



Welcome

Regulatory Developments on the Horizon in RoHS and Product Safety

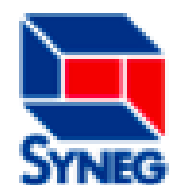
07 December 2021

Presenters: Joyce Costello & Valentina Marchetti



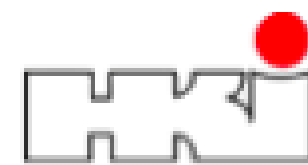
European Federation of
Catering Equipment Manufacturers

FRANCE



syneg.org

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EFCEM and Compliance & Risks Join Forces

Compliance & Risks and EFCEM partner to support catering equipment manufacturers get compliant products to market faster

EFCEM

European Federation of
Catering Equipment Manufacturers

- Advocates & influences current legislation
- Anticipates regulations
- Active in the formulation of standards for the industry



compliance & risks

- End-to-end global regulatory solutions provider
- Regulations, standards & requirements management
- Reliable legislative information, insights & actions

At Compliance & Risks

We help our clients monitor and manage regulations, standards and all other requirements to better mitigate risk.

- Brand protection
- Provide increased market access
- Peace of mind
- Future proofing of the business by aligning with global trends

Benefits for your Team

- **Sooner:** advanced warning of trends and proposed regulations
- **Faster:** understanding of regulations that matter with structured content, English summaries and the support of our regulatory compliance experts and knowledge partners.
- **Better:** all relevant content in one platform, along with the team's analysis and actions

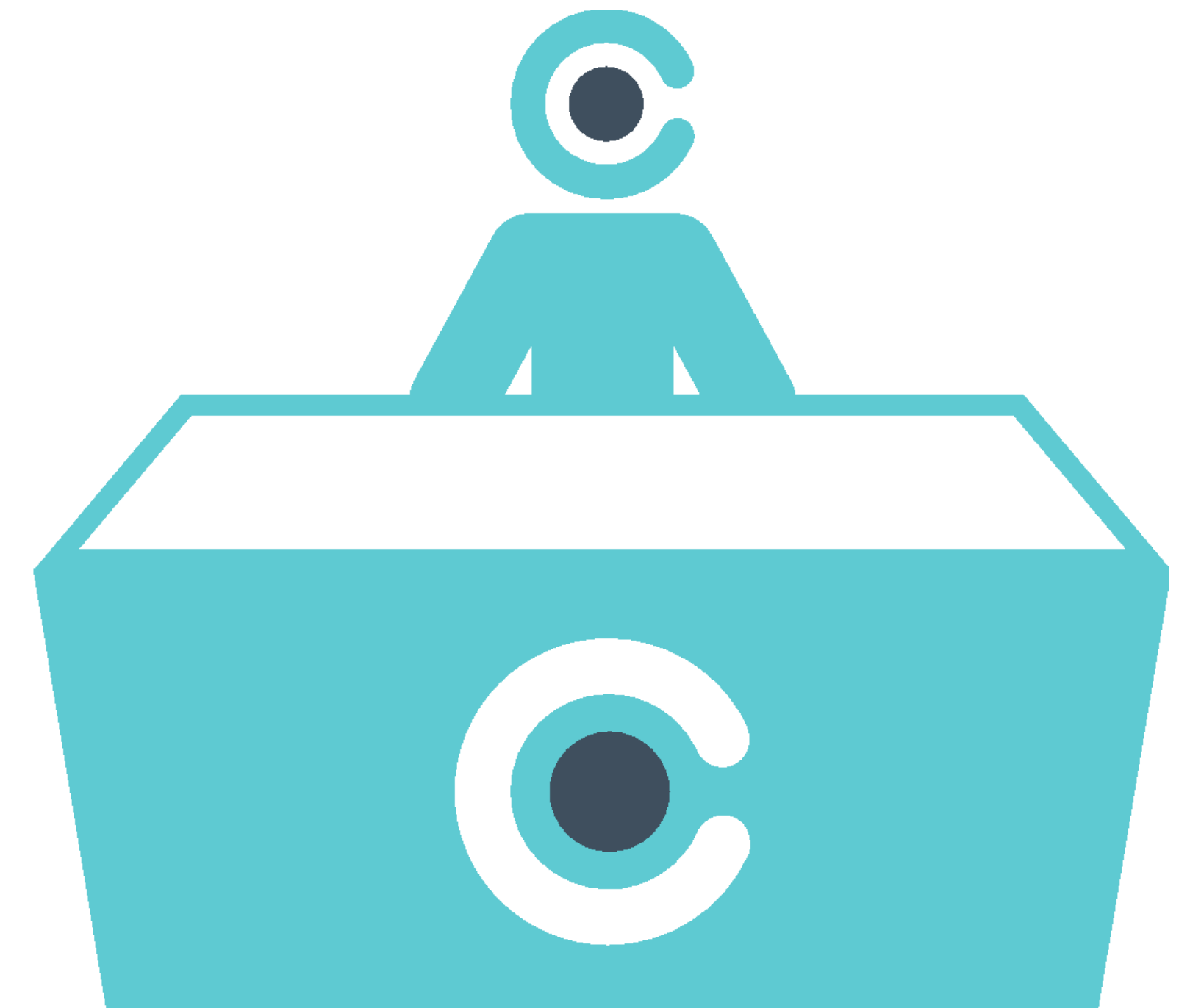
Answering Your Questions

Ask Our Experts

- Premier access to our global regulatory compliance team
- Your questions answered about regulations

Knowledge Partners

- Our global network shared with you
- Legal, business, supply chain and environmental specialists
- Providing 'on the ground' expert knowledge on hot topics
- Breaking news and analysis via your alerts



Chemicals in Products

Topics covered

- US EPA TSCA Restriction of PIP 3:1
- EU RoHS Recast and Possible Restrictions of MCCPs and TBBP-A
- RoHS-like Regulations: Global Update

US EPA TSCA Restriction of PIP 3:1

On January 6, 2021, the U.S. Environmental Protection Agency (EPA) published final rules under Toxic Substances Control Act (TSCA) Section 6(h) for the restriction of five persistent, bioaccumulative and toxic (PBT) chemicals. These chemicals include:

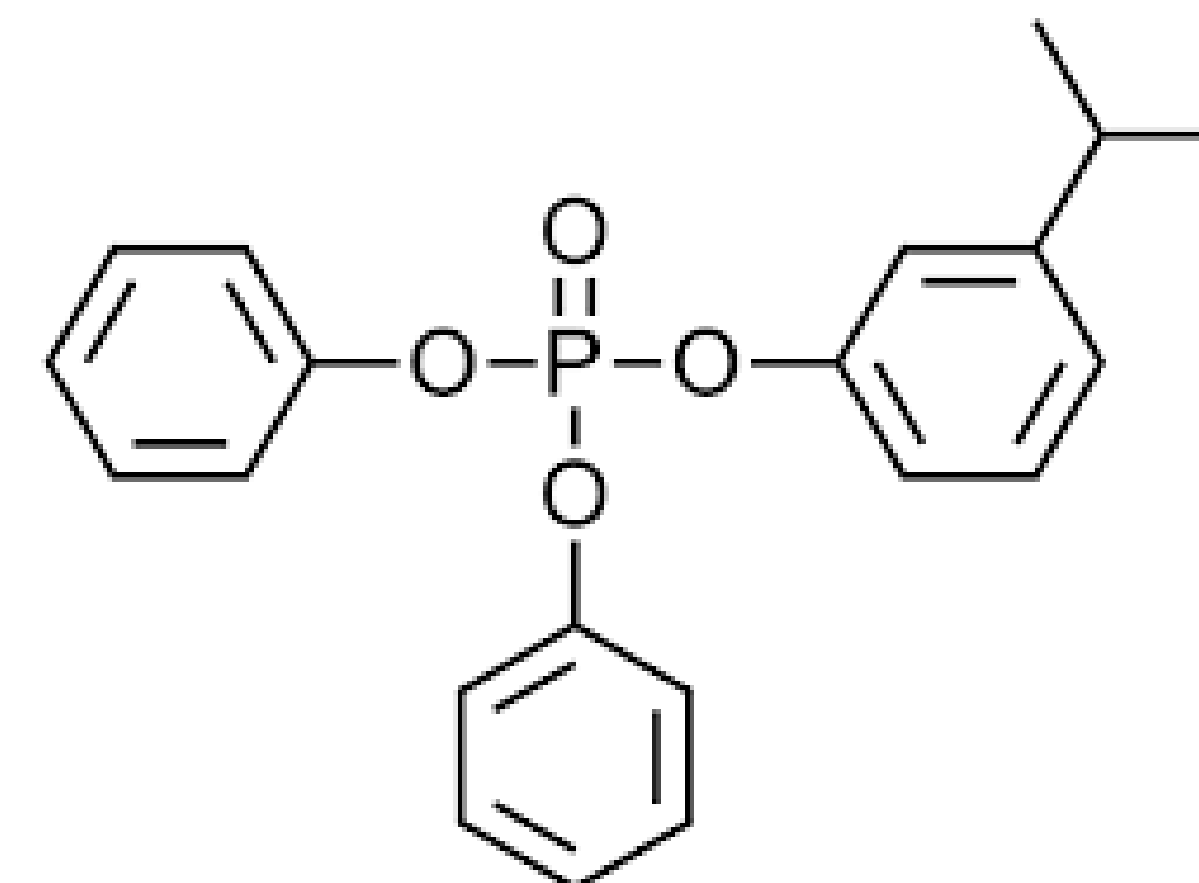
- PIP (3:1) (phenol, isopropylated phosphate (3:1), CAS 68937-41-7)
- DecaBDE (decabromodiphenyl ether, CAS 1163-19-5)
- 2,4,6 TTBP (2,4,6-tris(tert-butyl)phenol, CAS 732-26-3)
- HCBD (hexachlorobutadiene, CAS 87-68-3)
- PCTP (pentachlorothiophenol, CAS 133-49-3)

➤ Of the five listed substances, **PIP (3:1)** have the greatest impact in many industries (i.e.: **electrical appliances**, electronics, industrial products, etc.).

➤ **EPA identified uses:** PIP (3:1) is used as a plasticizer, a **flame retardant**, an anti-wear additive, or an anti-compressibility additive in hydraulic fluid, lubricating oils, lubricants and greases, various industrial coatings, adhesives, sealants, and **plastic articles**. As a chemical that can perform several functions simultaneously, sometimes under extreme conditions, it has several distinctive applications.

➤ **Identified Hazards** – PIP (3:1) is toxic to aquatic plants, aquatic invertebrates, sediment invertebrates and fish. Data indicate the potential for reproductive and developmental effects, neurological effects and effects on systemic organs, specifically adrenals, liver, ovary, heart, and lungs.

PIP (3:1)



What are the requirements on companies under the PIP 3:1 final rule?

- **Prohibition**: all persons are prohibited from all processing and distributing in commerce of PIP (3:1), including PIP (3:1)-containing products or articles after **March 8, 2021**, unless exempted.
- **Recordkeeping**: After **March 8, 2021**, persons who manufacture, process, or distribute in commerce PIP (3:1) or PIP (3:1)-containing products or articles must maintain, for a period of three years, ordinary business records, related to compliance with the prohibitions and other provisions.
- **Prohibition on releases to water**: After **March 8, 2021**, all persons are prohibited from releasing PIP (3:1) to water during manufacturing, processing and distribution in commerce of PIP (3:1) and PIP (3:1) containing products.
- **Downstream notification**: Each person who manufactures, processes or distributes in commerce PIP (3:1) or PIP (3:1)-containing products for any use after **July 6, 2021**, must, prior to or concurrent with the shipment, notify persons to whom those are shipped, in writing, of the restrictions described under the rule.

US EPA TSCA Restriction of PIP 3:1 amendment

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New compliance deadline: March 8, 2022
Proposed extension to October 31, 2024
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US EPA TSCA Restriction of PIP 3:1 amendment

What's going on since the publication of this final rule?

Shortly after the publication of the January 2021 final rule, a wide variety of stakeholders from various sectors, started raising concerns about the 8 March 2021 compliance date in that final rule for the prohibition on the processing and distributing in commerce of PIP (3:1) for use in articles and PIP (3:1)-containing articles. These stakeholders contended that they needed significantly more time to:

- identify whether and where PIP (3:1) might be present in articles in their supply chains (lack of data),
- find and certify alternative chemicals, and
- produce or import new articles that do not contain PIP (3:1).

➡ On 8 March 2021, **EPA issued a No Action Assurance (NAA)** to avoid supply chain disruption, i.e.: *EPA will exercise its enforcement discretion to not pursue enforcement actions for violations* regarding the prohibition of processing and distribution of PIP (3:1), PIP (3:1) for Use in Articles, and PIP (3:1)-containing articles. The NAA expired on September 4, 2021.

➡ On 16 March 2021, **EPA published a notification and request for comments** on the five final PBT rules in general and, more specifically, on the compliance date issues with respect to PIP (3:1)-containing articles that had been raised by stakeholders.

US EPA TSCA Restriction of PIP 3:1 amendment

➔ On 21 September 2021, EPA issued a final rule extending the compliance dates of prohibition and associated recordkeeping requirements for manufacturers, processors, and distributors of **certain PIP (3:1)-containing articles**, and the PIP (3:1) used to make those articles to **March 8, 2022**. EPA advised that this final rule was providing a necessary short-term extension to avoid immediate and significant disruption in the supply chains and to allow EPA additional time to further evaluate the need to again extend the compliance deadlines for PIP (3:1).

Extract from the supplementary information section of the amendment:

Does this action apply to me?

*You may be potentially affected by this action if you manufacture (including import), process, distribute in commerce, or use phenol, isopropylated phosphate (3:1) (PIP (3:1)), or PIP (3:1)-containing articles, especially **plastic articles that are components of electronics or electrical articles**.*

The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include: [...]

- *Machinery Manufacturing (NAICS Code 333);*
- *Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing (NAICS Code 333415);*
- *Small Electrical Appliance Manufacturing (NAICS Code 335210);*
- *Major Household Appliance Manufacturing (NAICS Code 335220); ...*

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On 28 October 2021, EPA published a proposed rule to **extend the deadline** for abovementioned requirements **further to 31 October 2024**.

- ➡
- ❖ The proposal is open to **comments until December 27, 2021**.
 - ❖ The proposed rule provides a description of the specific kinds of information the agency requires to support further extensions of the compliance date, like specific uses of PIP (3:1) in the supply chains and concrete steps taken to identify, test and qualify substitutes for these uses, etc.
 - ❖ In the proposed rule EPA also announced its intention to commence a new rulemaking effort on PIP (3:1) and the other four chemicals that have been regulated under TSCA section 6(h). This review is expected to culminate in **another proposal in 2023**.

What do we know about the next RoHS Recast?

✓ *Timeline*

The European Commission plans to publish a **Roadmap** and open a **Public consultation** on the next RoHS Recast (“RoHS 3” maybe?) **within the end of 2021**, which is expected to be adopted by **Q4 of 2022**.

The **Proposal for a Directive** will be presented to the European Parliament and Council for the legislative debate.

✓ *Potential content*

2 consultation projects have been completed in 2021 providing potential inputs for the next Recast.

Review: Restriction of the use of hazardous substances in electronics

[Have your say](#) > [Published initiatives](#) > Review: Restriction of the use of hazardous substances in electronics

In preparation

UPCOMING

Roadmap

FEEDBACK: UPCOMING

Public consultation

Planned for

Fourth quarter 2021

FEEDBACK: UPCOMING

Commission adoption

Planned for

Fourth quarter 2022

FEEDBACK: UPCOMING

About this initiative

Summary

EU rules limit the use of certain harmful substances in electrical and electronic equipment in order to protect human health and the environment and ensure proper functioning of the internal market. The initiative will simplify and increase the efficiency of the current rules and improve their enforcement.

Topic

Environment

Type of act

Proposal for a directive

Roadmap

FEEDBACK: UPCOMING

Public consultation

FEEDBACK: UPCOMING

Planned for

Fourth quarter 2021

Commission adoption

FEEDBACK: UPCOMING

Planned for

Fourth quarter 2022

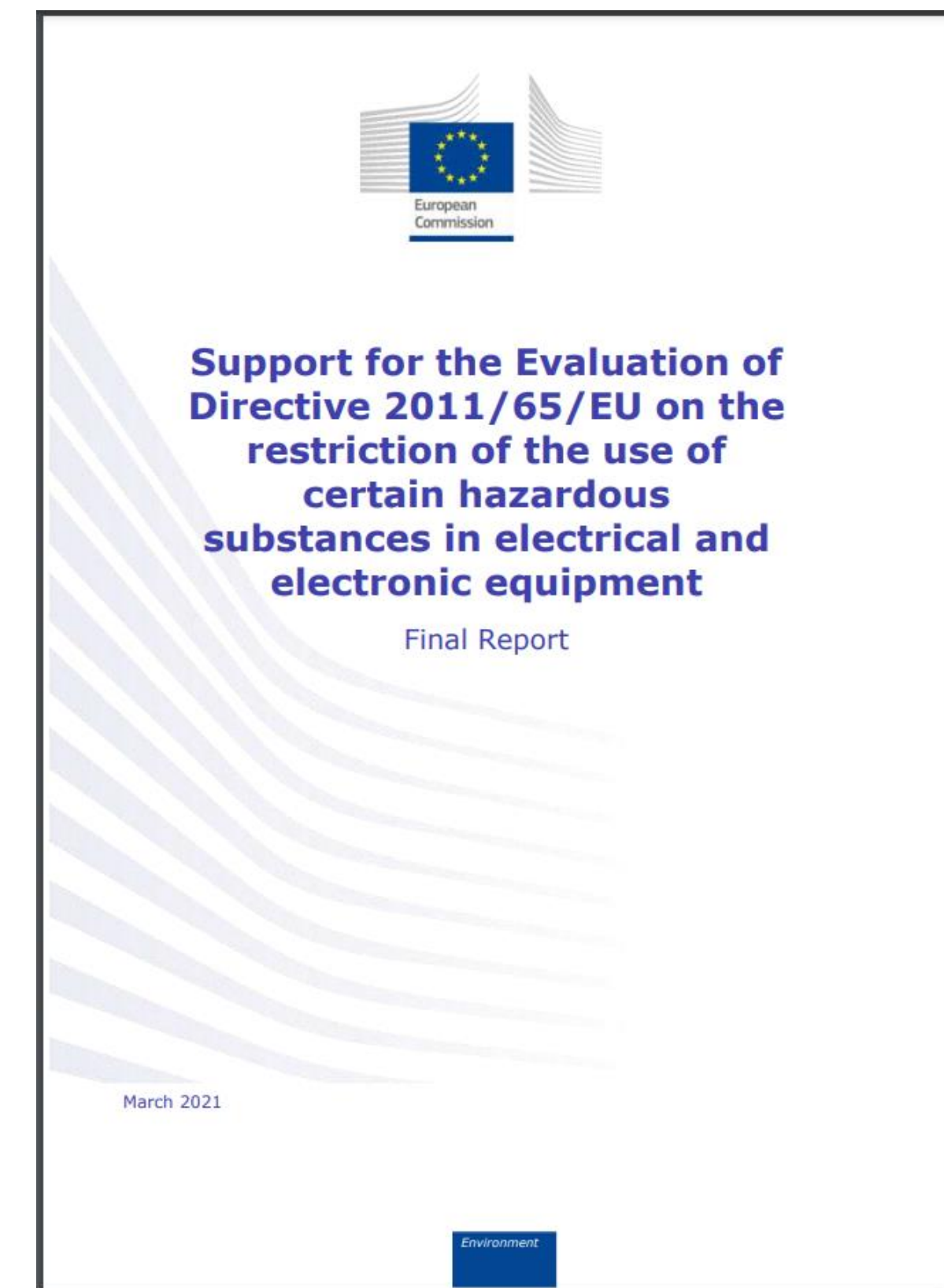
Link to monitor the roadmap to be notified and submit comments:

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13137-Review-Restriction-of-the-use-of-hazardous-substances-in-electronics_en

- Article 24(2) of the EU RoHS 2 Directive requires the Commission to carry out a general review of the Directive itself, and to present a report no later than 22 July 2021 to the European Parliament and the Council accompanied, if appropriate, by a legislative proposal.
- Third-party consultants Ecorys and Ramboll conducted the study on behalf of the European Commission.
- On April 14, 2021, the European Commission published the **final report on the evaluation of the Restriction of Hazardous Substances (RoHS) Directive**.
- The study provides an assessment of the Directive's effectiveness, efficiency, relevance, coherence, and its EU added value and pay attention to identifying opportunities for simplification

About the RoHS evaluation initiative:

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1891-Hazardous-substances-in-electrical-electronic-equipment-evaluation-of-restrictions_en



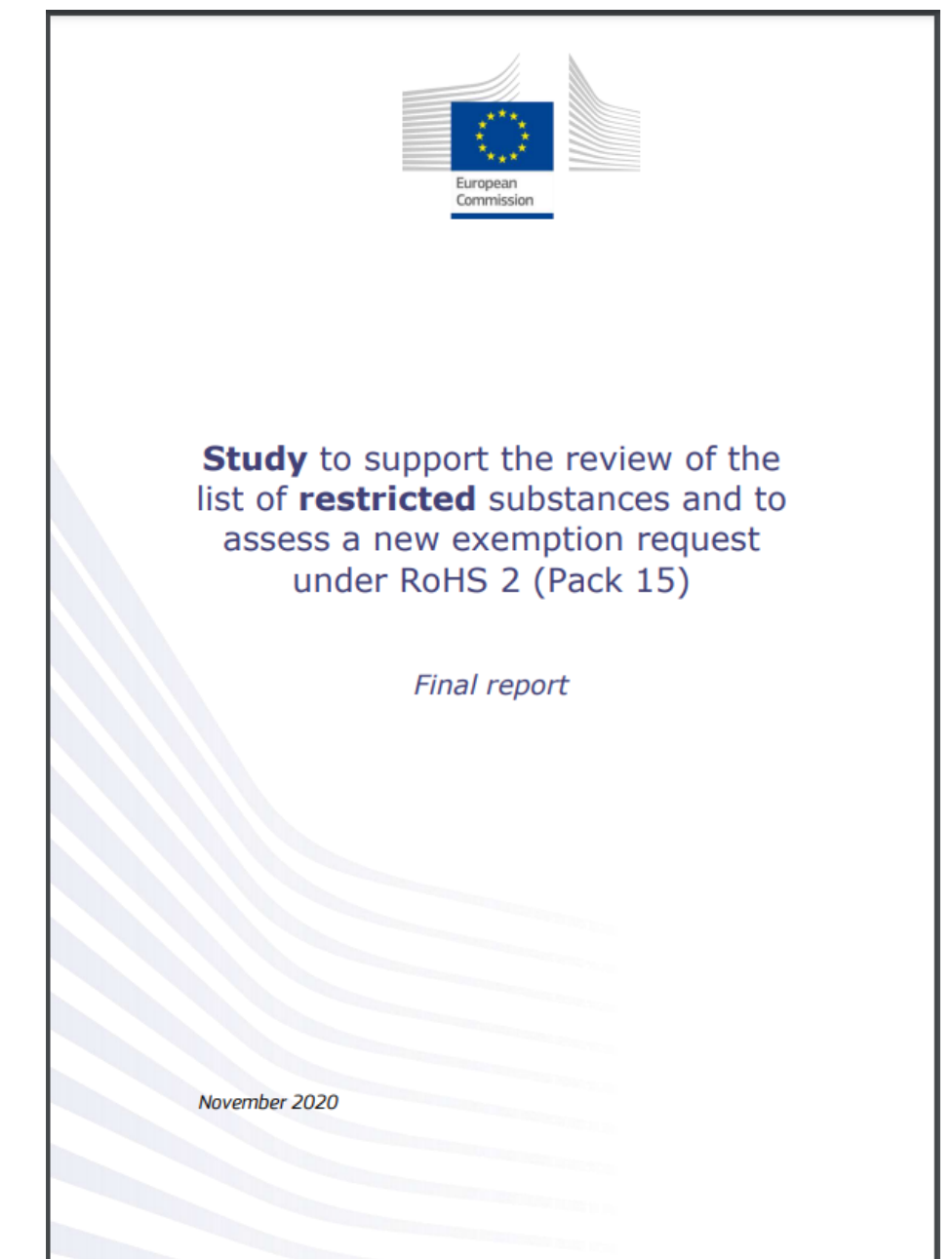
<https://op.europa.eu/en/publication-detail/-/publication/5b807311-9d93-11eb-b85c-01aa75ed71a1/language-en>

EU RoHS Consultants' Assessment Report Conclusion: *"The Directive has been successful in reaching the objective of reducing hazardous substances in EEE in the EU. The reduction of hazardous substances has contributed to the protection of human health and the environment, at different stages of the value chain (production, consumption and disposal). [...]"*

Some areas of possible improvement have been identified:

- **Coherence between regulations that can restrict or ban substances in EEE** - Stakeholders indicated that the overlap between RoHS and other legislative instruments (i.e.: POPs, REACH and EcoDesign) and the differences in mechanisms regarding, for example, the identification of substances for restriction, limit values, exemptions and their expiry dates may lead to legal uncertainty.
- Industry and national authorities need a **more comprehensive and well-maintained FAQ**: the current RoHS 2 FAQ from 2012 are, at least in some respects, outdated. Additionally, some definitions also need more clarification or guidance (e.g.: *Large-scale stationary industrial tools (LSIT)* and *Large-scale fixed installation (LSFI)*).
- The RoHS Directive **has not been flexible enough** to respond adequately to all developments in recent years:
 - **Exemption process is a pain point** – too slow, too complex and too time-consuming for smaller companies,
 - Substance restrictions are too few and limits have not been adapted to ensure the achievement of the Directive's objectives.

- Article 6 of RoHS 2 requires that the list of restricted substances in **Annex II be periodically reviewed**.
- A first review of the annex was performed between 2012 and 2014, resulting in the addition of four phthalates to the annex (the restrictions entered into force as of 2019) through RoHS amending Directive (EU) 2015/863.
- A consortium led by Oeko-Institut was requested by the European Commission to prepare a **study to support the review of the list of restricted substances** and to provide technical and scientific support for the evaluation of exemption requests under the RoHS 2 regime (i.e.: Pack 15 Project).
- In March 2021 the **Pack 15 Project final report** (dated November 2020) was published.
 - The report contains the assessment results **of seven substances** with a view to their possible restriction under RoHS:
 - Beryllium and its compounds
 - Five Cobalt salts
 - Diantimony trioxide (ATO, flame retardant)
 - Indium phosphide (InP)
 - Medium chain chlorinated paraffins (MCCPs) - Alkanes, 14-17, chloro
 - Nickel sulphate and nickel sulfamate
 - Tetrabromobisphenol A (TBBP-A, flame retardant)



https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Final_Results/RoHS_Pack_15_Final_Report_2020_compressed_version.pdf

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- ✓ ○ Nickel sulphate and nickel sulfamate
- ✗ ○ Tetrabromobisphenol A (TBBP-A, flame retardant)

"It is therefore recommended to restrict MCCPs and add an explanation that this entry covers chlorinated paraffins containing paraffins with a chain length of C14-17 – linear or branched."

"Recommended substance restriction formulation: additive application of 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol or tetrabromobis-phenol A (TBBP-A) (0,1 % per weight)"

Saudi Arabia

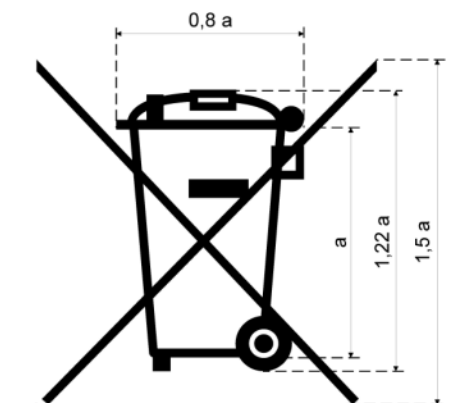
- On 9 July 2021, SASO issued the final Saudi Arabia RoHS Technical Regulation
- No significant changes between the draft and the final text
- Key elements: 6 categories in scope (household appliances included), 6 restricted substances, all products must undergo a conformity assessment and this includes obtaining a certificate of conformity (Type 1a) in accordance with IEC / ISO 17067 from a Notified Body recognized by SASO
- The regulation sets a deadline of **5 January 2022** for new EEEs to comply, but manufacturers can sell products already on the market until **9 July 2022**

Bangladesh

- On 10 June 2021, Bangladesh DoE issued the final Hazardous Waste (E-Waste) Management Rules (WEEE and RoHS Rules)
- Key elements: 5 categories in scope (household appliances included), 10 restricted substances, requirements for WEEE management (e.g.: EPR, registration, collection schemes and collection targets for manufacturers/importers, provide info on product label/packaging)
- The compliance deadline for chemical restrictions is set as **10 June 2026**

Eurasian Economic Union

- On 25 October 2021, the ECC issued a proposal to amend the EAEU RoHS Technical Regulation
- This proposal aims to align EAEU RoHS to the most updated EU RoHS, as well as to supplement it with WEEE requirements
- Key proposed changes:
 - Scope: addition of 4 phthalates to the list of restricted substances and a new “open scope” category of products
 - Exempted products: addition of “*large stationary production equipment*” and “*large stationary mounted installations*”
(examples for these are provided in Annex 6);
 - List of exemptions: new expiry dates for some existing exemptions and new exemptions have been proposed
 - WEEE requirements: separate waste collection marking to be affixed on products and documentation, processes for WEEE disposal
(as set in Annex 4)
- The proposed date of entry into force of this draft amendment is 180 days after its official publication
- The deadline to provide comments is **20 January 2022**



Proposed marking for EEE

EU Harmonised Legislation in 2021 : More Coherent Enforcement and Addressing New Risks From Emerging Technologies

Introduction

- Impact of new technologies on EU product safety rules
 - AI, IOT and robotics changing products and supply chains
 - Regulation must adapt to new reality & address gaps
 - EU is responding through the evaluation of existing rules:
- Machinery Directive 2006/42/EC
 - Market Surveillance Regulation (EU) 2019/1020
 - Liability for Defective Products Directive 85/374/EEC

EU Machinery

22 April 2021 EU Commission issues draft regulation to repeal Directive 2006/42/EC

- Proposal intended to complement the digital transition
- Coheres with emerging Union policy on artificial intelligence
- Covers new risks from emerging technologies not addressed in the Directive
- Directive to be converted into a Regulation:
 - reduce divergences in interpretation
 - internal market level playing field
 - no 'gold-plating'
- Alignment with [New Legislative Framework](#) (familiar structure, definitions, terminology)

What is changing?

- **Safety requirements**

- machinery including new technologies
- new category of high-risk machinery in Annex I
 - *24. Software ensuring safety functions, including AI systems*
 - *25. Machinery embedding AI systems ensuring safety functions*

- **Digital documentation**

- acceptance of instructions & manufacturer's DoC in digital format

- **Third party conformity assessment (use of Module B EC-Type Examination)**

- removal of internal check option for high-risk machines

Parliament has responded favourably to the proposal:

- Timely and necessary
- General objective of bringing products with digital content into the scope of the machinery regulation accepted

But *Commission receiving pushback on some provisions:*

- Requirement for third party conformity assessment burdensome
- Implementation : more needed to allow ample time for adaptation. Extend transitional period from 42 to 60 months

Next Steps:

- First examination by Council in progress
- [Draft Report](#) by the Rapporteur, Mr. Ivan Štefanec, to be discussed by IMCO from November 2021
- Vote on draft amendments in March 2022
- Incoming Council Presidency will work with the Parliament to try to reach agreement on draft at first reading

Market Surveillance Regulation (EU) 2019/1020

- Full application since 16 July 2021
- More coherent and effective enforcement of EU harmonisation legislation
- The regulation applies to a large number of products:
 - products covered by EU harmonised legislation and set out in Annex I*;
 - imported into the EU and not subject to specific legislation

**This includes typical LVE products, machinery, household appliances specifically intended for industrial/commercial use, professional kitchen and refrigeration equipment*

- Products in scope may not be offered for sale to EU consumers unless an **economic operator is established in the EU**
- This party will provide a **direct line of contact back to the manufacturer**
- This will empower market surveillance authorities to stem online sales of unsafe products and unfair commercial practices
- **Obligations of the economic operator** include:
 - *Verifying* that a Declaration of Conformity has been drawn up and retaining it should it be requested by a market surveillance authority;
 - *Informing* the market surveillance authority if they suspect a product does not comply;
 - *Cooperating* with the authorities, when asked, by taking immediate corrective action — from remedying the fault to recall or destroying the item — if a product is considered non-compliant, and helps to eliminate or mitigate risks;
 - *Indicating* name and contact details on the product, packaging or accompanying document

The digital transformation is creating an expanded marketplace and supply chains are complex.

Regulation (EU) 2019/1020 establishes an [EU Product Compliance Network \(EUPCN\)](#) for structured coordination and cooperation between enforcement authorities, streamline the practices of market surveillance within the Union, thereby making market surveillance more effective.

The Network -

- develops cooperation between the surveillance authorities and the Commission;
- contains national and Commission representatives and experts;
- organises a range of activities to improve market surveillance across the EU.

Civil Liability for Defective Products: Adapting Liability Rules to the Digital Age

Civil Liability for Defective Products

- Aim of liability framework: reassurance and safety for consumers; legal certainty for manufacturers
- Liability for Defective Products, **Directive 85/374/EEC** is approaching 40 years of enforcement (30 July 1985)
- System of strict liability of the producer for damage caused by a defect in their products
- In case of a physical or material damage, the injured party is entitled to compensation if he or she proves the damage, the defect in the product (i.e. that it did not provide the safety that the public is entitled to expect) and the causal link between the defective product and the damage.
- So **PRODUCT + DEFECT = DAMAGE**

Civil Liability for Defective Products

- Directive 85/374/EEC provides only for compensation for physical or material damage ...
- And the **age of AI-based products challenges conventional ideas** of products, defect and damage
- Digital content, data and software have a role to play in the safe functioning of many products but *it is not clear to what extent these intangible elements can be classified as products under the Directive*
- On 30 June 2021, the EU Commission issues a [Roadmap](#) for the evaluation of the Directive
- Commission will address the unique features of digital products and rethink now-outdated views on what bears on the concept of safety

Civil Liability for Defective Products

- Safety: design + production
- Safety: design + production + **software updates + data flows + algorithms**
- Consultation period 18 October 2021 - 10 January 2022
- Commission adoption planned for third quarter 2022



Thank You
