



WWF's RESPONSE TO THE COMMUNITY STRATEGY FOR ENDOCRINE DISRUPTORS

WWF

WWF is the world's largest and most experienced independent conservation organisation. It has 4.7 million regular supporters and a global network active in 96 countries. WWF aims to conserve nature and ecological processes by: preserving genetic, species and ecosystem diversity, ensuring that the use of renewable natural resources is sustainable both now and in the longer term for the benefit of all life on earth, and promoting actions to reduce to a minimum pollution and wasteful exploitation and consumption of resources and energy.

SUMMARY OF WWF'S RESPONSE TO THE COMMISSION'S STRATEGY FOR ENDOCRINE DISRUPTORS (EDCS)

WWF welcomes the Commission's initiative to set out a strategy to address this crucial issue. In particular, WWF agrees with the Commission's acceptance of the need for precautionary action on endocrine disrupting substances in some cases, but is disappointed that the proposed strategy does not go far enough in this respect.

WWF considers that there is a need to implement a more robust strategy to reduce exposures to endocrine disruptors, to protect wildlife and the health of the citizens of the EU. WWF believes that the current strategy does not adequately define and address this major problem. WWF believes this is mainly due to insufficient resources being allocated to investigate the effects of and explore preventative actions for endocrine disruption.

Endocrine disruption is now a key issue in the international debate on chemical policy, and it is therefore vital that the EU takes a leading role at this time. It can be predicted that those countries that find safer substitutes and safer ways of doing business will ultimately gain a greater share of world markets. A short-sighted and weak approach to the regulation of endocrine disrupting chemicals will not be the best way to ensure the long-term international competitiveness of the EU chemical industry.

BACKGROUND

WWF is particularly concerned about endocrine disrupting chemicals because these substances have been causally linked to impaired reproduction and development in many wildlife species, and are also suspected of causing effects in humans. The EU Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) has noted that for wildlife, "there is a potential global problem."

Throughout Europe, over the past few decades there has been an increased incidence of cancers of the breast, prostate, and testes. It is not known with certainty what is causing these effects, but these effects may be linked to substances that disrupt the sex hormones. There are now also numerous studies suggesting that at least in certain areas, sperm counts are declining and in addition, there are limited numbers of studies that have suggested birth defects, such as undescended testes and hypospadias have increased in baby boys. Furthermore, some organochlorine chemicals have been linked to affects on cognitive development and intelligence in children. It is also important to note that many of these effects can be replicated in animals exposed to endocrine disrupting chemicals (EDCs) in the laboratory.

If the EU population were being exposed unwittingly to harmful levels of oestrogen mimicking and anti-androgenic compounds, the possible predictable effects of this would include: - an increase in hormone related cancers (such as cancers of the breast, testes, and prostate), effects on sperm, increased rates of birth defects of the reproductive tract, and girls coming to puberty earlier. It is rather chilling that all these effects do appear to be happening, and it is this whole picture, rather than one particular effect taken in isolation, that leads many scientists to suggest that endocrine disrupting chemicals (EDCs) are causing, or at least partly to blame, for these effects.

A: RECOMMENDATIONS FOR GENERAL IMPROVEMENTS IN THE SCOPE OF THE STRATEGY:

Short-term actions to reduce exposures:

- WWF strongly recommends short-term actions to reduce exposures to known EDCs, on the basis of the precautionary principle. Although the Community strategy recognises the need to use the precautionary principle, it in fact only identifies policy actions for more research, rather than reducing exposures. The strategy does not, therefore, deliver a high level of protection for humans and the environment on this issue.
- The Commission's strategy accepts that there may be a need to modify existing risk assessment procedures, but the necessary timetable for reviewing such procedures is missing.
- WWF considers there is a need to take action now on substances that can disrupt the endocrine system of animals. WWF urges the Commission to review its strategy on the issue of short-term action. WWF believes there must be a *rapid* and full evaluation of the *available* scientific information relating to individual endocrine disrupting substances, but in some cases, it will be inappropriate to wait for further tests to be carried out. This is particularly because additive effects may be predicted to occur.
- Legislation is needed to ensure new substances are tested, prior to marketing, in order to avoid any new endocrine disrupting substances entering the marketplace.
- Mandatory reporting of EDCs releases: WWF considers that there is a need for legal powers to require manufacturers and downstream users to report the releases of suspected endocrine disrupting substances into air, water and land, and also the amounts released from the works in products.

Screening and testing:

- There is a clear need to agree a European screening and testing strategy, which could be done well in advance of validation of all the requisite test methods. The Commission strategy should address this. The number of chemicals that should undergo screening and testing, and the order of testing could be determined now. Some tests could also be undertaken in advance of the full test battery becoming available.
- The strategy should recognise the need to fully scrutinise all the 560-plus suspected endocrine disrupting substances that have been identified by the Commission's consultants from other lists of EDCs – if there is current exposure to these substances.
- There should be a clear EU strategy to investigate the bulk of chemicals in our environment for their ability to disrupt the endocrine system, to avoid the risk that many substances to which there is current exposure may be left unevaluated.
- The Commission's strategy should recognise that additional resources are needed for monitoring programmes to more fully investigate the extent of environmental contamination, and the effects of this contamination.
- The Commission's strategy should recognise that several EDCs have now been found to cause effects at very low dose levels and yet very few suspected EDCs have been adequately tested to determine the lowest levels that can cause unwanted effects.

Women's health:

- The strategy should include reports of the numerous adverse female health effects which have been linked to exposure to EDCs. These include the increased incidence of breast cancer over the last 20 years, endometriosis, and polycystic ovaries.
- The strategy notes that DES is the first documented example of a chemical which, when given to the pregnant mother, can cause cancer in her daughter. However, it omits to note that animal experiments show that this increased risk of cancer in the offspring is still evident in the offspring of the offspring (grand-daughters) who were not, themselves, exposed in the womb¹.

B: SPECIFIC COMMENTS ON THE COMMISSION EDCS STRATEGY:

The following text provides detailed comments numbered according to the paragraphs of the community strategy which they address:-

Female health effects

1. The strategy summarises some of the health concerns relating to exposure to EDCs and lists some of the conclusions of the Weybridge meeting. However, whilst the Commission acknowledges that the Weybridge workshop did not address potential effects on the female, their strategy fails to outline that numerous adverse female health effects have been linked to exposure to EDCs. These include, an increased incidence of breast cancer, endometriosis, and polycystic ovaries. Also, the strategy does not mention the concern that altered sex ratios have been noted in children born to people with extreme exposures to endocrine disrupters.

Need to reduce exposures

2. One of the objectives of the paper is to identify appropriate policy action on the basis of the precautionary principle. However, the strategy falls short of delivering a high level of

protection for humans and the environment, because the policy actions identified include more research rather than reducing exposures.

3.2. The strategy notes that DES is the first documented example of a chemical which, when given to the pregnant mother, can cause cancer in her daughter. However, it omits to note, that animal experiments show that this increased risk of cancer in the offspring is still evident in the offspring of the offspring, in other words, in the grand-daughters who were not, themselves, exposed in the womb. This provides a powerful argument for taking precautionary action over man-made chemicals that similarly exert their action on the oestrogen receptor.

4.1. The Commissions strategy noted that “until agreed test methods and an effective screening and testing strategy are available, many substances, for which little information is currently available, may escape attention when compiling lists of potential ED substances.” However, the Commission strategy does not address the need to set up a forum to agree such a European screening and testing strategy, which could be done well in advance of validation of all the requisite test methods. Furthermore, the strategy does not adequately recognise that, what is considered to be the definitive test for mammalian sex hormone disruption, the OECD test guideline 416 (two-generation reproduction toxicity study) has now been updated to include additional endocrine endpoints. This test could be used to test numerous suspected substances in advance of any full scale programme which would need to utilise validated tests on a number of endocrine systems and species. Therefore, many additional steps could be taken now, in order to define better the extent of this problem.

WWF believes there should be a two pronged approach. Firstly, there is a need to more fully scrutinise all 560-plus suspected endocrine disrupting substances that have been identified by the Commission’s consultants from other lists of EDCs, and to fully evaluate those to which humans and/or wildlife are exposed. To date, experts have only investigated the available literature on 116 of these substances, which include those that are high production volume chemicals (HPVs) and some metals. WWF considers that it would certainly be unwise not to fully evaluate the other approximately 420 substances, if significant exposure to them occurs, either due to diffuse usage patterns, or due to several companies trading at high volumes, but individually less than 1000 tonnes.

The Commission’s strategy is to draft a “ED-priority list” which is to be a small sub-set of the over 560 substances. This list is to be the focus of further research, but the strategy does not adequately address whether the other substances will be further evaluated or tested.

Secondly, apart from beginning work on the over 500 suspected EDCs, WWF considers that there is a need to ensure that there is a screening and testing strategy to investigate the bulk of chemicals (to which there is exposure in the EU) for their ability to disrupt endocrine systems.

WWF fully concurs with the need to develop and validate appropriate environmental monitoring tools, but the strategy needs to recognise that additional resources are needed to more fully investigate the extent of environmental contamination, and the effects of such contamination.

WWF also notes that several current research projects funded by the Commission and by the chemical industry are human epidemiological studies. However the strategy should recognise

that given the numerous confounding factors, the extent of exposures, and the fact that many chemicals may be implicated, epidemiological studies are unlikely to be of use in establishing causal links.

4.3. WWF agrees with the need for communication to the public. However, WWF suggests that the strategy should specify that such communication should not seek primarily to reassure the public, but rather should seek to accurately communicate all the uncertainties to the public, and the actions that are being taken to address the uncertainties and the problem in general.

5.3. WWF agrees with the need to ensure that endocrine disruptors are given due attention in the overall review of chemical legislation, and particularly welcomes the Commission's acceptance that policy action may need to be based on the precautionary principle. However, although an evaluation of all the readily available scientific information on a substance should be made, there is a need to recognise that precautionary action may be needed even though concentrations of that one substance might appear to be lower than currently known effect levels. Current risk assessment procedures do not take into account the fact that interactive (and possibly additive) effects may occur due to all the chemicals to which humans and wildlife are exposed. Also, it is likely that many endocrine disrupting substances can cause effects at lower concentrations than currently supposed, and indeed some of these substances may exhibit inverted U-shaped dose response curves.

WWF considers that scientific evaluation of highly suspected and known endocrine disrupting substances should be done rapidly, and in some cases, it would be inappropriate to wait for further tests to be carried out, rather public safety and wildlife should be given the benefit of the doubt. WWF wants to see action taken now to eliminate or reduce exposures to substances that can disrupt the endocrine system of animals.

5.5. The strategy acknowledges that it may be necessary to re-evaluate current risk assessment procedures in the light of emerging research results on potential synergistic and low dose effects of endocrine disruptors. WWF considers that it is now vital to re-evaluate current risk assessment procedures in the light of research which shows that additive effects may be relatively common. In addition, where exposure relates to pregnant women and children, it would certainly be appropriate to implement a precautionary approach to reducing exposures to EDCs, particularly for those substances with mechanisms of action which are suspected of giving rise to effects at low dosages.

6. The strategy acknowledges that because of the potential seriousness of the concerns, the Commission must adopt a strategy in line with the precautionary principle. However, WWF considers that the European Commission strategy does not go far enough in this respect. The Commission has identified that current risk assessment procedures may need to be adapted to take account of interactive effects and effects at low dosages, but it has not sought to set in motion such a review and modification of current risk assessment procedures. Furthermore, the Commission has not set up a programme of research to fully investigate the effects of endocrine disrupting substances at low dose levels, and their interactive effects, and potential inverted U shaped dose response curves. In addition, within the EU there is a scarcity of research into effects of EDCs on behaviour. However, the consequences of EDCs exposure may result in important population level effects, and may underline the urgent need for regulation.

6.1. WWF is concerned that only a small number of substance will be identified in the “ED priority list” and therefore that only a small number of substances will be taken forward for further evaluation of their role in endocrine disruption. The Commission’s strategy identifies that the ED priority list will be used to identify substances for “priority” testing once agreed test methods become available.

WWF is concerned that many substances could be left unevaluated, because the strategy does not set out in detail which chemicals will be subsequently evaluated after the investigation of the ED priority list (see under 4.1 above).

In addition, it should be recognised that there is little point speeding up the risk assessment of these substances, if the current risk assessment procedures do not adequately address potential additive effects and the concern about exposures to low doses of endocrine disrupters.

Establishment of monitoring programmes to estimate exposure

WWF notes that the Commission intends to consult stakeholders on the establishment of monitoring programmes. However, WWF considers that there is a need for legal powers to require manufacturers and downstream users to report the releases of suspected substances, to air water and land, and also the amounts released from the works in products.

WWF welcomes the Commissions intent to continue to engage in regular consultations with the Member States, industry and non-governmental organisations to exchange views on existing scientific data and results as well as regulatory issues.

There may be some place for voluntary initiatives, but the Commission’s strategy puts too much focus on these, partly because it suggests that identifying safer substitutes can only be launched when comprehensive test methods for identifying ED effects are available. This negates the fact that several tests are available now which can be used to identify with some certainty whether alternatives have endocrine disrupting effects in certain species.

IDENTIFICATION OF SPECIFIC CASES OF CONSUMER USE FOR SPECIAL CONCERN

In cases where potentially more vulnerable groups of consumers such as children are exposed to substances on the ED priority list or other known EDCs, the Commission must take action to reduce exposures immediately. This action should be taken in consultation with relevant Scientific Committees.

6.3. WWF agrees that current legislation will need to be revised to take account of endocrine disrupters. It is important that legislation is put in place to ensure that tests are undertaken on new substances, prior to marketing, in order to ensure that no new endocrine disrupting substances are unwittingly brought into commerce. Similarly, there needs to be a legislative

mechanism to put the onus on manufacturers of existing chemicals to test their chemicals up to the standards required for new chemicals.

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ⁱ Newbold R R, Hanson R B, Jefferson W N, Bullock B C, Haseman J, McLachlan J A, 1998
Increased tumors but uncompromised fertility in the female descendants of mice exposed
developmentally to diethylstilbestrol (DES).
Carconogenesis **19(9)**: 1655-1663