



EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
The Director-General

Brussels,
ENV.B.2/CCN/np

By registered letter with acknowledgment of receipt

Vincent Harmsen
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Advance copy by email:
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Dear Mr Harmsen,

Subject: Your applications for access to documents: Ref GestDem No 2017/4587

We refer to your e-mail dated 07/08/2017 in which you make a request for access to documents, registered under the above mentioned reference number and our holding reply Ref. Ares(2017)4222583 - 29/08/2017.

You requested access to:

"...documents which contain the following information:

All communications (including emails, letters, minutes of meetings and any other reports of such meetings) and all possible documents (including working documents and draft documents) held by DG Environment in relation to the following chapters of the impact assessment related to defining criteria for identifying endocrine disruptors (available online here: <http://bit.ly/2vhxylx>):*

-ANNEX 9:

- 1. ENDOCRINE DISRUPTORS AND HORMONE RELATED DISEASES - EVIDENCE**
- 1.2. Epidemiological and laboratory data on a link between exposure to EDs and "hormone related diseases"**
- 1.2.1. Interpretation of epidemiological data**
- 1.2.3. Toxicological principles (e.g. existence of safety thresholds, potency of chemicals, shapes of dose-response curve, low dose effects)**

-ANNEX 11:

3.1. Evidence on possible association between ED exposure and wildlife population declines

Of particular interest in relation to this request are -- although this request is not limited to -- all possible communications and/or documents (as specified above) where the following publications are discussed/mentioned/referred to in an explicit or implicit way:

-Lamb J.C. et al. 2014. Critical comments on the WHO-UNEP State of the Science of Endocrine Disrupting Chemicals – 2012, Regulatory Toxicology and Pharmacology.

-Bergman, Å., et al. 2015. Manufacturing doubt about endocrine disrupter science – A rebuttal of industry-sponsored critical comments on the UNEP/WHO report “State of the Science of Endocrine Disrupting Chemicals 2012”, Regulatory Toxicology and Pharmacology.

-Lamb, et al. 2015. Comments on the opinions published by Bergman et al. (2015) on Critical Comments on the WHO-UNEP State of the Science of Endocrine Disrupting Chemicals, Regulatory Toxicology and Pharmacology.

-Autrup, H., Barileb, F. A., Blaauboerc, B. J., Degend, G. H., Dekant, W., Dietrich, D., Domingog, J. L., Gorih G. B., Greim, H., Hengstlerd, J. G., Kacewj, S., Marquardtk, H., Pelkonenl, O., Savolainenm, K., and Vermeulenn, N. P. 2015. Principles of Pharmacology and Toxicology also Govern Effects of Chemicals on the Endocrine System, Toxicological Sciences.

-Zoeller, R. T., Bergman, A., Becher, G., Bjerregaard, P., Bornman, R., Brandt, I., Iguchi, T., Jobling, S., Kidd, K. A., Kortenkamp, A., et al. 2014. A path forward in the debate over health impacts of endocrine disrupting chemicals, Environmental Health. - Testai, E., Galli, C.L., Dekant, W., Marinovich, M., Piersma, A.H., Sharpe, R.M., 2013. A plea for risk assessment of endocrine disrupting chemicals, Toxicology.

-Borgert, C. J., Baker, S. P., and Matthews, J. C. 2013. Potency matters: thresholds govern endocrine activity, Regulatory Toxicology and Pharmacology.

-Diamanti-Kandarakis E. et al. 2009. Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement, Endocrine Reviews.

-Gore, A.C., et al. 2015. EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals, Endocrine Reviews.

-Gore, A.C., et al. 2015. Executive Summary to EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals, Endocrine Reviews.

-Ntzani EE, Chondrogiorgi M, Ntritsos G, Evangelou E, Tzoulaki I, 2013. Literature review on epidemiological studies linking exposure to pesticides and health effects.

-Levêque-Morlais, N., et al. 2015. The AGRiculture and CANcer (AGRICAN) cohort study: enrollment and causes of death for the 2005–2009 period, International Archives of Occupational and Environmental Health.

- Gerhard J. Nohynek, Christopher J. Borgert, Daniel Dietrich, Karl K. Rozman. 2013. *Endocrine disruption: Fact or urban legend? Toxicology Letters.*
- Autrup, H., et al. 2015. *Principles of Pharmacology and Toxicology Also Govern Effects of Chemicals on the Endocrine System, Toxicological Sciences.*
- European Commission. 2013. *Minutes of the expert meeting on endocrine disruptors.*
- C.J. Borgert, E.V. Sargent, G. Casella, D.R. Dietrich, L.S. McCarty, R.J. Golden. 2011. *The human relevant potency threshold: Reducing uncertainty by human calibration of cumulative risk assessments, Regulatory Toxicology and Pharmacology.*
- Lorenz R. Rhomberg, Julie E. Goodman. 2012. *Low-dose effects and nonmonotonic dose– responses of endocrine disrupting chemicals: Has the case been made?, Regulatory Toxicology and Pharmacology.*
- Piersma, A.H., et al. 2011. *Reproductive toxicants have a threshold of adversity, Critical Reviews in Toxicology.*
- Kroes, R., et al. 2004. *Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet, Food and Chemical Toxicology.*
- Kortenkamp, A., Martin, O., Faust, M., Evans, R., McKinlay, R., Orton, F., Rosivatz, E., 2011. *State of the art assessment of endocrine disrupters. Final Report.*

**'In relation to' in this request is to be interpreted in the broadest sense possible, meaning all communications and documents (as specified above) that hold any information whatsoever that sheds light on (discussions in relation to) the creation of the chapters mentioned: selecting sources, analyzing information, drafting texts, drawing conclusions etc. "*

We took note that a similar request was sent to DG SANTE who provided you with a separate reply on this issue with Ref. GestDem No 2017/4461.

We have identified 15 documents as potentially falling under the scope of your request (see table 1 attached to this reply).

Please note that none of these documents are as such specifically or exclusively related to the chapters of Annex 9 and Annex 11 of the Impact Assessment on defining criteria for identifying endocrine disrupters or to the list of scientific publications mentioned in your request. In fact, no such documents have been identified. However, we have interpreted your request in the broadest sense possible and we have identified documents which may "have shed light on (discussions in relation to) the creation of those chapters."

Having examined the documents, we have come to the following conclusions:

- i. For documents 1, 2, 3, 4, 8, 12, 14 and 15 please refer to the reply of DG SANTE with reference number Ares(2017)4401891 - 08/09/2017 (GestDem No 2017/4461).
- ii. For documents 5, 6, 7, 9, 10, 11 and 13, which are in one way or another linked to the documents referred to in the reply of DG SANTE mentioned above, as

already explained in their reply, disclosure of these documents is prevented by the exception to the right of access laid down in Article 4(3) first subparagraph of Regulation (EC) no 1049/2001.

These documents relate to a decision which has not yet been taken by the Institution as the criteria for determination of endocrine disruptors have not yet been adopted by the Commission and the possibility that the Commission might need in future to discuss again the criteria cannot be excluded at this stage. Disclosure of these documents would undermine the protection of the decision-making process of the Commission, as it would reveal preliminary views and policy options which might be considered. The Commission services must be free to explore all possible options before finalisation of a decision without this process being influenced. Therefore, the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies to these documents.

We have considered whether partial access could be granted to the documents 5, 6, 7, 9, 10, 11 and 13. However, these documents are fully protected by the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001.

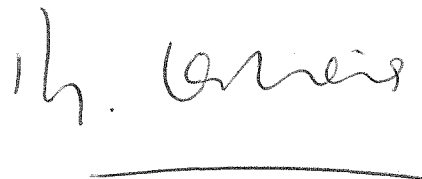
The exceptions to the right of access provided for in Article 4(3) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the requested documents. In your application, you did not submit any grounds concerning a public interest on the basis of which the interests protected in Regulation (EC) No 1049/2001 would have to be overridden, and we could not identify any such ground either. In these circumstances, we have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001.

In accordance with Article 7(2) of Regulation 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review its position on the matters already mentioned.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretary-General of the Commission at the following address:

European Commission
Secretary-General
Transparency unit SG-B-4
BERL 5/282
B-1049 Bruxelles
or by email to: sg-acc-doc@ec.europa.eu

Yours faithfully,



Daniel Calleja

Annex: Table with list of documents