

5 May 2022

Note for the attention of Katinka van der Jagt, Chairperson of the Member State Committee

Ref: Request to the Member State Committee (MSC) for an opinion on the endocrine disrupting properties for the environment of BPF, BPAF and for eight BPAF salts

This note is to request the MSC pursuant to Article 77(3)(c) of the REACH Regulation, to draw up an opinion on the endocrine disrupting (ED) properties for the environment of the substances BPF, BPAF and for eight BPAF salts.

1. Background

The substances BPF, BPAF as well as eight BPAF salts have not been identified through the Article 59 process, set out in REACH, as being Substances of Very High Concern. However, there are concerns that they may meet the criteria for endocrine disruption as defined by the WHO/IPCS (2002).

The substances are identified as follows:

Substance names:

4,4'-methylenediphenol (BPF)

EC N.	210-658-2
EC name	4,4'-methylenediphenol
CAS N.	620-92-8
Molecular formula	C ₁₃ H ₁₂ O ₂
Other names	Bisphenol F (BPF)

4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol (BPAF)

EC N.	216-036-7
EC name	4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol
CAS N.	1478-61-1
Molecular formula	C ₁₅ H ₁₀ F ₆ O ₂
Other names	Bisphenol AF (BPAF)

BPAF salts

Substance name	EC	CAS
benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)	278-305-5	75768-65-9
T-6627	425-060-9	
COMPOUND 7518	443-330-4	
Tributyl-2-methoxypropylphosphonium salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol]	468-740-0	
Not (publicly) available	469-080-6	
benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-	479-100-5	577705-90-

hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate		9
Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyl(diethylamino)diphenylphosphonium 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenolate (1:1)	943-265-6	
Reaction mass of 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol and benzyltriphenylphosphonium, salt with 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]bis[phenol] (1:1)	947-368-7	

The German Competent Authority (DE-CA) has indicated through an entry on the Registry of Intentions that they will submit in October 2022 a proposal to restrict these substances. Following submission and a positive conformity check, the hazards and risks of the proposal would be evaluated by ECHA's Risk Assessment Committee (RAC) and an opinion given on these aspects (among others).

The restriction proposal for BPF, BPAF and eight BPAF salts will be based on the ED hazard assessment by the DE-CA.

EU-wide opinion forming on the ED hazard assessment is generally performed by ECHA through the process under Article 59 for the identification of substances meeting the criteria referred to in Article 57 (identification of Substances of Very High Concern), and in particular Article 57(f) (substances raising an equivalent level of concern to the substances listed in Article 57(a) to (e)). Under this process the involvement of the MSC may be triggered. To avoid that RAC has to prepare an opinion on this and introduce a potential risk for divergent of opinions between ECHA committees, the MSC will be tasked with providing an opinion on whether the ED properties for the environment of the substances BPF, BPAF and eight BPAF salts meet the criteria for endocrine disruption as defined by the WHO/IPCS (2002), which can then be used in the further deliberation of RAC.

On the 4th of May 2022 the DE-CA submitted to ECHA their assessment of the endocrine disrupting properties of BPF and BPAF, which will be used for the hazard assessment in the format of an Annex XV report.

2. Terms of Reference

Pursuant to Article 77(3)(c) of the REACH Regulation, the MSC shall draw up an opinion on whether the relevant properties of BPF, BPAF and eight BPAF salts meet the criteria as defined by the WHO/IPCS (2002) without needing to examine whether these properties raise an equivalent level of concern under Art 57(f) of REACH. The opinion will be based on the assessment prepared by the DE-CA and submitted to ECHA on the 4th of May 2022 and the comments and responses received to the planned Consultation (see below).

3. Approach taken for the MSC opinion development

A 45 day consultation on the hazard assessment as proposed by the DE-CA will be organised by the ECHA Secretariat starting 6th of May 2022 and the DE-CA (as dossier submitter for the restriction proposal) has agreed to prepare responses to comments received. MSC Secretariat is to design and implement the process for MSC opinion forming through an appropriate adaptation of the RAC and SEAC frameworks for dealing with requests for opinions according to Article 77(3) of the REACH Regulation. MSC is expected to submit its opinion to the RAC Chairperson and its Rapporteur for RAC's evaluation on the Restrictions proposal submitted by DE-CA in October 2022.

4. Timescale for the MSC opinion

The opinion of the MSC should preferably be adopted by the time of its 80th plenary meeting on 12-16 December 2022. If the adoption of the opinion is not feasible by the indicated target date, I wish to be informed.

5. Remuneration

The task for MSC following from this request is not considered to fulfil any of the requirements of a transfer of funds to the competent authorities of the Member States pursuant to Article 14(1) of Regulation (EC) 340/2008 and therefore no remuneration will be paid by the Agency.



Shay O'Malley
Acting Executive Director

Cc: Mike Rasenberg