



**EEB and WWF comments
on the Stakeholders Consultation Meeting
on the EU Strategy for Endocrine
Disrupters,
held on February 21-22**



Brussels, 7th March 2002

In 2001, the EEB and WWF commented on the European Commission communication to the Council and the report of the European workshop held in Aronsborg, Sweden, and once again the EEB and WWF raised three issues that had already been mentioned in earlier reports.

The areas of concern were:

- The absence of proposals for a proactive policy based on the Precautionary Principle in order to respond quickly and effectively to the increasing exposure of humans and wildlife to Endocrine-Disrupting Chemicals (EDCs). This has been stressed by both the Council and the Parliament.
- The studies which are to be conducted should not be simply based on chemical structure or concentration, or on production volume, but also on analyses of: the effects on health of low dosages and long-term exposure, mixes with other chemicals, and synergies with other tissues and organs. Without this approach, suspected EDCs should not be excluded from the candidate lists.
- The absence of an action plan on the methods of communicating and disseminating all existing information on EDCs to experts and to the public.

These important topics have not been addressed in the recent stakeholder meeting documents. Two new studies were also presented; one concerning the 435 substances with insufficient data on ED or potential ED, and the other on an evaluation of the 12 substances for which there is scientific evidence but which are not addressed under existing legislation. These two studies were once again based on the strict collection and collation of available ‘robust’, significant, scientific data and a quantitative approach to the evaluation of expected exposure. This resulted in:

- a second cut to 173 substances for further evaluation (553 EDCs in the first candidate list, 435 with insufficient data have been left out after the first cut and 173 now), and
- From the 12 substances with scientific evidence but not being classified or addressed under existing legislation, only three were found to have enough available data on endocrine effects on humans and wildlife.

Special comments on the ‘Discussion documents’

The analysis of the “Discussion document” issued as a preparation to this meeting is apparently restricted to oestrogen, androgen and thyroid effects; some important effects are simply not considered, e.g. insulin metabolism and its multiple effects; and corticosteroids are not even mentioned.

- Even within the restricted field of oestrogenic action, the only metabolism to be mentioned is the receptor-based one. There is not even one word about the potential action of cytochrome P450 aromatase, nor about other mechanisms acting through the effects of Prolactin.

- Most of the data available on the effects of endocrine disruption in these reports has been focused on the adverse effects of synthetic chemicals based on obsolete toxicological considerations. The No Observed Effect Level (NOAEL) is repeatedly mentioned, overlooking the fact that endocrine disruption does not seem to have a threshold for its effects (not necessarily toxic), and that many effects are not macroscopically able to be observed. Furthermore, no single test or tender system will be able to cover all the observed effects.

- The latest developments in methods of testing methods are completely ignored:
 - In the molecular level, as an example, the methylation of the promoter of tumor suppressor genes is not mentioned, despite its major role in cancerogenesis.
 - In another field, new techniques such as functional Nuclear Magnetic Resonance and PET scan are not mentioned, despite the fact that they give firm evidence of developmental effects on the Central Nervous System; Neurobehavioral 'test batteries' in children are simply not mentioned. (These test batteries are well defined and allow for comparative development in children of different ages.)
 - The problem of synergetic actions between two, or several, substances is not evoked, despite the fact that it usually occurs (except the experimental settings) and the fact that data is available.

-Endocrine-disrupting effects on humans are assessed based on data from adults (workers, consumers), while the most sensitive population groups are foetuses, and young children.

Obviously the evaluation of the effects of ALL substances (agents) has to be thoroughly reconsidered by a panel of independent scientists, competent in the diverse analysed fields. May be the information gathering was dominated by the classical conventional toxicological approach, which is not scientifically sufficient.

Replies to the points for discussion: (page 8 of the document on the 435 EDCs)

1. Is it possible to rule out the effects of EDCs?.

No. Bioaccumulation has to be taken into consideration.

2. When do we decide that there is no scientific evidence for the inclusion of a substance on the list?

All candidate substances must be included on the list.

3. It is proposed to combine certain substances in one group and give them an overall ED categorisation on the basis of reference substances.

Yes. Grouping is a constructive tool and is important for selection.

4. How can the proposed methodology be implemented in a system to evaluate substances with new evidence?

By gathering more qualitative than quantitative data. Repeated dose toxicity, mixtures with other chemicals and synergies must also be taken into consideration.

Finally, we regret to say that it was obvious, once again, from these studies that the Commission does not set priorities for immediate precautionary action or for temporary requirements to control exposure to EDCs. Instead, priorities are only presented for more testing, more research and a call for 'robust' scientific evidence, which continuously results in reducing the lists which already exist at national level.

Next steps to follow

1. Implementation of the PP

It is true that there have been some positive developments concerning the Commission strategy on Endocrine disruption, but what is totally missing, and is an issue of concern for NGOs and Member States, is *the absence of proposals on a proactive policy* based on the Precautionary Principle. The precautionary principle as a term is stressed in many documents, but without any proposal for implementation - and so far without any development of the tools for making the principle operational, which means that uncertainty, ignorance and indeterminacy must be developed in order to guide the application of the precautions. The Precautionary Principle deals with uncertainties, and we have already had enough indications, suspicions and warnings to warrant a move forward to adopting a proactive risk management policy, which includes measures to minimise the exposure of humans and to wildlife to EDCs, including the temporary restriction of the use of certain EDCs, until all the appropriate data has been delivered.

2. Inclusion of EDCs in the proposed Authorisation System

Finally, the exclusion of EDCs from the proposed Authorisation System of the White Paper on a Strategy for a future Chemicals Policy, as covered by CMRs and POPs, cannot be justified.

Even if they meet the definition for reproductive toxicity, EDCs can still be present in consumer articles with the potential for acting below a certain concentration and for a long period of time.

Furthermore, in connection with CMRs, the definition for reproductive toxicity only covers the effects on mammals. Therefore the effects of many EDCs in lower order animals will be lost.

In addition, many hormone disrupters would not be expected to be reproductive toxins, as they disrupt other systems also (Immune System, Central Nervous System....).

In the end, the majority of hormone disrupters will not be restricted for many years, and exposure is likely therefore to continue.

3. Availability and dissemination of all current information to the public

No recommendation was given regarding the next steps to follow to ensure the better exchange of information to all interested parties, and not just between experts.

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