



REGERINGSKANSLIET

27 November 2007

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Ministry of the Environment
Minister for the Environment

Vice-President Verheugen
Commissioner Dimas
Executive Director Dancet

Dear Commissioners, dear Executive Director,

I would like to draw your attention to a new development in the interpretation and effectiveness of parts of the REACH Regulation which causes us considerable concern. It relates to access for consumers, professionals and industrial users in all Member States to crucial information on chemical substances of very high concern used in many different complex articles that are put on the market in the EU.

I would like to underline that the duty to disseminate such information is one of the most important elements of the REACH Regulation. The intention is to facilitate safe use, and at the same time allow informed choices of articles, thus fulfilling another main aim of REACH, namely to contribute to a progressive substitution of substances of very high concern with safer and viable alternatives.

However, according to the interpretation of the Commission Services as regards the new duty that has been presented to Member States and stakeholders, there will be no effective dissemination of such information by suppliers of articles, and specifically not for complex articles typically used by consumers. I fear that the interpretation of the Commission Services could pose a major obstacle to the protection of human health and the environment with respect to risks from the most dangerous substances in articles, as well as to fair competition and enforceability.

I would like to underline that the consequences of Commission's interpretation raise political concern and should also be discussed in a broader political perspective.

Therefore, I would welcome it if you would commence discussions with Member States, the Agency and the Commission on how to find, where

Postal address
SE-103 33 Stockholm
SWEDEN

Telephone
+46 8 405 10 00

E-mail: registrator@environment.ministry.se

Visitors' address
Drottninggatan 2

Fax
+46 8 24 16 29

Telex
154 99 MINEN S



possible, a more politically acceptable solution that fulfils the objectives of the REACH Regulation regarding the aforementioned problem.

For further detailed information, please see the enclosure.

Yours sincerely,

Andreas Carlgren
Andreas Carlgren
Minister for the Environment

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Therefore, I would welcome it if you would commence discussions with Member States, **cc: Ministers for the Environment in the EU**

Enclosure to letter from the Swedish Minister of the Environment, 27 November 2007: Interpretation of Reach provisions on information on SVHC in articles

The differing views that have arisen regarding the interpretation of the REACH Regulation cause us considerable concern. It relates to the scope of the information requirements for the content in articles of very problematic chemicals (substances of very high concern, SVHC), and also to the scope of the notification requirements for such contents. We feel it necessary to achieve broad agreement on a clear, effective and feasible interpretation of these requirements.

Recent cases of substances of very high concern (SVHC) in articles, such as the recall actions for toys containing lead compounds undertaken by a large manufacturer and the contamination of water recipients by Nonylphenol in imported textiles, remind us that considerable amounts of such chemicals may still be present in articles (often imported), which can cause severe risks for human health and the environment.

To tackle the shortage of information on such contents, REACH has introduced a requirement that the European Chemicals Agency (ECHA) be notified of articles containing SVHC and also that professional users and consumers be informed of articles containing such substances (Articles 7 and 33). These provisions enable ECHA to assess the scale of any possible problem, and allow the Commission to propose action at Community level if needed. The provisions also make it easier for operators to take safety measures, e.g., to comply with existing obligations such as legislation on occupational safety and product safety. The provisions also allow users, including consumers, to make informed choices.

During discussions at expert level, the Commission has defended an interpretation of REACH regarding the limit for application of the new provisions (0.1% content by weight of the article), which we believe will make the regulations largely dysfunctional. The Commission's view is that the limit should be applied to the entire, complex article, while a number of representatives of Member States and organisations representing professional users have underlined that it should be calculated on parts of the article being articles themselves, or something of the kind. The discussions thus have revealed fundamental differences of opinion as regards legal interpretation, which is a problem in itself for the application of REACH.

Using the Commission's interpretation, the information requirement would not apply when an article with a SVHC content above 0.1% is incorporated as part of a complex article, resulting in an average concentration in that article below 0.1%. Consequently, the information on SVHC content would not follow the complex article along the supply chain to the final user. We strongly believe that this cannot have been the intention of the legislators and is not in line with recital no 56: "...This important responsibility should also apply throughout the supply chain to enable all actors to meet their responsibility in relation to management of risks arising from the use of substances."

Limiting the application in this way would not only be problematic from the viewpoint of health and the environment. Competitive disadvantages would result for producers of complex articles in the EU compared with production outside the EU. Examples of this are where the incorporation of a SVHC into EU-made articles is regulated by an authorisation system, while there are no restrictions for imported articles due to lack of information, or when less market pressure from the EU does not encourage foreign suppliers of complex articles to abstain from using SVHCs. Arbitrary differences would result between e.g., suppliers of spare parts and suppliers of complex articles. Furthermore, enforcement would be made very difficult.

The Commission is currently planning to finalise the draft guidance document relating to substances in articles for subsequent endorsement by Member States and adoption by ECHA, despite the differing views of several Member States. We cannot agree to such a procedure.

We thus urge the Commission and ECHA to initiate a process to find a solution for reducing the negative implications accounted for above that could find the broadest possible support, while still aiming for the publication of clear and consistent guidelines in time.

In line with this, we recommend that

- ECHA elaborates a general procedure for elaboration, adoption and publication of guidance that includes communication to the public of any major differences as regards interpretation, if a guidance needs to be published as preliminary while the differences still remain, and that also includes a fast-track procedure for solving such differences
- The Commission hands over the RIP 3.8 file unfinished to ECHA for finalisation, adoption and publication according to the procedure.
- The Commission alternatively first asks MS for endorsement of RIP 3.8 parts not related to the 0.1% limit - i.e. most of the guidance - and ECHA publishes this as a first step, to ensure early availability of guidance for art 7.1 since it enters into force already 1 June 2008.
- Work is initiated to find a solution with respect to application of the limit that can get the broadest possible support, and aiming at publication of guidance for art 7.2 and 33 still in time with respect to the later dates for entry into force of these provisions