PETROVA Nevyana (ENV)

From: CLIFFORD Grace (ENV) on behalf of BORCHARDT Gustaaf (ENV)
Sent: 06 September 2012 09:28
To: HOUGARDY Yannik (ENV-EXT)
Subject: FW: Endocrine disrupting chemicals
Attachments: ACHS comments on Kortenkamp et al_final.docx; 120815 Letter to Commission on EDs.docx

Found it ;-)

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From: [redacted] (ERG-CPN) [mailto[redacted]@defra.gsi.gov.uk]
Sent: Friday, August 17, 2012 12:12 AM
To: BORCHARDT Gustaaf (ENV)
Cc: COZIGOU Gwenole (ENTR); RYS Andrzej Jan (SANCO); [redacted] (CN)
Subject: Endocrine disrupting chemicals

Dear Mr Borchardt

Please find attached a letter from [redacted] and an accompanying paper from the UK Advisory Committee on Hazardous Substances. I apologise that the latter document was missing from my earlier message.

Best wishes

[redacted]

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Department for Environment, Food and Rural Affairs (Defra)

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Advisory Committee on Hazardous Substances[1]

Comments on Kortenkamp *et al* (2012) "State Of The Art Assessment Of Endocrine Disrupters"[2]

At its June 2012 meeting the Advisory Committee on Hazardous Substances (ACHS) was invited to consider a Report by Kortenkamp *et al* entitled "State Of The Art Assessment Of Endocrine Disrupters"[3]. In particular, the Committee was invited to comment on the following:

1. The methodology used by the authors in their literature search, e.g. search terms, databases and inclusion/exclusion criteria.
2. The methodology used by the authors in their literature analysis and quality appraisal, particularly whether the full spectrum of alternative interpretations was considered and how contradictory information was evaluated and discussed.
3. Whether the report gives sufficient consideration to issues of comparative endocrinology, pharmacokinetics and bioavailability, exposure and causality.
4. Whether the views exposed in the report can be defined as reflecting the state of the science in Endocrine Disrupting Chemicals (EDCs) research, and if not, which additional sources of information, analysis or interpretation should be considered.

The Committee found the Kortenkamp *et al* Report to be ambitious in scope, aiming to review all aspects of the issue of endocrine disruption from mechanisms of intracellular signalling to the ecotoxicology of potential endocrine modulating agents. It recognised the challenging nature of the task undertaken (noting, in particular, that "endocrine disruption" cannot currently be anchored to specific assay outcomes in a straight forward way) and applauded the project team for its efforts; however, it had a number of concerns regarding the resulting report. Overall, the Committee found that the consequence of the wide-ranging nature of the report was that the coverage of each area tended to be superficial. The authors acknowledge that their report comprises a "review of reviews", the inevitable consequence of this approach being a reduced depth of analysis.

The Committee noted that the criteria applied by the Report's authors in order to assign an endocrine mode of action to reported effects are those presented by the World Health Organisation and International Programme on Chemical Safety (WHO/IPCS) in the 2002 Report "Global assessment of the state-of-the-science of endocrine disruptors" (http://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/; Chapter 3, p32). These are presented by WHO/IPCS as general principles for defining cause-and-effect relationships when considering possible endocrine effects. They are of value in determining whether the process under consideration is endocrine in nature; however, their usefulness in determining whether a proposed toxic effect has a mode of action involving endocrine modulation is limited. The WHO/IPCS report describes (in Chapter 7, p123) specific causal

[1] *The Advisory Committee on Hazardous Substances is an UK Government independent advisory body that* provides expert advice on the science behind hazardous chemicals. Further details can be found at: http://www.defra.gov.uk/achs/

[2] The views expressed in this statement are those of the ACHS and do not necessarily reflect the views or policy of UK Government. Comments are welcome, and should be directed to the ACHS Secretariat at: chemicals.strategy@defra.gsi.gov.uk

[3] A copy of "*State Of The Art Assessment Of Endocrine Disrupters*"can be found at: http://ec.europa.eu/environment/endocrine/documents/studies_en.htm

criteria for evaluation of the scientific evidence on endocrine modes of action based upon the Bradford Hill Criteria for establishing causality. These address five aspects of the phenomenon under consideration: temporality, strength of the association, consistency of the observations, biological plausibility of the effect, and evidence for recovery following diminution of the stressor. However, in the Report by Kortenkamp *et al,* which focuses very much upon potential hazards rather than attempting to assess risks, these aspects are not considered. This greatly reduces the level of critical appraisal and makes it very difficult to evaluate both the strength and validity of the conclusions drawn. .

Regarding the methodology used for literature search, the Committee had a number of concerns about the search strategy and inclusion/exclusion criteria adopted:

- The database(s) searched is/are not identified.
- The search strategies adopted are described as "(1) a keyword search and (2) a citation search". The precise methodology used is not described; in particular, it is unclear whether the keyword search used Subject Headings (major or minor MeSH headings) or free text searching. The former would be preferred as the primary approach since MeSH headings provide a systematic indexing system; free text searching generates less consistent results and should be used with caution.
- The search terms used are not listed, but are described as "combining the term "endocrine disrupt*" with terms denoting organ systems or systemic endpoints of interest". This would provide incomplete coverage of the literature in this area. By selecting "endocrine disrupt*" as the primary search term, an element of bias was potentially introduced; many publications in this field use less loaded terms such as "endocrine modulation" or "endocrine effects", which would not have been detected by the search strategy used. In addition, the secondary search terms used (if used in free text mode) would not identify all relevant papers; for example, the term "fertility" would not detect papers containing words such as fertile, infertile, infertility and fertilisation.
- The report is explicitly identified as a "review of reviews" covering the period from 2002 to 2010. This creates two limitations: by definition, it does not address the primary literature and it is subject to influence by the opinions of the authors of the reviews considered and, within each one, selective literature citation. Furthermore, it means that the data considered were generated much earlier than the period covered by the search. In order to have been generated, published in the primary literature and reviewed in the secondary literature it is likely that the original data considered were 2-5 years old by the time the reviews under consideration were published. Kortenkamp *et al* state that "we cited some pertinent papers that appeared in 2011", but their approach does not explain why these in particular were selected and, inevitably, precludes complete coverage of the current literature.

Overall, the Committee had concerns about the methodology used for literature searching but it was difficult to evaluate this in full because the report does not describe the approach taken in sufficient detail.

The Committee found that the methodology used for literature analysis and quality appraisal in this report lacked rigour. In particular, the heavy reliance upon secondary sources (and the fact that the report does not specify whether individual citations are from the primary or secondary literature) means that it is impossible for the reader to evaluate the strength of the scientific

data presented nor whether there was selective bias in the way the reviews and publications were identified and used. In addition, the report is very selective in the choice of references for citation. Although it relies heavily on the secondary literature, the views of key commentators in the field are incompletely represented; for example, only one single author review by Prof. Richard Sharpe is cited (and this is not from the peer-reviewed literature), although PubMed (searched on 21st June 2012) indicates that Prof. Sharpe has published 7 first or single author reviews in the peer-reviewed literature during the period covered by the Kortenkamp *et al* report. If a similar level of selectivity applies to the publications of other commentators it raises serious doubts concerning the balance and comprehensiveness of the report.

Regarding issues of comparative endocrinology, pharmacokinetics, bioavailability, exposure and causality, the Kortenkamp *et al* report explicitly states that "It is important to stress that the objective here was to summarise the state-of-the-science in terms of the involvement of chemical exposures in the aetiology of specific endocrine sensitive human diseases or wildlife endpoints, not assess the strength of the evidence that specific chemicals have endocrine disrupting properties". The approach taken is "process-orientated" rather than "chemical-specific". Each chapter provides a detailed, and often helpful, description of a different endocrine process or disorder together with a brief summary of chemicals or chemical classes which are thought to interfere with it. The criteria listed in Chapter 2 of the WHO/IPCS report (see above) are then applied in order to assign an endocrine aetiology to the effects observed. Issues of comparative endocrinology, pharmacokinetics, bioavailability, exposure and causality are, however, not addressed explicitly and the criteria from Chapter 7 of the WHO/IPCS report are not used to evaluate the strength of the associations observed. In particular, we re-emphasise that the focus of the report is exclusively upon potential hazards; the issue of exposure is not considered.

Overall, the Committee's opinion is that this report, which focuses on the possible hazards posed by chemical-induced endocrine disruption, does not adequately reflect the current state of the science in this important and rapidly evolving area. Specifically:

- Topics that are pertinent to risk assessment are juxtaposed and discussed in general terms, giving an overall impression of a potential risk, but the report lacks critical analysis of the evidence to support this contention.
- The information presented does not allow conclusions to be drawn as to whether biologically relevant concentrations of the chemicals under consideration modulate endocrine systems in intact organisms to cause adverse (irreversible) health effects in humans or wildlife.
- The approach taken precludes production of a fully up-to-date review and the search strategy adopted fails to ensure comprehensive coverage of the literature.

These issues could be addressed by means of a review of the primary literature using a more appropriate combination of MeSH headings and free text searching to ensure that all relevant information is retrieved. The information thus identified should be subjected to systematic critical evaluation using appropriate criteria such as those defined in Chapter 7 of the WHO/IPCS report. The Committee recognises that this would be an enormous and extremely time-consuming task but takes the view that such an evaluation would be of much greater utility and command greater confidence than the one it was asked to review. [July 2012]

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Department for Environment
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Mr Gustaaf Borchardt
Director, Water, Marine Environment & Chemicals
European Commission, Environment DG
B - 1049 Brussels
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Date: 16 August 2012

Dear Guus

ENDOCRINE DISRUPTING CHEMICALS

I write further to our recent discussions about the State of the Art Assessment of Endocrine Disrupters (SoAA) carried out for the Commission by Professor Kortenkamp and others.

Endocrine disruption is rightly a high profile issue in the EU. The Commission are currently: reviewing the Strategy adopted in 1999; considering the criteria to be set for identifying endocrine disrupters in the EU Regulations on plant protection and on biocidal products; and reviewing the handling of endocrine disrupters under REACH.

The UK has always accorded a high priority to these issues. We consider it vital that effective action is taken to protect the health of people and to protect the environment from harm caused by chemicals – including through endocrine disruption. But the measures adopted must also be proportionate. To achieve this balance, it is crucial that policy and regulation has a sound evidence base. We therefore welcomed the Commission's decision to carry out the SoAA as a chance to take stock of this highly complex issue and to help underpin well-founded and effective action in Europe.

The Kortenkamp *et al* report is a substantial piece of work that compiles a good deal of the research in the field. However, it does represent a particular interpretation of the published science, which is disputed by other recognised experts. This exchange of views by experts is a healthy part of the normal scientific discourse and something we would actively promote, but, given the importance of the SoAA to decision makers as well as scientists, that process needs in this case to be given structure and brought to a conclusion that affords confidence that the end product is widely accepted as being completely objective. If this is not done, the usefulness of the SoAA to the further development of EU policies and regulation could be severely limited.

As you know, we are therefore strongly of the view that it would be very beneficial to seek the views of the relevant European Scientific Committees on the SoAA, similar to the approach taken recently with the final report of the Commission's study contract "State of the Art of Mixture Toxicity". The Committees can complement the other avenues that you

are using to review the report by adding expertise, impartiality, rigour and transparency to the process.

Consistent with this approach, we have sought the view of our own independent expert Advisory Committee on Hazardous Substances (ACHS) and the Committee considered the Kortenkamp *et al* report in June. We asked the Committee, in particular, to comment on:

- the methodology used by the authors in their literature search.
- the methodology used in the literature analysis and quality appraisal, particularly whether the full spectrum of alternative interpretations was considered and how contradictory information was evaluated and discussed.
- the consideration given to issues of comparative endocrinology, pharmacokinetics and bioavailability, exposure and causality.
- whether the views in the report reflect the state of the science and, if not, which additional sources of information, analysis or interpretation should be considered.

The ACHS's comments are attached in full but, in summary, they raised a number of concerns including:

- The report is a "review of reviews", the inevitable consequence of this being a reduced depth of analysis.
- the criteria applied in order to assign an endocrine mode of action to reported effects are taken from Chapter 3 of the 2002 WHO/IPCS Report "Global assessment of the state-of-the-science of endocrine disruptors". The usefulness of these in determining whether a proposed toxic effect has a mode of action involving endocrine modulation is limited. Chapter 7 of the same report describes five specific causal criteria for evaluating the evidence on endocrine modes of action: temporality, strength of association, consistency of observations, biological plausibility of the effect, and evidence for recovery following diminution of the stressor. Kortenkamp *et al* do not consider these aspects; this makes it very difficult to evaluate the strength and validity of the conclusions drawn.
- the search terms used, and the fact that the report is a "review of reviews" covering the period from 2002 to 2010, limited the literature selected. The methodology used for literature analysis and quality appraisal lacked rigour. The reader cannot evaluate the strength of the scientific data presented or whether there was selective bias in the way the reviews and publications were identified and used.
- issues of comparative endocrinology, pharmacokinetics, bioavailability, exposure and causality are not addressed explicitly and the criteria from Chapter 7 of the WHO/IPCS report are not used to evaluate the strength of the associations observed. The focus of the report is exclusively upon potential hazards; the issue of exposure is not considered.

The Committee suggest that these concerns could be addressed through a review of the primary literature using a combination of Medical Subject Headings (MeSH) and free text searching to retrieve all relevant information. The information identified would be subject to systematic critical evaluation using appropriate criteria. They conclude that such an evaluation would be more valuable utility and command greater confidence than the Kortenkamp *et al* report.

The views of the ACHS tend to reinforce our own about the SoAA and we now wish to request more formally that the relevant EU scientific committees should be asked for their views on the questions considered by the ACHS. We appreciate that this step could lengthen somewhat the timetable for reviewing the Community Strategy. However, in our view it is an essential step if the SoAA is to make a reliable contribution to the provision of a sound evidence base for Community policy on this complex issue.

Both Defra's Chief Scientific Adviser – Professor Sir Bob Watson - and the Government Chief Scientific Adviser – Professor Sir John Beddington – take a keen interest in the effective use of scientific evidence in policy making, both in the UK and in the EU. They would be very interested in the outcome of deliberations by the EU expert scientific committees on this important issue.

I am copying this letter to Gwenole Cozigou in DG Enterprise and Andrzej Jan Rys in DG SANCO.

Yours sincerely

[redacted]

p.p. [redacted]

Direct line: 020 7238 [redacted]
Email: [redacted]**@defra.gsi.gov.uk**

EUROPEAN COMMISSION

ENVIRONMENT DIRECTORATE-GENERAL
Directorate D - Water, Marine Environment & Chemicals

The Director

Brussels, 07/09/2012
ENV D3/ BH/yh/Ares (2012)

Dear [redacted],

Endocrine Disrupting Chemicals- The Kortenkamp State of the Art Assessment (SoAA). Your Letter of 16th August and the attached opinion of the UK Advisory Committee on Hazardous Substances (ACHS).

The recent ACHS opinion raises similar issues to those included in the recent critique of the SoAA by Rhomberg and colleagues[1] and to which Professor Kortenkamp and colleagues have already replied[2]. I think there would be little added value in contributing my personal opinion in relation to these detailed exchanges other than to make clear my support for the views expressed by Professor Kortenkamp and in particular his insistence that there appears to be a basic misunderstanding with regard to the job he was contracted to do by the Commission. In relation to this last point I would offer a number of observations for your consideration.

Within the coming months the Commission is required to:

1) review and, if appropriate, revise the existing EU strategy on endocrine disruptors which dates from 1999;

2) to develop criteria for the identification of endocrine disruptors within the framework of EU legislation on plant protection products and Biocides;

3) to review the current arrangements for the authorisation of endocrine disrupting substances in the context of REACH.

To inform our reflections and conscious of the fact that a considerable amount of scientific research had taken place in the last decade, the Commission was anxious to obtain a policy-relevant synthesis of the latest scientific information concerning the effects of endocrine disruptors and the criteria for the identification of endocrine disruptors. We also wished to have an overview of the policy initiatives taken by Member States and third countries with regard to the control and management of endocrine disrupting substances. With this in mind the Commission launched an open, competitive

[1] Rhomberg et al 2012, Critical Reviews in Toxicology 2012. Early on-line 1-9

[2] Kortenkamp et al Critical Reviews in Toxicology 2012. Early on line 1-3. See also response by Rhomberg et alCritical Reviews in Toxicology, 2012. Early on-line 1-2.

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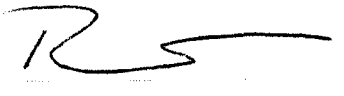
call for tender that resulted in the award of a contract to a value of € 300K to Professor Kortenkamp and associates.

As is the case with all such contracts, Professor Kortenkamp worked under the instructions of the responsible Commission service and opportunities were also provided to Member States and stakeholders to provide comments and suggestions regarding the design and the results of the study. Wherever it was appropriate and practicable these comments and suggestions were acted upon. In early 2012 the final version of the report was published on the web-site of DG ENV. The report fulfils admirably the purpose for which it was commissioned, namely to provide a solid foundation for the Commission to sustain a discussion with Member States and stakeholders regarding the policy initiatives that must be taken within the next 12 months (see second paragraph of the present letter). Obviously, if the report is judged by other criteria such as those used by referees in peer reviewed scientific journals then changes to the study design and in particular the need to access primary data may be regarded as desirable but this was not our objective.

In relation to the types of policy challenges posed by endocrine disruptors, Member States of the EU and the stakeholder community are accustomed to a working method that involves a preparatory phase based on background documents and rigorous discussion at the expert level which provides the input for the Commission to prepare its proposals. Subsequently, the Commission proposals are subject to further scrutiny by the Council/ Parliament, or by Committee, in accordance with the Treaty and, if relevant, by the parent legislation. If in the course of the preparatory process there are specific issues of a scientific/technical nature upon which the Commission considers that further advice/guidance is required then formal requests for opinions can be addressed to one, or more, of the scientific Committees. As you point out in your letter, this was a course of action we followed in relation to the issue of mixture toxicity but the context there was very different-no specific legislation, a very broad and open-ended problem and no legal obligations and deadlines to be respected by the Commission regarding the submission of proposals. In addition, it should not be forgotten that our on-going programme gives full recognition to the importance of the science/ policy inter-face and to that end individual members of the Scientific Committees are invited to participate in our discussions.

In conclusion, I consider that the SoAA report from Kortenkamp and colleagues fulfils the purpose for which it was commissioned. Furthermore, the process we are following in relation to the development of future Commission proposals on endocrine disruptors is consistent with our usual practice. I am confident that with the support of the other Commission service sand the consultation process we have established with the Member States, stakeholders and the scientific community, we will be able to fulfil our commitments and deliver our proposals as foreseen.

Sincerely,



Gustaaf BORCHARDT

Copies: Peter Korytar, Gwenole Cozigou (DG Enterprise), Andrzej Jan Rys (DG SANCO)

PETROVA Nevyana (ENV)

From: [redacted] (CN) <[redacted]@defra.gsi.gov.uk>
Sent: 08 January 2013 10:44
To: KORYTAR Peter (ENV); HANSEN Bjorn (ENV)
Cc: ARENA Francesca (SANCO); MUNN Sharon (JRC-ISPRA); [redacted]
Subject: RE: Community Strategy on endocrine disuption - UK comments

Dear Peter and Bjorn,

Just to confirm that this is the correct version of the UK comments; a slightly earlier e-mail was sent by mistake last night, which I tried to retrieve but may not have been successful.

I forgot to say that we don't support the proposed filming of the group by the French television company. We agree with openness, but there may be discussion on animal testing which could be misinterpreted outside the confines of the meeting. As you know, this is a very sensitive issue and it would be preferable not to have pictures of delegates placed in the wider media.

Best regards,

[redacted]

[redacted]

UK National Co-ordinator (Environment) OECD Test Method Development Programme
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From: [redacted] (CN)
Sent: 07 January 2013 18:39
To: 'Peter.KORYTAR@ec.europa.eu'; 'Bjorn.HANSEN@ec.europa.eu'
Cc: 'Francesca.ARENA@ec.europa.eu'; 'sharon.munn@ec.europa.eu'; [redacted]

[redacted]

Subject: Community Strategy on endocrine disuption - UK comments

Dear Peter and Bjorn,

Happy New Year to both of you!

At the recent meeting of the *Ad hoc* Group on EDCs, you requested further comments on the development of the Community Strategy. Given the Christmas holidays and the pressures of other work, I'm afraid that we've only been able to provide some general UK views, as below. We look forward to working closely with the Commission and Member States in developing these ideas.

Background

We agree that, where they occur, negative impacts of EDCs need to be addressed using a reliable evidence base and appropriate action taken. However, we need to ensure that risk assessment (where provided for by the legislation) is central to decision making in order to provide the best protection of public health as well as the environment. It is therefore essential to target the true causal agent of any negative impact, otherwise the real culprit may be allowed to continue causing harm – for example, lifestyle factors may be more important than exposure to EDCs. It is important to take into account that naturally occurring as well as synthetic substances may have endocrine disrupting properties.

To date, there remains a lack of definition of what represents a low dose and whether low dose, endocrine disruption has permanent or reversible effects. Although low-dose and non-monotonic dose-response relationships have been claimed for EDCs, this is still an area for research. It is surrounded by much controversy and inconsistency in reported findings.

Further, there is a tendency for effort on EDCs perhaps to overshadow other issues which have a bearing on sustainable chemical management areas of (e.g. mixtures, unless linked to EDCs).

Ways Forward

Further scientific development is of course welcome, but it has to be proportionate and well grounded; good research should be targeted and supported; stepping up international work is fine within existing structures (such as the very successful collaborations between the UK and Japan and within the OECD Test Method development Programme), but finance for additional initiatives might pose problems at many national and international levels.

A better strategic approach would be for the EU to concentrate on improved understanding of the general issues surrounding the endocrine disruption phenomenon. The identification and listing of individual substances as EDs and the determination under legislation of what should happen to EDs could be viewed, with the benefit of the hindsight experience we now have, as being premature. The balance of scientific expert views and quality scientific data over the last 10 or so years has clearly shown that the concern about endocrine disruption shouldn't be as great as was suggested in the mid-late 1990s - what is needed is for the strategy to aim at understanding properly and agreeing across the EU the generalities of endocrine disruption and providing definitive scientific understanding once and for all on aspects such as dose-response curve shapes, combined effects, the ability to manage on risk rather than ban on hazard, etc.

I trust you find these comments of interest.

Best regards,

[redacted]

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Department for Environment, Food and Rural Affairs (Defra)

PETROVA Nevyana (ENV)

From: [redacted] (Defra) <[redacted]@defra.gsi.gov.uk>
Sent: 11 March 2013 14:40
To: KORYTAR Peter (ENV); HOUGARDY Yannik (ENV-EXT); [redacted]; CLAYTON Helen (ENV); DE GAETANO Federica (SANCO); ECCLES Catherine (RTD); FABRIZI Laura (SANCO); GIRAL-ROEBLING Anne (ENTR); GOUMENOU Marina (JRC-ISPRA); [redacted] JACOBS Miriam (EFSA); [redacted]; KARJALAINEN Tuomo (RTD); [redacted] LEPPER Peter (ECHA); [redacted] MUNN Sharon (JRC-ISPRA); PASSANTE Lara Grazia (RTD); [redacted]
Cc: HANSEN Bjorn (ENV) [redacted]
Subject: UK Comments on Possible Elements of the Revised Strategy on Endocrine Disruptors
Attachments: 2013-03-10 UK Comments on Possible Elements for Community Strategy.doc

Dear Peter, Bjorn and Colleagues,

Please find attached comments from the UK on Peter's presentation at the recent Ad Hoc meeting on "Possible Elements of the Revised Strategy on Endocrine Disruptors".

Best regards,

[redacted]

[redacted]

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Department for Environment, Food and Rural Affairs (Defra)

Possible Elements of the Revised Strategy on Endocrine Disruptors – presentation by Peter Korytar at Ad Hoc meeting on 20th February 2013

The UK has the following comments:

Slide 3 (Policy Objectives)

2nd bullet point (~~T~~Where unacceptable human and/or environmental risks are identified to promote the substitution of endocrine disrupting chemicals where technically feasible and economically feasible alternatives, with clear human health and/or environmental benefits, exist).

Insert 'Where unacceptable human and/or environmental risks are identified' at beginning and 'with clear human health and/or environmental benefits' just before end.

Note: amendments needed for consistency with slide 5.

In addition, this bullet also needs to take into account that alternatives should not present a negative sustainability impact, especially in terms of production and consumption patterns.

3rd bullet point (To minimise exposures to humans and the environment from endocrine disrupting chemicals where appropriate)

Insert 'where appropriate' at end.

Note: This qualifier is needed as, in addition to the comments above on the 2nd bullet, many vegetables and fruit contain natural endocrine disruptors (for example). We would not want to minimise consumption of these items, as the benefits from eating them far outweigh the risks.

Slide 4 (Ensure a horizontal and harmonised approach to identification of endocrine disruptors across legislation)

1st bullet point (to adopt horizontal criteria for ~~identification~~ assessment of endocrine disruptors as a first step on which to develop regulatory criteria specific to individual ~~applicable across all relevant~~ legislation and to establish a regulatory class(es) of "endocrine disruptors" in the same way as for PBTs.)

Replace 'identification' with 'assessment'; replace 'applicable across all relevant' with 'as a first step on which to develop regulatory criteria specific to individual'; add 'in the same way as for PBTs' to end of bullet.

Note: Horizontal criteria applicable across all legislations appears to contradict some of the comments made by DG Env at the most recent Ad-hoc meeting, about different legislation considering the different regulatory consequences and therefore developing sector-specific criteria. Therefore, the horizontal

criteria should only be the basis on which to develop regulatory criteria specific for each legislation/sector.

In addition, it should be remembered that it has taken a very long time to establish all the criteria in GHS CLP and to put endocrine disrupting chemicals forward for labelling is likely to be a very protracted process. Most of the significant effects observed will be covered by existing systems, such as carcinogen, reproductive toxins etc, so the need is questionable.

Slide 5 (Harmonise and strengthen the EU legislative framework as regards endocrine disruptors)

Fully endorse the approach set out here. Also important to note that this is the same as the aim of the registration and supply chain parts of REACH.

Slide 8 (Fully use / Accelerate the use of existing legislation)

Replace current wording: (*To prepare Annex XV dossiers as regards endocrine disrupting properties and depending on the outcome to nominate those substances on the candidate list*)

With: *To prepare Risk Management Option analyses following screening for endocrine disrupting properties according to the SVHC 2020 Roadmap and, depending on the outcome, to prepare Annex XV dossiers to introduce regulatory controls.*

PETROVA Nevyana (ENV)

From: [redacted] (Defra) <[redacted]@defra.gsi.gov.uk>
Sent: 07 June 2013 18:31
Cc: [redacted] VAN DER JAGT Katinka (ENV)
Subject: RE: Follow-up to the 7th Ad hoc meeting of Commission Services, Agencies and Member States under teh Community Strategy for Endocrine Disruptors (30 May 2013)
Attachments: Determination of environmental thresholds for endocrine disruptors.pdf

Dear Peter

Please find attached additional UK comment on the question of thresholds for EDs in the environment.

Regards

[redacted]

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From: Peter.KORYTAR@ec.europa.eu [mailto:Peter.KORYTAR@ec.europa.eu]
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Subject: Follow-up to the 7th Ad hoc meeting of Commission Services, Agencies and Member States under teh Community Strategy for Endocrine Disruptors (30 May 2013)

Dear colleagues,

Thank you for participating to the last meeting..Herewith I would like to remind you the deadlines for commenting as agreed at the meeting:

7th of June – replies to the questions in the meeting document ED-AD-HOC-7/2013/14 (Thought starter) + any other comments related to the issue whether endocrine disruptors should be considered as non-threshold chemicals

14th of June – comments on the draft summary record from 6th Ad hoc group meeting

Best regards,

[redacted]

Determination of thresholds for endocrine disruptors
Further UK comment

The UK submitted comprehensive views on whether a threshold can be determined for endocrine disruptors identified as Substances of Very High Concern in response to DG Environment's previous call for evidence. This current note addresses only the additional question of whether it is practicable to apply a threshold for endocrine disruptors in the environment.

To satisfy the WHO/IPCS definition of an ED there must be data that shows an adverse effect with good evidence to link the adverse effect to endocrine disruption as the underlying mode of action. For ecotoxicological EDs this data needs to relate to a particular taxonomic group or be open to read across. If data is lacking on a particular taxonomic group then the substance cannot be identified as an ED. As with all substances identification of a particular hazard requires knowledge of positive effects; it cannot be ascribed in the absence of data. If there is no evidence to consider a substance an ED then questions about thresholds are not relevant.

It is argued that it is difficult to extrapolate for the effects of endocrine disruptors between fish or invertebrate species. This is true, but the difficulty applies equally to any other chemical hazard. No particular properties have been identified for EDs which would make such extrapolation intrinsically more difficult for these chemicals.

The standard way to get around this problem is to use tried and tested empirical assessment factors. The UK does not consider that the uncertainties surrounding EDs are of a fundamentally different nature to other chemicals, although the scale may be greater; as a result, the UK considers that such factors can still be used for EDs, although their size may well need discussion and international agreement.

PBT/vPvB substances will usually have thresholds for their intrinsic toxicity. However, they are treated as having no threshold as a precautionary policy choice, based on the difficulties of preventing contamination of remote environments, and the potential for unexpected impacts on organisms in the environment. I.e. it is the P and B criteria that lead to these chemicals as being treated as if they were non-threshold.

By analogy, if a potent endocrine disruptor were very persistent and/or subject to long range transport then it might be considered for policy reasons to present an unacceptable risk to remote environments, and therefore managed as if it had no safe threshold, but not on the basis of its ED properties alone. If, for example, it is not very potent or is readily biodegradeable then it should be possible to use assessment factors, whilst also reflecting any uncertainties over and above those applied for other endpoints. If the EC10/NOECs are low, the result could be a very low PNEC which in turn might be practically the same as saying there is no safe threshold. However, this should depend on the individual case under consideration.

In conclusion the view of the UK is that there is no reason to exclude EDs in the environment from the consideration and application of thresholds.