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Herrn Bundesminister
Sigmar Gabriel
Bundesministerium für Umwelt, Naturschutz
und Reaktorsicherheit
Alexanderstrasse 3
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30 April 2008

CANDIDATE LIST OF CHEMICALS UNDER THE EU CHEMICALS REGULATION (REACH)

Dear Minister Gabriel

We are writing to you today because Germany is currently preparing the proposition of priority chemicals of very high concern which need better controls under the new European chemicals legislation. WWF, the Health & Environment Alliance (HEAL) and CHEM Trust have repeatedly demonstrated their concern for both humans and the environment resulting from widespread exposure to man-made chemicals. Of particular concern are contaminants that are persistent and bio-accumulative and can be found in people's blood; as WWF recently demonstrated through several blood testing studies. We believe that it is crucial that REACH (the EU Regulation for the Evaluation, Authorisation and Restriction of Chemicals) is adequately implemented to protect human health and the environment.

To achieve this, we have four specific and important requests:

1. We recommend that as a matter of urgency the German competent authority for REACH (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAUA) propose the widely used chemical PFOA (perfluorooctanoic acid) as a substance of very high concern under REACH. PFOA was found in the majority of children in a recent WWF DETOX bio-monitoring study. It has persistent, toxic and bio-accumulative properties and has recently caught considerable media attention in Germany when found in significant concentration in rivers. Appendix 1 to this letter provides supplementary information to underpin this recommendation.

2. We request that the BAUA with support from the other authorities such as UBA and BfR ensure that as many as possible of the chemicals meeting the criteria for substances of very high concern under REACH are put onto the candidate list as soon as possible. We note that chemicals already classified as carcinogens, mutagens or reproductive toxicants (CMRs category 1 and 2) can be proposed relatively easily, as the submitted information is often limited to the current legislation. However, we feel it is vital that new knowledge on hormone disrupting properties should also be included.

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3. We request that all chemicals that meet the PBT criteria according to EU technical experts are made the subject of Annex XV dossiers as soon as possible and we expect Germany to show leadership in this respect.

4. We recommend that Germany considers including some of the acknowledged hormone-disrupting chemicals (for example Bisphenol A) in the candidate list for authorisation due in autumn 2008. We request that you also consider recommending that at least one acknowledged hormone-disrupting chemical is included on the first priority list of substances to be subject to the authorisation procedure.

Such action is necessary to tackle the increase of hormone related diseases such as breast cancer, and would also probably have a significant beneficial impact on public health in general; particularly in reducing adverse effects on male reproductive health, including testicular cancer. In order to underline the consensus of scientific opinion concerning the need to reduce exposure to chemicals with hormone disrupting properties, we would like to refer you to the 2005 Prague Declaration, signed by over 200 scientists, including leading researchers from across the EU, many of whom have been involved in EU funded research projects on endocrine disruptors.

With the political will to make the REACH "candidate list" a comprehensive list of substances of very high concern, CHEM Trust, HEAL and WWF believe that this list would provide useful guidelines to industry to already reduce their use of these substances in advance of them actually coming under the stricter controls that the authorisation procedure itself would trigger. Giving industry this opportunity to lead and to begin research into safer alternatives, would also serve to reduce the costs.

We are asking you to ensure that adequate resources are available in the German authorities and institutions to undertake these important tasks in the REACH implementation process, in order to better protect human health and the environment from exposure to harmful chemicals.

Yours sincerely,

Tony Long
WWF European Policy Office
Director

Genon Jensen
Health and Environment Alliance
Director

Elizabeth Salter Green
CHEM Trust
Director

Other recipients of this letter include:

Olaf Scholz, Bundesminister für Arbeit und Soziales
Isabel Rothe, Präsidentin der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAUA)
Prof. Dr. Andreas Troge, Präsident des Umweltbundesamts (UBA)
Professor Dr. Dr. Andreas Hensel, Präsident des Bundesinstituts für Risikobewertung (BfR)

Appendix 1 - Putting PFOA on the candidate list for authorisation

We request that as a matter of urgency to protect future generations of children and wildlife, Germany consider drafting an Annex XV dossier to bring PFOA onto the Candidate List as a chemical with persistent, bioaccumulative and toxic properties.

The provisional classification of PFOA or its salts as a Category 2 reprotoxic substance, when confirmed in the future, would allow proposing this substance as a substance of very high concern under REACH (Article 57(c)). However, we believe that much of the particular concern about PFOA relates to its persistence. Therefore, it would be more appropriate to draft the Annex XV dossier for PFOA without delay as a substance of very high concern with PBT properties meeting the criteria in Article 57(f).

The official guidance[i] states that when considering the concept of equivalent concern it is useful to consider the protection goals behind the PBT concept. When PFOA is evaluated (compared with any PBT substance), it can be seen that concern would be equivalent, because of the long persistence of PFOA in human serum (around 3.9 years). This means that once ultimately harmful effects on humans or ecosystems are observed, such effects will be difficult to reverse by control.

PFOA does not meet all the PBT criteria in Article 57(d) as laid out in Annex XIII of REACH. However, it clearly meets both the P and T criteria. For example, data in the OECD 2008 draft SIDS Initial Assessment Profile[ii] clearly identifies that the P criterion is met. Also, the T criterion is met because it is classified for chronic effects (R48/23 and also Xn R48/22) and EU technical experts have recommended that PFOA is classified as a Category 2 reprotoxin. Even if the classification was changed to a Category 3 reprotoxin, then PFOA would still meet the T criterion in Annex XIII. Moreover, there are added reasons for concern. PFOA and its salts have been found to cause cancer in rats and the Scientific Advisory Board PFOA review panel of the US EPA has recommended that PFOA be classified as likely to be carcinogenic to humans. In addition, adverse effects in the immune system in mice have been reported, and in monkeys it gives rise to moderate to high systemic toxicity following long term oral exposure[iii]. Developmental neurotoxicity has also been recently reported in mice[iv], and several studies implicate PFOA as an endocrine disruptor[v,vi]

PFOA does not meet the current B criteria in Annex XIII of REACH, which only refers to bioconcentration in the fatty tissues of fish. PFOA does have bioaccumulative properties, but these are not identified by a BCF where transport across fish gills and skin is important. The route of entry of PFOA seems to be via the air, and air breathing mammals may be particularly at risk. PFOA has been reported in human breast milk in EU countries and elsewhere,[vii] and with a reported serum half-life of around 4 years, on-going exposure will lead to bioaccumulation in humans. The universal distribution of PFOA in the human population across a wide age range and in many geographical locations adds to the concern.

For cases like this, the Article 57f was created in order to identify bioaccumulation by other means than bioconcentration in fish. The official guidance notes the need to consider other mechanisms of accumulation, including blood protein binding which is applicable to PFOA.

Other data suggest a potential for biomagnification, e.g. in marine mammals and Canadian Arctic food webs[viii]. There are data to show PFOA has bioaccumulated over time in the liver of polar bears[ix]. Current bioaccumulation factors, designed to address lipophilic pollutants building up in body fat, relate to whole body measurements. However, bioaccumulation in target tissues is important and should be particularly considered. Another recent study of 128 polar bears has noted that concentrations show significant annual increases for PFOA (2.3%).[x]

Apart from accumulation in the environment and the difficulty of reversing any effects, the guidance suggests that remote areas should be protected from further contamination by hazardous substances and that the intrinsic value of pristine environments should be protected. PFOA is reported in biota and higher predators at remote regions distant from the sites of production and use. This long range transport and the fact that PFOA is now found as a contaminant in marine environments across the globe, therefore add to the evidence of equivalent concern.

In conclusion, it would be appropriate to judge PFOA to have P, B, T properties and thereby to meet Article 57(f). PFOA generates a similar level of concern, and has a likelihood of probable serious effects at least equivalent to that of an Annex XIII PBT substance. This means a PEC/PNEC approach leading to "adequate control of the risks" is clearly not possible. One could therefore consider it imprudent to judge that, if left unregulated and unchecked, serious effects due to PFOA are unlikely.

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[i] ECHA (European Chemicals Agency) (2007). Guidance for the preparation of an Annex XV dossier on the identification of substances of very high concern, Guidance for the implementation of REACH.
[ii] PFOA/APFO, CAS 335-67-1 and 3825-26-1, OECD SIDS assessment agreed March 2008, in press.
[iii] See above.
[iv] Johansson N et al (2008). Neonatal exposure to perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) causes neurobehavioural defects in adult mice, Neurotoxicology, 29(1),160-9
[v] Wei Y et al (2008). Toxicogenomic analysis of the hepatic effects of perfluorooctanoic acid on rare minnows (Gobiocypris rarus), Toxicol Appl Pharmacol., 226(3), 285-97.
[vi] Jensen AA and Leffers H (2008). Emerging endocrine disrupters: perfluoroalkylated substances. Int J Androl., 31(2),161-9.
[vii] Tao et al., 2008. Perfluorinated Compounds in Human Milk from Massachusetts, U.S.A. Environmental Science & Technology.
[viii] Houde M et al (2006). Biomagnification of perfluoroalkyl compounds in the bottlenose dolphin (*Tursiops truncatus*) food web, Env Sci Tech., 40,4138-4144
[ix] Smithwick et al. (2006) Temporal trends of perfluoroalkyl contaminants in polar bears (Ursus maritimus) from twho location in the North American Arctic 1972-2002, Environmental Science and Technology, 40:1139-1143.
[x] Dietz et al (2008). Increasing perfluoroalkyl contaminants in East Greenland polar bears (Ursus maritimus): A new toxic threat to the Arctic bears, Environmental Science and Technology, 42:2701-2702.