Date: 7 September 2008

To: Barbara Richter
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Re: Legal Advice on REACH

I. Background

The Norwegian Pollution Control Authority (*Statens Forurensningstilsyn*) has proposed to the Norwegian Ministry of the Environment that restrictions should be placed on the use of certain substances (including Bisphenol A) in consumer goods. No such restrictions on these substances existed on the date of entry into force of REACH in Norway.

Norway envisaged to adopt already in 2007 a very similar proposal (hereinafter the "2007 proposal"), i.e. prior to the date of entry into force of REACH.

Against this background you have asked for legal advice on two specific questions, namely whether

(1) Norway has the right to impose a restriction on any substance not previously restricted after the date of entry into force of REACH in Norway; and

(2) Whether the submission of a notice of a proposal to introduce a restriction before the date of entry into force of REACH in Norway ranks equally with the existence of a restriction which existed at the date of entry into force?

You have received already legal advice from us concerning the compatibility of the 2007 proposal under the free movement of goods provisions of the EEA Agreement. The advice from us and separate advise from Haavind Vislie also explain Norway's status under the EEA Agreement and its rights and obligations as the consequence of the incorporation of REACH into Annex II of the EEA Agreement.

In order to avoid any duplication with our previous advice, we will focus now on the two questions you have posed to us.

II. First Question

Does Norway has the right to impose a restriction on any substance not previously restricted after the date of entry into force of REACH in Norway ?

1. Applicability of Article 67(3) REACH ?

You have mentioned that Article 67(3) REACH could be of relevance in answering the first question. Article 67(3) reads:

> "*Until 1 June 2013, a Member State may maintain any existing and more stringent restrictions in relation to Annex XVII on the manufacture, placing on the market or use of substance, provided that those restrictions have been notified according to the Treaty. The Commission shall compile and publish an inventory of these restrictions by 1 June 2009*."

We have analysed Article 67(3) REACH, and have concluded that is not applicable to the case at hand. In this respect, we concur with the view expressed by DG ENTR (Unit G/1 – REACH), which you have attached to your email of 27 August 2008.

In summary, DG ENTR takes the view that "*since Bisphenol-A is not listed in Annex XVII of REACH, Article 67(3) REACH would not be applicable. Article 67(3) REACH only foresees for the possibility of maintaining existing national measures (for transitional period of time) related to substances already listed in Annex XVII*."

As DG ENTR has pointed out, first of all the Norwegian measure is not an existing restriction in the sense of Article 67(3), since it has not yet been adopted, and it does not relate to a substance listed in Annex XVII.

Our assessment is that DG ENTR's opinion seems to be correct. The purpose of this provision is to enable Member States[1] to maintain their existing restrictions, which go beyond the restrictions under REACH, for a transitional period. This rationale is also confirmed by recital 85 of REACH. Thus, the national restriction would have to relate to substances already listed in Annex XVII.

The interpretation of DG ENTR was informally confirmed to us by DG ENV and the Commission's Legal Service. In our view therefore, Article 67(3) REACH does not provide the key to the answer and it is, under the circumstances of this case, not applicable.

However, the question needs to be addressed whether Member States are still allowed to introduce national restrictions for substances which are not listed in Annex XVII?

[1] In this memo we will not differentiate between the notion of Member States, EFTA States or EEA States, since Norway's obligations under the EEA Agreement, with regard to REACH, correspond in essence to the obligations of Member States.

2. Applicability of Title VIII and Annex XVII of REACH before 1 June 2009 ?

First of all, it is important to note that the Community restrictions in Annex XVII will only apply from 1 June 2009. Although Article 141(1) REACH states that the Regulation enters into force on 1 June 2007, it also states in Article 141(4) REACH that Title VIII[2] and Annex XVII will apply from 1 June 2009.

Until that date Directive 76/769/EEC[3] is still applicable. This is confirmed by Article 139 REACH which states that Directive 76/769/EEC will be repealed with effect from 1 June 2009.

In other words, until 1 June 2009 national restrictions have to be assessed in light of Directive 76/769/EEC.

3. Scope of Directive 76/769/EEC

It is therefore necessary to establish whether Member States are still entitled to regulate some substances until 1 June 2009, or whether Directive 76/769/EEC precludes this.

At the outset it should be observed that whilst Article 30 EC allows the maintenance of national restrictions on the free movement of goods, justified on grounds which constitute fundamental requirements recognized by Community law, recourse to Article 30 EC is not possible where Community directives provide for harmonization of the measures necessary to achieve the specific objective which would be furthered by reliance upon that provision[4].

With regard to the scope of Directive 76/769/EEC, the Court of Justice has held that since this Directive only states certain minimum requirements it presents no obstacle to the regulation by Member States of the marketing of substances that do not fall within its scope[5]. To our knowledge, Bisphenol A is not covered by Directive 76/769/EEC. Hence, the case-law suggests that Directive 76/769/EEC does not prevent a Member State from regulating substances which are not covered by this Directive (subject to the general principles of free movement of goods which still apply). Whether this judgment still has the same weight once all Titles of REACH are fully applicable is questionable. REACH aims to ensure a high level of protection of human heath and the environment as well as the free movement of substances, on their own, in preparations and in articles while enhancing competitiveness and innovation. The complete set of rules under REACH will make it, in our view, in the future more difficult for Member States to adopt unilateral measures. That might indeed be one of the reasons why Norway reflects on the adoption of measures before 1 June 2009.

[2] Title VIII: Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, preparations and articles.
[3] Council Directive 76/769/EEC of 27 July on the approximation of laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ 1976 L 262, p. 201, as amended).
[4] See for example: Case C-5/94 *Hedley Lomas* [1996] ECR I-2553.
[5] Case C-473/98 *Toolex Alpha AB* [2000] ECR I-5681.

4. Article 128 REACH

Article 128 REACH might hinder Norway to impose a restriction on any substance not previously restricted. According to Article 141(2) REACH, Article 128 REACH applies from 1 June 2008. Article 128 REACH states:

> "*1. Subject to paragraph 2, Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a preparation or in an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.*
>
> *2. 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."*

On first glance, Article 128 REACH suggests that Member States have limited scope to introduce unilateral restrictions. On the other hand, Article 128(1) refers to substances which comply with REACH, suggesting that Member States' powers to introduce restrictions are limited to substances which have not been harmonised under REACH. This is confirmed by the wording in Article 128(2) REACH, which clarifies that Member States may introduce national restrictions, as long as REACH does not harmonise the requirements on manufacture, placing on the market or use. The informal view of DG ENV is that since Bisphenol A is not yet harmonized under REACH, it seems that there remains scope for Norway to introduce unilateral measures.

Bisphenol A is not listed in any of the Annexes of the Regulation (in particular on restrictions[6] or authorization[7]). However, the word "*harmonise*" can be subject to different interpretations. REACH entered into force on 1 June 2007 and most of its provisions are already applicable since 1 June 2008. In particular, the requirements laid down by REACH on pre-registration, registration, evaluation, notification and information within the supply chain for all substances falling into the scope of REACH already apply. Bisphenol A falls into the scope of REACH. Article 5 (*no data, no marketing* principle) and many other provisions of REACH could also be interpreted in constituting an harmonisation of the requirements on manufacture, placing on the market or use, which is precisely the purpose of REACH. In our view, one could argue that REACH has gone much further than the previous legislation and in particular Directive 76/769/EEC and therefore could constitute harmonization. This element is subject to interpretation and the Commission now seems to take the opposite view than the view it took in the Toolex case, even though REACH has gone much further in harmonizing the requirements for chemicals than Directive 76/769/EC. Therefore, we would recommend to request the formal view of the Commission on this point.

[6] Only applicable from 1 June 2009.
[7] Still not yet adopted.

It would also be useful to get the formal view of the Commission on the applicability of Article 129 REACH. We believe that one could argue that the procedure laid down in this safeguard clause should apply here, even if Norway is not seeking a restriction at EEA level but is only considering to restrict the use of the substance on its national territory. Norway should in this case inform the Commission, the EFTA Surveillance Authority, the Agency and other Member States and should be "*giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based.*" The EFTA Surveillance Authority would then take a decision on the national measure and either authorize the measure for a certain period or require Norway to revoke the measure.

5. Conclusion

Should Norway decide to go ahead and adopt national legislation before 1 June 2009, which will restrict the use of Bisphenol A, such law would have to be assessed under the general free movement of goods provisions in the EEA Agreement (which correspond in essence to the provisions of the EC Treaty) and Article 128 REACH. We have already provided you with our assessment of the 2007 proposal under these rules. As you have stated in your email of 21 August 2008, the new proposal seems to be very similar to the 2007 proposal. In light of the similarity of these two proposals, we attach the highly critical opinion of the EFTA Surveillance Authority, which assessed the 2007 proposal[8] under the DTR procedure[9]. We believe that it would be beneficial to request the formal view of the Commission on both the extent of the possible restriction of the free movement of goods under Article 128(2) and the applicability of the procedure laid down in Article 129.

III. Second Question

> Does the submission of a notice of a proposal to introduce a restriction before the date of entry into force of REACH in Norway rank equally with the existence of a restriction which existed at the date of entry into force?

In light of the above, we see no necessity to answer the second question. However, it will be interesting to see whether Norway has the intention to notify the new proposal to the EFTA Surveillance Authority under the DTR procedure. That would make sense, and is indeed an obligation under the DTR procedure, if the proposal substantially deviates from the 2007 proposal[10]. Should the proposal still correspond in substance to the 2007 proposal, then the EFTA Surveillance Authority's critical comments of August 2007 are still of relevance.

[8] The proposal was notified to the EFTA Surveillance Authority for comments (DTR 2007/9016/N).
[9] The Draft Technical Regulation (DTR) procedure under Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, as amended.
[10] Member States have to notify a draft again if they make changes to the draft that have the effect of significantly altering its scope, shortening the timetable originally envisaged for implementation, adding specifications or requirements, or making the latter more restrictive.

IV. Final remarks

It seems that until 1 June 2009 Norway has some scope to adopt measures for substances which are not covered by Directive 76/769/EEC. However, such measures would have to be in compliance with the free movement of goods provisions of the EEA Agreement and Article 128 REACH. If the new proposal corresponds in essence to the 2007 proposal, then there are strong concerns whether such a measure would be compatible with the EEA Agreement, as expressed in our previous advise and the EFTA Surveillance Authority's comments to the 2007 proposal. In our view, such a national measure should also be submitted to the EFTA Surveillance Authority for approval under Article 129 REACH.

In light of the national procedure in Norway and your intention to submit very soon comments to the Norwegian authorities, we have tried to keep this advise short and provide you with a rapid and preliminary assessment of your specific questions. If required we will expand on any of the points made above. As explained above, we also think that it would be useful to request the formal position of the Commission on this matter.

White & Case LLP, Brussels

1 Attachment