AGREEMENT OF THE MEMBER STATE COMMITTEE

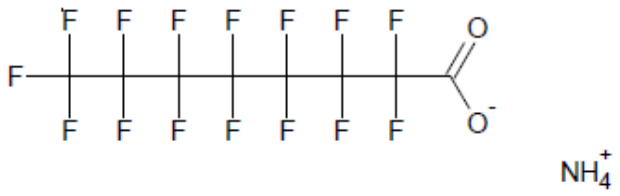
ON THE IDENTIFICATION OF
AMMONIUM PENTADECAFLUOROOCTANOATE (APFO)

AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of
Regulation (EC) 1907/2006[1]

Adopted on 14 June 2013

This agreement concerns

Substance name:	**Ammonium pentadecafluorooctanoate (APFO)**
EC number:	**223-320-4**
CAS number:	**3825-26-1**
Molecular formula:	**$C_8H_4F_{15}NO_2$**
Structural formula:	

[1]Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

Germany presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (27 February 2013, submission number DE006551-66) on identification of *Ammonium pentadecafluorooctanoate (APFO)* as a substance of very high concern due to its toxic for reproduction and PBT properties.

The Annex XV dossier was circulated to Member States on 4 March 2013 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received from both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 21 May 2013 and was discussed in the meeting on 11-14 June 2013 of the Member State Committee.

Agreement of the Member State Committee in accordance with Article 59(8):

Ammonium pentadecafluorooctanoate (APFO) **is identified as a substance of very high concern because:**

a) it meets the criteria of Article 57 (c) of Regulation (EC) 1907/2006 (REACH)[2] as toxic for reproduction 1B, and
b) it meets the criteria of Article 57 (d) of REACH as a substance which is persistent, bioaccumulative and toxic, in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH).

[2] Based on the opinion of the ECHA Committee for Risk Assessment (http://echa.europa.eu/about/organisation/committees/rac/committee_opinions_en.asp) adopted in accordance with Art 37(4) of the CLP Regulation (Regulation 1272/2008) that PFOA should be classified as toxic for reproduction 1B and STOT RE1 in accordance with the CLP Regulation, and as Repr. Cat. 2 and T; R48/23 according to Directive 67/548/EEC

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Toxicity for reproduction:

In its opinion of 2 December 2011 on the proposal for harmonised classification and labelling at EU level of Ammoniumpentadecafluorooctanoate (APFO) ECHA's Risk Assessment Committee (RAC) concluded that the evidence is sufficiently convincing to classify APFO for developmental effects as Repr. 1B (H360D May damage the unborn child) and as STOT RE 1 (liver) (H372 – Causes damage to organs (liver) through prolonged or repeated exposure) according to CLP criteria (Regulation (EC) 1272/2008) and as Repr. Cat. 2 (R61 - May cause harm to the unborn child) and as T; R48/23 (R40-61-48/23) according to DSD (Council Directive 67/548/EEC).

Therefore, even though APFO is not yet listed in Annex VI of CLP (Regulation (EC) 1272/2008) there is evidence based on the RAC opinion on APFO that the substance meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH.

PBT

A weight of evidence determination according to the provisions of Annex XIII of REACH is used to identify the substance as P and B. The available results are assembled together in a single weight of evidence determination. The individual results have been considered in the assessment with differing weights depending on their nature, adequacy and relevance.

Persistence:

All degradation results show that PFOA is persistent and does not undergo any abiotic or biotic degradation under relevant environmental conditions. According to Annex XIII (section 1.1.1), PFOA meets the criteria for being persistent (P) and very persistent (vP).

Bioaccumulation:

The numeric criterion as suggested in REACH Annex XIII for a bioaccumulative substance is not fulfilled for APFO. Due to its notable water solubility, APFO might quickly be excreted via gill permeation. Furthermore, APFO occurs mainly in protein rich tissues like blood and liver (OECD, 2006; Kelly et al. 2009). Hence, bioconcentration in gill breathing organisms and the accumulation in lipids may not be the most relevant endpoint to consider. Field studies show, that air-

breathing organisms are more likely to biomagnify PFOA compared to water breathing organisms. Therefore, the numerical bioaccumulation (B) criterion defined in the REACH regulation (sections 1.1.2 and 3.2.2(a)) is not suitable for APFO to assess its bioaccumulation potential.

Annex XIII (section 3.2.2) defines information which should be taken into account when the numerical criterion is not applicable, for example data on the bioaccumulation potential in terrestrial species or in endangered species (Annex XIII, 3.2.2 (b)).. APFO was found in terrestrial species as well as in endangered species as shown for the polar bear and in animals which are likely to become endangered in the near future (narwhale and beluga whale). These findings are of high concern and indicate on a bioaccumulation potential.

Furthermore Annex XIII (section 3.2.2 (b)) allows taking data from human body fluids or tissues and the toxicokinetic behavior of a substance into account. For APFO a gestational and lactational exposure in humans was shown, which are of special concern as the foetus and newborn babies are highly vulnerable to exposure to toxic substances. On top of that data from human body fluids clearly provide quantitative proof of the bioaccumulation of APFO: Half-lives in humans are around 2-4 years. In addition, recent studies, taking into account relevant confounding factors, show that APFO blood concentrations in humans increase with increasing age.

Finally Annex XIII (section 3.2.2 (c)) foresees that the ability for biomagnifications in food chains of a substance is assessed. For APFO field studies provide trophic magnification factors (TMFs) or biomagnification factors (BMFs) for APFO for aquatic and terrestrial food chains. When air breathing organisms are top predators in these food chains biomagnification was quantitatively demonstrated by TMFs and BMFs > 1 for several food chains, for example TMFs 1.1 – 2.4 in the food chain on wolfs 6.3 – 13 in the food chain of dolphins and 1.4 – 2.6 (protein corrected) in the food chain of beluga whale.

Conclusion:

1. APFO does not accumulate in water breathing animals
    a. BCFs range from 1.8 to 8.0,
    b. BAFs range from 0.9 to 266,
    c. BMFs range from 0.02 to 7.2 whereas most of the data are below 1,
    d. TMFs range from 0.3 to 0.58 in aquatic piscovorous food webs.

2. There is evidence that APFO biomagnifies in air-breathing mammals

    a. BMFs range from 1.3 – 125 for selected predator prey relationships,

    b. TMFs range from 1.1 to 13 for selected food chains.

3. APFO accumulates in humans

    a. APFO is present in human blood of the general population,

    b. Half-lives in blood range from 2 - 4 years in humans,

    c. APFO levels increase with age after adjusting for relevant confounding factors

    d. Elevated levels in human body fluids where the population had been exposed to APFO contaminated drinking water and in workers in fluorochemical production sites (up to 114,100 ng/ml),

    e. Mothers excret APFO via breast milk and transfer APFO to infants. After giving birth and at the end of breast feeding APFO is reaccumulating in maternal blood.

Overall, taken all available information together in a weight of evidence approach the data from environmental species and humans indicates that APFO bioaccumulates. Therefore it is considered that the B criterion of REACH Annex XIII is fulfilled.

Toxicity:

There is evidence based on the RAC opinion on APFO that the substance meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH and as specific target organ toxic after repeated dose category 1 (STOT RE 1). As a consequence the toxicity criterion of REACH Annex XIII (section 1.1.3 (b) and (c)) is fulfilled.

In conclusion APFO meets the criteria for a PBT substance according to Article 57 (d).

Reference:

1. Support Document *Ammonium pentadecafluorooctanoate (APFO)* (Member State Committee, 14 June 2013)