13th March 2012

JBCE Position on the Restrictions Proposal of 4 Phthalates (DEHP, BBP, DBP, DIBP)

The Japanese Business Council in Europe (JBCE - organisation representing companies of Japanese parentage operating in Europe), has taken note of Denmark's initiative to submit an Annex XV restrictions report with the proposal for a restriction on 4 phthalates (DEHP, BBP, DBP, DIBP) [1] and appreciates the opportunity to provide comments.

We would like to raise a number of concerns which relate to the scientific basis of the report, as well as to the practicality of the proposed restriction.

Yours sincerely,

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ABOUT JBCE

The Japan Business Council in Europe was established in 1999 as the representative organization of Japanese companies operating in the European Union. Our membership consists of more than 60 leading multinational corporations that are active across a wide range of sectors, including electronics, automotive, and chemical manufacturing. The key goal of JBCE is to contribute to EU public policy in a positive and constructive way. In doing this, we can draw upon the expertise and experience of our member companies.

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[1] Danish Environmental Protection Agency (2011) – Annex XV Restriction Report – Proposal for a Restriction - Bis-(2-ethylhexyl) phthalate 5DEHP), Benzyl butyl phthalate (BBP), Di-butyl phthalate (DBP) and Di-isobutyl phthalate (DIBP) – Version Number 2, 12 August 2011
http://echa.europa.eu/doc/restrictions/restriction_report_phthalates.pdf

1. Scientific Basis of the Restriction Report

The Restrictions Report of the Danish Environmental Protection Agency (EPA) makes reference to two concepts which have been discussed – to some extent even in great detail, but have not yet been fully agreed in the European Union (EU). The Restrictions Report also makes use of risk assessment methods that have equally not yet been finally established scientifically.

a. Concepts which have not yet been fully agreed in the EU

- Combined effect[2]

The concept of "combined effect" is often used to express the effect a mixture of multiple chemical substances can have on human health and/or the environment.

In this context however the concept of "combined effect" has not been fully clarified and clearly defined. More importantly, no robust scientific risk assessment method has yet been established.

In their preliminary opinion approved for public consultation concerning the 'Toxicity and Assessment of Chemical Mixtures' the Scientific Committees on Consumer Safety (SCCS), Health and Environmental Risks (SCHER) and Emerging and Newly Identified Health Risks (SCENIHR) recommend a decision tree for risk assessment, but at the same time emphasise the existence of knowledge gaps, which has strong implications for legislation.[3]

To the question *'Does current knowledge constitute a sufficiently solid foundation upon which to address the toxicity of chemical mixtures in a more systematic way in the context of EU legislations?'* the answer states that *'In many cases, knowledge is insufficient for a robust scientific analysis'*.[4]

[2] The Danish Restriction Proposal has introduced an assessment method based on Combined Effects. Within this proposal dose additional models, combined exposures, combination effects and others are all treated as "Combined effect"

[3] European Commission, Health & Consumer Protection Directorate-General, Scientific Committee on Consumer Safety (SCCS), Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *Toxicity and Assessment of Chemical Mixtures (Preliminary Opinion approved for Public Consultation)*, 2011

[4] Ibid., p. 34.

- Endocrine disruption

Currently there is no agreed scientific assessment method in place for identification of endocrine disruptors.

The risk assessment method is still being discussed in the EU. The assessment by the Danish EPA is thus premature. Indeed, the JBCE believes that the aspect of endocrine disruption can only be assessed thoroughly after conclusion is reached on the appropriate scientific assessment method.

b. Risk assessment methods

- Toxicity assessment method

The JBCE considers that in its toxicity assessment method the Danish EPA has made use of a number of conservative (overly cautious) index values.

This is the case for determining the Derived No Effect Levels[5] (DNEL) where the uncertainty factor defining margins of safety have been set too high resulting in overestimated risks.

Next to that there is confusion on the selection of endpoints[6], leading to a situation where risks that are unlikely have also been evaluated. Not only have the reproductive and developmental toxicities been mentioned as an endpoint, but also the endocrine disrupting effect of phthalates, which seems a great leap of logic.

- Exposure assessment method

The JBCE feels that the exposure assessment method makes use of some extreme examples which should be considered unlikely in a day-to-day situation.

On the one hand exposure estimates are presented which are overestimated and unlikely for articles such as erasers and sandals[7]. On the other hand the main target of biomonitoring[8] were infants (age 2-3 years) which resulted in environmental exposure estimates that are unlikely under normal circumstances.

[5] Annex XV Restriction Report, Table 16 (page 70-71)
[6] Annex XV Restriction Report, line 5-9 (page 16)
[7] Annex XV Restriction Report, line 38 (page 16) and line 11 (page 17)
[8] Annex XV Restriction Report, line 11-21 (page 20)

2. Authorisation Process prior to Restrictions Process

The JBCE is concerned about the Restrictions process running in parallel with the Authorisation process and, more specifically, the possibility of restrictions of uses of the 4 phthalates becoming effective before authorisation of the uses of the 4 phthalates has become effective/fully implemented. This situation is potentially creating uncertainty in the EU and global supply chain.

3. Practicality of the Danish Restrictions Proposal

Based on the proposal as currently defined within the Restrictions Report the JBCE has identified a number of issues which could negatively affect and hinder a successful implementation by industry.

a. Articles that may come into direct contact with the skin or mucous membranes

In view of the identified risk exposures the JBCE would like to see clarification that the ban only applies to those articles where plasticised materials come into direct contact with the skin or mucous membranes.

Furthermore, we would appreciate that taking into consideration the risk exposures identified the restriction would only consider prolonged direct contact with the skin or mucous membranes. To provide legal certainty the term “prolonged” should however be further defined, preferably in line with existing practice.

b. Transitional period

The current proposal envisages a transitional period of 12 months from entry into force of the restriction. However, to provide consistency within industry the JBCE would strongly recommend that the timeline for these instructions is aligned with the authorisation timeline for each of these substances. In respecting these timelines no restriction should become effective before the authorisation sunset date.

c. Concentration values

The JBCE sees difficulty in controlling substances within its supply chain where concentration thresholds are defined not on an individual substance level, but in function of a number of substances.

We recommend that the concentration values be defined on the level of the individual substance, to accommodate uniform and correct substance information within the supply chain.

d. Derogations

The proposal in its current form does not provide derogations for spare parts intended for repair of articles which are placed on the market before the restriction enters into force.

In support of the "repair as produced" principle the JBCE would recommend to consider such a derogation.

4. Conclusion

1. The EU is still discussing how to approach the issue of the combined effects of chemicals. Prior to any decision on the combined effects of these phthalates the EU needs to agree on how to deal with significant knowledge gaps preventing robust scientific analysis and arrive at scientifically validated criteria.

2. In view of potential supply chain difficulties we would appreciate if restrictions decisions on the 4 phthalates were not to be made before the authorisation process concerning these phthalates has been finalised.

3. Restrictions proposals must provide for clear and unambiguous measures that appropriately address identified risk exposures and which allow industry to ensure effective implementation within its supply chain

Finally, as an involved stakeholder, the JBCE remains available for further consultation and cooperation on the above and related issues in current and future discussions.