Dissenting views on the Guidance on requirements for substances in articles

Received from

Ständige Vertretung Österreichs
bei der Europäischen Union

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GZ: 4.12.2/4/08

Brüssel, am 14. Mai 2008

Betreff: **österreichischen Stellungnahme zum Entwurf REACH-Leitfaden**

Sehr geehrter Herr Dancet,

die Ständige Vertretung beehrt sich, im Namen der zuständigen österreichischen Behörde, des Bundesministeriums für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft, in der Anlage die österreichische Stellungnahme zu „Guidance on requirements for substances in articles under REACH" zu übermitteln.

Mit freundlichen Grüßen

Cornelia JÄGER
(Attaché)

Beilagen:

EUROPÄISCHE CHEMIKALIENAGENTUR
Herrn Geert DANCET
(echa-guidanceupdate@echa.europa.eu)
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FINNLAND

ALLGEMEINE UMWELTPOLITIK
Sektion V

lebensministerium.at

An die
Ständige Vertretung Österreichs
bei der Europäischen Union
z.Hd. Herrn Gesandten Mag. Walter Grahammer

per E-Mail

Wien, am 14.05.2008

Ihr Zeichen/Ihre Geschäftszahl Ihre Nachricht vom	Unsere Geschäftszahl	Sachbearbeiter(in)/Klappe
	BMLFUW-UW.1.5.7/0140-V/8/2008	Blei/DW 1301

Betreff: Übermittlung der österreichischen Stellungnahme zum Entwurf REACH-Leitfaden an ECHA

Sehr geehrter Herr Gesandter Grahammer!

Das Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft ersucht um Weiterleitung der österreichischen Stellungnahme zu „Guidance on requirements for substances in articles under REACH; comments by Austria (ECHA Document GD/jn D(2008/1183)“ per E-Mail an **echa-guidanceupdate@echa.europa.eu** zu veranlassen.

Vielen Dank im Voraus.

Mit freundlichen Grüßen

Mag. Elisabeth Freytag
Leiterin der Abteilung
EU – Angelegenheiten Umwelt

GENERAL ENVIRONMENTAL POLICY
Department V

lebensministerium.at

Mr
Geert Dancet
Executive Director
European Chemicals Agency
Annankatu 18
PO Box 400
00200 Helsinki
Finland

Vienna, 14.05.2008

Your Refence/Your File Number Your letter dtd.	Our File Number	Official-in-charge/Ext.
	BMLFUW-UW.1.5.7/0140-V/8/2008	Mr Martin Wimmer 2345

Subject: Guidance on requirements for substances in articles under REACH; comments by Austria (ECHA Document GD/jn D(2008)/1183

Declaration

Austria does not agree with the interpretation of Articles 7(2) and 33 expressed in sections 2.2 and 2.3 of the Guidance, that the threshold of a concentration of 0,1 % weight by weight (w/w) relates to a complex article as produced or imported. Austria is of the opinion that the limit value should normally relate to individual articles, parts or materials that a complex article consists of. In line with our dissenting view, we have not endorsed publication of those parts of the Guidance[1] that relate to the interpretation of the limit.

Austria welcomes that ECHA has undertaken to review the guidance as soon as possible. The aim for this review in our view should be to find a solution that can get the broadest possible support, based on workability and legal correctness.

Justification

Since Article 7(2) on its own can be interpreted in different ways, it should be read in its context, being the definition of 'article', the *ratio legis* in the recitals and the context of similar community legislation. Moreover practicability and enforceability should be considered as well.

The wording of Article 7.2 has to be read in conjunction with the definition of "article" in REACH, i.e. an *"object which during production is given a special shape, surface or design*

[1] *This is to be understood as in particular sections 2.2, 2.3, 5.2, 8 (8.4, 8.5, 8.7), and appendix 4, as well as lines 385-387 of section 3 and lines 37-39 of appendix 1*

which determines its function to a greater degree than does its chemical composition" (Article 3 lit. 3). This makes it clear that "*article*" in REACH refers not to complex articles composed of different parts, but to the object that is produced when the condition in Article 3lit.3 is fulfilled. The concept of a complex article is not defined or referred to anywhere in REACH.

Other pieces of EU legislation about chemicals in articles often specify how the content should be measured. Such provisions never relate to complex articles. There are a number of examples in Annex XVII. Article 7(8) identifies a need for implementation measures relating to the Article, which seem particularly appropriate for this case. No such measures have yet been decided or discussed. The interpretation given in the guidance would lead to arbitrary differences in application depending on whether the article is marketed as a separate part or integrated in a complex article. This interpretation will thus preclude effective dissemination by suppliers of articles of information on Substances of Very High Concern throughout the supply chain to the final user, especially for complex articles typically used by consumers. This could pose a major obstacle to the protection of human health and the environment with respect to risks from Substances of Very High Concern in articles. It could further pose a major obstacle to fair competition and enforceability. This cannot have been the intention of the legislators and is not in line with REACH recitals n°48 [2] and 56[3].

Follow-up

Austria intends to carefully examine the practical consequences of the Guidance as soon as Substances of Very High Concern will have been identified and published pursuant to article 59 (10). Should the enforcement bodies identify a specific case which verifies the concerns expressed above, Austria will bring this fact to the attention of ECHA and the Commission, aiming at an appropriate modification of the present Guidance.

In charge of the Federal Minister:
Thomas Jakl, PhD

Electronically signed

[2] "*This Regulation should be without prejudice to the full and complete application of the Community competition rules*"

[3] *„Part of the responsibility of manufactures or importers fort the management of the risks of substances is the communication of information on these substances to other professionals such as downstream users or distributors. In addition, producers or importers of articles should supply information on the safe use of articles to industrial and professional users, and consumers on request. 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"*

federal public service
HEALTH, FOOD CHAIN SAFETY AND ENVIRONMENT

Directorate-General for Environment
General Directorate

YOUR LETTER OF 28-04-2008
YOUR REF GD/jn D(2008)/1183
OUR REF NDR/941/05/08
DATE 14 -05- 2008
ENCL(S) 1

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Mr Geert Dancet
Executive Director of ECHA

SUBJECT Belgium's dissenting view concerning the Guidance on the requirements for substances in articles under REACH

Dear Sir,

As invited by your letter of 28-04-2008, please find annexed the declaration and the justification of Belgium's dissenting view concerning the Guidance on the requirements for substances in articles under REACH.

This position has been agreed on officially by the Coordination Committee on the International Environment Policy (CCIEP) –the decision making body in Belgium for national positions on environmental policy matters– following your invitation to notify dissenting views on this matter. This standpoint has its origin in the position that was followed by Belgium during all the negotiation processes on the REACH Regulation.

Belgium considers the interpretation in the guidance to be a serious obstacle to the protection of human health and the environment, as well as to fair competition and enforceability.

Therefore I would like to thank you for having taken the commitment to publish the dissenting views voiced by several Member States, and for having taken the commitment to review the guidance as soon as possible. We are convinced that this review will seek the broadest possible support, based on workability and legal correctness.

Yours sincerely

Roland Moreau
Chair of CCIEP
Director of DG Environment
Federal Public Service Health, Food Chain Safety and Environment

Declaration and justification of Belgium's dissenting view concerning the Guidance on the requirements for substances in articles under REACH

Declaration

Belgium does not agree with the interpretation expressed in sections 2.2 and 2.3 of the Guidance, where it is stated that the concentration threshold of 0,1 % (w/w) in Articles 7(2) and 33 relates to the complex article as produced or imported. Belgium is of the opinion that the limit value should relate to individual articles, parts or materials that a complex article consists of. In line with our dissenting view, we have not endorsed publication of those parts of the Guidance that relate to the interpretation of the limit.[1] This position already has been voiced by the Belgian MSCA at the 2nd meeting and by the Belgian representative at the Management Board meeting on the 23th of April 2008.

Belgium thanks the Executive Director of ECHA for having taken the commitment to review the guidance as soon as possible. We are convinced that this review will seek the broadest possible support, based on workability and legal correctness.

Justification

Since Article 7(2) on its own can be interpreted in different ways, it should be read in its context, being the definition of 'article', the *ratio legis* in the recitals and the context of similar community legislation. Moreover practicability and enforceability should be considered as well.

The definition of 'article' in REACH, i.e. an "*object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*" (Article 3(3)), makes it clear that 'article' in REACH refers not to complex articles composed of different parts, but to the object that is produced when the condition in Article 3(3) is fulfilled. Such an object would often consist of one single material that could at some stage form a part of a complex article. The concept of a complex article is not defined or referred to anywhere in REACH, however.

Other pieces of EU legislation about chemicals in articles often specify how the content should be measured. As far as we are aware of, such provisions never relate to complex articles. Even in REACH itself, there are a number of examples in Annex XVII where the threshold explicitly relates to certain relevant parts of the article, rather than the whole complex article. Article 7(8) identifies a need for implementation measures relating to paragraphs 1 to 7 of this Article, which seem particularly appropriate for this case. No such measures have yet been discussed or decided on.

The interpretation given in the guidance would lead to arbitrary differences in application, depending on whether the article is marketed as a separate part or integrated in a complex article (e.g. spare parts of a car). This interpretation will thus preclude effective dissemination of information by suppliers of articles on Substances of Very High Concern throughout the supply chain to the final user, especially in the case of complex articles typically used by consumers. This could pose a major obstacle to the protection of human health and the environment considering the risks emerging from Substances of Very High Concern in articles, as well as to fair competition and enforceability.

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[1] *This is to be understood as in particular sections 2.2, 2.3, 5.2, 8 (8.4, 8.5, 8.7), and appendix 4, as well as lines 385-387 of section 3 and lines 37-39 of appendix 1*

Belgium strongly believes that this cannot have been the intention of the legislators and is not in line with REACH recitals n°48 and 56.[2]

[2] Recital 48: This Regulation should be without prejudice to the full and complete application of the Community competition rules.
Recital 56: Part of the responsibility of manufacturers or importers for the management of the risks of substances is the communication of information on these substances to other professionals such as downstream users or distributors. In addition, producers or importers of articles should supply information on the safe use of articles to industrial and professional users, and consumers on request. 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.

Declaration and justification of the dissenting view of Denmark concerning the Guidance on requirements for substances in articles under REACH

Declaration

Denmark does not agree with the interpretation of Articles 7(2) and 33 of REACH expressed in sections 2.2 and 2.3 of the Guidance, that the threshold of a concentration of 0.1 % weight by weight (w/w) relates to a complex article as produced or imported. Denmark is of the opinion that the limit value should relate to individual articles, parts or materials that a complex article consists of. In line with our dissenting view, we have not endorsed publication of those parts[1] of the Guidance that relate to the interpretation of the limit.

Denmark welcomes that the Executive Director of ECHA has undertaken to review the guidance as soon as possible. The aim in our view need to be to find a solution that can get the broadest possible support, based on workability and legal correctness.

Justification

Since Article 7(2) on its own can be interpreted in different ways, it should be read in its context, being the definition of 'article', the *ratio legis* in the recitals and the context of similar community legislation. Moreover practicability and enforceability should be considered as well.

Article 7(2) does not give any indication that the 0.1 % w/w threshold refers to the total weight of the substance in question accumulated for all individual articles, parts or materials that a complex article consists of, and as a proportion of the total weight of the complex article. On the contrary, Article 7(2) specifies that the threshold is a w/w *concentration* which in the context of chemicals safety generally means a concentration in a preparation or material whether in a (gaseous), liquid or solid state.

The wording of Article 7.2 has to be read in conjunction with the definition of "article" in Reach, i.e. an "*object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*" (Article 3(3)). This makes it clear that "article" in Reach refers not to complex articles composed of different parts, but to the object that is produced when the condition in Article 3(3) is fulfilled. Such an object would often consist of a material and could at some stage form a part of a complex article. The concept of a complex article is not defined or referred to anywhere in Reach, however.

Other pieces of EU legislation about chemicals in articles often specify how the content should be measured. As far as we are aware of, such provisions never relate to complex articles. Even in REACH itself, there are a number of examples in Annex XVII where the threshold relates to certain relevant parts of the article, rather than the whole complex article. Article 7(8) identifies a need for implementation measures relating to the Article, which seem particularly appropriate for this case. No such measures have yet been decided or discussed.

[1] *This is to be understood as in particular sections 2.2, 2.3, 5.2, 8 (8.4, 8.5, 8.7), and appendix 4, as well as lines 385-387 of section 3 and lines 37-39 of appendix 1*

The interpretation given in the guidance would lead to arbitrary differences in application depending on whether the article is marketed as a separate part or integrated in a complex article. This interpretation will preclude effective dissemination by suppliers of articles of information on Substances of Very High Concern throughout the supply chain to the final user, especially for complex articles typically used by consumers. This could pose a major obstacle to the protection of human health and the environment with respect to risks from Substances of Very High Concern in articles, as well as to fair competition and enforceability.

Denmark strongly believes that this cannot have been the intention of the legislators and is not in line with REACH recitals number 48 and 56[2].

[2] Recital 48: "This Regulation should be without prejudice to the full and complete application of the Community competition rules"
Recital 56: "Part of the responsibility of manufacturers or importers for the management of the risks of substances is the communication of information on these substances to other professionals such as downstream users or distributors. In addition, producers or importers of articles should supply information on the safe use of articles to industrial and professional users, and consumers on request. 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."

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RÉPUBLIQUE FRANÇAISE

MINISTÈRE DE L'ÉCOLOGIE, DE L'ÉNERGIE,
DU DÉVELOPPEMENT DURABLE ET DE L'AMÉNAGEMENT DU TERRITOIRE

Direction de la Prévention
des Pollutions et des Risques

Sous-direction des produits et déchets
Bureau des substances et préparations chimiques
Référence : NoteECHA-PositionFR-RIP 3-8.doc
DPPR/SDPD/BSPC/LC n° **080304**

Affaire suivie par : Emmanuel MOREAU
Tel. : 01 42 19 19 89 – Fax : 01 42 19 14 68
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Paris, le **14 MAI 2008**

Le directeur de la prévention
des pollutions et des risques,
délégué aux risques majeurs

à

Monsieur le Directeur Exécutif de l'Agence
Européenne des Produits Chimiques
ECHA
P.O. BOX 400
00121 HELSINKI
FINLANDE

Objet : Position française relative à l'interprétation du seuil de 0,1% dans le RIP 3.8

Les autorités françaises regrettent l'interprétation des articles 7.2 et 33 du règlement Reach exprimée aux sections 2.2 et 2.3 du guide technique 3.8, selon laquelle le seuil de concentration de 0,1% masse sur masse (m/m) s'applique aux articles complexes, produits ou importés. Les autorités françaises partagent l'avis que cette valeur limite devrait s'appliquer aux articles individuels, constituants ou parties d'un article complexe. En cohérence avec cette position, les autorités compétentes françaises n'ont pas adopté la publication des éléments du guide technique faisant référence à cette interprétation.

Les autorités françaises remercient le Directeur Exécutif de l'Agence Européenne des Produits Chimiques d'avoir pris l'engagement de réviser le guide le plus rapidement possible. A notre sens, l'objectif de cette révision serait d'atteindre un consensus le plus large possible, sur une base légale et applicable.

L'article 7.2 ne précise pas que le seuil de 0,1% (m/m) est calculé comme le poids total de la substance en question cumulé pour tous les articles individuels, constituants ou parties d'un article complexe, rapporté au poids total de l'article complexe.

L'article 7.2 précise au contraire que ce seuil est une concentration m/m qui dans le cadre de la sécurité des produits chimiques s'entend généralement comme la concentration

dans une préparation ou un matériau que ce soit sous une forme liquide ou solide. Le contenu de l'article 7.2 doit être lu en relation avec la définition de « article » dans Reach, à savoir « *un objet auquel sont donnés, au cours du processus de fabrication, une forme, une surface, ou un dessin particuliers qui sont plus déterminants pour sa fonction que sa composition chimique* » (Article 3.3). Cette définition indique que « article » dans Reach ne fait pas référence à des articles complexes composés de différentes parties, mais à l'objet qui est produit quand la condition de l'article 3.3 est remplie. Un tel objet pourra à un stade ultérieur former un constituant d'un article complexe. Il n'est par ailleurs nulle part défini ou fait référence dans Reach à la notion d'article complexe.

D'autres dispositions de la législation européenne sur les produits chimiques dans des articles spécifient comment leur contenu doit être mesuré. Un certain nombre d'exemples figure à l'Annexe XVII. L'article 7.8 identifie un besoin de modalités pratiques de mise en œuvre, notamment de l'article 7.2, ce qui paraîtrait particulièrement approprié dans ce cas. De telles modalités n'ont pas pour l'instant été décidées ou discutées.

L'interprétation figurant dans le guide technique 3.8 pourrait conduire à des différences arbitraires d'application selon que l'article est mis sur le marché comme pièce détachée ou bien intégré dans un article complexe. Cette interprétation conduirait également à ce que l'information sur la substance extrêmement préoccupante n'accompagnerait pas l'article complexe le long de la chaîne d'approvisionnement jusqu'à l'utilisateur final, et cela tout particulièrement pour les articles complexes utilisés par les consommateurs. Cela serait problématique en termes de protection de la santé et de l'environnement au regard des substances extrêmement préoccupantes dans les articles, mais également en termes d'application du règlement et de désavantage compétitif pour les producteurs européens.

Les autorités françaises sont persuadées que cela n'a pu être l'intention des législateurs et que l'interprétation n'est pas cohérente avec les considérants n°48 (*« Le présent règlement ne devrait pas porter préjudice à l'application pleine et entière des règles communautaires de concurrence »*) et 56 (*« ...Cette importante responsabilité devrait s'appliquer également tout au long de la chaîne d'approvisionnement pour permettre à tous les acteurs de s'acquitter de leurs obligations en matière de gestion des risques résultant de l'utilisation des substances »*).

Le directeur de la prévention
des pollutions et des risques,
délégué aux risques majeurs

Laurent MICHEL

Ständige Vertretung
der Bundesrepublik Deutschland
bei der Europäischen Union
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An die
Europäische Agentur für chemische Stoffe
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per e-mail:
info@echa.europa.eu

BETREFF **Leitfaden (RIP 3.8) für die Anforderungen für Stoffe in Erzeugnissen nach der REACH-VO**
HIER **Mitteilung einer abweichenden Meinung zum Leitfaden**
BEZUG Schreiben des Exekutivdirektors der Europäischen Chemikalienagentur vom 28.04.08
ANLAGE
GZ Wi-701-11 (bitte bei Antwort angeben)

Brüssel, 15. Mai 2008

Sehr geehrte Damen und Herren,

anliegend übersende ich Ihnen eine Mitteilung der Regierung der Bundesrepublik Deutschland sowie die entsprechende Höflichkeitsübersetzung in oben genannter Angelegenheit.

Mit freundlichen Grüßen
Im Auftrag

gez.
Romeis

Bundesministerium
für Umwelt, Naturschutz
und Reaktorsicherheit

EINE NATUR • EINE WELT • UNSERE ZUKUNFT
UN-Naturschutzkonferenz Bonn 2008

Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit, IG II 4,
Postfach 12 06 29, 53048 Bonn

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über:

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Leitfaden (RIP 3.8) für die Anforderungen für Stoffe in Erzeugnissen nach der REACH-VO
Mitteilung einer abweichenden Meinung zum Leitfaden

Schreiben des Exekutivdirektors der Europäischen Chemikalienagentur vom 28.4.08

Aktenzeichen: IG II 4 - 61060-2/2
Bonn, 13.05.2008

Ich bitte um Weiterleitung der beigefügten Mitteilung der Regierung der Bundesrepublik Deutschland sowie der beigefügten Höflichkeitsübersetzung an die Europäische Chemikalienagentur. Für Übersendung eines Abdrucks Ihres Schreibens zur Weiterleitung der Mitteilung wäre ich dankbar.

Im Auftrag

Dr. Drossard

Anlagen
Mitteilung der Bundesrepublik Deutschland
Höflichkeitsübersetzung

Mitteilung
der Regierung der Bundesrepublik Deutschland
an die Europäische Chemikalienagentur
vom 15. Mai 2008

Leitfaden für die Anforderungen für Stoffe in Erzeugnissen nach der REACH-Verordnung

Die Regierung der Bundesrepublik Deutschland beehrt sich, der Europäischen Chemikalienagentur folgendes mitzuteilen:

Mit Schreiben vom 28. April 2008 (Aktenzeichen: GD/jn D(2008)/1183) hat der Exekutivdirektor der Europäischen Chemikalienagentur (ECHA) die Mitgliedstaaten darüber informiert, dass die ECHA den Leitfaden zu Stoffen in Erzeugnissen (RIP 3.8) auf ihrer Webseite unter Verweis auf abweichende Meinungen der Mitgliedstaaten veröffentlichen wird.

Die Bundesregierung vertritt hinsichtlich der Auslegung des 0,1%-Grenzwertes in Artikel 7 (2) und 33 der REACH-VO eine andere Auffassung als die im Leitfaden genannte und bittet daher darum, bei der Veröffentlichung des Leitfadens auf die folgende Position Deutschlands hinzuweisen:

„Die Bundesregierung widerspricht den Aussagen in den Kapiteln 2.2, 2.3, 5.2, 8 (8.4, 8.5, 8.7), im Anhang 4, in den Zeilen 385-387 von Kap. 3 und Zeilen 37-39 von Anhang 1 des Leitfadens zur Frage, auf welche Bezugsgröße sich im Falle komplexer Erzeugnisse der 0,1 %-Grenzwert nach Artikel 7 (2) und 33 der REACH-Verordnung bezieht. Die Bundesregierung hat erhebliche Zweifel an der Richtigkeit der den genannten Passagen zugrunde liegenden Auslegung, wonach sich der Grenzwert bei komplexen Erzeugnissen allein auf das Gesamterzeugnis, nicht jedoch auf die in diesem Erzeugnis enthaltenen Teilerzeugnisse bezieht. Sie befürchtet, dass diese Auslegung in der Praxis weithin zu einem Leerlaufen der betreffenden, insbesondere für den Verbraucherschutz wichtigen Vorschriften der REACH-Verordnung führen würde, und ist der Auffassung, dass dies dem u. a. in Erwägungsgrund 56 ausdrücklich zum Ausdruck gebrachten Willen des REACH-Gesetzgebers nicht entspräche.

Die Bundesregierung begrüßt vor diesem Hintergrund die Bereitschaft der ECHA, den Leitfaden in diesem Punkt nochmals zu überprüfen. Sie bittet, diese Überprüfung nach Möglichkeit so zügig vorzunehmen, dass bei dem praktischen Wirksamwerden der betreffenden Vorschriften ein einheitlicher Vollzug in Europa erreicht werden kann."

Eine Höflichkeitsübersetzung des zu veröffentlichenden Textes ist als Anlage beigefügt.

The German government disagrees with the statements in chapters 2.2, 2.3, 5.2, 8 (8.4, 8.5, 8.7), in Annex 4, in lines 385-387 of Chapter 3 and lines 37-39 of Appendix 1 of the Guidance regarding, in the case of complex articles, the reference standard to which the 0.1% threshold of Articles 7 (2) and 33 of the REACH Regulation applies. The German government has considerable reservations concerning the validity of the interpretation which is taken as the basis for the passages indicated, according to which the threshold for complex articles relates solely to the whole article, but not to the article parts contained within this article. The German government is concerned that in practice this interpretation would largely lead to the relevant REACH Regulation provisions which are especially important for consumer protection being inoperative. In Germany's opinion this does not comply with the will of the REACH legislator as specifically expressed i.a. in recital 56.

Against this background, the German government welcomes the fact that ECHA is prepared to review the guidance again with regard to this point. Germany requests that as far as possible this review be undertaken speedily, so that a uniform enforcement throughout Europe can be achieved when the provisions concerned come into effect.

REGERINGSKANSLIET

15 May 2008

Ministry of the Environment

Anna-Maria Wide Nelson
Deputy Head of Division
Division for Ecomanagement and Chemicals

Executive Director Gert Dancet
European Chemicals Agency
P.O. Box 400
00121 Helsinki
Finland

Declaration and justification of Sweden's dissenting view concerning the Guidance on requirements for substances in articles under REACH

Declaration

Sweden does not agree with the interpretation expressed in sections 2.2 and 2.3 of the Guidance, where it is stated that the concentration threshold of 0,1 % weight by weight (w/w) in REACH Articles 7(2) and 33 relates to a complex article as produced or imported. Sweden is of the opinion that the limit value should relate to individual articles, parts or materials that a complex article consists of. In line with our dissenting view, we have not endorsed publication of those parts[1] of the Guidance that relate to the interpretation of the limit.

Sweden welcomes that the Executive Director of ECHA has undertaken to review the guidance as soon as possible. The aim in our view needs to be to find a solution that can get the broadest possible support, based on workability and legal correctness.

Justification

Article 7(2) does not give any indication that the 0,1 % w/w threshold refers to the total weight of the substance in question accumulated for all individual articles, parts or materials that a complex article consists of, and as a proportion of the total weight of the complex article. On the contrary, Article 7(2) specifies that the threshold is a w/w *concentration* which in the context of chemicals safety generally means a concentration in a preparation or material whether in a (gaseous), liquid or solid state.

The wording of Article 7(2) has to be read in conjunction with the definition of "article" in Reach, i.e. an "*object which during production is given a special shape, surface or design which determines its function to a greater degree than does*

[1] This is to be understood as in particular sections 2.2, 2.3, 5.2, 8 (8.4, 8.5, 8.7), and appendix 4, as well as lines 385-387 of section 3 and lines 37-39 of appendix 1.

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its chemical composition" (Article 3(3)). This makes it clear that "article" in Reach refers not to complex articles composed of different parts, but to the object that is produced when the condition in Article 3(3) is fulfilled. Such an object would often consist of a material and could at some stage form a part of a complex article. The concept of a complex article is not defined or referred to anywhere in Reach, however.

Other pieces of EU legislation about chemicals in articles often specify how the content should be measured. As far as we are aware of, such provisions never relate to complex articles. Even in REACH itself, there are a number of examples in Annex XVII where the threshold relates to certain relevant parts of the article, rather than the whole complex article. Article 7(8) identifies a need for implementation measures relating to the Article, which seem particularly appropriate for this case. No such measures have yet been decided or discussed.

The interpretation given in the guidance would lead to arbitrary differences in application depending on whether the article is marketed as a separate part or integrated in a complex article. This means that in some cases the users will get information on a certain substance and in some cases not, even if the risk for exposure to this substance is the same in all these cases. This interpretation will preclude effective dissemination by suppliers of articles of information on Substances of Very High Concern throughout the supply chain to the final user, especially for complex articles typically used by consumers. This could pose a major obstacle to the protection of human health and the environment with respect to risks from Substances of Very High Concern in articles, as well as to fair competition and enforceability.

Sweden strongly believes that this cannot have been the intention of the legislators and is not in line with REACH recitals number 48 and 56[2].

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[2] Recital 48: "This Regulation should be without prejudice to the full and complete application of the Community competition rules"
Recital 56: "Part of the responsibility of manufacturers or importers for the management of the risks of substances is the communication of information on these substances to other professionals such as downstream users or distributors. In addition, producers or importers of articles should supply information on the safe use of articles to industrial and professional users, and consumers on request. 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."