High" concern** associated with the other priority endpoints listed in Exhibit 6, including: • Human health hazards, such as neurotoxicity, irritation, sensitization, and other human health endpoints • Environmental hazards, such as wildlife toxicity, eutrophication, mobility and other environmental endpoints • Physical hazards, such as corrosivity, explosivity, and others
Please see UNECE, 2019 for classification criteria for the above endpoints.

D. Consider Data Gaps and Uncertainties

- At a minimum, select a specific strategy that best meets your assessment goals, and then **be transparent** in your documentation.
- *Note*: The guidance includes 7 strategies for considering uncertainties (NRC 2014), with pros and cons for each, including:
  - Use external expert knowledge
  - Exclude alternatives with missing data
  - Penalize data gaps

Minimum requirements for:

Comparative Exposure Assessment

Is the alternative preferable, equivalent to, or potentially worse than the priority chemical given the potential for exposure?

Identify Exposure Pathways and Reasonable Use Scenarios throughout the Lifecycle

- Identify potential routes of exposure for the substance and each alternative given its conditions of use

RECOMMENDED ASSESSMENT PRACTICE

Identify potential routes of exposure (such as dermal, inhalation, and ingestion pathways for human health and air, water, and soil pathways for the environment) for the substance that needs to be substituted and each alternative given conditions of use.

Step 1: Based on the scope of the assessment, identify the life cycle stage(s) where concerns for exposure trade-offs may occur. Examples include:

- Chemical manufacturing
- Product manufacturing
- Product use
- End of life
- Reuse in a recycled form

Step 2: Within each life cycle stage, identify potential routes of exposure and receptors given conditions of use and conditions of potential misuse of the substance. This could be accomplished by:

- Engagement with stakeholders (relevant worker, consumer or environmental stakeholders)
- Review of the literature
- Use of conceptual exposure maps (See Greggs et al. 2019 for examples)

Compare Exposure Potential

- Use physical-chemical properties and/or exposure models to compare exposure data for alternatives

MINIMUM CRITERIA AND RECOMMENDED ASSESSMENT PRACTICE
Step 1: Exclude routes of exposure that are unlikely based on measured exposure data or physical-chemical properties such as: • physical state • vapor pressure • molecular weight • water solubility • log k_{ow} • boiling point • melting point • Henry Law's Coefficient • particle size **Step 2:** Qualitatively compare the above exposure data or physical-chemical properties for the relevant exposure routes to identify if the alternative is likely to result in greater, equivocal, or less exposure.
If uncertainty or conflicting information prevents the identification of a safer alternative, collect and use exposure information to better understand use patterns and exposure pathways to assess trade-offs, using commonly used tools and references.

Minimum requirements for:

Integrating Hazard and Exposure Assessment Results

How to Assess Tradeoffs to Select a Safer Alternative?

Integrate Hazard and Exposure Assessment Results

- Transparently document the strategy used to integrate hazard and exposure results.
- *Note: The guidance includes 4 strategies (NRC 2014), with pros and cons for each.*

RECOMMENDED ASSESSMENT PRACTICES: Transparently document strategies used to integrate hazard and exposure results. Use one or more of the strategies listed below:	
Comparison Matrices: For hazard endpoints that are not classified as "low," integrate exposure potential for each alternative being considered as less than (-), equivalent (0) or greater than (+) the chemical being replaced. The resulting heat map can be visually used to integrate the hazard and exposure information.	**Pros:** Useful to have an integrated visual display of all of the hazard and exposure assessment findings. These heatmaps/matrices are useful especially when the assessor is not making a decision (e.g., assessment is generated by government agencies or NGOs) and supports decision-making by other entities. **Cons:** When exposure potential is not equivalent, it will be difficult to use these comparison matrices alone to adjust the hazard assessment findings in light of the exposure assessment results.
Adjusting for Exposure Potential: Focuses on the integration of exposure potential with individual hazard endpoints. This weighting can upgrade or downgrade the severity of a particular hazard (category) based on the potential for exposure information.	**Pros:** Supports further weighting of specific endpoints when considering trade-offs (Exhibit 14). **Cons:** There may be toxicological knowledge and nuances to consider regarding how exposure potential modifies the hazard assessment results.
Narrative Exposure Summary: Focuses on a narrative summary of potential exposure concerns for an alternative to allow the assessor to understand trade-offs.	**Pros:** Simple narrative phases are easy to develop and understand. **Cons:** May not help adequately discern between alternatives.
Descriptive Exposure Phrases: Similar to hazard phrases (such as high, medium, and low), such phrases would help with hazard assessment results provide an indication of how an alternative might increase or decrease exposure compared to alternatives.	**Pros:** A simple characterization that can be used by multiple assessors. **Cons**: May not help adequately discern between alternatives.

Navigate Trade-offs and Make a Decision

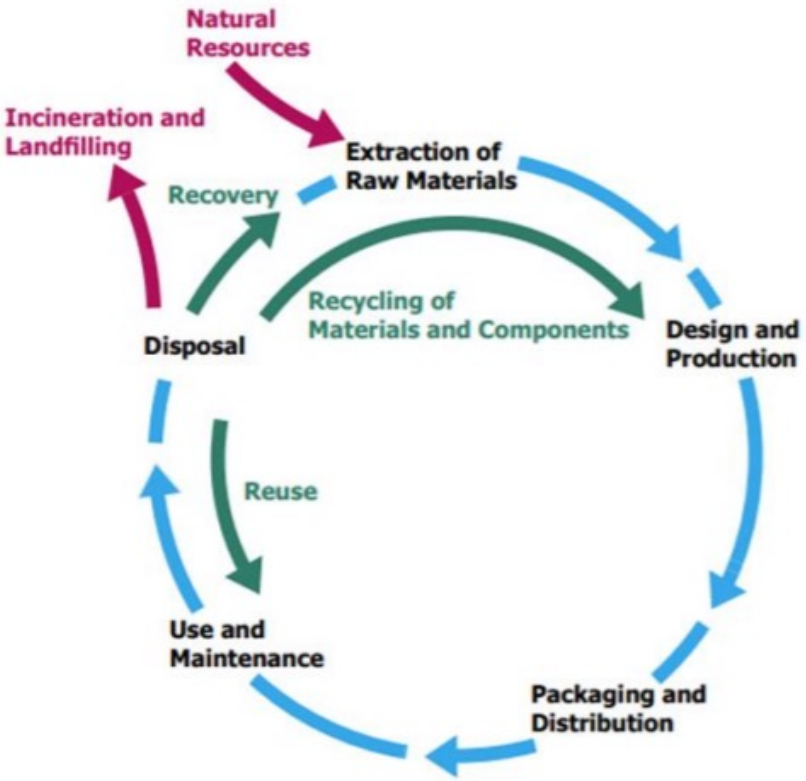
- At a minimum, engage stakeholders and **transparently** document strategies used.
- The guidance includes 6 strategies (NRC 2014), with pros and cons for each, including:
  - Eliminate the alternative if its scores “high” on any hazard endpoint
  - Equal weighting of endpoints
  - Weighted scoring of endpoints
  - Comparative evaluation matrices

Summary of Minimum Requirements

- Clearly document all decisions and strategies
- The minimum set of criteria and practices should not preclude assessors from including more comprehensive approaches in their assessments
- As science advances, these criteria and practices may evolve

Beyond Safer to More Sustainable Substitution

- A growing emphasis on sustainability and product stewardship across OECD delegations
- Section 5 of the Guidance:
  - Discusses sustainability trade-offs
  - Includes resources in identifying, considering, and evaluating broader sustainability impacts
  - Provides an overview of life-cycle aspects relevant to chemical substitution decisions (from the German Environmental Agency)



Thanks for Listening!

Download the Guidance at:
HTTPS://WWW.OECD.ORG/CHEMICALSAFETY/RISK-MANAGEMENT/

Reflections on the Guidance

Q&A

Join A4

A new professional association solely dedicated to advancing the science, practice, and policy of alternatives assessment and informed substitution

Working collaboratively to accelerate the use of safer chemicals, materials, processes, and products.

THANK YOU

ASSOCIATION FOR
THE ADVANCEMENT
OF ALTERNATIVES
ASSESSMENT