
The consultation was launched on 6 May 2022 and closed on 20 June 2022.

Background info:
Background info (extract from DE dossiers):
The German Competent Authority (DE CA) has indicated through an entry in the Registry of Intentions that they plan to submit a proposal in October 2022 to restrict 4,4’-isopropylidenediphenol (EC 201-245-8, CAS 80-05-7, Bisphenol A) and bisphenols exhibiting a similar concern for the environment from uses which lead to emissions to the environment. Following submission of the restriction dossier and a positive conformity check, the hazards and risks of the proposal would be evaluated by ECHA’s Risk Assessment Committee (RAC).

In addition to bisphenols with confirmed endocrine disrupting properties for the environment, the restriction proposal is planned to also include the following bisphenols for which no EU-wide consensus has so far been reached on their endocrine disrupting properties for the environment:
• 4,4’-methylenediphenol (EC 210-658-2, CAS 620-92-8, "Bisphenol F")
• 4,4’-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol (EC 216-036-7, CAS 1478-61-1, "Bisphenol AF") and its salts (8 salts)

Generally, EU-wide opinion forming on whether a substance has endocrine disrupting properties is achieved through its identification as a Substance of Very High Concern (SVHC), which involves opinion making by the ECHA Member State Committee (MSC). To avoid a situation where RAC is required to conclude on whether a substance fulfils the criteria for endocrine disruption, rather than the MSC, it is anticipated that ECHA will facilitate an ad-hoc process under Article 77(3)(c) of REACH to enable the MSC to give an opinion on the endocrine disrupting properties of the substances identified above, which can then be used by RAC as the basis of their evaluation.

Submitted on 20.06.2022 via web:
BPF
General comments:
CHEM Trust strongly supports the development of a restriction proposal to address the risks of BPA and structurally relevant bisphenols to the environment. In our report from 2018 ‘From BPA to BPZ – a toxic soup?’, we demonstrated the fact that companies are being allowed to replace the well-known hormone disrupting chemical BPA with chemicals having a similar hazardous profile.
to BPA. Our analysis also highlighted BPF and BPAF as relevant substitutes which need to be addressed as a priority in a group approach.

We have long argued that a group restriction for BPA and structurally related bisphenols is long overdue. A comprehensive group restriction for the bisphenols would be a very important step forward to increase the protection level. It would also be responding to the EU Chemicals Strategy for Sustainability which commits to a ban of EDCs in consumer products as soon as they are identified and allowing their use only, where it is proven to be essential for society. Thus, any derogation should only be granted in exceptional cases based on well-documented reasons and with a time-limit.

In April this year ECHA published the results of an in-depth evaluation of the regulatory needs on the group of bisphenols. ECHA and the Member States have assessed a group of 148 bisphenols and recommended that more than 30 bisphenols need to be restricted due to their potential hormonal or reprotoxic effects. BPF and BPAF are among those 34 bisphenols recommended for a group restriction.

We support the chosen procedure of asking MSC for an opinion of the ED properties in order to make efficient use of previous ECHA committee assessments and to avoid further delays and duplication of work.

**Specific Comments:**

On the evaluation of endocrine disrupting properties for the environment for 4,4'‐methylenediphenol (EC 210‐658‐2, CAS 620‐92‐8, “Bisphenol F”) (BPF) by Germany. CHEM Trust supports the evaluation conducted by Germany that BPF has endocrine disrupting properties for the environment.

Overall, the presented data clearly show that BPF has endocrine disrupting properties. BPF may have several modes of action, EATS; estrogenic, anti-androgenic, thyroidal activity and interference with steroidogenesis, where the estrogenic and anti-androgenic activity can be linked to adverse effects relevant for population levels in fish. BPF shows clear and consistent adverse effects on reproduction and sexual development in zebra fish that are plausibly linked to the estrogenic and anti-androgenic mode of action. Supportive evidence is also that BPF seems to interfere with the HBT-axis as shown by in vitro and in vivo data from fish and amphibians. In addition, studies in rats show a decrease in serum testosterone levels and a decrease in sperm motility in the offspring of treated female rats, which support the conclusion of an estrogenic/antiandrogenic mode of action. This is further supported by the analogy of BPF to BPA and BPB, both of which have been identified as having endocrine disrupting properties for human health and the environment. In conclusion, there is clear evidence that BPF fulfils the WHO/IPCS definition for an ED in line with the 2013 recommendations from the ECHA ED Expert Advisory Group and further, the substance has similar properties as BPA and BPB, both of which have been identified as endocrine disruptors. The substance can thus be identified to have endocrine disrupting properties for the environment as proposed by Germany without the need for any duplication of resource‐intensive assessment procedures. Further, in our opinion, BPF should also be identified as an ED for human health considering the conservation of the hormonal system across species, and the fact that endocrine disrupting effects have also be shown in rat studies.
**BPAF**

**General comments:**
CHEM Trust strongly supports development of a restriction proposal to address the risks of BPA and structurally relevant bisphenols to the environment. In our report from 2018 “From BPA to BPZ – a toxic soup?” we demonstrated the fact that companies are being allowed to replace the well-known hormone disrupting chemical BPA with chemicals having a similar hazardous profile to BPA. Our analysis also highlighted BPF and BPAF as relevant substitutes which need to be addressed as a priority in a group approach.

We have long argued that a group restriction for BPA and structurally related bisphenols is long overdue and we, therefore, welcome the approach of covering a group of bisphenols in the restriction. A comprehensive group restriction for the bisphenols would be a very important step forward to increase the protection level. It would also be responding to the EU Chemicals Strategy for Sustainability which commits to a ban of EDCs in consumer products as soon as they are identified and allowing their use only, where it is proven to be essential for society. Thus, any derogation should only be granted in exceptional cases based on well-documented reasons and with a time-limit.

In April this year ECHA published the results of an in-depth evaluation of the regulatory needs on the group of bisphenols. ECHA and the Member States have assessed a group of 148 bisphenols and recommended that more than 30 bisphenols need to be restricted due to their potential hormonal or reprotoxic effects. BPF and BPAF are among those 34 bisphenols recommended for a group restriction.

We support the chosen procedure of asking MSC for an opinion of the ED properties in order to make efficient use of previous ECHA committee assessments and to avoid further delays and duplication of work.

**Specific Comments:**

Comments to: evaluation of endocrine disrupting properties for the environment for 4,4’-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol (EC 216-036-7, CAS 1478-61-1, ”Bisphenol AF”) and its salts (BPAF and salts) by Germany.

CHEM Trust supports the evaluation conducted by Germany that BPAF, and in addition eight BPAF salts, have endocrine disrupting properties for the environment. Overall, the presented data clearly show that BPAF has endocrine disrupting properties. BPAF has clearly shown estrogenic and anti-androgenic activity in fish studies as well as BPAF shows clear adverse and population-relevant effects on reproduction in fish, which are very plausibly linked to the estrogenic and anti-androgenic mode of action. Significant adverse effects on the fertilization rate of spawned eggs are shown in zebra fish and both estrogenic and anti-androgenic modes of action are well known to be involved in the regulation of sexual development and reproduction. The link to the estrogenic/anti-androgenic MoA is further supported by a concomitant decrease in testosterone levels, increases in plasma estradiol and vitellogenin levels as well as by gene expression in male fish.

RAC adopted an opinion for classification as reprotoxicant 1B. During the assessment RAC concluded that BPAF clearly caused adverse effects on sexual function and fertility in mammals and based on the available data, an estrogenic or anti-androgenic mechanism area thought to play a dominant role in vivo. This is further supported by the analogy of BPAF to BPA and BPB, both of which have been identified as having endocrine disrupting properties for human health and the environment. The expected dissociation of the eight salts of BPAF under environmental conditions justify a read across from BPAF, so these BPAF salts should also be identified as having endocrine disrupting properties.
In conclusion, there is clear evidence that BPAF fulfils the WHO/IPCS definition for an ED in line with the 2013 recommendations from the ECHA ED Expert Advisory Group and further, the substance has similar properties as BPA and BPB, both of which have been identified as endocrine disruptors. Therefore, the substance and the salts can be identified to have endocrine disrupting properties for the environment as proposed by Germany without the need for any duplication of resource-intensive assessment procedures. Further, in our opinion, BPAF should also be identified as an ED for human health considering the conservation of the hormonal system across species, and the fact that adverse effects on sexual function and fertility, indicative of endocrine activity, have also be shown in rats as concluded by RAC.