Dear Madam/Sir

Prohibition of perfluorooctanoic acid (PFOA)

Reference is made to the Authority’s letter of 30 October 2013 on the Norwegian prohibition of perfluorooctanoic acid (PFOA), and the extension of the deadline for a reply granted in your letter of 2 December 2013. The Norwegian Government’s observations and comments on the content in the Authority’s letter are provided below.

The prohibition – rationale and background
PFOA is widely recognized as a substance harmful to health and the environment. PFOA is present in blood, plasma, the liver, breast milk and umbilical cord blood in humans, and has been found widespread in humans and the environment, also in the Arctic, far away from the sources of the release. A study of human blood in Norway and Siberia has established the presence of PFOA in all samples.

PFOA is a persistent, bioaccumulative and toxic substance, and substances with these properties are in Norway termed as ecological toxins. The effects of these substances are very serious because it is almost impossible to control the long term risks once they have been released into the environment. Such substances represent a serious threat to the health of future generations, to the environment and to future food safety. The Norwegian Government has established a national target for eliminating releases of all ecological toxins, including PFOA, by 2020.

1 Norwegian Pollution Control Authority report TA-2184/2006, see also Impact assessment of regulating perfluorooctanoic acid (PFOA) and individual PFOA salts and esters in consumer products for a fuller documentation of PFOA in humans and the environment.
These serious concerns on the risks of PFOA are widely recognised internationally. This is evidenced by, inter alia, the fact that PFOA was recognised as a substance of very high concern within the EU and placed on the Candidate List of Substances of Very High Concern for Authorisation in June 2013. Further information on the ongoing work on PFOA is given below.

The risks related to PFOA are also addressed globally. Perfluorinated Chemicals have been identified as an emerging issue under the global voluntary agreement Strategic Approach to International Chemicals Management (SAICM). The worldwide presence of these substances, combined with their persistence, toxicity, and bioaccumulative potential, makes these chemicals a particular concern. PFOA and PFOS (perfluorooctane sulfonate) are generally regarded as those substances among the perfluorinated chemicals with the highest risks connected to them. On the web portal for the work on perfluorinated substances under SAICM, there is an overview of government efforts on PFOA and other perfluorinated substances.

Under the Stockholm Convention on persistent organic pollutants (POPs) PFOS has already been regulated. Indeed, the Norwegian Government views PFOA as a candidate for regulation under this convention as a natural next step. After a thorough screening and consideration of available scientific data, the Norwegian Environment Agency recommended in 2012 PFOA as one of the two substances that they recommended for inclusion in this global convention.

Reference is also made to the U.S. Environmental Protection Agency having entered into an agreement with the largest fluoropolymer producers in the United States. The producers have committed themselves to a 95% reduction in PFOA emissions and discharges before 2010 and 100% before 2015 (the “PFOA Stewardship Programme”). Canada identified PFOA as a priority substance in 1999, with regulatory implications.

In 2006, the Norwegian Government put forward the Report No. 14 (2006-2007) to the Storting Working together towards a non-toxic environment and a safer future. There was broad political agreement on the policies proposed. The need for international cooperation to reduce chemicals risks was highlighted, in particular the need for an active policy in seeking regulations under REACH and under global treaties. As an additional step, the Government decided to consider introducing a comprehensive prohibition against ecological toxins in products intended for private consumers. PFOA was among the substances subject to the proposed regulations.

The presence of PFOA in consumer products is an important source of uncontrolled dispersion of PFOA into the environment. This particularly applies to textiles, impregnation agents, ski waxes and carpets. This use leads to a general dispersion of PFOA into the environment from many different products throughout their lifecycle, through use and as waste. It is therefore seen as critically important that the use of products with PFOA be

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2 http://www.oecd.org/ehs/pfc/governmenteffortsonmanagingpfc.htm
3 http://www.epa.gov/oppt/pfoa/pubs/stewardship/index.html
limited. The main presence of PFOA in consumer products is in impregnated textiles. PFOA is mostly present in these products as an impurity. By choosing raw materials of high quality and applying good manufacturing practice, it is possible to produce such textiles that comply with the regulation.

Originally it was proposed to prohibit 18 substances in consumer products. After considering comments received in the national hearing and the draft technical regulation (DTR) procedure under Directive 98/34/EC, it was decided to resubmit proposals for prohibiting four of the substances in consumer products; PFOA, lead, medium-chain chlorinated paraffins (MCCP) and pentachlorophenol (PCP). These proposals were duly notified under the DTR procedure and under WTO rules. After considering carefully the comments received, and taking into account regulatory steps under the REACH regulation on the use of lead, MCCP and PCP, the Norwegian Government decided to adopt only the ban on PFOA in consumer products, cf. the proposal of 27 May 2013. Some adjustments to the original proposal were made in light of the comments, such as raising a concentration limit and adjusting the entry into force provision.

**Norwegian work under the REACH Regulation**

The Norwegian Government sees international regulation as the best way of reducing risks to human health and the environment. Since releases of many hazardous substances are spread internationally through long range transport across borders far away from the sources of release, as well as through trade in products containing such substances, it is clear that only an ambitious international cooperation can deal sufficiently well with the risks posed by a substance like PFOA.

Norway is therefore very active under the REACH regulation and has been the rapporteur for several proposals for restrictions, classifications and labelling and identification of substances as substances of very high concern. Norway is also active at the global level and has nominated three substances to the Stockholm Convention on persistent organic pollutants.

Indeed, the Norwegian Government is leading the work under REACH to develop regulation of PFOA at a European level, in cooperation with Germany. The aim is to submit a restriction proposal for PFOA in 2014. Norway was also active in proposing PFOA as a substance of very high concern, which led to the identification of PFOA as such a substance in June 2013.

Thus, Norway is working actively to achieve the establishment of EEA wide regulations of PFOA under the REACH regulation, this together with Germany in particular. When PFOA is regulated under REACH, Norway will amend its national regulation of PFOA so that it is in line with the regulation under REACH.

**Harmonisation by the REACH regulation – comments on the Authority’s analysis**

The Authority holds in the letter of 30 October that the REACH regulation prevents Norway from adopting national regulations on PFOA. Based on the brief assessment in the said letter and on previous contact with the Authority, the Government understands the Authority’s position to be based on the alleged harmonising effect of the _procedure_ under Title VIII of the
regulation. This procedure may eventually lead to the adoption of concrete requirements on
the manufacturing, placing on the market or the use of a substance.

Whereas the Government fully acknowledges the harmonising effect of such final regulations
by means of Annex XVII entries, it cannot follow the Authority’s assessment of the
harmonising effect of the procedure that may – or may not – lead to such regulations. Hence,
the Government’s position is that it is entitled to maintain or introduce restrictions on a
substance until an EEA wide regulation is in place. This must be the conclusion also when the
procedure under Title VIII of the REACH regulation has been initiated. The mere initiation of
this procedure does therefore not imply that all EEA States are prohibited from regulating the
substance nationally.

This seems to be the most natural understanding of the REACH regulation, and in particular
of Articles 68, 69, 128 and 129 seen in conjunction. According to Article 68(1), Annex XVII
shall be amended when, generally speaking, there are unacceptable risks that need to be
addressed on a Community-wide basis. If a Member State considers such risks to be present,
it must follow the procedure outlined in Article 69(4), which may entail the obligation to
submit an Annex XVII dossier to the European Chemical Agency (ECHA).

The possible harmonising effect of the procedure set out in Title VIII, including the
submission of an Annex XVII dossier, must be assessed in the light of Article 128. Under the
first paragraph of that Article, Member States may not unilaterally impose restrictions on a
substance “falling within the scope of [the] Regulation” as long as the substance complies
with the Regulation itself or with implementing measures. However, Article 128(2) further
clarifies the harmonising effect of the REACH regulation, which reads:

“Nothing in this Regulation shall prevent Member States from maintaining or laying
down national rules to protect workers, human health and the environment applying in
cases where this Regulation does not harmonise the requirements on manufacture,
placing on the market or use.”

The REACH regulation does therefore not harmonise a substance only because a substance
falls within the wide scope of the Regulation, as set out in Article 128(1). National rules to
protect workers, human health and the environment are only prohibited if the Regulation does
indeed “harmonise the requirements on manufacture, placing on the market or use” of a
substance, cf. the second paragraph. These concepts of “manufacturing”, “placing on the
market” and “use” of a substance, as further defined in Article 3 nos 8), 12) and 24, all
indicate that the harmonising effect relates to the use of the substance by producers, suppliers
or consumers. It therefore presupposes that an actual regulation of the substance in question
exists. Conversely, if no such regulation exists, Member States are not precluded from
adopting national legislation. This must be the case also during the period when a possible
Community-wide regulation is assessed. Notably, no reference is made in Article 128 to the
harmonising effect of the procedure that may eventually lead to a situation where the REACH
regulation – to rephrase Article 128(2) - does harmonise the requirements on manufacture,
placing on the market or use.
It is also noted that Article 128(2) refers to both maintaining existing rules and laying down new national rules, both of which may be legitimate provided that the manufacturing, placing on the market and the use of the substance has not been harmonised. It is difficult to see how the Authority’s understanding may allow for situations where the states may legitimately lay down national regulation within the scope of the REACH regulation. Hence, this understanding would, in effect, pre-empt Article 128(2) of its meaning. In this respect, it is recalled that Article 128(2) was introduced by the Council and the European Parliament during the legislative procedure. This must be fully respected when interpreting the harmonising effect of the procedures under the REACH regulation.

It is recalled, furthermore, that the REACH regulation rests on previous EU legislation, such as Directive 76/769/EEC (the Marketing Directive) and Regulation (EEC) No 793/93 (the Risk Evaluation Regulation). The Court of Justice has clarified that the fact that a substance fell within the scope of a directive like the Marketing Directive, did not preclude national legislation until the substance was actually regulated on the Community level. Moreover, the fact that the procedure for such regulation was initiated under the Risk Evaluation Regulation was immaterial for the freedom of Member States to adopt national legislation as this procedure did not harmonise the use of the substance. The wording of Article 128(2) of REACH echoes this established state of law. Even though the REACH regulation has further enhanced the regulation of the procedure of harmful substances, the Government cannot see that this important division of competence and duties between the EEA States on the one hand and the Community procedure on the other is altered radically as proposed by the Authority.

The Authority correctly notes that a prohibition of any national legislation would further enhance the objective of ensuring the free movement of goods within the EEA. However, ensuring a high level of protection of human health and the environment is an equally important objective. The Government’s understanding does, it is submitted, best ensure a balanced application of this twofold objective of the REACH regulation.

It is also noted that several EU States, i.a. in a discussion on this issue in the expert group for Competent Authorities for REACH and CLP (CARACAL), have expressed similar views as the ones set out by the Norwegian Government in this letter. Some of these, notably Denmark, Germany and Sweden, have also submitted their views in letters to the Commission.

This brief assessment hence calls for the following conclusion. In a transition period, where the restriction procedure has been initiated but has not yet resulted in any Community-wide harmonisation – or if the outcome of the procedure is that no harmonisation is eventually adopted – Member States can impose national regulations on a substance so long as it is in accordance with the conditions of Article 128(2). Any such national regulation would need to

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4 See, in particular, Case C-473/98 Toolex, paragraph 30.
5 Toolex, paragraphs 31-32.
6 Cf. also Case C-358/11, holding in paragraph 33 that Article 128 of the REACH regulation shows that there is harmonisation “in certain cases”, but apparently not in all cases falling under the scope of the Regulation.
7 See, for comparison, Toolex, paragraph 4.
be founded on legitimate concerns, be non-discriminatory in nature and be appropriate and necessary to reach the objective. The Norwegian prohibition of PFOA in consumer products fulfils these criteria.

This is different from when a harmonised, Community-wide regulation has come in place. In such cases, the manufacture, placing on the market and/or use of a substance is indeed harmonised, and any national action would have to be within the limits of the safeguard clause of Article 129 of the Regulation.

Other comments
The Authority points to a possible legal unclarity in the Norwegian regulation, in that a previous definition of consumer products is lacking. The definition in the regulation is superfluous due to the fact that the very same definition of consumer products already follows from the overarching Product Control Act, and consequently also applies to the regulation. This definition is relevant in other areas and has not been regarded as problematic with respect to enforcement. Furthermore, we refer to the provisions in Annex XVII to Regulation (EC) No 1907/2006 on REACH, cf. entries 28 to 30, which prohibit the placing on the market for supply to the general public of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1A or 1B or of mixtures containing them in concentration above specified concentration limits. It follows from Annex XVII that the intention of this prohibition is to also cover products that are made available for consumers, even though the products are meant for professional use only. This is in line with the definition in the Product Control Act which defines the consumer as “a natural person who is acting mainly for purposes not within the sphere of commercial or professional activities.” Consequently, we cannot see that any new uncertainty or unclarity is introduced by the new regulation with regard to consumer products.

The Authority further points to the possibility of the regulation being in conflict with existing harmonised EEA legislation, in particular on medicinal products, cosmetic products and electrical and electronic equipment. It follows from our legal system that the specific product regulations on medicinal products, cosmetics and electrical and electronic equipment implementing harmonised EEA-legislation have precedence over general product regulations without this being stated directly in the Product Regulation. Hence, the Product Regulation section 2-32 is fully compatible with existing harmonised EEA legislation on medicinal products, cosmetic products and electrical and electronic equipment.

Regarding electrical and electronic equipment PFOA is not explicitly regulated in the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive), and the Norwegian prohibition of PFOA does not contradict any harmonised regulation through the RoHS Directive.

Concluding remarks
Norway’s main policy on addressing chemicals risks is that it should be achieved at an international level. Norway is therefore together with Germany leading the work on PFOA under the REACH regulation.
When there is a harmonised regulation of manufacture, marketing or use of PFOA under REACH, we agree that national regulations will have to be in line with this. Norway is ready to change its regulation of PFOA when this becomes a reality.

It is the Government's view, that the text of the REACH regulation itself does not support the view that REACH harmonises not only the regulation of manufacture, placing on the market or use of substances, but also procedures for developing all kinds of restrictions.

We therefore believe that an EEA State may introduce well-founded, non-discriminatory and proportionate restrictions nationally in the absence of harmonised Community-wide regulations. In our view, our national regulation on PFOA in consumer products is in line with the obligations under the REACH regulation as well as under the general provisions of the EEA Agreement.

We kindly ask that these observations and comments are taken into account by the Authority in your further considerations on this issue.

Yours sincerely,

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