

**PETROVA Nevyana (ENV)**

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**From:** [REDACTED]@hse.gsi.gov.uk  
**Sent:** 24 November 2011 13:33  
**To:** MURPHY Patrick (ENV); KORYTAR Peter (ENV)  
**Cc:** [REDACTED]

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**Subject:** State of the Art Assessment of Endocrine Disrupters - comments of UK governmental/regulatory authorities

**Importance:** High

**\*\*MESSAGE SENT ON BEHALF OF ALL RELEVANT UK GOVERNMENT/REGULATORY DEPARTMENTS**

Dear Patrick and Peter -

**STATE-OF-THE-ART ASSESSMENT OF ENDOCRINE DISRUPTERS**

Thank you for the opportunity to comment on the section of the draft "State-of-the-art" report on endocrine disrupters presented by Andreas Kortenkamp at the meetings in Brussels last week (16 and 17 November). At this stage, given the very tight timescale and the fact that Member States have not been asked to endorse the report, our comments are brief; we will be happy to provide further details at a later point if that would be useful.

We would want the report to state explicitly that it represents the views of the contractor, not an agreed position of the EU. UK regulatory authorities do not agree with some of the key positions taken by the authors in the report; and consider that the scientific picture presented does not necessarily accord with the balance of expert scientific opinion across the EU and worldwide. The authors seem to suggest that current regulatory testing, hazard identification (through classification) and risk assessment is inadequate to deal with endocrine disruption, such that major changes are needed. The UK takes issue with many aspects of these conclusions. The authors also suggest that, in regulating a substance as an endocrine disrupter, no account should be taken of its potency - not because potency is an invalid consideration, but because the authors foresee that it will be too difficult to obtain agreement across the EU. We do not think that this is a valid stance and believe this should be an issue for future debate, not one for exclusion from the outset.

Best wishes

[REDACTED] (on behalf of UK government/regulatory departments)

\*\*\*\*\*

[REDACTED]  
Director of Chemicals Schemes and Human Health  
Chemicals Regulation Directorate (CRD)  
UK Health and Safety Executive (HSE)  
Redgrave Court (Bootle) and Mallard House (York)  
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**Cc:**

Please find attached comments from the UK on the "revised version of possible elements for criteria for identification of endocrine disruptors". We hope they will contribute to the ongoing debate and that you will take them into account in finalising the criteria.

With kind regards

Regulatory toxicologist  
Human Health & Chemical Schemes Unit  
Chemicals Regulation Directorate  
4N.G Redgrave Court  
Bootle  
Tel 0151 951 [REDACTED]



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Dear Michael

The first report is available at [http://randd.defra.gov.uk/Document.aspx?Document=11345\\_PS2812finalreportfull.pdf](http://randd.defra.gov.uk/Document.aspx?Document=11345_PS2812finalreportfull.pdf) and considers the implications for the approval of around 100 active substances used in PPPs. I also enclose a summary of its findings.

The second report is available at [http://randd.defra.gov.uk/Document.aspx?Document=11346\\_PS2818finalreportfull.pdf](http://randd.defra.gov.uk/Document.aspx?Document=11346_PS2818finalreportfull.pdf) and considers the potential agronomic and economic impacts of withdrawing substances identified as endocrine disruptors.

With best wishes



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Dr Michael Flüh  
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European Commission  
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BELGIUM

Director of Regulatory Policy  
Chemicals Regulation Directorate  
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Date: 24 July 2013

BY EMAIL

Reference: hm20Jul13

Dear Dr Fluh

I am writing to draw the Commission's attention to the results of a study, undertaken by the Water Research Centre (WRc) in the UK, on the impacts of alternate potential criteria for the identification of endocrine disruptors (EDs) under Regulation 1107/2009.

The study principally addressed potential criteria for EDs in relation to human health. EDs were identified as being more or less likely to pose a risk based on two possible approaches to ED identification/categorisation. The essential difference between the two approaches is that in one the potency of the active substance is used to distinguish those more likely to pose a risk from those less likely to pose a risk.

Some 98 compounds were reviewed, of which five were classed as more likely to pose a risk and a further nine as less likely. A further 26 substances could not be categorised on the basis of the data available to the reviewers due to the lack of mechanistic information, but raised a concern in relation to their potential for endocrine disruption. Should these substances be identified as EDs on the basis of positive mechanistic data, four would be classed as more likely to pose a risk and 22 less likely.

Thus, on the basis of the human health results alone we anticipate that 5% or 14% of the currently approved active substances will be lost, depending on whether potency is included as a regulatory criterion. These figures rise to up to 9% or up to 36% depending on how many of the potential EDs are confirmed on the basis of mechanistic data.

A second study, conducted by the Food and Environment Research Agency (Fera), has considered the agronomic consequences of these withdrawals. This study estimates that financial losses would range between £150 and £440 million depending on whether potency is included and the final number of EDs identified. These figures seem bound to be substantial underestimates, since they assume that all substances not considered in the study remain available.

It has not so far proved possible to extend this analysis in relation to potential criteria for environmental EDs, because of the limited ecotoxicology data available to the reviewers and the fact that discussions on possible approaches to identification were at an early stage when the study commenced. However, a small study of 20 substances for which data were available in the published literature suggests that, depending on the criteria finally adopted, a number of active substances not identified as EDs in relation to human health will be identified as environmental EDs (2 out of 20).

In addition, the WRc analysis has considered endocrine disruption only in relation to a limited number of better established modalities within the endocrine system. As scientific knowledge of the highly complex endocrine systems in man and animals develops, we would anticipate that the number of substances might grow indefinitely if pragmatic considerations such as potency are ignored.

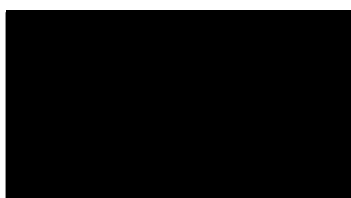
A summary of the overall results from the WRc project is attached to this letter. The full WRc report is available at [http://randd.defra.gov.uk/Document.aspx?Document=11345\\_PS2812finalreportfull.pdf](http://randd.defra.gov.uk/Document.aspx?Document=11345_PS2812finalreportfull.pdf) and the Fera report at [http://randd.defra.gov.uk/Document.aspx?Document=11346\\_PS2818finalreportfull.pdf](http://randd.defra.gov.uk/Document.aspx?Document=11346_PS2818finalreportfull.pdf)

We recognise that this is a difficult issue but we are very concerned that the development of unnecessarily precautionary criteria for defining EDs will have a severe impact on plant protection without any significant reduction in risk to humans or the environment. We very much welcome the fact that the Commission has now decided that an impact assessment for plant protection products and biocides needs to be undertaken before proposals for defining endocrine disruptors are made.

My colleagues and I would be happy to contribute our experience to this study if that would be helpful.

I am copying this letter to DG Environment and to our contacts in other Member States attending the Pesticide Legislation Committee.

Yours sincerely



**Director of Regulatory Policy**

## WRc REPORT: ENDOCRINE DISRUPTERS

### SUMMARY IMPACT ASSESSMENT

Overall, the study considered 98 active substances for toxicological assessment and 20 for ecotoxicological assessment. The findings for each group are summarised below.

#### Toxicological assessments (98 substances)

The toxicological assessment indicates that a number of agronomically important active substances would be eliminated as being more likely to pose a risk (five substances), whilst others might also be eliminated despite being less likely to pose a risk (nine substances), depending upon the final criteria adopted. Additional data (predominantly mechanistic data) would have to be generated and evaluated before the status of a significant number of “potential” endocrine disruptors could be determined (26 substances). Should these 26 substances be identified as endocrine disruptors on the basis of positive mechanistic data, four would be more likely to pose a risk (those designated ‘ML’ in the table) and the remaining 22 less likely.

ED more likely to pose a risk	ED less likely to pose a risk	Potential ED - Further information needed	Not considered ED
<b>Fungicides (37)</b>			
Mancozeb	Bupirimate Iprodione Myclobutanil Prochloraz Tebuconazole Thiophanate-methyl	Carbendazim Cymoxanil Fluazinam (ML) Fosetyl aluminium Hymexazol Mandipropamid Prothioconazole Silthiofam Thiram	Azoxystrobin Boscalid Captan Chlorothalonil Cyazofamid Cyflufenamid Cyprodinil Dimethomorph Dimoxystrobin Fenhexamid Fenpropimorph Fludioxonil Fluoxastrobin Imazaquin Kresoxim-methyl Metalaxyl-M Metrafenone Propamocarb Pyraclostrobin Tolclofos-methyl Triazoxide
<b>Herbicides (36)</b>			
Ioxynil Linuron	Metribuzin Propyzamide	2,4-D Chlorpropham Dimethenamid-P Ethofumesate Fluazifop-p-butyl Glufosinate-ammonium Lenacil S-metolachlor (ML) Pinoxaden Tepaloxymid Terbuthylazine (ML)	Bentazone Bromoxynil Chloridazon Clomazone Clopyralid Dicamba Diquat Fluroxypyr Glyphosate Isoxaben Mecoprop Mesosulfuron-methyl

			Metamitron Metazachlor Metsulfuron-methyl Napropamide Oxadiazon
			Phenmedipham Prosulfocarb Tri-allate Triclopyr

ED more likely to pose a risk	ED less likely to pose a risk	Potential ED - Further information needed	Not considered ED
<b>Insecticides (20)</b>			
Abamectin Thiacloprid	Spiromesifen	Chlorpyrifos (ML) Clothianidin Beta-cyfluthrin Lambda-cyhalothrin Spinosad Spirotetramat	Cyflumetofen Cypermethrin Diflubenzuron Dimethoate Fenoxycarb Imidacloprid Malathion Methiocarb Pirimicarb Pymetrozine Tebufenpyrad
<b>Plant growth regulators (4)</b>			
			Chlormequat Maleic hydrazide Paclobutrazol Prohexadione
<b>Insect growth regulators (1)</b>			
			Methoprene

#### Ecotoxicological assessments (20 substances)

This assessment is less applicable to potential regulatory outcomes given that appropriate regulatory data were not available and there was less certainty over the potential criteria for classification. However, the assessment, based largely on published data, suggests that some compounds, not considered EDs for human health purposes, will be classed as ecotoxicological EDs (two out of 20).

ED more likely to pose a risk	ED less likely to pose a risk	Potential ED - Further information needed	Not considered ED
<b>Fungicides (7)</b>			
Iprodione Myclobutanil Prochloraz Tebuconazole		Carbendazim Chlorothalonil Thiram	
<b>Herbicides (5)</b>			
loxynil		2,4-D S-metolachlor Metribuzin	Glyphosate

Insecticides (8)			
Cypermethrin Fenoxycarb	Abamectin	Chlorpyrifos Beta-cyfluthrin Lambda-cyhalothrin	
		Dimethoate Malathion	
Plant growth regulators			
Insect growth regulators			

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## PETROVA Nevyana (ENV)

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**From:** HANSEN Bjorn (ENV)  
**Sent:** 25 July 2013 18:54  
**To:** [REDACTED]@hse.gsi.gov.uk  
**Cc:** VAN DER JAGT Katinka (ENV); GALLEGO Mateo (ENV); KORYTAR Peter (ENV)  
**Subject:** RE: Endocrine disrupters: UK impact assessments

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Dear [REDACTED],

No problem and thanks a lot for sending it to us.

This is indeed a very good transparent report which gives really good insights for us to use in our further work.

I skimmed through many of the pages (great way to spend a long hot afternoon in Brussels) and have a few questions which I would really appreciate if you could help answering:

- (1) It is a very long and comprehensive report, so I may have missed a lot, but I do not manage to find in the report a clear interpretation of adversity of effects. I know the report uses the WHO/IPCS 2004 definition, but exactly what it means when looking at organs or parameters measures in standard tests is not so clear to me.

The easiest is if I illustrate this. Quite some of the chemicals which end up being EDs in the study, under the header of 'less likely to pose a risk' are EDs due to changes in weight or function of the thyroids (e.g. B.28, B.51). However, quite many of these substances are not classified either as Repro, nor as Carcinogens nor as STOT RE. It would therefore be interesting to know if the lack of classification is due to the fact that the observed alterations in the thyroids were deemed not adverse (and hence do not lead to classification) or actually should lead to classification but this just has not gone through the formal process yet.

I ask this, because the DG ENV criteria define adversity for the effects covered by GHS as being those in GHS.

- (2) The reports cover the identification of EDs and the cost of the phase-out, but not the benefits of the phase-out. Is this on purpose or is the benefits study coming?

To add to these general questions, I have some specific substance related observations:

B.16

It is a Carc.Cat.2, so the ED effects observed in the Carc study were not clear enough to put it in Carc.Cat.1. It is not classified as a Reprotox substance, so the effects observed in the repro studies were not deemed as being adverse – never the less the study concludes it is an ED. If the lack of classification means indeed the WRc study did not find the repro studies sufficiently convincing to see it as an ED, then the ED classification can only come from the new studies (the 2007/2009 ones), which of course have not yet led to a change in classification. Clarification here would be useful.

B.21, B.27

The adversity of observed ED effects put the substance in Repro.Cat.2, so using the ENV criteria this substance would be an ED Cat 2 – hence not subject to phase-out.

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B.22

No classification for repro. As the effects observed in the WRc study are linked to repro, it seems that WRc sees the repro effects as being adverse even though the observed adverse effects do not lead to classification.

Bjorn

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[Isabelle.Heilier@ec.europa.eu](mailto:Isabelle.Heilier@ec.europa.eu); [REDACTED] [Karin.NIENSTEDT@ec.europa.eu](mailto:Karin.NIENSTEDT@ec.europa.eu); [REDACTED]

**Subject:** Endocrine disrupters: UK impact assessments

Dear Michael

I enclose a letter from [REDACTED] concerning two reports which assess the potential impact in the UK of EU proposals for determining endocrine disrupting chemicals.

The first report is available at

[http://randd.defra.gov.uk/Document.aspx?Document=11345\\_PS2812finalreportfull.pdf](http://randd.defra.gov.uk/Document.aspx?Document=11345_PS2812finalreportfull.pdf) and considers the implications for the approval of around 100 active substances used in PPPs. I also enclose a summary of its findings.

The second report is available at

[http://randd.defra.gov.uk/Document.aspx?Document=11346\\_PS2818finalreportfull.pdf](http://randd.defra.gov.uk/Document.aspx?Document=11346_PS2818finalreportfull.pdf) and considers the potential agronomic and economic impacts of withdrawing substances identified as endocrine disrupters.

With best wishes

██████

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## KORYTAR Peter (ENV)

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**From:** [REDACTED] (CRD) <[REDACTED]@hse.gsi.gov.uk>  
**Sent:** 19 April 2011 15:09  
**To:** [REDACTED] MONTES Francisco Javier (EFSA); STREISSL Franz (EFSA); tobias.frische@uba.de; KORYTAR Peter (ENV);  
**Cc:** [REDACTED]  
**Subject:** UK CRD proposals for a definition of an ecotoxicological endocrine disrupter for regulatory purposes

Dear Sir/Madam,

Over the past year, specialists at the UK CRD Environment Branch have been working on a regulatory definition of an ecotoxicological endocrine disrupter. Please find attached the UK CRD proposals for a definition of an ecotoxicological endocrine disrupter for regulatory purposes. We would be very interested to hear your views on the UK proposals and look forward to future discussions on how to take forward the regulatory evaluation of chemicals purported to be endocrine disrupters.

Yours sincerely,

[REDACTED]  
[REDACTED]  
Ecotoxicologist  
Chemicals Regulation Directorate,  
2nd Floor, Mallard House,  
Kings Pool, 3 Peasholme Green,  
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Attachments:

UK CRD proposals for a definition of an ecotoxicological endocrine disrupter for regulatory purposes\_final.docx  
(65496 Bytes)

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**KORYTAR Peter (ENV)**

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**From:** [REDACTED] (CN) <[REDACTED]@defra.gsi.gov.uk>  
**Sent:** 07 September 2011 12:44  
**To:** MURPHY Patrick (ENV); KORYTAR Peter (ENV)  
**Cc:** [REDACTED]  
**Subject:** UK Comments on State of the Art Assessment of Endocrine Disruptors - Part 1 Summary of the State of the Science

Dear Patrick and Peter,

As you'd expect, the recent Interim Report by Evans *et al.* generated quite a bit of interest in the UK and we've received several sets of comments. We've co-ordinated these, but were not sure who to forward them to. So please find them attached here – if you're not the correct recipients, we'd be very grateful if you could send them on as appropriate.

<<2011-09-06 UK Comments - EC Report Summary of State of the Science Evans et al 2011.docx>>

No doubt other Member States will be commenting on the report as well, we wondered whether Evans *et al.* will be providing detailed responses and whether the report will be subsequently updated?

We'd also be very grateful to know when the 2<sup>nd</sup> Report is expected and any details of the future timetable – will you be aiming for Council Conclusions this coming December?

With best regards,

[REDACTED]

[REDACTED]

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