Review of the ECHA **'PVC and its Additives'** Investigation Report

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Views expressed in this presentation are those of the author, not of Eastman Chemical Company

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Agenda

1. Background of the investigation
2. Calls for Evidence (CfE)
3. Published report
4. Assumptions and deficiencies
5. Conclusions and path forward

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Background of the investigation

2020 — European Commission asked RAMBOLL Germany to conduct a comprehensive review of PVC

2022/2 — "The use of PVC in the context of a non-toxic environment" was published

2022/5 — European Commission 'requests' ECHA to perform an investigation into potential risks to human health and the environment from PVC and its additives

My conclusions from the Ramboll report:

- Nearly every aspect of the report was biased and outdated

- Ignored the progress made in the manufacturing process, specifically the shift away from hazard-classified additives, but also the improvements in worker safety

- But it was enough to get the EC to have ECHA dive deeper into PVC and its main additives

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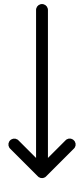
Calls for Evidence

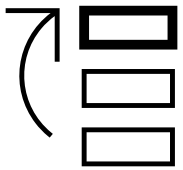
Call for Evidence 1: completed 9 September 2022

470 additives

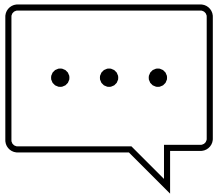
identified as used in PVC formulations/products



Make list manageable



Submit comments to prioritize



Only 17 comments received

Reduced to 63 Additives in Focus

21 stabilisers + 30 plasticisers + 12 flame retardants

european plasticisers

vinyl plus® COMMITTED TO SUSTAINABLE DEVELOPMENT

ESPA European Stabiliser Producers Association

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Call for Evidence 2: 2/11/2022 – 6/1/2023

Purpose of CfE2:

- Gather data on the applications and volumes for each of the 'additives in focus'
- Included a grouping strategy that ECHA expected to use during the investigation

My conclusions

ECHA made categorization mistakes, especially with plasticisers	TEHTM and DEHT grouped with ortho-phthalates.	Led to confusion and consternation in the market.*
77 stakeholders responded to CfE2	Due to competition law concerns, trade groups could not provide the requested volume data so individual companies supplied this data.	

*Several comments helped clarify the mistakes and ECHA did revise the list starting with CfE3

Call for Evidence 3: 1/2/2023 – 31/3/2023

Purpose of CfE3:

- Called for alternatives to the 'additives in focus' and PVC itself

My conclusions

ECHA failed to understand that most of the additives in focus were ***already*** successful and safe alternatives

No need for alternatives to substances that work perfectly well and are non-hazardous!

- Cadmium and lead stabilisers ----> non-hazardous zinc and calcium
- Low molecular weight ortho-phthalates --> non-hazardous DINP, DINCH, and DEHT

81 stakeholders responded to Cf3

I can't think of anything nice to say about CfE3…

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Report published: ECHA published late November 2023

Obvious that ECHA strayed from a SCIENTIFIC approach in favor of an EXPEDIENT approach

ECHA assumed that any 'potential' hazard was an actual hazard and risk

ECHA identified all additives as risks to environment:

- "…based on a pragmatic approach applied in the absence of a more complete set of data."
- Despite most of the additives having complete REACH dossiers and a clear lack of environmental toxicity.

ECHA seemingly ignored most of the data submitted

- Several examples where existing REACH dossier data and submitted data were not considered

Report had over 500 pages and 6 appendices

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Report published: Positive findings from ECHA

ECHA acknowledges:

- That replacing PVC in all uses would be costly and with no guarantee that the replacement(s) would be safer
- That the production of PVC already has adequate controls, based entirely on voluntary industry initiatives, to protect workers, consumers, and the environment

"This information seems then to indicate that the operational conditions and risk management measures implemented in the VCM/PVC industry are adequate and effective to control the risk for workers from EDC and VCM."

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Result of expediting: assumptions and deficiencies

EHCA made many assumptions	PLASI model was used for additive release predictions - PLASI uses polypropylene at its core • PVC and PP are nothing alike
Ignored existing data	• There is existing toxicokinetic data in the REACH dossiers of many of the additives • There is also biomonitoring data available on some key additives that directly contradict ECHA's assumptions
Led to faulty conclusions	ECHA relied on a faulty model instead of actual data

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Result of expediting: assumptions and deficiencies

EHCA made many assumptions	Assumed that PVC microplastics* and all additives are very persistent and bio-accumulative and therefore environmentally hazardous
Ignored existing data	Their assumptions are directly disproven by existing data in the REACH dossiers
Led to faulty conclusions	ECHA suggests regulatory actions to minimize release of PVC and the prioritized additives despite a lack of environmental hazards

*Report acknowledges that PVC makes up a very small amount of microplastics

ECHA report: major conclusions

Concluded that regulatory action needed to minimise risks from:

Ignored existing risk assessments

ortho-phthalates	Existing assessments show that DINP and DIDP **do not need to be replaced**
organotin substances	Existing assessments from around the world showing **no problem with organotins**
PVC microplastics	**Ignoring lots of existing regulations** on recycling centers and landfills

Concluded that follow-up on flame retardants used in PVC as already proposed in ECHA's strategy on flame retardants.

No specific recommendation

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What this means and what to do next…

This report will likely be used for future restriction actions

- ECHA's own words are a primary argument to NOT rely on this report:

> "not to wait until each of these substances (or subgroups) have gone through the steps of CLH, SVHC or even data generation before a restriction would take place"

- This is outside the established legal pathway in REACH Article 68
- Sets a dangerous precedent for future restriction proposals
- Industry groups and companies actively discussing the flawed report with appropriate member state authorities and the European Commission

1. Contact your member state competent authorities
2. Educate them on the deficiencies of this report
3. Ask for support in encouraging European Commission to require additional work BEFORE the ECHA initiates the proposed restrictions

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Questions?

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