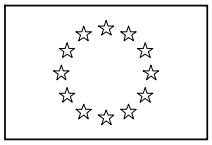

COMMISSION OF THE EUROPEAN COMMUNITIES

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**COMMUNICATION FROM THE COMMISSION
TO THE COUNCIL AND THE EUROPEAN PARLIAMENT**

Community Strategy for Endocrine Disrupters

a range of substances suspected of interfering with the hormone systems of humans and wildlife

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ANNEXES

1. INTRODUCTION

Endocrine Disruption is a mechanism whose effects relate to the functioning of the Endocrine system, that is, development, growth, reproduction and behaviour of human beings and wildlife. There is growing concern about a range of substances, which are suspected of interfering with the endocrine system - so-called "endocrine disrupters". These substances may cause adverse health effects such as cancer, behavioural changes and reproductive abnormalities. The phenomenon has attracted significant media attention. In the EU, an increasing number of parliamentary questions have been addressed to the Commission since 1997 concerning the use and regulation of a range of suspected endocrine disrupting substances.

In 1997, the European Parliament decided to draw up an 'own-initiative' Report on the topic, which was debated and voted on in the Plenary Session in October 1998. In its Resolution, the Parliament calls upon the Commission to take specific actions, in particular with a view to improve the legislative framework, to reinforce research efforts and to make information available to the public.

In addition, several Member States have launched national research programmes on endocrine disruption (e.g. DK, SF, and UK). Other Member States have already introduced specific measures to limit or phase out the use of certain suspected substances on the basis of reported toxic effects (S, B, UK, NL, DK).

In December 1996 a European workshop was organised in Weybridge on the impacts of endocrine disrupters on human health and wildlife. At this workshop over 70 scientists and policy-makers from the EU, USA and Japan as well as from organisations such as OECD, WHO, ESF and CEFIC and non-governmental organisations, concluded *inter-alia* that:

- There is sufficient evidence that testicular cancer rates are increasing, and the apparent decline in sperm counts in some countries is likely to be genuine.[1]

- Some cases exist in the EU where adverse endocrine effects, or reproductive toxicity, in birds and mammals coincide with high levels of substances, shown to have endocrine-disrupting properties in some test systems.

- The considerable uncertainties and data gaps should be reduced by research and monitoring into exposure and effects in wildlife and humans, but meanwhile, consideration should be given to measures to reduce exposure to endocrine disrupters in line with the "precautionary principle".

More recently, on 4 March 1999, the Commission Scientific Committee for Toxicity, Ecotoxicity and the Environment (SCTEE) presented its Opinion "*Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with emphasis on Wildlife and on Ecotoxicology test methods"*. It identified a "potential global problem" for wildlife. It states that "impaired reproduction and development causally

[1] It should be noted that the Weybridge workshop participants did not include experts in female reproductive health or breast cancer and that as a consequence a recommendation was made to convene a separate group to consider adverse effects on women's health.

linked to endocrine disrupting chemicals are well-documented in a number of wildlife species and have caused local and population changes".

Public policy-makers urgently need to address this issue. It is therefore proposed that the Commission adopt a strategy with short-, medium- and long-term actions in order to respond quickly and effectively to the problem.

2. OBJECTIVES OF THE PAPER

The objectives of this paper are two-fold.

- To identify the problem of endocrine disruption, its causes and consequences.
- To identify appropriate policy action on the basis of the precautionary principle[2] in order to respond quickly and effectively to the problem, thereby alleviating public concern.

3. THE PROBLEM OF ENDOCRINE DISRUPTION

3.1. What are endocrine disrupters?

The endocrine system consists of a set of glands, such as the thyroid, gonads and adrenal glands, and the hormones they produce, such as thyroxine, oestrogen, testosterone and adrenaline, which help guide the development, growth, reproduction, and behaviour of animals, including human beings. Hormones are signalling molecules, which travel through the bloodstream and elicit responses in other parts of the body. Endocrine disrupters are believed to interfere with the functioning of this complex system in at least three possible ways:

- by mimicking the action of a naturally-produced hormone such as oestrogen or testosterone, and thereby setting off similar chemical reactions in the body;
- by blocking the receptors in cells receiving the hormones (hormone receptors), thereby preventing the action of normal hormones; or
- by affecting the synthesis, transport, metabolism and excretion of hormones, thus altering the concentrations of natural hormones.

The International Programme for Chemical Safety (IPCS - which involves WHO, UNEP and ILO) has, together with Japanese, USA, Canadian, OECD and European Union experts, agreed the following *working* definitions for endocrine disrupters:

- A potential endocrine disrupter is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or its progeny, or (sub)populations.

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[2] The Court of Justice, in its Judgement of 5 May 1998, C180/96, Point 99, has said that "where there is uncertainty as to the existence or extent of risks to human health, the Commission may take protective measures without having to wait until the reality and seriousness of those risks become apparent"

- An endocrine disrupter 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.

There are two classes of substances which can cause endocrine disruption:

- *'Natural' hormones* which include oestrogen, progesterone and testosterone found naturally in the body of humans and animals, and phytoestrogens, substances contained in some plants such as alfalfa sprouts and Soya beans which display oestrogen-like activity when ingested by the body;

- Man-made substances which include

– *Synthetically-produced hormones*, including those hormones which are identical to natural hormones, such as oral contraceptives, hormone replacement treatment and some animal feed additives, which have been designed intentionally to interfere with and modulate the endocrine system; and

– *Man-made chemicals* designed for uses in industry such as in some industrial cleaning agents, in agriculture such as in some pesticides, and in consumer goods such as in some plastic additives. It also includes chemicals produced as a by-product of industrial processes such as dioxins, which are suspected of interfering with the endocrine systems of humans and wildlife.

Plants containing '*natural' hormones*, such as phytoestrogen, have been shown to have some beneficial effects on human health such as in the prevention of cardiovascular diseases, osteoporosis and some cancers. It is believed that the human body is able to easily break down and readily excrete these 'natural' substances. This means that they spend very little time inside the body and do not accumulate gradually in body tissue, which is the case with certain man-made substances. There may however be risks associated with changes in lifestyle and altered food and consumer habits, leading to higher intakes of food containing these substances.

Synthetically-produced hormones are substances which are produced and designed by manufacturers to ensure specifically that they interfere with and modulate the endocrine system. Dose-response relationships are measured and manufacturers are required to publish any available information on the possible side effects of use of these substances. The public is frequently in a position to inform itself of the benefits and possible risks before deciding to avail of these substances. There may, however, be risks associated with direct or indirect exposure, leading, for instance, to the unintended uptake of these substances by non-target populations such as the presence of synthetic hormone residues in food or in sewage effluent. On 30 April 1999, the Scientific Committee on Veterinary matters relating to Public Health (SCVPH), delivered an opinion[3] on the potential risks to human health from hormone residues in bovine meat and meat products. The Committee concluded that for the six hormones under review[4], endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged. It also

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3 Internet address: http://europa.eu.int/comm/dg24/health/sc/scv/index_en.html

4 The 3 natural, or identical to natural, hormones: 17 B Estradiol, Progesterone, Testosterone, and the 3 synthetic hormones MGA, Trenbolone and Zeranol

concluded that there is a substantial body of recent evidence suggesting that 17 Beta Estradiol[5] has to be considered as a complete carcinogen.

This particular issue is addressed by the Commission in the context of the World Trade Organisation ruling of 13 February 1998 on hormones.

Man-made chemicals comprise thousands of new and existing man-made chemicals which are designed for use in industry, agriculture and consumer goods and which, apart from the uses for which they were designed, may have unforeseen adverse or synergistic effects. There is also insufficient scientific information available on the biochemical mechanisms of these substances in humans and ecosystems.

3.2. Effects and sources of exposure

The phenomenon of endocrine disruption (ED) itself is not new. In 1938 DES (diethylstilbestrol) was designed as a drug to prevent miscarriages in women and to stimulate growth in cattle. In the 1970s/1980s, it was shown to cause severe problems to male and female reproductive systems, including congenital abnormalities and cancer. It is the first documented example of a chemical which, when given to the mother, can cause cancer in her daughter.

Apart from the example of DES, suspected ED chemicals have been considered to be potentially involved in a range of human and animal health-related effects. The Commission Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE), has, in its Opinion of 4 March 1999[6], conducted a review of the existing literature and scientific opinion on the evidence for chemically-induced endocrine disruption. It concludes that for human health effects "there are associations between endocrine disrupting chemicals, so far investigated, and human health disturbances" such as testicular, breast and prostate cancers, decline in sperm counts, deformities of the reproductive organs, thyroid dysfunction as well as intelligence and neurological problems. However, a causative role has not been verified.

For wildlife effects, the Committee concludes that "there is strong evidence obtained from laboratory studies showing the potential of several environmental chemicals to cause endocrine disruption at environmentally realistic exposure levels" and that "although most observed effects currently reported concern heavily polluted areas, there is a potential global problem".

"Impaired reproduction and development causally linked to endocrine disrupting chemicals are well documented in a number of species and have caused local or regional population changes. These include:

- masculinization (imposex) in female marine snails by tributyltin, a biocide used in anti-fouling paints, is probably the clearest case of endocrine disruption caused by an environmental chemical. The dogwhelk is particularly sensitive and imposex

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5 a natural oestrogen secreted, inter-alia, by the ovaries of adult women which, in its 'identical to natural' form, is authorised and widely used as a growth promoter in certain countries.

6 "*Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with emphasis on Wildlife and on Ecotoxicology test methods"*, Opinion of Commission Scientific Committee for Toxicity, Ecotoxicity and the Environment (SCTEE), adopted 4 March 1999.

has resulted in decline or extinction of local populations world-wide, including coastal areas all over Europe and the open North Sea.

- DDE-induced egg-shell thinning in birds is probably the best example of reproductive impairment that caused severe population declines in a number of raptor species in Europe and North America. Developmental exposure to the DDT complex has been firmly linked to the induction of ovotestis in male Western gulls.

- endocrine disrupting chemicals have adversely affected a variety of fish species. In the vicinity of certain sources (e.g. effluents of water treatment plants) and in the most contaminated areas this exposure is causally linked with effects on reproductive organs, which could have implications for fish populations. However, there is also a more widespread occurrence of endocrine disruption in fish in the United Kingdom, where oestrogenic effects have been demonstrated in freshwater systems, in estuaries and in coastal areas.

- in mammals, the best evidence comes from the field studies on Baltic grey and ringed seals and from the semi-field studies on Wadden Sea harbour seals, where both reproduction and immune functions have been impaired by PCBs in the food chain. Reproduction effects resulted in population declines, whereas suppression of immune functions has likely contributed to the mass mortalities due to morbillivirus infections.

- distorted sex organ development and function in alligators has been related to a major pesticide spill into a lake in Florida, U.S.A. The observed oestrogenic/anti-androgenic effects in this reptile have been causally linked in experimental studies with alligator eggs to the DDT complex."

For terrestrial (land-living) wildlife, including aquatic mammals, exposure is primarily expected to be of dietary origin. The situation is different for aquatic wildlife where direct uptake of dissolved chemicals from the water is a significant route of exposure. Additionally, the reproductive cycle of aquatic organisms with an unprotected embryonic and early life stage development occurring in the free environment makes them particularly susceptible to chemicals in the water.

For humans, possible pathways of exposure to endocrine disrupters include direct exposure via the workplace or via consumer products such as food, certain plastics, paints, detergents, cosmetics as well as indirect exposure via the environment (air, water, soil).

In general, the vulnerability of a given species will depend on the intrinsic properties of the chemical, on the magnitude, duration, frequency and route of exposure and on the way in which a given species can absorb, distribute, transform and eliminate substances. It will also depend on the sensitivity of specific organs at different stages of development.

4. ADDRESSING THE PROBLEM OF ENDOCRINE DISRUPTION

The main case studies concerning the phenomenon of endocrine disruption associate adverse effects with exposure to high levels of specific chemical substances. This has fuelled public concern and placed pressure on policy-makers and regulators to address the problem as a matter of urgency. In this Paper, four key elements are identified on the basis of which an appropriate set of actions is recommended. These are:

- the need for further research
- the need for international co-ordination
- the need for communication to the public
- the need for policy action

The first three elements will be addressed in this section while the fourth element, the need for policy action, will be addressed separately in Section 5.

4.1. The need for further research

Lists of suspected ED chemicals have been drawn up by various organisations on the basis of available information. However, further scientific data collection and research is necessary to identify the selection criteria used to place substances on these lists. In addition, it is necessary to assess the quantities of these substances in the environment, based on an examination of the material flow of each substance. This includes production volumes, consumption in further processing and final products and import/export volumes. To this end, the Commission has launched a study, the results of which are expected in early 2000. It will serve as a first step in establishing a list of substances for further evaluation of their role in endocrine disruption.

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. It is therefore essential to carry out further research in these areas and to investigate the need for refinement of current risk assessment methodologies to address EDs. The Commission is currently financing research efforts aimed at the development and validation of test methods for the identification of EDs.

In order to support a rapid development of test methods, a focused research effort is required into the mechanisms of action of the endocrine system and the range of effects, including the role of hormones at key stages of life cycles. This should also facilitate the development of useful models both for estimation of exposures and for biological testing strategies.

In addition, further investigations are required into the links between adverse health effects in humans and wildlife and exposure to specific substances or mixtures of substances, including the health consequences of phytoestrogens and hormones used

as growth promoters. This has to be done via laboratory studies, epidemiological studies, field studies and monitoring programmes.

There is also a need to develop and validate appropriate environmental monitoring tools.

It should be noted that a broad range of research activities into endocrine disruption is ongoing in Europe. Several EU Member and Associated States are conducting national research programmes and a number of other States have a significant level of individually driven research work.[7]

Under the Community Fourth Framework Programme on Research and Technological Development (1994-1998), fourteen (14) transnational research projects have been or are currently funded with an EC financial commitment of circa 8 M€. A further two (2) projects have been launched to date under the Fifth Framework Programme on RTD (1999-2002) with funding of circa 3M€. In addition, results from ongoing studies launched by the Commission into the risks associated with hormone residues in bovine meat and meat products and in the environment will contribute to the overall pool of scientific evidence required to address the phenomenon of endocrine disrupters. The European chemical industry, through CEFIC (the European Chemical Industry Council), is engaged in a global research programme covering human health issues, environment issues and testing and testing strategies.

4.2. The need for international co-ordination

Due to the complexity and cost of the research to be carried out, it is essential that the work is planned and conducted as efficiently as possible. This will require co-operation and co-ordination among the key stakeholders, not only in the context of the EU but also at a global level, in order to pool knowledge and avoid duplication of efforts. This was emphasised at the Summit Meeting of the Environment Leaders of the Eight, who met in Miami in May 1997 where a Declaration, encouraging international co-ordination in research efforts on endocrine disruption, was adopted.

To this end, the Inter-governmental Forum on Chemical Safety made a number of recommendations concerning approaches and means for co-ordinating and/or supporting efforts to address the issues internationally. A global inventory of research (GEDRI), initially based on inventories established in the USA, Canada and Germany, has been established at the Joint Research Centre in Ispra, Italy and is publicly accessible via Internet[8]. In addition, a global assessment of the state-of-the-science on endocrine disruption is already underway and is expected to be published in mid-2000. The Secretariat for the follow-up of these activities is provided by the International Programme for Chemical Safety (IPCS) and OECD and a Steering Group, co-chaired by the Commission and the US Environmental Protection Agency, has been established. In addition, under the EC-US Science and Technology Co-

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7 Ecosystems Research Report No 29 “Endocrine Disrupters Research in the EU, Report of a Meeting, Brussels, 4 November 1997”, CEC Report EUR 18345.

8 Internet address: http://endocrine.ei.jrc.it/

operation Agreement, endocrine disruption has been identified as one of four priority research topics[9].

International co-operation and co-ordination is equally important in order to facilitate harmonisation of any regulatory actions which may eventually be decided upon, taking due account of international trade aspects. In this context, the European Community has signed, in June 1998, a Protocol on Persistent Organic Pollutants (POPs) under the 1979 UNECE Convention for Long-Range Transboundary Air Pollution and is currently participating in international negotiations towards a global instrument on POPs. Furthermore, the European Commission and twelve (12) EU Member States are Contracting Parties to the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic, under which a Strategy with regard to Hazardous Substances was agreed in July 1998. For endocrine disrupters, this Strategy proposes to develop and apply appropriate evaluation criteria, using internationally recognised testing procedures where available, to establish whether substances have the potential to cause adverse effects to organisms in the marine environment. It also proposes to collaborate with various international fora with a view to optimising international research efforts.

4.3. The need for communication to the public

Following the Resolution on Endocrine Disrupting Chemicals adopted by the European Parliament in October 1998, there is a strong need to improve communication in order to address the concerns of the public in this area. It should be noted that risks are often perceived differently by the general public than by the scientific community. Both the feelings of lack of information as well as of control on the source and routes of exposure to chemical substances need to be addressed.

The public concern stems from media reports based on published epidemiological evidence on environmental effects but may also, to some extent, be due to a lack of clear comprehensible information about the ED phenomenon itself and actions that are being undertaken to address the problem. This void is of significant political importance and needs to be managed carefully. It will therefore be necessary to identify appropriate channels through which to communicate reliable information to the public on a regular basis, taking due account of specific approaches already adopted by individual Member States.

5. THE NEED FOR POLICY ACTION

5.1. Substances under suspicion

Under existing legislation, a substantial number of chemicals, which feature on various lists of suspected ED chemicals are already subject to regulatory measures.

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[9] Six main ED research areas have been identified for further coordination: expansion of international efforts to standardize and validate screening and testing methods; determination of normal ranges of values for critical endocrine parameters in wildlife; support for international assessment of the status of marine mammals; provision of an easily accessible, indexed searchable database on the literature of ED effects; identification of human health effects in potentially sensitive international subpopulations based on life stage and exposure; and development of international databases of existing human tissue sample collections and cohort studies.

However, these measures are usually taken on the basis of reported toxic effects of the substances without necessarily identifying the underlying mechanisms of action.

Given that endocrine disruption is a mechanism of action, it follows that the effects which these measures address are not necessarily related to the endocrine system and that EU legislative instruments may not fully address all effects potentially caused by EDs. This is in particular the case for the environment. In its Opinion of 4 March 1999, the Commission SCTEE cited causal links between tibutyltin (TBT), DDT and PCBs and impaired reproduction and development in wildlife. Examples of current measures involving these substances include a ban on organostannic compounds for use in anti-fouling paints on certain types of boats and in inland waters of the Community and a ban on the use of DDT. Polychlorinated biphenyls (PCBs) are already subject to bans due to their reproductive toxicity and bio-accumulation effects. Other examples of measures involving suspected chemicals include two pesticides which have been classified as toxic for reproduction and several others which have been classified as carcinogenic or mutagenic.

Given the potential scale and seriousness of ED effects, it will be necessary to consider whether, in the short-, medium- and long-term, substances can be controlled more comprehensively, by considering for example their endocrine disrupting effects through existing legislative instruments.

5.2. Independent scientific advice

In its Communication on Consumer Health and Food Safety[10], the Commission established its policy with regard to scientific advice as a basis for ensuring a high level of protection of health. The Commission subsequently created the Scientific Committee on Toxicity, Ecotoxicity and the Environment[11] (SCTEE) with particular competence on scientific questions relating to examination of the toxicity and ecotoxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. This Committee, together with other relevant Scientific Committees established by the Commission, has a key role to play in providing independent scientific advice to the Commission.

In a first step, the SCTEE adopted an Opinion on 4 March 1999 "*Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with emphasis on Wildlife and on Ecotoxicology test methods"*. In developing future steps, the Scientific Committees of the Commission will continue to be consulted.

5.3. The approach taken in existing Community legislation

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.

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[10] COM (97) 183 final of 30.4.1997

[11] Decision 97/579/EC of 23.7.1997

For each of these stages, the amount of available scientific evidence for individual substances can vary greatly. Thus, a key consideration underpinning this approach is the precautionary principle. In the case of BSE[12], the Court of Justice has said that "where there is uncertainty as to the existence or extent of risks to human health, the Commission may take protective measures without having to wait until the reality and seriousness of those risks become apparent". The Court of First Instance has used the same wording in another case concerning protection of the environment[13]. In seeking to identify appropriate policy action on the basis of the precautionary principle, there are at least two aspects to be taken into account. One is the need to base policy on proper scientific evaluation and the other is the need to be able to respond quickly and effectively to specific concerns as scientific knowledge evolves.

It should be noted that in November 1998 the Commission adopted a Report on the Operation of four instruments (Directive 67/548/EEC, Directive 88/379/EEC, Regulation (EEC) No.793/93 and Directive 76/769/EEC) concerning the Community policy on chemicals.[14] One of the issues identified in this Report is the need to ensure that these instruments keep up with new scientific developments such as the potential threat of EDs. In December 1998, as a follow-up to this Report, the Council underlined the necessity to work on the development of an integrated and coherent approach to the future chemical policy of the Community – adequately reflecting the precautionary principle. The Council welcomed the Commission's intention to develop such a strategy in consultation with Member States and other stakeholders. It is clear that the current strategy on endocrine disrupters will in the longer-term form an integral part of the overall strategy to be developed.

5.4. Instruments

For the **hazard identification stage**, Directive 67/548/EEC relating to classification, packaging and labelling of dangerous substances is the main umbrella Directive which provides for the classification of substances based on their inherent properties while Directive 88/379/EEC provides for the classification, packaging and labelling of dangerous preparations. The recently adopted Directive 1999/45/EC extends the scope of Directive 88/379/EEC to cover plant protection products and preparations, which are deemed to be dangerous for the environment.

For the **risk assessment (RA) stage**, there are a number of legislative instruments, which cover new and existing substances and preparations. In addition there is specific legislation, which provides for the RA of pharmaceuticals, cosmetic products, food additives and food contact materials. These instruments are listed in Annex 1.

Finally, for the **risk management stage**, there are three broad categories of instruments: product-oriented instruments; process-oriented instruments; and media-oriented instruments. *Product-oriented instruments* provide for restrictions on marketing and use of substances, preparations and products or for maximum levels of contaminants in products. *Process-oriented instruments* provide for the control of releases of substances by means of emission limits and the application of Best

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12 Judgement 5 May 1998, C180/96, Point 99.

13 Judgement 16 July 1998, T199/96.

14 Commission Working Document, Report on the Operation of Directive 67/548/EEC, Directive 88/379/EEC, Regulation (EEC) 793/93 and Directive 76/769/EEC, SEC(1998)1986 final.

Available Techniques. *Media-oriented instruments* provide for acceptable quality levels or environmental quality standards (EQS) for specific substances in the environment. These instruments are listed in Annex 1.

In order to "catch" EDs in the EU legislative net, it will be necessary to assess whether the main instruments for each of the three stages - hazard identification, risk assessment and risk management - cover EDs.

5.5. Use of Instruments

Annex 2 provides a brief assessment of how the main instruments for each of the three stages can be used to cover EDs.

For the **hazard identification** stage, a key requirement for adaptation of existing legislation is the availability of test strategies/methods. There are currently no test strategies/methods available, which specifically detect all effects, which have been linked to the ED mechanism. However, the OECD has set up a Working Group on Endocrine Disrupters with the specific objective of developing a harmonised approach to the screening and testing of chemicals. The Commission, Member States, USA, Japan and other OECD member countries, as well as industry and non-governmental organisations, are represented in this Working Group. It is expected that the validation of a first set of tests and agreement on these test guidelines will take 2-4 years to complete.

In addition to the need for agreed test methods, 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 disrupters.

For **risk management**, the tailor-made choice of instrument(s) with which to address endocrine disruption will also only become clear once appropriate test methods are available to assess the extent of the phenomenon. However, there may be instances where the use of certain substances carries the possibility of a particularly high risk for certain consumer groups, for instance children. In such cases, it will be necessary to consult the relevant Scientific Committees of the Commission, such as the Scientific Committee on Toxicity, Ecotoxicity and the Environment, the Scientific Committee on Food, the Scientific Committee on Plants and the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers, for independent scientific advice. It will also be necessary to consider the use of existing instruments, such as Directive 92/59/EEC, which allow for short-term emergency action.

In addition, given the wide range of potential ED chemicals, which includes a substantial number of pesticides, there is a need to focus on existing instruments such as Directive 76/769/EEC and Directive 79/117/EEC. Their scope covers a wide range of dangerous substances, preparations and plant protection products. They provide for long-term general and targeted action, such as prohibition or restrictions on marketing and use. In cases where the release of specific substances into the environment needs to be controlled, it will be necessary to consider the use of process-oriented and media-oriented instruments.

Finally, it should be noted that, for certain classes of dangerous substances, there is a direct link between Directive 67/548/EEC and Directive 76/769/EEC, that is, from

hazard identification to risk management. As the extent and seriousness of endocrine disruption becomes better-understood, it will be necessary to consider whether the conditions enabling such a link between hazard identification and risk management may need to be revised.

6. STRATEGY

In view of its role in protecting EU citizens and the environment, and because of the potential seriousness of the concerns, the European Commission must adopt a strategy in line with the precautionary principle in which Community actions are entirely transparent. 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. Community action has to take into account the wider international context. It will also be necessary to analyse and take account of the compliance costs for any given policy action as well as the potential impact of each policy action.

At present, a number of initiatives are already underway or under consideration within the Commission. In addition, scrutiny of existing legislative instruments has already provided policy options for possible future action. It should be noted that the short-, medium- and long-term actions identified below are based on an assessment of the likely timeframe within which *results* can be achieved, i.e. 1-2 years for short-term actions, 2-4 years for medium-term actions and more than 4 years for long-term action. Finally the strategy must be sufficiently flexible to be able to incorporate new scientific knowledge on endocrine disruption, as this becomes available.

6.1. Short-term action

Establishment of a priority list of substances for further evaluation of their role in endocrine disruption

The Commission intends to establish a priority list of substances for further evaluation of their role in endocrine disruption, hereinafter referred to as the "ED priority list". In a **first step**, an independent review of peer-reviewed scientific literature, emerging research results and assessment reports publicly available under existing legislation will be conducted as well as the identification of sources/pathways of exposure of humans and wildlife and a quantification of production volumes. The Commission has already launched a study to address this task, a key element of which will be the consultation of stakeholders on selection criteria.

In a **second step**, the existing expert groups established under Regulation (EEC) No.793/93, Directive 67/548/EEC and Directive 91/414/EEC as well as the Commission's SCTEE will be consulted in this priority-setting exercise. The Commission will ensure co-ordination between these expert groups and the SCTEE in order to avoid duplication.

The priority list will be used, inter-alia:

- to identify substances for 'priority' testing once agreed test methods become available,

- to identify substances which can be, or already being addressed, under existing Community legislation covering hazard identification, risk assessment and risk management,

- to identify gaps in knowledge on aspects such as dose/response relationships, sources/pathways of exposure and epidemiological studies of cause/effect relationships which will help guide further research and/or monitoring efforts, and

- to identify specific cases of consumer use, for example, the case of potentially more vulnerable groups of consumers such as children, for special consideration from a consumer policy point of view.

Use of legislative instruments

Although adaptation/amendment of current legislation is a long-term action, there are a number of actions, which can be taken by the Commission in the short-term:

- urge the Member States to speed up the risk assessment of these substances. This can be the case where some substances on the ED priority list already feature on existing priority lists under Regulation (EEC) No.793/93 and Directive 91/414/EEC for reasons other than endocrine disruption.

- urge the Member States to consider the substances on the ED priority list for classification using existing test results for reproductive toxicity, carcinogenicity and danger to the environment. Classification under Directive 67/548/EEC on the basis of endocrine disrupting effects requires test strategies/methods, which are not yet available.

It is also noteworthy that the recently adopted Directive 1999/51/EC, (a technical adaptation of Directive 76/769/EEC), provides for a review of the provisions on tributyltin (TBT) in the light of the decision of the International Maritime Organisation to impose a global ban on the use of tin in anti-fouling ship paints by 1 January 2003.

Establishment of monitoring programmes to estimate exposure to and effects of the substances on the ED priority list

Once an ED priority list has been established, it will be possible to identify those substances, which already feature on priority lists or which may be included in subsequent priority lists using the methodology agreed under existing legislation. For those substances on the ED priority list, which are not covered by the current legislation, the Commission intends to consult stakeholders on the establishment of monitoring programmes. This would give an estimation of exposure, both direct and indirect, by determining the quantity of these chemicals likely to be released into the environment. Such programmes would also need to estimate the proportion of this release to air, water and soil as well as their use and fate in food, consumer products and in the workplace.

In addition, there is a clear need to collect data on observed effects in order to contribute to the understanding of whether causal links exist between effects and exposure to specific chemicals, including such issues as dose and timing of exposure as well as synergistic effects.

Identification of specific cases of consumer use for special action

In cases where potentially more vulnerable groups of consumers such as children are exposed to substances on the ED priority list and where these substances are not covered by the methodology agreed under existing legislation, the Commission will consult the relevant Scientific Committees of the Commission for independent scientific advice. In such cases, carefully focused questions shall be addressed to the Committees whose Opinions will be made public, in accordance with normal practice, in the interests of transparency and public confidence. Such advice will be used to consider potential restrictions on use through Community legislative instruments.

Information exchange and international co-ordination

Information exchange and co-ordination among the Commission, national governments or administrations, industry and other organisations sponsoring research in this area will be essential in order to ensure a proper share-out of research with clear contributions from all stakeholders, to remain abreast of research results, and to avoid duplication of efforts. International trade aspects will also need to be taken into account when considering specific policy actions. The Commission and Member States as well as other stakeholders are currently involved in the follow-up of the Intergovernmental Forum on Chemical Safety (IFCS) and the EU-US Science and Technology Co-operation Agreement, in the ratification of the UNECE POPs Protocol, as well as in the negotiations towards a global UNEP instrument on POPs and in the implementation of the OSPAR Commission's Strategy with regard to Hazardous Substances. Furthermore, the creation of databases on risk assessment and of European networks under the Community action programme on pollution-related disease[15] will help to improve information exchange and international co-ordination.

Communication to the public

The Commission plays an active role in collecting, exchanging, assessing and providing information, as well as in monitoring ongoing activities concerning the ED phenomenon. In the short-term and on an ongoing basis, information to the public on such activities, on the mechanisms and possible effects as well as the uncertainties concerning cause/effect relationships and on the relative exposures to man made chemicals is essential.

In particular, it will be necessary to consider an appropriate mechanism to communicate the ED priority list to be established as well as those substances on the list, which are already subject to regulatory measures. The Commission intends to make information available and accessible to the public in the appropriate form, to ensure a feedback loop from the public to the regulatory authorities and to ensure periodic re-assessment. For this task, the Commission will, as far as possible, avail of a number of existing Community Programmes, on health information and education and on pollution-related disease, as well as new instruments to be developed within the framework of public health. Assistance will also be sought from, *inter-alia*, the European Environment Agency.

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Consultation of the stakeholders

In addition to allaying public concern through the provision of clear, comprehensible information, the Commission will 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.

6.2. Medium-term action

Identification and assessment of endocrine disrupters

Agreed test methods for effects such as reproductive toxicity and carcinogenicity already exist but these are not considered to be sufficiently specific to detect all the effects, which have been associated with endocrine disruption.

In 1998, the OECD set up a specific Working Group to develop a harmonised approach to the development of test methods/strategies for endocrine disruption. At the first meeting of this Working Group, the US tabled a detailed draft Proposal on a screening and testing strategy. It is essential that the Commission and Member States ensure that sufficient resources are allocated to this Working Group in order to prepare a position and to participate fully in this work, particularly in the validation of test methods and in the development of an appropriate testing strategy.

The Commission already works closely with the Member States via the Working Group 'National Co-ordinators for Test Guidelines' in order to co-ordinate EU input at OECD on the improvement and development of existing and new test guidelines. This Working Group has a key role to play in order to ensure harmonised input to the OECD Working Group on endocrine disruption. In addition, the Commission is supporting and will continue to support an extensive research effort into test methods, which also serves as an input to this process.

While a number of existing standard tests on human health effects can be applied to the issue of endocrine disruption, this is not the case for the existing standard tests on environmental effects. In the medium to long-term, the Commission asks the Member States to develop a new set of standard tests on this issue for use in European environmental legislation, particularly in view of the fact that more scientific evidence is available of endocrine disruption in the environment than in human health. The Commission SCTEE, in its Opinion of 4 March 1999, has identified for example the need to design tests for wildlife, which detect target organ toxicity, including endocrine disruption.

Research and development

Research is essential in understanding the phenomenon of endocrine disruption. It is essential particularly when it comes to understanding the mechanisms themselves, to establishing whether there are causal links between exposure to substances and adverse effects in humans and wildlife, and to investigating risk assessment concepts. In addition, it is essential in developing test strategies and methods and in developing environmental monitoring tools.

A key instrument for the Community is the Framework Programme for R&D. Results from ongoing and newly started research projects under the 4th Framework

Programme (1994-1998) are expected in the short- to medium-term. The 5th Framework Programme (1999-2002) will ensure ongoing research efforts in the medium- to long-term, under the specific programmes "Quality of life and management of living resources" and "Energy, Environment and Sustainable Development".

In addition, the Commission has a key role to play in bringing together researchers across projects to exchange information and in facilitating co-ordination among Member States.

Identification of substitutes and voluntary initiatives

Assistance will be necessary to identify substitutes, in order to facilitate possible restrictions on the substances on the ED priority list. Such an exercise can only be launched in a comprehensive manner when test methods for identifying endocrine disrupting mechanisms and effects are available; otherwise possible substitutes will be open to the same suspicions as the substances they may replace. In the meantime, the Commission will consider voluntary initiatives, in collaboration with other stakeholders, to eliminate substances, to find/develop replacements and to promote clean technologies and a reduced use of agrochemicals in farming.

6.3. Long-term action

Legislative actions

A preliminary analysis of the existing legislation covering environmental and human health aspects of chemicals indicates that two key legislative instruments, Directive 67/548/EEC on classification and Regulation (EEC) No.793/93 on risk assessment, will require review to take specific account of EDs. For Directive 67/548/EEC, this will involve either adaptation or amendment of the Directive. The Commission is already undertaking a comprehensive evaluation of both instruments and any actions related to endocrine disruption will need to take account of this evaluation process.

Depending on the results of hazard identification and/or risk assessment, the Commission, in consultation with the Member States, will consider the use of appropriate risk management instruments such as Directive 76/769/EEC. It covers a broad spectrum of dangerous substances and preparations and will be used to introduce appropriate restrictions on marketing and use.

In addition, the Commission, in consultation with the Member States, will consider the adaptation of Directives 79/117/EEC and 91/414/EEC on Plant Protection Products (PPPs) and 98/8/EC on Biocidal Products to take account of substances on the ED priority list which fall within the category of PPPs or biocidal products. Under the Proposed Water Framework Directive, the Commission will ensure that endocrine disrupters are taken into account in a future review of priority substances to be considered for specific measures at Community level. Moreover, the Commission intends to launch a study on the role of EDs in drinking water in order to assess if it is necessary to include such a parameter in a future revision of Directive 98/83/EC.

Finally, although most of the POPs in the UNECE POPs Protocol are no longer used or produced in the EU, the Commission is considering the need to adapt or amend

existing Community legislative instruments in order to comply formally with the provisions of the Protocol.

7. CONCLUSIONS

The epidemiological evidence of potential relationships between exposure to chemical substances and endocrine disruption is a general cause for concern. Although a considerable amount of research is still required to ascertain the scope and seriousness of endocrine disruption, including confirmation of epidemiological results, it is essential that the Commission adopt a strategy, which takes into account the current concern on the basis of the precautionary principle. The strategy includes short-, medium- and long-term actions.

- In the short-term, the Commission intends to gather scientific evidence on substances for further evaluation of their role in endocrine disruption. Once substances are identified, the Commission urges the Member States to make use of existing legislative instruments to their full, where appropriate. The Commission considers it equally essential in the short term to alleviate public concern by effectively communicating. Finally, international co-operation and co-ordination is a key requirement in order to make best use of available resources and to avoid duplication of efforts.

- In the medium-term, the Commission and Member States will ensure that sufficient resources are allocated to the development of agreed test methods within the framework of OECD and to the development of an appropriate EU testing strategy. Results of ongoing research projects need to be fed into the policy process. Research and development efforts under the Community's Fifth Framework Programme on R&D need to be strengthened. In addition, identification of substitutes and consideration of voluntary initiatives will be an important action in order to eliminate or find replacements for chemicals of concern.

- In the long-term, it will be necessary for the Commission to envisage proposing the adaptation and/or amendment to present EU legislative instruments, which cover chemicals as well as consumer, health and environmental protection in order to take account of endocrine disrupting effects.

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ANNEX 1

LISTING OF LEGISLATIVE INSTRUMENTS COVERING RISK ASSESSMENT AND RISK MANAGEMENT

1. RISK ASSESSMENT

- Directive 67/548/EEC, which under its seventh amendment - Directive 92/32/EEC - provides for the RA of new substances,

- Regulation (EEC) No.793/93 on the evaluation and control of the risks of existing substances which provides for the RA of existing substances - those which were placed on the Community market before 18 September 1981 and are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS),

- Directive 91/414/EEC concerning the placing of Plant Protection Products on the market which provides for the RA of Plant Protection Products - commonly known as pesticides,

- Directive 98/8/EC concerning the placing of Biocidal Products on the market which provides for the RA of non-agricultural pesticides, now known as biocidal products,

- Directive 76/769/EEC relating to restrictions on marketing and use of certain dangerous substances and preparations, which provides for a targeted RA in cases where there is an urgent need for RA.

2. RISK MANAGEMENT

2.1 Product-oriented instruments

For short-term emergency action

- Directive 92/59/EEC on general product safety which provides for temporary restrictions on products in emergency situations.

For long-term general and targeted action

- Directive 76/769/EEC relating to restrictions on marketing and use of certain dangerous substances and preparations,

- Directive 79/117/EEC prohibiting the placing on the market and use of Plant Protection Products containing certain active substances,

- Directive 91/414/EEC concerning the placing of Plant Protection Products on the market,

- Directives 86/362/EEC, 86/363/EEC and 90/642/EEC providing for maximum pesticide residue limits in agricultural products and foodstuffs,

- Directive 95/2/EC on food additives,

- Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of betaagonists.

- Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.

- Regulation (EEC) No.2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin.

- Regulation (EC) No.194/97 setting maximum levels for certain contaminants in foodstuffs,

- Directives 89/109/EEC and 90/128/EEC relating to materials and articles intended to come into contact with foodstuffs,

- Directive 88/378/EEC concerning the safety of toys,

- Directive 76/768/EEC relating to cosmetic products,

- Recommendation 89/542/EC on the labelling of detergents and cleaning products,

- Directives 76/116/EEC relating to fertilisers.

2.2 Process-oriented instruments

- Directive 96/61/EC, concerning integrated pollution prevention and control,

- Directives 89/369/EEC, 89/429/EEC and 94/67/EEC, concerning municipal waste and most hazardous waste incineration.

- Daughter Directives adopted under Directive 76/464/EEC on pollution caused by certain dangerous substances discharged into the aquatic environment.

2.3 Media-oriented instruments

- Directives 92/72/EEC and 93/389/EEC on air quality,

- Directive 98/83/EC relating to the quality of water intended for human consumption,

- Directive 76/160/EEC concerning the quality of bathing water.

It should be noted that the proposed Water Framework Directive, establishing a framework for Community action in the field of water policy, covers product-, process- and media-oriented controls.

ANNEX 2

EXISTING COMMUNITY LEGISLATION COVERING ENVIRONMENTAL AND HUMAN HEALTH ASPECTS OF CHEMICALS

ASSESSMENT OF THEIR USE IN ADDRESSING ENDOCRINE DISRUPTION

1. HAZARD IDENTIFICATION

Directive 67/548/EEC on classification, packaging and labelling of dangerous substances

Directive 67/548/EEC currently includes fifteen (15) classes of danger relating to the effects of substances and preparations. The explicit detection of endocrine disrupting properties of new or existing substances is not addressed in the Directive and evaluation criteria/test methods for endocrine disrupting effects are not specified. However, Article 2(2)(l), (n) and (o) of the 7th amendment of Directive 67/548/EEC (Directive 92/32/EEC) refer to the classes of danger "carcinogenicity", "toxic for reproduction" and "dangerous to the environment" respectively. It is possible to use these references, in conjunction with the *adaptation* of specific annexes of the Directive, to test and evaluate ED effects of new substances. The procedure for *adaptation* of the Directive is laid down in Article 29 of Directive 92/32/EEC "Procedure for adaptation to technical progress". The adaptations that may be necessary include

(1) Development and validation of test methods for identification of endocrine disrupting properties (Annex V to the Directive).

(2) Development of general criteria for the interpretation of test data for human health and the environment (Annex VI to the Directive).

(3) Extension of current testing requirements for new substances (Annex VII and Annex VIII to the Directive)

The adaptation of the Directive in this way provides the basis for a cascade of actions in related risk management instruments, a range of which are listed in the attachment to this Annex.

Since the identification of effects related to the endocrine disrupting mechanism is the subject of ongoing research, it may in future be necessary to include new classes of danger relating to these effects in Directive 92/32/EEC. This would necessitate an amendment of the Directive and would include adaptation of the Annexes as described above.

2. RISK ASSESSMENT

Regulation (EEC) No.793/93 for Risk Assessment of Existing Substances

Regulation (EEC) No.793/93 aims at the protection of (i) man from exposure to dangerous substances via all possible routes and (ii) all compartments of the environment. 'Man' in this context includes "worker, consumer and man via the environment". The Regulation introduces two key steps: (1) the establishment of priority lists of substances and (2) risk assessment.

For EDs, the first step will involve the establishment of a priority list within the meaning of Article 8 of the Regulation. The second step comprises a comprehensive risk assessment on the priority list substances or the use of Article 12.2 to ask for information, which may include a request for supplementary tests. This would be for special cases where there are valid reasons to believe that an existing substance (in EINECS) may present a serious risk to human health or the environment. It should be noted that any available data on potential ED effects are considered in the current risk assessment process on a case-by-case basis.

Comprehensive risk assessments under Regulation (EEC) No.793/93 currently require a considerable length of time and may lead to requests for further information on testing. Requests for supplementary information and testing under Article 12.2 have not yet been implemented under this Regulation.

Directive 91/414/EEC concerning the placing on the market of Plant Protection Products

Directive 91/414/EEC provides for risk assessment of active substances contained in Plant Protection Products (PPPs). The Directive works on the basis of priority lists of active substances, which are subject to, risk assessments. It provides, in its Annexes II and III, detailed data requirements addressing toxicology and exposure in accordance with the current state of scientific knowledge in order to ensure a high level of protection for human health and the environment. Annex VI of this Directive provides for uniform principles which Member States apply in granting authorisations of plant protection products. To the extent that the concerns on endocrine disruption are confirmed by scientific evidence, the Commission will update these annexes, after consultation of experts in the framework of the Standing Committee on Plant Health.

Directive 98/8/EC concerning the placing on the market of Biocidal Products

Directive 98/8/EC on Biocidal Products provides for risk assessment of active substances contained in Biocidal Products. The Directive works on the basis of priority lists of active substances, which are subject to, risk assessments. It is therefore possible, under this instrument, to address substances on the ED priority list which fall within the category of biocidal products by the establishment of a priority list followed by a comprehensive risk assessment.

Directive 89/109/EEC and its specific Directives relating to materials and articles intended to come into contact with foodstuffs

Directive 89/109/EEC and its main specific Directive 90/128/EEC on plastics for food applications provide for risk assessment of substances used in the manufacture of plastic articles. Directive 89/109/EEC provides a list of authorised substances, following a risk assessment by the Scientific Committee on Food (SCF). It is therefore possible to evaluate the risks associated with substances on the ED priority list in food contact materials falling within the scope of the Directive.

Directive 76/769/EEC relating to restrictions on marketing and use of certain dangerous substances and preparations

In cases where there is an urgent need for risk assessment e.g. for substances classified as carcinogenic, mutagenic or toxic for reproduction (Categories 1 and 2) under Directive 67/548/EEC, or where there are widespread health concerns or national restrictions have already been notified, it may be necessary to perform a targeted risk assessment with a view to introducing harmonised restrictions under Directive 76/769/EEC. According to this procedure, an independent consultant would examine, according to Community principles, only the effect(s) of concern and this risk assessment report, developed in close co-operation with all stakeholders and peer-reviewed by the Commission Scientific Committee on Toxicity, Ecotoxicity and the Environment, would be the basis for risk management under the Directive.

3. RISK MANAGEMENT

3.1 Product-oriented instruments

Short-term emergency action

Directive 92/59/EEC on general product safety

Directive 92/59/EEC ensures that consumer products placed on the market are safe. The term ‘safe’ means that a product, be it in composition, presentation or in combination with other products, does not pose any risk or only the minimum risk compatible with a high level of protection for the safety and health of persons. To achieve this, Directive 92/59/EEC lays down specific requirements for the producers and empowers Member States to check, monitor and, if the case warrants it, control, restrict, withdraw or prohibit the placing on the market of products which have been deemed as ‘dangerous’. Moreover, under certain conditions, the Commission can take emergency measures concerning products, which are found to pose serious and immediate risks.

Long-term general and targeted action

Directive 76/769/EEC relating to restrictions on marketing and use of certain dangerous substances and preparations

In cases where a comprehensive risk assessment under Regulation (EEC) No.793/93 has been completed and there is a recommendation to introduce restrictions on marketing and use, the matter will be taken up in the framework of Directive 76/769/EEC. The availability and likely risk of available substitutes will be considered. An independent study of the advantages and drawbacks of Community risk reduction measures will supplement the risk assessment. On this basis, and after obtaining independent scientific advice from its Scientific Committees, the Commission may propose an amendment to Directive 76/769/EEC or adapt its Annex I to technical progress.

In addition, there is a direct link between Directive 67/548/EEC and Directive 76/769/EEC, that is, from hazard identification to risk management. Half a year after publication in Annex I of Directive 67/548/EEC of substances classified as carcinogenic, mutagenic or toxic for reproduction (Category 1 or 2), the Commission must submit a Proposal to the European Parliament and to Council in order to possibly restrict such substances under Directive 76/769/EEC.

Directive 79/117/EEC prohibiting the placing on the market and use of Plant Protection Products

Directive 79/117/EEC provides for the prohibition of the marketing and use of plant protection products containing active substances listed in the annex of the Directive, because of their harmful effects on human or animal health, or their unacceptable adverse effects on the environment.

Directive 91/414/EEC concerning the placing of Plant Protection Products on the market

Directive 91/414/EEC provides that Member States can only authorise plant protection products when it is demonstrated that, under the envisaged conditions, their use will not result in, *inter-alia*, harmful effects on human or animal health, directly or indirectly (e.g. through drinking water, food, or feed), or on groundwater and in unacceptable effects on the environment. Member States must cancel an authorisation when these conditions are no longer satisfied.

Directive 91/414/EEC provides also for an examination of the safety for human and animal health and for the environment of any *new* active substance at the time it is due to be placed on the market, and of any *existing* active substance (i.e. on the market before 28 July 1993) in the framework of the re-evaluation programme provided for in Article 8(2) of the Directive. For a first series of 90 *existing* active substances, this re-evaluation is currently in progress under Regulation (EEC) No.3600/92. On the basis of this evaluation, the active substance may be included in Annex 1 of the Directive, 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.

Directive 91/414/EEC also stipulates that when the holder of an authorisation obtains new information on potentially dangerous effects of a plant protection product or its residues, the competent authority must be notified of this information; this information must also be circulated to the other Member States and to the Commission.

Finally, it should be noted that Directive 91/414/EEC also provides for the possibility of immediate action in terms of withdrawal of authorisations of plant protection products by Member States when the safety requirements are no longer satisfied.

Directives 86/362/EEC, 86/363/EEC and 90/642/EEC providing for maximum pesticide residue limits in agricultural products and foodstuffs

Directives 86/362/EEC, 86/363/EEC and 92/642/EEC provide for the setting of maximum residue levels of pesticides in agricultural commodities, on the basis of the toxicological data, consumer exposure and the established good agricultural practice data for these pesticides.

Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of betaagonists.

This directive bans the placing on the market of, among others, stilbenes, stilbene derivatives and their salts and esters for administering to animals of all species. The Directive repeals all existing measures in this area since 1981.

Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.

In Annex 1 of Directive 96/23/EC, group A substances include substances having anabolic effect and unauthorised substances, which need to be controlled in residue monitoring plans of Member States. These substances will be detected from the type of animal and its feeding-stuffs, including drinking water and primary animal products.

Directives 89/109/EEC and 90/128/EEC relating to materials and articles intended to come into contact with foodstuffs

Directive 89/109/EEC stipulates that materials and articles, in their finished state, must not transfer their constituents to foodstuffs in quantities, which could endanger human health or bring about an unacceptable change in the composition of foodstuffs. The Directive is a framework Directive, which lists groups of materials and articles, such as plastics, regenerated cellulose, elastomers and rubber etc., which shall be subject to specific directives. The specific directives may include, inter alia, a list of substances, the use of which is authorised to the exclusion of all others, and if necessary provisions aimed at protecting human health against any hazards which might arise through oral contact with materials and articles. Article 5 of Directive 89/109/EEC stipulates that a Member State may temporarily suspend or restrict the use of an authorised

substance if, as a result of new information or a reassessment of existing information, the Member State has detailed grounds for establishing that its use may endanger human health.

Directive 90/128/EEC is a specific Directive setting specific migration limits for the transfer of constituents from plastics materials and articles to foodstuffs.

3.2 Process-oriented instruments

Directive 96/61/EC concerning integrated pollution prevention and control

Directive 96/61/EC is the main instrument to prevent and control emissions of polluting substances from mainly large industrial installations. It is a framework Directive that refers to the use of Best Available Techniques as a basis for setting permit conditions and on an integrated approach to emissions to air, water and land as well as energy consumption and eventual decommissioning of plant. In its Annex, this Directive specifies that substances and preparations, which may affect reproduction in or via the air or the aquatic environment must be taken into account if they are relevant for fixing emission limit values for industrial installations.

3.3 Combined process- and media-oriented instrument

Proposal for Water Framework Directive, establishing a framework for Community action in the field of water policy.

The Proposal for the Water Framework Directive aims to eliminate pollution of dangerous substances by the use of a combined approach: application of emission controls at source; and establishment of environmental quality objectives. For substances, which present a high risk to the aquatic environment, uniform Community controls are envisaged. In its Annex VIII, which provides an indicative list of the main pollutants to be considered in taking measures under the Directive, it is likely that specific reference will be made to EDs, thereby leaving the door open for specific future measures on EDs. It should also be noted that this Proposal covers not only the presence of man-made substances in water but also synthetic and natural hormones.

Attachment to Annex 2

EU RISK MANAGEMENT INSTRUMENTS

- Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers

- Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

- Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products

- Council Directive 82/501/EEC of 24 June 1982 on the major-accident hazards of certain industrial activities (Seveso-Directive)

- Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the Safety of Toys

- Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

- Council Directives 89/109/EEC and 90/128/EEC relating to materials and articles intended to come into contact with foodstuffs

- Council Regulation (EEC)No.2377/90 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin

- Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC) (Workers Protection Directive)

- Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (Pesticide Directive)

- Council Directive 91/689/EEC of 12 December 1991 on hazardous waste

- Council Regulation (EEC)No.880/92 of 23 March 1992 on a Community Eco-label award scheme

- Council Regulation (EEC)No.2455/92 of 23 July 1992 concerning the export and import of certain dangerous chemicals

- Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding

– Council Directive 94/33/EEC of 22 June 1994 on the protection young people at work

– Council Directive 98/24/EC of April 1998 on the protection of workers from chemical agents in general