Environmental Endocrine Disrupters Assessment: Strategy of the European Commission

Claudia Roncancio Peña
European Commission – DG Environment

Existing Community legislation on environmental and human health aspects of chemicals is based on a three-stage approach. It includes a **hazard identification** stage, in which a substance's inherent capacity to cause adverse effects on human health and the environment is identified, on the basis of the intrinsic properties of a substance. The second stage consists of **risk assessment**, which is based on an assessment of the hazard combined with an assessment of exposure to the chemical substance. The third and final stage is one of **risk management**, in which strategies for the management of the risks are developed. For each of these stages, the amount of available scientific evidence for individual substances can vary greatly.

In view of its role in protecting EU citizens and the environment, and because of the potential seriousness of the concerns, regarding Endocrine Disrupting Chemicals, the European Commission must adopt a strategy in line with the precautionary principle. The strategy should include actions in the short-, medium- and long-term and at each stage take account of existing policies in the areas of consumer, health as well as environmental protection.

In December 1999, The Commission adopted **a "Communication on a Community Strategy for Endocrine Disrupters"** (COM(1999)706) which has been implemented in 2001 (COM(2001) 262).

Short-term actions: a first list of 553 candidate substances for further evaluation of their role in endocrine disruption has been identified. From that list 118 substances were characterised as endocrine disrupter or potential endocrine disrupters. 109 are currently regulated or addressed under existing Community legislation: i.e. the Directive concerning placing on the market of Plant Protection Products, the Regulation for Risk Assessment of existing substances or the Directive relating to restrictions on marketing and use of certain dangerous preparations.

It has been found that nine substances were not regulated under existing Community legislation and it was decided to give priority for an in-depth evaluation of these substances, together with three natural or synthetic hormones -Oestrone, 17 B oestradiol, 17 A ethinyloestradiol–. In addition to the in-depth evaluation of the 9+3 substances, it was decided to give equal priority to gathering data/information on persistence, production volumes and legal status on another 435 candidate substances for which there was insufficient data (due to a lack of resources to gather the data rather than the lack of data itself) to decide on endocrine disruption or potential endocrine disruption. These two studies are going to be submitted to wide consultation between stakeholders and the different Scientific Committees of the European Commission in 2003.

As part of the communication to the public action, early 2003 a new endocrine disrupter website will be available, which will cover the scientific background, as well as the Commission activities on this area.

Concerning information exchange and international cooperation a study will be launched to gather information on the different activities on endocrine disrupters in Members States and in other countries/organizations in the world.

Medium-term actions. Includes the identification and assessment of endocrine disrupting chemicals, work leaded by OECD, the Commission is committed to support the process of development and validation of test methods by working closely with Member States to coordinate the European Union input at OECD.

Regarding research and development, endocrine disruption has been covered under the different Community Framework Programs for Research and Technological Development. At the 4th framework program (1994-1998), endocrine disruption was recognised as a research priority and approximately €18M funding was provided on this program. Projects included the development of test methods, biomonitoring and the study of ecological and human health effects.

At the 5th framework program (1998-2002) most of the projects have focused on the effect of estrogenic compounds on the human reproductive system, but other compounds and end points were also under investigation. Other areas included, the study of the ecotoxicological impact of possible endocrine substances in freshwater and marine ecosystems as well as the establishment of the CREDO cluster (the Cluster of Research into Endocrine Disruption in Europe), which includes a group of projects addressing endocrine disrupter issues.

Endocrine Disruption in the 6th framework program (2003-2006), will be covered under the Thematic Priorities 5 "Food Quality and Safety", Subarea: Environmental Health Risks, and the Priority 6 "Sustainable development, global change and ecosystems.

Long-term actions. Although adaptations/amendment of current legislation is a long-term action, a number of actions has been taken by the Commission in the meantime. For example, the adoption of the Directive 1999/51/EC (a technical adaptation of directive 76/769/EEC, relating to restriction on marketing and use of certain dangerous preparations) presents a review of the provisions on tributyltin (TBT) in the light of the decision of the International Maritime Organization to impose a global ban on the use of tin compounds in anti-fouling ship paints by 1st January 2003.

Some legislative instruments can be used by the European Commission to deal with the problem of endocrine disrupters, which includes the Water Framework Directive (Dir 2000/60/EC). A priority list of 32 hazardous substances (11 of them included in the "Priority list of substances for further evaluation of their role in endocrine disruption) has been identified and for which the Commission shall produce proposals for emission controls and quality standards.

The Drinking Water Directive (Dir 98/83/EC). Under the frame of this directive the revision of the annexes, in the light of scientific and technical progress, have to be done in order to assess the possibility to include the analysis of endocrine disrupters in a future revision of the Directive.

Directive concerning the placing of Plant Protection Products on the market (Dir 91/414/EEC). Under the frame of this directive the revision of the annexes is currently in progress. This task includes the re-evaluation of safety for human and animal health and for the environment of active substances. On the basis of this evaluation, the active substance may be included in Annex 1 of the Directive and where necessary associated with restrictions, which Member States must take into account in the authorisations of the plant protection products containing the active substance concerned.

On 13 February 2001, the Commission adopted a White paper on a Strategy for a Future Chemicals Policy, known as REACH system (For registration, evaluation and authorization of chemicals). One of the key elements of the proposed strategy is an Authorisation procedure for substances of very high concern –CMR (carcinogenic, mutagenic and toxic to reproduction) and substances with POPs characteristics. The procedure would require authorities to give specific permission before such a substance could be used for a particular purpose, marketed as such or as a component of a product, and given that many of the health effects associated with endocrine disrupting chemicals are

CMR effects, it is likely that many of endocrine disrupting chemicals will fall under this authorisation procedure. Other issues includes the rigorous testing for long-term effects of substances exceeding a production volume of 100 tons, the obligation of manufacturers, importers and downstream users to carry out appropriate risk assessments.

Q&A

Morita: Thank you very much. That was a very important report from the European Community focusing on the risk assessment of endocrine disrupting chemicals. We realize that there are very steady, sound, and very strong approaches being taken by the European Community. We would like to invite questions or comments from the floor. Are there any questions?

Question: I take it you mean to limit the substances that are released into the environment more than 100 tons in quantity. What is the reason for the basis by which this was decided?

Peña: Yes, the basis for deciding concerning all the substances that enter into the European Commission. They take now the new regulation it will be based under different threshold limits of tons. So they calculate it at 1 ton, 10 tons, and 100 tons. It is just an indicative threshold now for this limit for the new chemical regulation.

Morita: Today we heard from Dr. Schlumpf a report about sunscreens. Are these substances subject to the measures the EC is taking?

Peña: Up to now only industrial chemicals have been taken into account on this list, but it is the aim in the future to include some cosmetics and some detergents, also. All of these cosmetics and detergents are on the list of endocrine disrupters, because one of the aims of this list is to be an active one. So there will be some chemicals that can enter but also some chemicals that get out; it depends on the new scientific evidence that will come.

Morita: Thank you. Yes.

Question: You said in your presentation that drinking water and sewage would be reviewed every five years. Compared to the past, a review every five years appears to be quite speedy reform from the perspective of government, and appears to be quick in terms of traditional pace. In terms of quickness and change of scientific knowledge of environmental problems, if you consider changes in Japanese law and recent environmental initiatives, it would appear that it is a bit too much time. Anyway, this is my impression. Is there some way of adapting to such change?

Peña: Between one review and another, this has to be consulted with the Council and with the Parliament. This is why we put some deadlines for having the time to make all of these consultations with the stakeholders, with some other scientific member groups, and with the Council and the Parliament. This is the minimum time; for administrative and political reasons it has to be done like this.

Morita: This is relevant to not only this presentation, but to other speakers', and in some cases relevant to the entire symposium. I would like to make a comment on the importance of internal exposure concerning risk assessment. That is, I would like to know if you have a comment on how this fits into the EU's risk assessment framework.

In other words, the question of whether or not the correct amount is actually administered by various researchers on the individual researcher level when studying the endocrine disrupting effect of extremely low doses, as well as on the international level when assessing risk of endocrine disrupters. As far as I know, such validation is not being carried out. There is consequently a question of how much of certain substances are actually in the specimens' bodies when observing effects of extremely low doses in experiments conducted all over the world concerning endocrine disrupters or chemical substance in general. I think internal dose exposure must be included in the framework of risk assessment in the future. I would like to know if you have a comment on this.

Peña: For the risk assessment done under the different directives, the internal body, the internal exposure is not taken completely into account. But due to this new problem of endocrine disrupters, it is the aim to include and make some modifications on this risk assessment for the new chemical legislation.

Morita: Last question.

Becker: Thank you. Just a point or comment that you asked the question is; is there a mechanism for UV filters to be evaluated? Just to note, in case it was not apparent that the Scientific Committee for Cosmetic Products and Non-Food Products of the European Commission has the authority and responsibility to review the scientific information presented on these filters.

In fact, they did look at that information about a year ago, and I assume if there is new information coming forward they would again convene a scientific panel. So even if it might not be within the same framework that was discussed here, there is certainly opportunity for an expert panel, scientific review, and consultation to be provided to the Commission.

Peña: I think that also here you can find in the room a person who works at and who is an expert of the Scientific Committee on Cosmetic and Non-Food Products. So Dr. Christian Laurent, maybe he can give some idea of these endocrine disrupter UV filters.

Laurent: Concerning the activity of the SCCNFP group in the European Commission, for now we have established new guidelines and new objectives to make hazard assessment and risk assessment of cosmetics including UV filters, but the endocrine disrupter activity has not yet been completed and not yet been included in what we have done. But it is planned to be done within the next year.