

## The Chemicals Strategy for Sustainability (CSS) and its impact for flame retardants (FR)

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A pinfa Frequently Asked Questions (FAQ) document

### 1. What is REACH?

[REACH](#) (EC 1907/2006 Registration, Evaluation, Authorisation and Restriction of Chemicals) is core chemicals regulation of the European Union (EU). It aims to protect human health and environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry.

REACH applies to all chemicals (substances) used both in industry and in day-to-day life (e.g. cleaning products, paints, clothes, furniture, electrical appliances). The responsible Agency for the implementation of REACH is ECHA (European Chemicals Agency). REACH has impacts on companies across the EU: Manufacturers, Distributors, Importers and Downstream Users.

To comply with the regulation, chemical companies must identify and manage the risks linked to the substances they manufacture or sell in the EU. They have to demonstrate to ECHA how the substance can be safely used, and they must communicate the risk management measures to the users. If the risks cannot be managed, authorities can restrict the sale or use of substances in different ways. Authorities can ban hazardous substances if their risks are unmanageable. They can also decide to restrict a certain use or make it subject to prior authorisation. In the long run, the most hazardous substances should be substituted with less dangerous ones.

Companies must register their substances by submitting a dossier to ECHA. In line with the One Substance One Assessment (OSOA) principle, to do this, they need to work together with other companies who are registering the same substance by grouping up and voluntarily forming a REACH Consortium. Some chemicals are partially or totally [exempted](#) from registration, for example: substances with low risk (listed in Annex IV of REACH); substances occurring in nature (Annex V); certain applications of substances (scientific research, food & feedstuffs, medicines ...).

REACH has an impact also on non-EU companies: such companies cannot sell their chemicals into the EU, unless via a registration made either by EU-established importers or by a registration made by an “Only Representative” (OR) in the EU.

The REACH registration status of PIN FRs can be directly consulted in the [pinfa product selector](#). The full registration dossiers are available on the [ECHA website](#) by searching the substance name or EC or CAS number.



In particular, the pinfa Product Selector enables to find, for different PIN FR's: identification, REACH regulatory status and GHS classification (Globally Harmonised System), supplier companies and trade names, indications of the different polymers in which the PIN FR can be used and a list of the PIN FRs which are effective in given polymers and/or type of applications.

## 2. What is relevant for FRs in the current revisions of REACH and CLP?

The European Commission is moving towards finalisation of the [proposals](#) for revising the REACH Regulation and the [CLP Regulation](#) (Classification, Labelling and Packaging of substances and mixtures) Regulation. This is part of the EU Chemical Strategy for Sustainability (CSS) which is explained in more detail below (point 3). The priority aspects of the revision include increased information requirements for low tonnage substances and for the most hazardous substances, extension of the Generic approach to Risk Management (GRA), reform of the Authorisation and Restriction procedures, the new Mixture Allocation Factor (MAF), establishment of the "essential use" concept, polymer registration/declaration, and additional enforcement provisions. The proposed amendments will have impacts on all chemicals registered in the EU, including FRs.

Several aspects of the proposed REACH revision may impact how the safety of FRs is assessed. The revision clearly aims to raise the bar on consumer protection.

One proposal, which may impact certain PIN FRs, is to extend GRA to other hazard classes (PBT/vPvB, STOT-RE 1, endocrine disruptors, respiratory sensitisers)\* and to some professional uses. This will not impact the many PIN FRs which do not have relevant hazard classifications. GRA is based on generic risk considerations meaning that in certain situations a substance could be flagged under GRA, and potentially restricted or banned, because in some applications there are limited possibilities to control the risk, despite that its use in many FR applications is controlled and safe. Another important change is that (certain) polymers will need to be REACH registered, whereas they were exempt until now. The PIN FR industry will assess which polymeric FRs fall under the new registration requirement and what studies or tests are required as a consequence.

\* *PBT = Persistent Bio-accumulative Toxic. vPvB = Very Persistent Very Toxic. STOT-RE = Specific Target Organ Toxicity Repeated Exposure*

New hazard classes will be introduced in the CLP Regulation, such as:

- Endocrine Disruptors (ED)
- Persistent, Mobile and Toxic (PMT) / very Persistent and very Mobile (vPvM)
- Persistent, Bioaccumulative and Toxic (PBT) / very Persistent and very Bio-accumulative (vPvB)

These new classifications will impact GRA as explained above.

These new hazard classifications may have an impact on certain FRs. The PIN FR industry will carry out any additional tests or studies identified for these hazard classification endpoints if not already covered by the data of the existing REACH dossiers.



### 3. What does the Chemicals Strategy for Sustainability (CSS) mean for flame retardants?

The EU [Chemicals Strategy for Sustainability](#) (CSS) is part of the EU's zero pollution ambition, which is a key commitment of the [European Green Deal](#). The CSS is a major, highly ambitious initiative to boost innovation for safer and more sustainable chemicals. It will prioritise prevention and substitution, re-define EU chemicals policy, and will strongly move towards generic restrictions. It contains 56 major actions, most of them legislative changes, to be implemented between 2021 – 2024, including those discussed above under REACH and CLP.

The Chemical Strategy for Sustainability will greatly enhance sustainability requirements for all chemicals in Europe, accelerating bans of chemicals with health or environment questions, introducing new hazard classes (see above), requiring information on LCA (life cycle assessment) and recycling, introducing registration or declaration of all polymers and with possible regulatory “grouping” of chemicals.

Because flame retardants are widely used in consumer and industrial products to reduce fire risks, they are one of the uses of chemicals already being assessed by the EU under the CSS and the European Chemicals Agency (ECHA) published a “Regulatory Strategy for Flame Retardants” in March 2023 (see pinfa Newsletter n°147 and below).

The Chemical Strategy for Sustainability offers opportunities by promoting innovation and market acceptance of more benign FRs. However, it also poses challenges where the FR industry needs to address and manage substances of concern. pinfa thus sees important opportunities for PIN FRs. pinfa has prepared, in dialogue with external experts and stakeholders, a Roadmap for Chemicals Sustainability for FRs. This will be implemented with specific studies, leading to definition of policy proposals and product stewardship actions across the PIN flame retardant industry.

pinfa underlines that the Chemicals Strategy for Sustainability implementation must ensure a level playing field by putting the same demands on imported chemicals and finished products (“articles”) as on the European chemicals industry, with effective enforcement at national levels. So, if done right, it will support a positive image of FRs which make products safer for workers and consumers.

### 4. What is the Assessment of Regulatory Needs (ARN)? Is there an ARN for flame retardants?

The purpose of the Assessment of Regulatory Needs is to help authorities conclude the most appropriate way to address (potential) identified concerns for a group of substances or a single substance.

An Assessment of Regulatory Needs can conclude that regulatory risk management at the EU level is required for a (group of) substances, that currently no (further) regulatory action is required at the EU



level or that further data on hazards and on risks in use and risk mitigation may be needed before regulatory actions can be defined

The Assessment of Regulatory Needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the processes defined in the legislation but aims to support them. This means that even if an Assessment of Regulatory Needs concludes that regulatory action should be initiated, this does not have any direct legal implications. For this, one or more of the EU's formal regulatory management and decision-making processes are required, under REACH or CLP (e.g. harmonised classification and labelling, Candidate List inclusion, restriction) or other EU legislation.

The main source of information to support ECHA's Assessments of Regulatory Needs is the REACH registration dossier including the (potential) hazards identified, the relevant uses and exposure potential.

ECHA's Assessments of Regulatory Needs for individual chemical substances are available via ECHA's PACT website ([Public Action Coordination Tool](#)) or via the [ECHA Assessment of Regulatory Needs list](#). The Assessment of Regulatory Needs list includes substances for which an assessment either is under development or has been completed.

For flame retardants, ECHA has carried out and published an Assessment of Regulatory Needs as part of the [ECHA Regulatory Strategy for Flame Retardants](#) (March 2023, see pinfa Newsletter n°147).

This Strategy identifies most PIN flame retardants as low hazard, with no regulatory action needed, including mineral, nitrogen, inorganic phosphate and several types of organophosphorus FR. The Strategy proposes "grouping" (see below) of all aromatic brominated FRs, and preparation of a wide and generic restriction for this group. The Strategy also calls for more data on aliphatic brominated FRs and on some organophosphorus FRs.

## 5. What does a grouping of FRs mean?

Does the Chemicals Strategy for Sustainability mean that flame retardants might be restricted as a group? Until today and under the current REACH, the European Chemicals Agency (ECHA) assesses a chemical substances one by one. The increasing complexity of the assessments, evaluation of the submitted studies and discussions with stakeholders mean that the time required for a final conclusion is much too long and is regarded as not acceptable by the registrants, ECHA, and the European Commission. Therefore, as part of the Chemicals Strategy for Sustainability it is proposed that ECHA will, in some cases, assess "groups" of substances.

There are many ways to group chemicals, not all of them are meaningful for assessing their hazards and risks.

The ECHA Regulatory Strategy for Flame Retardants considers that all FRs cannot be "grouped" together for regulatory action.



For example, a number of very different types of organophosphorus chemical are used as PIN FRs to reduce fire risk in different applications and materials. In a constructive approach, pinfa commissioned chemical science and risk expert, [Peter Fisk](#), to suggest a science-based grouping of organophosphorus FRs taking into account oxidation numbers, chemical structure, and toxicological data (see pinfa Newsletter n°142). This was shared with ECHA and their adopted “grouping” approach in the ECHA Regulatory Strategy for Flame Retardants is not too different.

ECHA’s Regulatory Strategy for Flame proposes nine “groups / subgroups” for PIN organophosphorus FRs:

- Triphenyl phosphate derivatives,
- Trialkyl phosphates,
- Alkyl aryl and cyclic esters of phosphoric acid: Non-cyclic alkyl aryl ester
- Alkyl (<C8) diesters of hydrogenphosphonates and alkyl(<C8)phosphonates,
- Alkyl esters of alkyl(≥C8)phosphonates,
- Other hydrogenphosphonates and alkyl phosphonates, their salts and esters with alkyl chains <C8
- Dibenzo oxaphosphorine oxide (DOPO) derivatives
- Tetrahydroxymethyl and tetraalkyl phosphonium salts
- Ethoxylated alcohol phosphates and phosphinic acid derivatives

ECHA have also confirmed that if additional studies show that a group assessment does not mirror correctly the hazard or risk of a given chemical then an individual risk assessment may be pursued.

## 6. What is the Restriction process? What does it mean for FRs?

Until the assessment of the proposed changes suggested in the CSS and their introduction in the revised REACH Regulation is in place, the CSS prioritises CMR, EDs, vPvBs and other high priority substances for restrictions for all uses and by “grouping”, instead of regulating them one by one. To facilitate this, the Commission has prepared a roadmap to prioritise these substances for (group) restrictions under REACH, herein called the “Restrictions Roadmap” (see pinfa Newsletter n°138)

The Restrictions Roadmap suggests that “all flame retardants” will be assessed, with “a particular focus on brominated flame retardants and their prioritisation for restrictions. ...”, and also borates (as a group). This led to the ECHA Strategy for Flame Retardants (see above).

This is in addition to the existing “Community Rolling Action Plan” ([CoRAP](#)), published by ECHA, which sets out which restrictions are planned or are being prepared and their progression. It lists (groups of) substances which are under discussion for a risk management measure or for which an entry in the [Registry of Intentions](#) (RoI) has been submitted.



The following PIN FRs only are in the CoRAP list (as of July 2023): Tetraphenyl m-phenylene bis(phosphate), Tributyl phosphate, Triphenyl phosphate, Triphenyl phosphite, Tris(methylphenyl) phosphate, Trixylyl phosphate

## 7. What is regrettable substitution? How can it be avoided?

Regrettable substitution is when one banned chemical is replaced with another chemical which is just as harmful, or has hazardous properties leading to concerns that subsequently need to be addressed.

The concept does not appear in the CSS but in the European Parliament Resolution on the CSS ([10<sup>th</sup> July 2020](#)) and in other Commission documents

An example is cited by the European Commission ([SWD\(2019\)199](#)) is “The use of TCEP as a flame retardant in children's toys is an example of regrettable substitution. It replaced other brominated flame retardant subject to risk management measures in the EU”.

Another example cited by ECHA in the 2023 Flame Retardants Strategy (p.9) is “decabromodiphenyl ethane (DBDPE) being widely marketed as replacement for decabromodiphenyl ether (decaBDE)”.

As indicated by ECHA ([here](#)), the use of grouping in chemicals assessments is intended to avoid such regrettable substitutions.

Regrettable substitution can be caused by insufficiency of risk data on the new chemical, wrong assumptions about its functional use (either as such or in its comprehensive context of application), tradeoff of one hazard endpoint for another, failure to consider its life-cycle, defect in exposure analyses, wrong overall “ban & replace” design, rushed or untimely decisions. See ECHA web page “[Data to prevent regrettable substitution](#)”.

Substitution of a FR identified as potentially harmful, for a given application, is often not possible by simply replacing one chemical with another. It can be a complex process which involves many variables such as but not limited to hazards, exposures, technical performance, economic aspects and also wider factors like energy & resource use, waste, recycling, socio-economic impacts.

There are different options to substitute a given use of a harmful FR : switching to a less hazardous or non-hazardous FR, using an alternative fire safety approach (such as an inherently non-flammable material), creating a new product design. When designing a brand-new product, the approach should take into account safety and sustainability across the entire lifecycle. A process for FR substitution should at least:

- Characterise the substance of concern and its overall risk framework, as well as its key functions and performances in production processes and in end-products;
- Look for and identify different safer and more sustainable alternative FRs, considering in particular implications for users, in application / formulation / processing, in the final product and in end-of-life / recycling;



- Assess, compare and select the alternatives, including the comprehensive assessment of hazards and risks for human health and for the environment, performance, economic viability, energy & resource use, waste, recycling, social impact;
- Test, implement and improve by carrying out iterative series that involve pilot testing, applications of the alternatives, continuous improvement of process and product, avoidance of undesired impacts;
- Inform all the supply chain stakeholders who are impacted by the change.

For specific questions about possible substitution of PIN FRs, you should address the company supplying the PIN FRs concerned.

## 8. What is pinfa's view on "essential use" for PIN FRs?

The European Commission [intends](#) to introduce into chemicals and other regulations the concept of "essential use" for the most harmful chemicals in order to streamline the process of their restriction.

This is [specified in the CSS](#): "define criteria for essential uses to ensure that the most harmful chemicals are only allowed if their use is necessary for health, safety or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health".

The concept does not exist in REACH and is not part of the existing REACH governance. An example (proposed in [Cousins et al. 2019](#)) is perfluorinated compounds which may be essential in certain medical applications, but cannot be considered as an "essential use" in ski wax or water repellent leisure clothing.

Whilst pinfa definitely believes that flame retardants provide an important contribution to the safety and wellbeing of people, we have so far restrained from the debate, because we believe that an "essential use wild card" is not needed for PIN flame retardants, because they have very limited hazards and risks. In addition, the legal definition and implementation of "essential use" is still under discussion.

See the Cefic position on "essential use" [here](#).

See also Cefic information on the Chemicals Strategy for Sustainability [HERE](#).



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#### About pinfa :

*[pinfa](#) is the Phosphorus, Inorganic and Nitrogen (PIN) Flame Retardants Association (a Sector Group within [Cefic](#), the European Chemical Industry Council). [www.pinfa.org](http://www.pinfa.org) . We bring together (with [pinfa North America](#) and pinfa China) nearly 40 companies who manufacture or use non-halogenated flame retardants, smoke suppressants and synergists, based on chemistries of one or more of phosphorus, nitrogen, and inorganics*

