EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

Brussels,
SANCO.E3/FV/sc (2012)

NOTE TO

MR KARL FALKENBERG, DIRECTOR GENERAL ENVIRONMENT
MR DANIEL CALLEJA CRESPO, DIRECTOR GENERAL DG ENTERPRISE

Subject: Request to the EFSA Scientific Committee for an opinion on the human health and environmental risks of endocrine disruptors (EDC)

Please find enclosed for your information a copy of the letter (reference: ARES (2012 930851 of 01/08/2012) sent to the European Food Safety Authority (EFSA) requesting for an opinion on the human-health and environmental risks of endocrine disruptors.

Paola Testori Coggi p.o.

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299.11.11.
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Ref. Ares(2012)1147827 - 01/10/2012

Ref. Ares(2012)930901 - 31/08/2012

EUROPEAN COMMISSION
Health and Consumers Directorate General

Director General

INCOMING N° 6060
01 AGO. 2012
EFSA

Brussels,
sanco.ddg1.d.3(2012) 1D/ed/1040197

Dear Ms Geslain-Lanéelle,

Subject: **Request to the EFSA Scientific Committee for an opinion on the human health and environmental risks of endocrine disruptors (EDs)**

Attached please find a mandate on the subject of EDs for submission to the EFSA Scientific Committee.

The subject of EDs is receiving considerable public and scientific attention. Member States, the European Parliament, and the Council have called on the Commission to update all the relevant pieces of legislation to include criteria for the identification and the assessment of the health and environmental risks of EDs.

Several pieces of SANCO legislation, including the Plant Protection Products Regulation (PPPR), the food contact materials legislation, the medicines legislation, and the cosmetics regulation either make reference to EDs or contain specific provisions for the development of specific criteria to identify and assess EDs.

For PPPR, the Commission is obliged to make proposal to incorporate such criteria in the Regulation by the end of 2013. For Cosmetics, the deadline is end of 2015. Other pieces of EU legislation outside the competences of DG SANCO (e.g. REACH, biocides) need to also be updated to include similar provisions. Thus, sound scientific advice on the definition, criteria and methodologies to identify and assess Endocrine Disruptors is urgently needed.

Ms Catherine Geslain-Lanéelle
Executive Director
European Food Safety Authority - EFSA
Via Carlo Magno 1A
IT-43126 Parma

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11
[illegible]

On the basis of the above, I kindly request that EFSA, in collaboration with the European Medicines Agency (EMA) and the Commission Scientific Committees, elaborates an opinion on the basis of the attached mandate, by March 2013.

Yours sincerely,

Paola Testori Coggi

Enclosure: Request for an opinion on the human-health and environmental risks of endocrine disruptors

c.c.: Mr. D. Liem (EFSA)
Mr M. Seychell, Mr L. Miko, Mr. E. Poudelet, Ms. J. Minor, Mr A. Rys, Mr M. Vallette, Mr B. Gautrais, Ms. M. Matthews, Mr. T. Gumbel, Mr R. Vanhoorde, Ms. S. Lecrenier, Ms. P. Brunko, Ms C. Bruetschy, Mr. M. Flueh, Mr M. Walsh, Mr T. Daskaleros (SANCO)

(European Food Safety Authority) (EFSA)

Request for an opinion on the human-health and environmental risks of endocrine disruptors

1. Background

The endocrine system plays a crucial role in maintaining human homeostasis and is often affected by exogenous stimuli. A range of synthetic as well as naturally occurring agents have been identified as interacting with the endocrine system. If the interaction of these exogenous substances with the endocrine system leads to adverse health effects in an intact organism or its progeny or (sub)populations these substances are referred to as "endocrine disruptors"[1] (EDs).

Given the range of EU legislation under which these substances are regulated (such as plant protection products, biocides, pharmaceuticals, cosmetics, chemicals), the European Commission (EC) published its proposed Community Strategy for Endocrine Disruptors[2] in 1999. The European Parliament called on the EC in 1998 to examine the many research and regulatory questions related to endocrine disruption.

The Community Strategy called for the establishment of "a list of substances requiring priority evaluation ("ED priority list") *of their role in endocrine disruption and to identify inter alia* substances which can already be addressed under existing legislation, gaps in knowledge and specific cases of consumer use for special consideration." On the basis of independent reviews of peer-reviewed scientific literature, and in consultation with the Commission's Scientific Committee on Toxicity, Ecotoxicity and the Environment, a candidate list of 553 synthetic chemicals and 9 hormones was published in 2000, together with a series of actions proposed to further evaluate the role of these substances in endocrine disruption. The final long-term goals of the Community Strategy are "legislative actions" to control substances having harmful effects on humans, wildlife, and/or the environment.

In recognition of the need to address the problem of endocrine disruptors, many pieces of EU legislation contain specific provisions on this issue, e.g. REACH, Food and feed legislation, Plant Protection Products Regulation, Biocides Regulation, Regulation on cosmetics, Water Framework Directive and others. Currently, the main focus, both within the EU and internationally, is to agree on approaches for the identification and risk assessment of endocrine disruptors.

2. Terms of Reference

In light of the above EFSA is asked to advise the Commission on the following questions:

1) What scientific criteria may be used to distinguish between EDs and other groups of chemicals with different modes of action? The answer should examine the following: low-dose effects, including non-monotonic dose response, critical windows of susceptibility, threshold effects etc.

2) What scientific criteria may be used to distinguish between physiological modulation (adaptive response) and adverse effects on humans and on the ecosystem as a result of exposure to endocrine active substances?

3) Are the existing toxicity testing methods appropriate for the identification and characterisation of effects mediated by endocrine active substances (both humans and ecosystem should be considered)?

In developing this opinion, EFSA is requested to take account of the latest available published scientific information, including the final report "State of the Art Assessment of Endocrine Disruptors"[3]

With a view to ensuring consistency, other Scientific Advisory Bodies, including the European Medicines Agency (EMA), the European Chemicals Agency (ECHA), and the European Commission Scientific Committees (SCCS, SCHER and SCENIHR) should be involved during the preparation of the opinion.

3. Deadline

The Commission would ask the EFSA to provide its final opinion to the present request by March 2013

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[1] "An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations." International Programme on Chemical Safety, 2002. Global Assessment of the State-of-the-Science of Endocrine Disruptors. World Health Organization, Geneva, Switzerland.

[2] http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/chemical_products/l21277_en.htm

[3] http://ec.europa.eu/environment/endocrine/documents/4_SOTA%20EDC%20Final%20Report%20V3%206%20Feb%2012.pdf

Ref. Ares(2013)314126 - 11/03/2013

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

Brussels,
SANCO/E3/LF/bp

NOTE FOR THE ATTENTION OF MR K. FALKENBERG
DIRECTOR-GENERAL, DG ENV

Subject: Endocrine disruptors – the "2nd version of elements for criteria on endocrine disruptors identification" proposed by your Services and the way forward

On 20 February 2013, your services submitted for discussion to the "*6th Ad-hoc meeting of Commission Services, European Agencies and Member States under the Community Strategy for Endocrine Disruptors*" the "2nd version of elements for criteria on endocrine disruptors identification" and invited the representatives of the ad-hoc working group to send comments.

I would like to reiterate, as already done in bilateral exchanges between our services, the need to wait for the EFSA Opinion and the JRC Report, before discussing any draft criteria. In this respect, DG SANCO will offer detailed comments upon examination of these two reports, which are due to be published within the current month.

Concerning the implementation of the criteria, I believe that we have to put in place a solid and scientifically robust mechanism to develop the necessary technical guidance. However, I disagree that such guidance should be developed by the "Expert Advisory Group". As I already made clear in other circumstances and recently in the discussions on chemical mixtures, such guidance should be developed jointly only by the agencies (EFSA, EMA, ECHA) and the Scientific Committees which have the regulatory and scientific competences to do so in an independent and objective manner.

In the coming days I would like to share with you for your comments and input a draft mandate for the development of such guidance to be sent to the relevant Agencies and Scientific Committees.

Paola Testori Coggi

Cc: L. Miko, M. Seychell, D. Spanou, E. Poudelet, M. Flueh, R. Vanhoorde, T. Piha, M. Walsh, P. Daskaleros, A. Schaefer, S. Goux, G. Ciarlo, F. De Gaetano, A. Ajour, T. Gumbel, A. Cusimano, F. Arena, L. Fabrizi (DG SANCO)

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EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

Brussels,
SANCO/E3/LF/np

NOTE FOR THE ATTENTION OF MR K. FALKENBERG
DIRECTOR-GENERAL, DG ENV

Subject: Endocrine disruptors – DG SANCO's view on the way forward

On 20 March 2013, EFSA presented its "Scientific Opinion on the Hazard Assessment of Endocrine Disruptors" to the press and to over 140 stakeholders and interested parties. During the same event the JRC also presented its "Report on Key Scientific Issues relevant to the Identification and Characterization of Endocrine Disruptors".

These two pieces of work, together with the DG ENV proposal for criteria for endocrine disruptors (2nd version of elements for criteria on endocrine disruptors identification) bring us to a turning point on this highly sensitive file which in my view requires, before proceeding with the next steps, agreement by all Commission services concerned. For DG SANCO, there are at this stage two important elements: the adoption of the criteria and the development of technical guidance for their implementation.

Following my previous note of 11 March 2013, I would like to provide you with DG SANCO's view on the two elements mentioned above and the way forward as regards endocrine disruptors.

DG SANCO's view

1. Criteria on endocrine disruptors identification

It is my understanding that your services aim at laying down the criteria on the identification of endocrine disruptors in a Commission Recommendation to be adopted within the next months. The same criteria would then be used when setting exclusion criteria in the plant protection products and biocides Regulations. The basis for the Recommendation is the "2nd version of elements for criteria on endocrine disruptors identification" proposed by your services at the "*6th Ad-hoc meeting of Commission Services, European Agencies and Member States under the Community Strategy for Endocrine Disruptors.* The DG SANCO views on this document are as follows (see also attachment for details):

- I support the definition of endocrine disruptor and the general structure of the proposed criteria foreseeing two categories based on different weight of evidence (sections 1 and 2).

- In section 3 (criteria for placing substances in categories) however, I believe that the bullet points should be deleted, as reported in the enclosed Annex 1. They do not add any clarity to

the text and, on the contrary, might be misinterpreted due to ambiguous terms such as "plausible".

- Finally, section 4 titled "Additional Considerations" should be also deleted from the final proposed criteria, as it addresses issues to be considered at the stage of hazard characterization and not of hazard identification. These issues would be best addressed by the technical guidance to be developed.

2. Development of technical guidance

There is a need to further work on the technical guidance for the horizontal application of the criteria. During the stakeholders' event held on 20 March 2013, the JRC announced that, once the criteria are agreed, the Endocrine Disruptors Advisory Expert Group chaired by the JRC will develop technical guidance for the implementation of the criteria, as requested by DG ENV.

As already made clear in my note of 11 March (enclosed Annex 2), DG SANCO cannot agree with such an approach. Considering that the implementation of the criteria will concern all sectors dealing with chemicals and in line with our independent science-based policy making principles, DG SANCO considers as the only appropriate way forward to mandate the Agencies (EFSA, EMA, ECHA, EEA) and the Scientific Committees (SCHER, SCENIHR, SCCS) to jointly develop the technical guidance for the horizontal application of the criteria, once they are finally adopted. DG ENV, DG ENTR, DG TRADE and DG AGRI will be consulted when this mandate to the Agencies and the Scientific Committees will be drafted. The JRC could of course contribute to developing the technical guidance, as it did in the context of the recently published EFSA opinion.

I therefore count on your collaboration on this general approach, which will provide a solid, horizontal and independent scientific basis for the criteria on endocrine disruptors, which the Commission would be able to defend in international fora. This is all the more important when it comes to regulatory decisions that will inevitably be taken on a number of chemicals and that could have a significant impact on trade.

In order to move forward, I would suggest that we meet as a matter of urgency.

Paola Testori Coggi

Encl: Note Ares(2013)314126 – 11/03/2013

DG SANCO revised version of possible elements for criteria for identification of endocrine disruptors (tracked changes)

Cc: D. Calleja Crespo (DG ENTR), D. Ristori (DG JCR), J.M. Silva Rodriguez (DG AGRI), J.L. Demarty (DG TRADE), C. Day (SG)

L. Miko, M. Seychell, D. Spanou, E. Poudelet, B. Van Goethem, M. Valletta, B. Gautrais, A. Ajour, T. Gumbel, M. Flueh, R. Vanhoorde, T. Piha, E. Strickland, S. Lecrenier, S. Juelicher, C. Bruetschy, M. Walsh, P. Daskaleros, A. Schaefer, S. Goux, G. Ciarlo, F. De Gaetano, A. Cusimano, F. Arena, L. Fabrizi (DG SANCO)

Ref. Ares(2013)516288 - 27/03/2013

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director-General

Brussels,
SANCO/E3/LF/bp

NOTE FOR THE ATTENTION OF MR K. FALKENBERG
DIRECTOR-GENERAL, DG ENV

Subject: Endocrine disruptors – the "2nd version of elements for criteria on endocrine disruptors identification" proposed by your Services and the way forward

On 20 February 2013, your services submitted for discussion to the "*6th Ad-hoc meeting of Commission Services, European Agencies and Member States under the Community Strategy for Endocrine Disruptors*" the "2nd version of elements for criteria on endocrine disruptors identification" and invited the representatives of the ad-hoc working group to send comments.

I would like to reiterate, as already done in bilateral exchanges between our services, the need to wait for the EFSA Opinion and the JRC Report, before discussing any draft criteria. In this respect, DG SANCO will offer detailed comments upon examination of these two reports, which are due to be published within the current month.

Concerning the implementation of the criteria, I believe that we have to put in place a solid and scientifically robust mechanism to develop the necessary technical guidance. However, I disagree that such guidance should be developed by the "Expert Advisory Group". As I already made clear in other circumstances and recently in the discussions on chemical mixtures, such guidance should be developed jointly only by the agencies (EFSA, EMA, ECHA) and the Scientific Committees which have the regulatory and scientific competences to do so in an independent and objective manner.

In the coming days I would like to share with you for your comments and input a draft mandate for the development of such guidance to be sent to the relevant Agencies and Scientific Committees.

Paola Testori Coggi

Cc: L. Miko, M. Seychell, D. Spanou, E. Poudelet, M. Flueh, R. Vanhoorde, T. Piha, M. Walsh, P. Daskaleros, A. Schaefer, S. Goux, G. Ciarlo, F. De Gaetano, A. Ajour, T. Gumbel, A. Cusimano, F. Arena, L. Fabrizi (DG SANCO)

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Director General

Brussels,
SANCO/E3/LF/iv

NOTE FOR THE ATTENTION OF MR K. FALKENBERG
DIRECTOR GENERAL, DG ENV

Kare,

Subject: Endocrine disruptors – Way forward following the Note from the Secretariat General

Following the note that we received from the Secretariat General on 2 July 2013 (enclosed Annex), I would like to agree with you on the way forward for the criteria on endocrine disruptors.

The Secretariat General suggests presenting a single package for adoption by the College, whose key elements would be a delegated act (ENV) and an implementing act (SANCO). Considering that the two proposals need to be identical and that the latter will have to take into account the positions of the Member States voting at the Standing Committee, it follows that the implementing act should precede the delegated act.

The Secretariat General invites our DGs to support our two proposals by a joint impact assessment in the context of the Regulations on biocides and plant protection products.

The operational steps for the joint impact assessment include preparing a common roadmap, setting an Impact Assessment Steering Group and organising a public consultation. The note of the Secretariat General acknowledges that carrying out such impact assessment implies a possible delay in the adoption of the two legal acts to early 2014. This timeline is quite optimistic, given the complexity of the issue, the numerous comments that we can expect to receive in the public consultation phase and the need to coordinate between our two DGs. Anyhow, pending the adoption of final criteria, strict interim criteria are in place for both biocides and plant protection products.

As regards the roadmap, I believe that it will have to include both your and our options, with no indication of preference for any of them. I suggest that my services contact your services to arrange for a first coordination meeting before the summer break, in order to start planning the activities from September onwards.

Paola Testori Coggi

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Encl: Note Ares(2013) 2559007 – 02/07/2013
Endocrine disruptors – next steps

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Encl: Note Ares(2013) 2559007 – 02/07/2013

Endocrine disruptors – next steps

Cc: C. Day (SG), A. Glover (CSA), D. Calleja Crespo (DG ENTR), D. Ristori (DG JRC), J.B. Plewa (DG AGRI), J.L. Demarty (DG TRADE), K. Richelle (EMPL), R. J. Smits (RTD), L. Evans (MARE)

L. Miko, M. Seychell, E. Poudelet, D. Spanou, B. Van Goethem, M. Valletta, B. Gautrais, A. Ajour, T. Gumbel, M. Flueh, R. Vanhoorde, T. Piha, E. Thevenard, S. Lecrenier, S. Juelicher, C. Bruetschy, F. Mittermayer, E. Strickland, M. Walsh, P. Daskaleros, A. Schaefer, S. Goux, G. Ciarlo, F. De Gaetano, S. Hoeke, A. Cusimano, F. Arena, L. Fabrizi (DG SANCO)

EUROPEAN COMMISSION
DIRECTORATE-GENERAL ENVIRONMENT

The Director-General

Brussels, 10/08/2012
ENV D3/BH/io/ARES (2012)

Note for the Attention of Paola COGGI TESTORI,
Director General, DG SANCO

Subject: **Request to the EFSA Scientific Committee for an opinion on the human health and environmental risks of endocrine disruptors (EDC). Your note of 3/08/2012, Ref ARES(2012)944239**

The request from SANCO to the EFSA Scientific Committee in relation to EDCs is a significant concern for DG ENV. The request appears to duplicate the work being led by DG ENV in co-ordination and in consultation with DG SANCO and supported by JRC and DG RTD, to develop criteria for the identification of endocrine disruptors. In addition to the other Commission services and related Agencies, including EFSA, Member States, stakeholders and academia have all invested heavily in this activity. This work has been on-going for several years and is based upon a written agreement between our two DGs and there is a considerable amount of related correspondence. In order to ensure the appropriate level of co-ordination between our services there have been several meetings over the last 12 months involving Martin Seychell and Ladislav Miko from DG SANCO and Gustaaf Borchardt from DG ENV. Martin Seychell also played a key role in the recent Commission conference on Endocrine Disruptors at which the current work programme was presented by the Commission and supported by the 300 participants.

In the light of the above you will understand our concerns in relation to the request that you have sent to EFSA. Our partners in the Member States and among the interested stakeholders as well as the European Parliament will have great difficulty to understand the relationship between your initiative and the on-going Commission work. Indeed, I think the Commission will be called upon to clarify this issue as a matter of urgency.

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Partners that have invested 2 years in the on-going programme will want to be re-assured that their contributions have been worthwhile and that the Commission has not created a parallel and duplicative process lead by EFSA.

I regard this issue as extremely important and very urgent and I would welcome the opportunity to discuss it with you at the earliest opportunity.

Karl Falkenberg

Cc: Dominique Ristori (JRC),
Daniel Calleja Crespo (DG ENTR), Robert-Jan Smits (DG RTD),
Gustaaf Borchardt, Bjorn Hansen, Peter Korytar (DG ENV)

Ad-hoc meeting between DG SANCO and DG ENV.

Subject: Endocrine disruptors (EDs)

Date 30th March 2012 . Time: 11:00 to 12:30. Location B 232-8/120.

Participants: SANCO - Martin Seychell (DDG), Willem Penning, Michael Walsh, Panagiotis Daskaleros, Federica De Gaetano. ENV - Gustaaf Borchardt (Director), Bjorn Hansen, Peter Korytár, Pat Murphy.

Background paper (attached).

[redacted]

Endocrine Disruptors

Suggested Issues for Discussion between DG ENV and DG SANCO.

PETROVA Nevyana (ENV)

From: HANSEN Bjorn (ENV)
Sent: 03 August 2012 14:08
To: DASKALEROS Panagiotis (SANCO)
Cc: LAURSEN Henrik (ENV); BERNSEL Johanna (ENV); KORYTAR Peter (ENV); BINTEIN Sylvain (ENV); BORCHARDT Gustaaf (ENV); SEYCHELL Martin (SANCO); VOGELGESANG Juergen (SANCO); GARKOV Vladimir (SANCO); CIARLO Giulia (SANCO)
Subject: Summary: ENV - SANCO cooperation - meeting on 19 of July

Dear Takis,

Apologise for the delay in getting this summary done, but here is what we could collect as the main points of discussion, agreement and action from our meeting two weeks ago.

Greetings,

Bjorn

[redacted]

Attendance :

ENV : G. Borchardt, B. Hansen,

SANCO : M Seychell, R. Vanhoorde, M. Flueh, M. Valletta, P. Daskaleros, A. Ajour

Date: 14 September 2012

Main outcomes from the discussion:

[redacted]

[redacted]

Meeting between DG SANCO and DG ENV

Subject: Involvement of EFSA and scientific committees in the process for development of scientific criteria for identification of endocrine disruptors

Date 19th September 2012. Time: 17:30 to 18:30. Location B 232-7/108.

Peter Korytar's notes from the meeting

Participants: SANCO – Paola Testori (DG), Martin Seychell (DDG), Robert Vanhoorde, Francesca Arena, ... ENV – Karl Falkenberg (DG), Gustaaf Borchardt (Director), Patrick Murphy, Peter Korytár.

[redacted]

Ad-hoc meeting between DG SANCO and DG ENV.

Subject: Endocrine disruptors (EDs)

Date 10th January 2013. Time: 9:00 to 10:30. Location BU-9 4/60.

DG ENV's summary of the meeting

Participants: SANCO – Michael FLUEH (HoU), Francesca ARENA, Laura FABRIZI, Panagiotis DASKALEROS (DHoU), Michael WALSH (DHoU), ENV – Bjorn HANSEN (HoU), Peter KORYTAR.