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Update on Formaldehyde Regulation and IPBC Registration Review

ILMA Metalworking Fluid Committee

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Arxada

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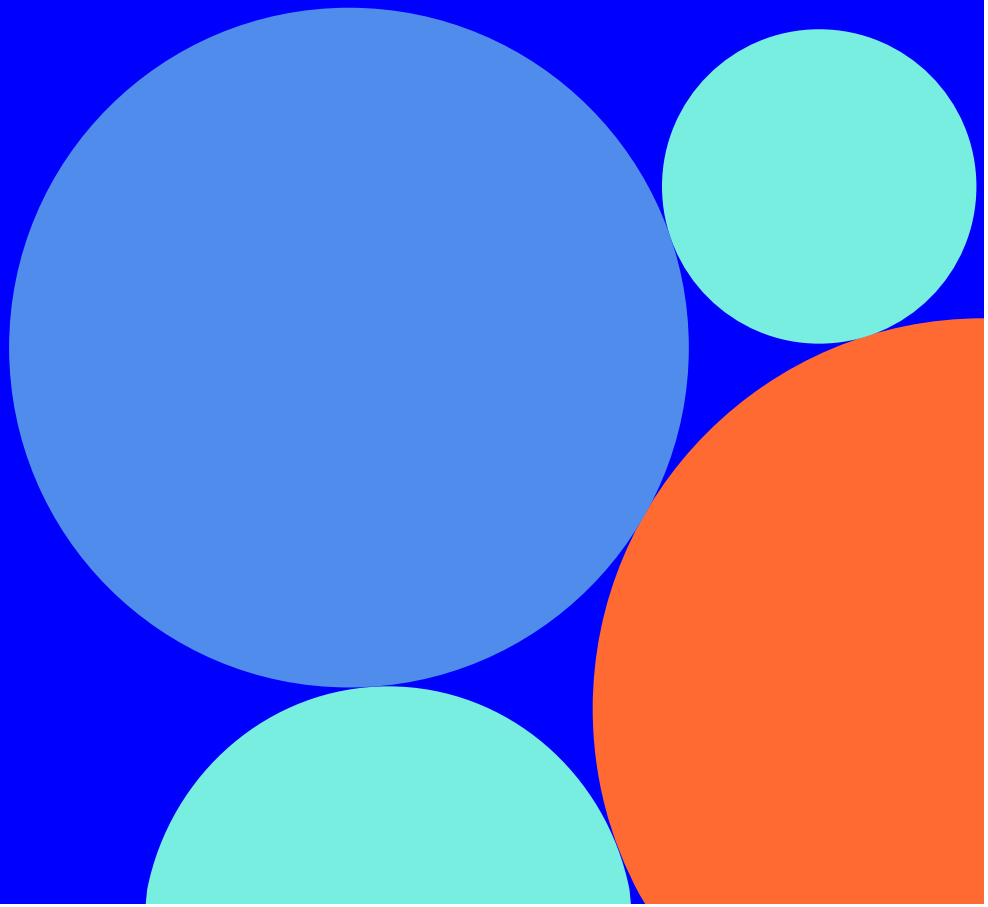

Regulatory Update on Formaldehyde and IPBC

Agenda

Formaldehyde

- 1. Regulatory History
- 2. Current Status
- 3. Implications on 2024 and beyond

IPBC Registration Review

- 1. Office of Pesticides Registration Review Program
  a. Schedule
  b. Current Status
  c. Preliminary Interim Decision (PID)

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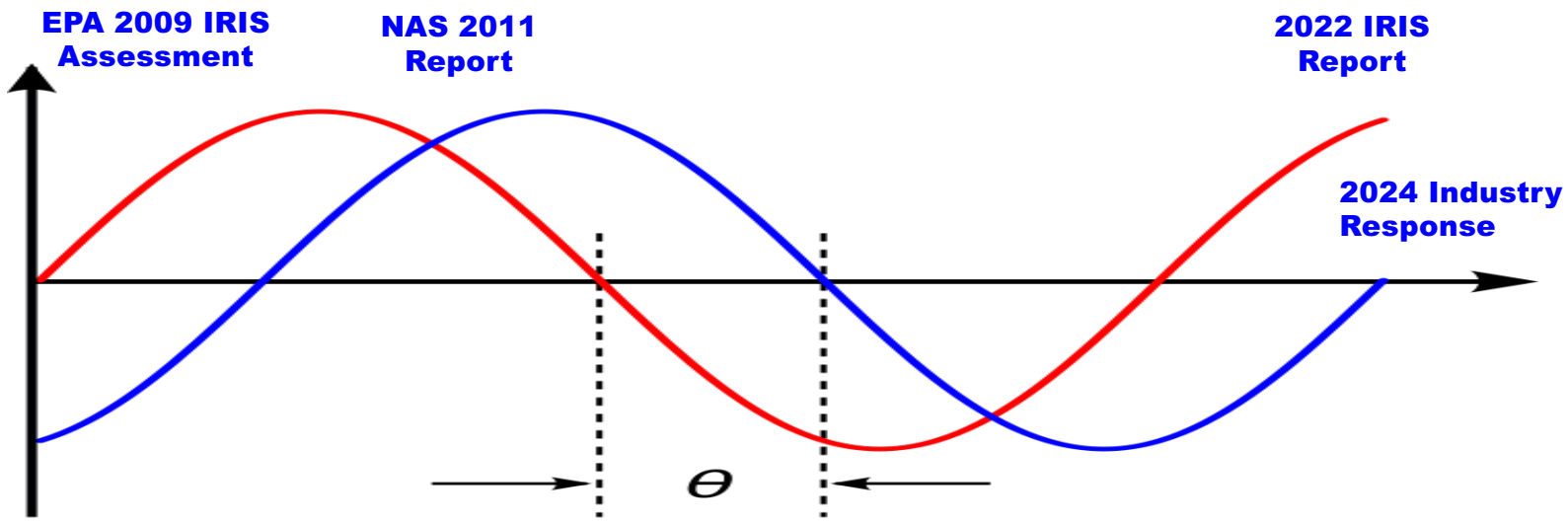
Formaldehyde

Regulatory Update on Formaldehyde

Historical Regulatory Perspective



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Historical Regulatory Perspective:

2011 National Academy of Science Report indicated:

- Lack of mechanistic data and systemic approach;
- “Cherry-picking” of data used in the assessment;
- Lack of use of the most current data for assessment purposes.
- Need for revision of the report was clear,

BUT

EPA NEVER CORRECTED THE 2009 REPORT AND A NEW IRIS REPORT WAS RELEASED IN 2022

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Historical Regulatory Perspective since 2022

2022 IRIS Report highly controversial; National Academy of Science indicated

- EPA is still “cherry-picking” data;
- EPA used a new approach towards systematic review;
- Lack of key data such as mechanistic data;
- Mis-characterization of existing data;
- Cut-off for sources of data was 2017;
- Over 100 new studies (academia/industry) were not incorporated into the assessment
- 2011 concerns never addressed in this assessment
- New concerns raised for cancer (sinonasal LHM’s, NPC, Leukemia);
- New concerns over non-cancer effects (e.g. asthma, reproductive effects)

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Historical Perspective since 2022:

Non-cancer reference concentration comparison between IRIS reports (2009 vs. 2022)

2009 IRIS Report	VS	2022 IRS Report
0.005 mg/m^3 (5 ppb)		0.007 mg/m^3 (7 ppb)

Compared to other regulatory standards:

OSHA 2017 TLV= 0.1 ppm (123 ug/m^3 for 8-hr)

EU SCOEL derived OEL = 0.3 ppm (300 ug/m^3) (inhalation)

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Historical Perspective since 2022:

Draft used as the primary basis for the US EPA OPPT formaldehyde assessment issued in 2023;

Draft used as the primary basis for the 2024 US EPA OPP formaldehyde draft risk assessment;

Industry responded with comments and participated in the EPA OPPT May, 2024 SACC (Scientific Advisory Chemical Committee) public meetings- *ILMA was a participant in the public sector meeting.*

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Current Status

Report was finalized August 19, 2024;

Primary conclusions are:

- Inhaled formaldehyde can cause health effects in humans, most notably respiratory effects. Children and those with respiratory disease appear to be most susceptible;
- Formaldehyde is carcinogenic to humans by the inhalation route of exposure;
- The non-cancer reference concentration (RfC) is 0.007 mg/m3, Confidence in the RfC is high;
- The cancer inhalation unit risk (IUR) is 1.1 x 10-5 per ug/m3 (1.1 x 10-2 mg/m3). Confidence in the IUR is medium.
- Main issue: this document forms the basis of both EPA TSCA and FIFRA risk assessments

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Current Status

What is the EPA IRIS (Integrated Risk Information System) Report?

The IRIS Report does not impose restrictions;

Its prepared to inform regulatory decision making and provide input for occupational exposure levels;

It is being used by OPPTS (TSCA) and OPP FIFRA formaldehyde risk assessments as the basis for establishing cancer and non-cancer effects for each EPA division

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What's next for formaldehyde?

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Current Status

For the first time OPPT (TSCA) and OPP (FIFRA) Offices worked together on a joint project to prepare separate risk assessments.

TSCA draft risk assessment published March 15, 2024;

- 60-Day comment period;
- Final comments submitted by industry May 14, 2024
- Subsequent Scientific Assessment of Chemicals Committee (SACC) public meetings held in May, 2024
- Affects non-pesticidal uses for multiple use scenarios and businesses'

FIFRA Registration Review draft risk assessment published April 10, 2024

- Primarily addresses formaldehyde and paraformaldehyde;
- No mention of approach towards formaldehyde donor adduct chemistries;
  - ✓Troy Chemical Corp. an Arxada company submitted comments to EPA on June 18, 2024

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Current Regulatory Status-2024

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Focus on FIFRA DRA

Main comments addressed:

- Systematic review; failure to utilize the most “up-to date” science ->100 studies not included;
- Reliance on draft IRIS assessment and cancer endpoints;
- How will this inform EPA of exposure concerns (acute, intermediate, chronic)
- Non-cancer endpoints such as asthma, sensitization (induction and elicitation);
- Use of sensory effects for the establishment of acute endpoints (blinking frequency and nasal irritation)-contrary to HSRB comments
- DRA was silent on formaldehyde donor chemistries (only addressed formaldehyde and paraformaldehyde

How will EPA assess these products?

Will models be used (e.g. WPEM)?

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Next steps in formaldehyde regulation

Will science play any role in the assessment of formaldehyde?

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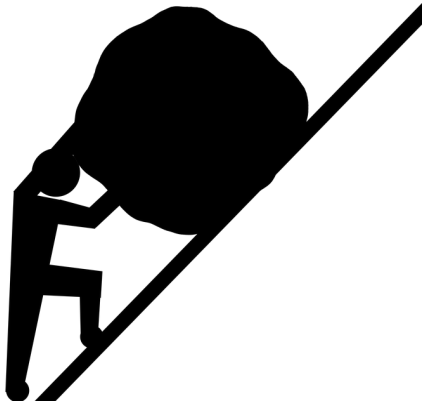
Current Status-2024

Next steps:

Two sets of actions: What we know and potential actions

- What we know:
- EPA will respond to both TSCA and FIFRA risk assessment industry comments:
- EPA could finalize their TSCA assessment and issue a PID this calendar year;
- Industry will have another opportunity to comment via TSCA and FIFRA
  - Representatives of the SACC have indicated their disagreement over EPA's conclusions amongst them:



Lack of a holistic approach/selection of points of departure and foundational studies

- Potential actions:
  - Stars are lining up for a lawsuit and proposed stay of current regulatory levels

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Summary

Timing and Impact to the End-User Community:

EPA could finalize the TSCA Risk Assessment and Pesticide Assessment before end of CY 2024

EPA would use the IRIS assessment to establish new regulations for the workplace substantially lower than current levels.

Before end of CY2024 EPA could issue a Preliminary Interim Decision for Formaldhyde donor chemistries based on their new regulatory thresholds.

Before end of CY 2024 new exposure assessments could occur for MWF biocides based on indoor air modelling with potentially new workplace restrictions.

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Conclusion:

Regulation is following separate but parallel tracks in the U.S. versus EU and ROW.

In the EU formaldehyde is being scrutinized for ED and cancer;

The ROW will follow the EU lead

→ Arxada continues to invest and support formaldehyde releaser chemistries globally

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IPBC

Regulatory Update on IPBC

IPBC and Registration Review

Update on recent OPP Registration Review activities

Arxada's response

Implications to the MWF industry

Timetable

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EPA Registration Review Process:

- Periodic review of all registered pesticides --occurs every 15 years
- Docket Opening - PWP
- Focus Meetings
- Final Work Plan – FWP
- Issue Data Call-In
- Draft Risk Assessment
- Proposed Interim Decision or Proposed Final Decision
- Interim Decision or *Final Decision
- Risk mitigation/label changes

*The final decision may be preceded by an interim decision. The conclusion of a particular registration review occurs once a final decision is issued.

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Registration review program

Delays due to resource constraints let to delays in issuance of the DRA

- DRA was delayed over 1.5 years
- DRA was issued by mistake in March 2024
- DRA was officially issued by EPA May 16, 2024
  - 60 day comment period
  - Response coordinated amongst the NA IPBC Task Force consisting of:
    - Troy Chemical Corp. an Arxada company;
    - Lanxess Corp.;
    - Thor Specialties inc.

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IPBC DRA Main Findings/Concerns:

Toxicology

- Toxicology endpoints for inhalation and dermal exposure established for risk assessment purposes;
- Cancelled the requirement for a comparative thyroid subchronic study

Environmental Effects (based on screening approach):

- Concerns for all taxa based on current ecotoxicity and environmental fate data;
- Uses of most concern were: MWF's, exterior paint uses, pulp and papermills based on the assumption that there is direct discharge to surrounding waters from industrial activity.

Exposure Assessment

- Occupational
  - Unacceptable inhalation and dermal risks for open pour liquids, powders, airless spray and MWF's
- Residential
  - Unacceptable inhalation and dermal risks for paint use, sprays/wipes, mopping of floors

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IPBC DRA Main Actions/Findings/Concerns:

Based on the exposure concerns MWF risks are unacceptable for a number of end uses.

Focus on derived toxicological inhalation and dermal endpoints. Can they be revised?

Clear EPA erred in their assessment of MWF's due to:

- Based on a surrogate use for inks at a maximum rate of use 10,000 ppm;
- Assumed no POTW or on-site treatment of MWF waste;
- Assumed direct discharge into surrounding bodies of water;
- Assumed no degradation of IPBC;
- Did not factor degradates exposure into the assessment

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IPBC DRA Main Actions/Findings/Concerns:

IPBC TF used different revised inhalation and dermal toxicity endpoints which affected the negative risk assessment conclusions for MWF's;

- Revised the maximum use rate for MWF's from 10,000 ppm to 2500 ppm;
- Provided information on degradate ecotoxicity;
- Provided information from ILMA sources on on-site remediation of MWF wastes
  - No POTW treatment;
  - EPA assumed direct discharge into surrounding waters;
  - No degradation;
  - Most sensitive ecotoxicity endpoints used for POD's
- With these revisions MWF's pass the occupational risk assessment.

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IPBC DRA Main Actions/Findings/Concerns:

IPBC TF DRA comments submitted to the EPA on July 19, 2024

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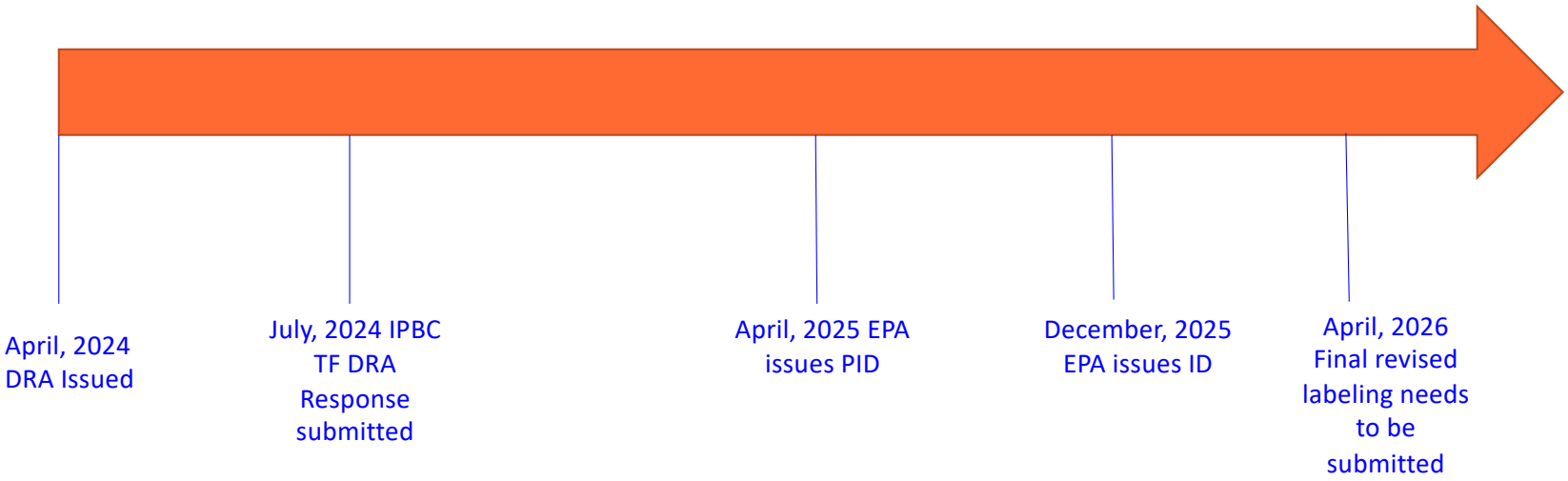
Summary

IPBC Registration Review Timeline



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Impact and Timing:

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Worst case:

EPA rejects DRA comments and previous errors and moves to restrict MWF use;

Results in label revisions due in April, 2026;

Negotiate 18 months for using up old labeling

Best case:

EPA accepts DRA Comments and revises labeling and use restrictions;

New revised label language incorporated April, 2026;

No change to current uses and application rates for MWF's

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Delivering added-value to customers

Sustainable offerings to match the regulatory landscape

- Innovative product offerings, favorable health and environmental safety profiles, securing use, managing risks

Comprehensive regulatory support

- Single point of contact, global support, regional presence, coordinated hazard assessment, global product registration strategies

Best in class science and technical expertise

- Experts across all regulated markets, strong study databases, up-to-date risk assessments

Advocating your needs up to highest political levels

- Strong presence in advocacy groups and direct contact to decision makers, authorities and agencies

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Arxada Regulatory Affairs

Delivering Value Added to Customers
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Thank You!