CHEM Trust comments on proposed nominations for Substances of Very High Concern (SVHC), October 2022

Introduction
The document includes CHEM Trust’s contribution on the substances being proposed for identification as SVHC at the ECHA Member State Committee Meeting in December 2022. The substance specific comments have been submitted as part of the public consultation by ECHA. The decision on inclusion of chemicals into the candidate list according to REACH article 57 is based on the hazardous properties of the substances.

The inclusion in the REACH candidate list is a very important step and already triggers obligations for information in the supply chain and a right to know for consumers.

Any information about uses and exposure will be taken into account at a later stage when substances are being prioritised for the REACH authorisation list.

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4,4'-sulphonyldiphenol (bisphenol S; BPS)
EC Number: 201-250-5
CAS Number: 80-09-1
Dossier submitter: Belgium (link Annex XV dossier here)

Examples of uses: e.g. the manufacture of pulp, paper and paper products, textile, leather or fur (see also ECHA substance information page on BPS).

CHEM Trust’s comments on identity and properties:
CHEM Trust supports the inclusion of 4,4'-sulphonyldiphenol (BPS) in the REACH candidate list due to its classification as reprotoxicant based on article 57 (c). We also strongly support the identification under article 57 (f) based on its endocrine disrupting properties. The dossier has convincingly compiled the relevant studies which demonstrate that BPS in line with other bisphenols have endocrine disrupting properties for human health and the environment.

For BPS consistent in vivo and in vitro evidence is available on steroidogenesis, and in particular on estrogenic activity. BPS consistently affects the estrous cyclicity in female rodents, and this is considered as EATS-mediated. In addition, other reproductive adverse effects on female and male rodents, including EATS-mediated, have also been reported. There is strong evidence that the adverse effects on fertility and sexual function are plausibly linked to the estrogenic activity of the substance.

In zebra fish BPS impairs VTG levels and thus shows estrogenic mode of action, and BPS also disrupts steroidogenesis. BPS exposure leads to clear adverse effects by a change in reproduction and development. The reproductive endocrine system is highly conserved not only between mammals, but also between mammals and vertebrates like fish.

Thus, based on all available scientific evidence, it can be concluded that BPS has a clear endocrine mode of action which is shown both in vitro and in vivo. BPS has clear adverse effects in mammals and fish, and these are considered to be a consequence of the endocrine mode of action. Therefore, BPS fulfils the WHO/IPCS (2002) definition of an endocrine disruptor with regard to both human health and the environment.

The effects of BPS due to its endocrine disrupting properties are considered to be of equivalent level of concern according to REACH Article 57(f). Impacts on estrous cycle, sex ratio etc (observed following developmental exposure) can impair population stability and lead to severe and irreversible health effects. Thus, future generations are not protected. Moreover, a wide range of taxa in different ecosystems may be adversely affected due to conservation of the endocrine system across species. Therefore, BPS should be identified as an SVHC according to Art. 57 (f) based on its endocrine disrupting properties for human health and for the environment.
Specific comments on Part II 'Information on Use, Exposure, Alternatives and Risks':
Today BPS can be found worldwide and is ubiquitous in several environmental compartments. Besides indirect exposure via the environment, humans are exposed via several consumer products (food contact material, paper products, personal care products). Furthermore, biomonitoring data demonstrate the presence of BPS in human urine and blood serum, as presented extensively in the Annex XV dossier. BPS reaches diverse environmental compartments and biota of remote areas. Therefore, many environmental species and humans can be exposed more or less continuously to BPS and exposure can thus not be avoided. This also underlines the urgency for control of BPS and other bisphenols exposure as CHEM Trust has already pointed out in 2018 in the CHEM Trust report: `From BPA to BPZ: a toxic soup?’ The whole BPS case is a sad illustration that the current regulatory approach works in favour of keeping toxic chemicals on the market, to the disadvantage of consumers and environment. Already in 2015 ECHA’s RAC committee had advised against a substitution with BPS due to concerns about endocrine disrupting effects (in its opinion on the BPA restriction in thermal paper). Thus, a comprehensive bisphenols group restriction aimed at overall exposure reduction should finally be pursued with high priority, also building on ECHA’s group assessment work.

Perfluoroheptanoic acid and its salts
EC Number: -
CAS Number: -
Dossier submitter: The Netherlands (link Annex XV dossier here)
Examples of uses: The substances are not registered under REACH.

CHEM Trust’s comments on identity and properties:
CHEM Trust supports the inclusion of perfluoroheptanoic acid and its salts in the REACH candidate list because of its reproductive toxicity (article 57(c)) as well as due to its PBT and vPvB properties (articles 57 (d) and (e). The dossier makes a convincing case based on a weight-of-evidence determination according to the provisions of Annex XIII, bringing together the evidence for a combination of these harmful properties. The very high persistence together with low adsorption potential and high mobility imply a very high potential for increasing pollution stock in the environment and for irreversible and increasing exposure of both wildlife and humans exposed via the environment. Also, their low adsorption potential and high water solubility mean that PFHpA and its salts are highly bioavailable for uptake via water. The additional concern due to the substances’ high mobility in water, the potential for being transported in the water phase over long distances, difficulty of remediation and water purification is an important justification for an equivalent level of concern identification, i.e. including it also under article 57 (f).
Melamine
EC Number: 203-615-4
CAS Number: 108-78-1
Dossier submitter: Germany (link Annex XV dossier here)
Examples of uses: The substance is used in polymers and resins, coating products, adhesives and sealants, leather treatment products, and laboratory chemicals.

CHEM Trust’s comments on identity and properties:
CHEM Trust supports the inclusion of melamine in the REACH candidate list according to article 57 (f). The dossier highlights clear evidence of the substance’s high persistence and high mobility in water. Taken together with the potential to cause cancer and damage to the urinary tract organs through prolonged or repeated exposure, there is sufficient scientific evidence of probable serious effects to human health and the environment which gives rise to an equivalent level of concern to those substances listed in points (a) to (e) of Article 57 REACH. Melamine had been included in the SIN list already in 2019 due to its persistent, mobile and toxic properties and frequent findings in (ground)water, human breast milk and urine.

CHEM Trust’s comments on exposure:
Given the application of melamine in the manufacture of consumer items like tableware, the uses as food contact material should be one of the priorities for exposure reduction and substitution efforts.

In 2019 the German Risk assessment institute has warned against drinking hot drinks (or eating hot meals) from cups/kitchenware made with melamine resins or bamboo.
https://www.bfr.bund.de/de/presseinformation/2019/47/geschirr_aus_bambusware_nicht_fuer_heisse_getraenke_oder_speisen_nutzen-243171.html

Isobutyl 4-hydroxybenzoate (Isobutylparaben; IBP)
EC Number: 224-208-8
CAS Number: 4247-02-3
Dossier submitter: Denmark (link Annex XV dossier here)
Examples of uses: The substance is used in the manufacture of substances and in coating products, fillers, putties, plasters, modelling clay, and inks and toners.

CHEM Trust’s comments on identity and properties:
CHEM Trust supports the inclusion of Isobutyl 4-hydroxybenzoate (IBP) in the REACH candidate list based on its endocrine disrupting properties according to article 57( f).

IBP shows clear evidence of endocrine activity in vitro and in vivo, specifically estrogenic activity. The Annex XV dossier convincingly presents a read across-approach to butylparaben (BP), which is already identified as an ED and SVHC, and which shows several similarities with IBP both structurally and for estrogenic activity.
BP exposure leads to adverse effects on sperm count, sperm motility and reduced number of normal sperm, after perinatal exposure. It is biologically plausible that ER activation during development leads to the observed adverse effects on the male reproductive system following perinatal exposure to IBP. Thus, based on all available scientific evidence including read across to BP, it can be concluded that IBP shows endocrine activity via an estrogenic mode of action, leading to adverse effects on the male reproductive system after perinatal exposure. Therefore, IBP fulfils the WHO/IPCS (2002) definition of an endocrine disruptor with regard to human health.

The effects of BPS due to its endocrine disrupting properties are considered to be of equivalent level of concern according to REACH Article 57(f). The observed effects are irreversible and are shown to occur later in life after exposure in the perinatal period only. These effects are considered severe as similar effects in humans could cause sub- and infertility. Sub- and infertility is not only detrimental to the propagation of the species, but also has a major impact on quality of life. Fertility treatment and counselling carries high societal costs.

In addition to the identification as an ED for human health, CHEM Trust also strongly recommends identification of IBP as an endocrine disruptor for the environment. The estrogenic mode of action leading to adverse effects on the male reproductive system is also relevant for mammals in the environment. Moreover, the reproductive endocrine system is highly conserved not only between mammals, but also between mammals and vertebrate species like fish.

**Bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof**

**EC Number:** -
**CAS Number:** -
**Dossier submitter:** Sweden (link Annex XV dossier [here](#))
**Examples of uses:** The substance is used as a flame retardant and as a plasticiser for flexible polyvinylchloride and for use in wire and cable insulation, film and sheeting, carpet backing, coated fabrics, wall coverings and adhesives.

**CHEM Trust’s comments on identity and properties:**
CHEM Trust supports the inclusion of bis(2-ethylhexyl) tetrabromophthalate covering any of the individual isomers and/or combinations thereof in the REACH candidate list based on its very persistent and very bioaccumulative properties. The dossier shows convincingly that the criteria of Annex XIII of the REACH Regulation are fulfilled, thus justifying the inclusion via Article 57 (e).

**Barium diboron tetraoxide**
**EC Number:** 237-222-4
**CAS Number:** 13701-59-2
**Dossier submitter:** Sweden (link Annex XV dossier [here](#))
**Examples of uses:** The substance is used in paints and coatings.

**CHEM Trust’s comments on identity and properties:**
CHEM Trust supports the inclusion of Barium diboron tetraoxide in the REACH candidate list based on its classification as toxic for reproduction category 1B in accordance with Article 57 (c) of REACH.

**Reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine (FC-770)**
EC Number: 473-390-7
CAS Number: -
Dossier submitter: Belgium (link Annex XV dossier [here](#))

**Examples of uses:** The substance is used in articles, by professional workers (widespread uses), in formulation or re-packing, at industrial sites and in manufacturing.

**CHEM Trust’s comments on identity and properties:**
CHEM Trust supports the inclusion of reaction mass of 2,2,3,3,5,5,6,6-octafluoro-4-(1,1,2,3,3,3-heptafluoropropan-2-yl)morpholine and 2,2,3,3,5,5,6,6-octafluoro-4-(heptafluoropropyl)morpholine (FC-770) in the REACH candidate list due to its vPvB properties based on article 57 (e). The dossier presents a convincing weight-of-evidence determination according to the provisions of Annex XIII of REACH.

**2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol-A; TBBPA)**
EC Number: 201-236-9
CAS Number: 79-94-7
Dossier submitter: Norway (link Annex XV dossier [here](#))

**Examples of uses:** The substance is used as a reactive flame retardant and as an additive flame retardant in the manufacture of polymer resins, in products such as epoxy coated circuit boards, printed circuit boards, paper and textiles.

**CHEM Trust’s comments on identity and properties:**
CHEM Trust supports the inclusion of tetrabromobisphenol-A (TBBPA) in the REACH candidate list based on its classification as a carcinogen category 1B in accordance with Article 57 (c) of REACH.

**CHEM Trust’s comments on exposure:**
TBBPA is the most widely used brominated flame retardant in the world. REACH registration volumes are 10 000 to < 100 000 t/ya. Given its widespread use including in consumer articles it will be very important to adopt risk reduction measures as swiftly as possible.
The Commission’s restrictions roadmap from April 2022 states: ‘ECHA will prepare an overall strategy on flame retardants by 2022, which will support COM when it decides to request (a) restriction dossier(s). The substances in scope are in principle all flame retardants, and there will be particular focus on brominated flame retardants and their prioritisation for restrictions.’

There should be no further delays with taking regulatory action. The concern regarding TBBPA is not new: Already in 2005 WWF reported findings of TBBPA in blood samples of its 3 generation human biomonitoring study: The flame retardant TBBP-A, used in printed circuit boards in electronic appliances, was found in 18 family members (3 grandmothers, 7 mothers and 8 children). The young generation has the highest median level of this chemical and the highest level was found in a child.  

TBBPA has also been detected in environmental samples in the Arctic (see e.g. Vorkamp et al: Current-use halogenated and organophosphorous flame retardants: A review of their presence in Arctic ecosystems, Emerging contaminants 5 (2019), 179-200.)

1,1’-[ethane-1,2-diylbis(oxy)]bis[2,4,6-tribromobenzene]
EC Number: 253-692-3
CAS Number: 37853-59-1
Dossier submitter: Spain (link Annex XV dossier here)
Examples of uses: The substance is not registered under REACH.

CHEM Trust’s comments on identity and properties:
CHEM Trust supports the inclusion of 1,1’-[ethane-1,2-diylbis(oxy)]bis[2,4,6-tribromobenzene] covering any of the individual isomers and/or combinations thereof in the REACH candidate list based on its very persistent and very bioaccumulative properties. The dossier shows convincingly that the criteria of Annex XIII of the REACH Regulation are fulfilled, thus justifying the inclusion via Article 57 (e). BTBPE is on the SIN list since 2014, based on its persistent, bioaccumulative and toxic properties. It has been widely detected in environmental samples from various regions.