6.

STEFANOVA Desislava (ENTR)

From: [redacted]@hse.gsi.gov.uk
Sent: 28 March 2013 18:17
To: GIRAL-ROEBLING Anne (ENTR); KORYTAR Peter (ENV)
Subject: FW: Call for contribution on EDs and REACH Review according to Art 138(7) - scientific documents from the UK REACH CA
Attachments: ~~SE CA Position Article 138_7_UKcomments_March13.DOC~~; UK commentary_REACH_Art 138(7).doc

Dear Anne and Peter

Since I have not received an acknowledgment of receipt of the documents I sent yesterday to the generic email accounts, I am sending them again to yourselves. Can you acknowledge receipt please, if possible?

Happy Easter

[redacted]

[redacted]
Human Health & Chemical Schemes Unit
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From: [redacted]
Sent: 27 March 2013 15:09
To: 'entr-caracal@ec.europa.eu'; 'env-caracal@ec.europa.eu'
Cc: [redacted]
Subject: Call for contribution on EDs and REACH Review according to Art 138(7) - scientific documents from the UK REACH CA

Dear Colleagues

In response to the call for information above, the UK REACH CA in HSE would like to submit a scientific commentary on the issue. We also attach an annotated version of the SE CA paper on Art 138(7) with some brief remarks.

We would appreciate it if you could acknowledge receipt of the documents and hope that they will contribute to the review/evaluation being undertaken by the Commission.

Best wishes

[redacted]

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Commentary -
UK views on the issue of whether or not a threshold can be determined for endocrine disruptors identified as Substances of Very High Concern under REACH

Background

REACH Art 138(7) states:

"By 1 June 2013 the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60(3) to substances identified under Article 57(f) as having endocrine disrupting properties. On the basis of that review the Commission may, if appropriate, present legislative proposals."

This implies that by 1 June 2013 the Commission needs to come to a conclusion on whether endocrine disruptors (EDs) identified as Substances of Very High Concern (SVHCs) and included in Annex XIV of REACH should be authorised through the socio-economic route or the adequate-control route. The socio-economic route (Art 60(3)) is currently reserved to CMR 1A or 1B substances and substances of "equivalent" concern for which it is not possible to determine a threshold in accordance with section 6.4 of Annex I (i.e. it is not possible to determine a DNEL or a PNEC) and to PBT and vPvB substances.

Therefore, extending the scope of Art 60(3) to all EDs identified as SVHCs by default hinges around the concept of whether or not it is possible to determine a threshold/DNEL/PNEC for such substances.

With this commentary, the UK REACH CA would like to offer some initial views on the interpretation of the available evidence surrounding the issue of the determination of a threshold for substances with endocrine disrupting properties.

In our view, it is vitally important that EU regulatory positions are based on the best science available at the time. Where there are different views, regulatory positions should reflect where the balance of opinion lies across the relevant fields of expertise in the EU and worldwide and the scientific advisory system that is in place. To do otherwise is to negate the value of expertise and nullify the purpose of the EU's standing arrangements for the provision of advice.

General considerations on thresholds

The first consideration is what Art 60(3) implies by the term "threshold". There are many definitions, interpretations and types of thresholds: theoretical, absolute, mathematical, biological, toxicological, practical, true, experimental, apparent, regulatory, etc. It is evident from the legal text that the term "threshold" is used in Art 60(3) to be equivalent to the DNEL or PNEC and hence to signify a regulatory, practical exposure standard the adherence to

of interaction (threshold of adversity) might be lower in the developing organism than in the adult, and the nature of the effect might be different (severe, permanent damage in the foetus vs a less severe effect in the adult), but a threshold of adversity must exist.

It is also often argued that since EDs display "low-dose" effects and non-monotonic dose responses (NMDRs), the threshold level (apparent NOAEL) identified by conventional toxicity testing is incorrect. There is no consensus in the scientific community on the existence and relevance in toxicology of these phenomena. However, if and when they occur, they do not preclude the existence of a threshold. Therefore, it is premature to assume that these phenomena are the rule and to justify the abandonment of the standard, thresholded risk assessment paradigm on this basis.

Conclusion

Overall, there is nothing special or unique about endocrine disruption or greater uncertainties in its assessment compared to other non-genotoxic forms of toxicity to justify adopting a non-threshold approach by default. Biology predicts that thresholds of adversity exist and are the rule for all endpoints, including those arising from endocrine disruption.

Therefore, extending the scope of Art 60(3) to all EDs identified as SVHCs by default is not supported.

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DISCLAIMER: **This document was finalised in March 2013. Since then several scientific papers have been published in the open literature, which further support the conclusions reached in the document. The commentary is a working document produced to contribute to ongoing EU discussions and policy development on endocrine disruptors.**