Procedure file

Basic information COS - Procedure on a strategy paper (historic) Public health: endocrine disrupters, consequences on human and animal health Subject 3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety

| Key players | | | |
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| European Parliament | Committee responsible | Rapporteur | Appointed |
| | ENVI Environment, Public Health, Consumer Policy | | 22/03/2000 |
| | | PSE <u>LUND Torben</u> | |
| | Committee for opinion | Rapporteur for opinion | Appointed |
| | ITRE Industry, External Trade, Research, Energy | | 19/04/2000 |
| | | V/ALE AHERN Nuala | |
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| Souther of the European Officin | Environment | 2253 | 30/03/2000 |
| European Commission | Commission DG | Commissioner | |
| · | Environment | | |

| events | | | |
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Public health: endocrine disrupters, consequences on human and animal health

PURPOSE: to present the Communication on a Community Strategy for Endocrine Disrupters, a range of substances suspected of interfering with the hormone systems of humans and wildlife. CONTENT: the strategy focuses on man-made substances, including chemicals and synthetic hormones, which may harm health and cause cancer, behavioural changes and reproductive abnormalities. The objectives of the new strategy are to identify the problem of endocrine disruption, its causes and consequences, and to identify appropriate policy action on the basis of the precautionary principle in order to respond quickly and effectively to the problem. The strategy points to the need for further research, international cooperation, communication to the public and appropriate policy action and identifies actions in the short, medium and long-term to meet these requirements. The endocrine system consists of a set of glands and the hormones they produce, which help guide the development, growth, reproduction and behaviour of animals and human beings. There is a growing concern about a range of man-made substances which are designed for use in industry, agriculture and consumer goods as well as substances produced as a by-product of industrial processes. These substances are now suspected of interfering with the endocrine system. In October 1998, the European Parliament adopted a Resolution calling upon the Commission to take action in this area to improve the legislative framework, reinforce research efforts and to make information available to the public. In March 1999, the Scientific Committee for Toxicity, Ecotoxicity and the Environment (SCTEE) issued a report, "Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with emphasis on Wildlife and on Ecotoxicology test methods". The report identifies a "potential global problem" for wildlife. It also states that "impaired reproduction and development causally linked to the endocrine disrupting chemicals are well-documented in a number of wildlife species and have caused local and population changes". Against this background, the Commission Communication on the new strategy has identified 4 key requirements to address the phenomenon of endocrine disruption: further research: international cooperation; communication to the public; and appropriate policy action. Short, medium and long-term action is proposed to cover these requirements. In the short term, the Commission intends to gather scientific evidence on the substances for further evaluation of their role in endocrine disruption. Once these substances are identified, the Commission urges the Member States to make use of the existing legislative instruments to their full, where appropriate. The Commission considers it equally essential to alleviate public concern by communicating effectively. Lastly, international cooperation and coordination is necessary to make the best use of available resources and to avoid duplication of efforts. In the medium term, it is essential that the Commission and the Member States ensure that sufficient resources are allocated to the development of agreed test methods within theframework of the 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 Research and Development (R&D) need to be strengthened. In addition, identification of substitutes and consideration of voluntary initiatives will be important in order to eliminate or find replacements for substances of concern. In the long term, it will necessary for the Commission to envisage proposing the adaptation and/or amendment to present EU legislative instruments, which cover those substances as well as consumer health and environmental protection disrupting effects.?

Public health: endocrine disrupters, consequences on human and animal health

The committee adopted a report by Torben LUND (PES, DK) on a Commission paper for an EU strategy on endocrine disruptors. A major challenge to the Commission's stance was that whereas the latter would first like to draw up a list of substances suspected of being endocrine disruptors and subject them to further testing, the committee wanted immediate action. It said a list of substances should be identified, against which immediate steps should be taken under the precautionary principle. Measures should include banning, phasing out and/or limiting the use of these substances and the measures should be decided upon before mid-2001. The committee stressed that it was almost impossible to

set limit values for hormone-mimicking substances. The Commission and Member States were also urged to establish a European screening and testing strategy. The report said a European scientific research programme should be drawn up, aimed at gathering information and scientific knowledge and encouraging the exchange of information on endocrine disruptors. The committee called on the Commission, which was proposing to analyse existing legal instruments only in the long run, to complete its study by mid-2001. ?

Public health: endocrine disrupters, consequences on human and animal health

The European Parliament has adopted the report drafted by Mr Torben LUND (PES, Dk) on the communication on a Community strategy for endocrine disrupters - a range of substances suspected of interfering with the hormone systems and wildlife. A major challenge to the Commission's stance is that whereas the latter would like to draw up a list of substances suspected of being endocrine disruptors and subject them to further testing, Parliament want action now. It says that list of substances should be indentified, against which steps should be taken under the precautionary principle. It should be pointed out that the report adopted by the committee responsible mirrors the report adopted at plenary, therefore, please refer to the decision of the committee responsible in the previous legislative step for the main specifications. In addition, the Parliament calls on the Commission and the Member States to ensure that efficient resources from the forthcoming 6th Framework Programme on Research and Development are allocated to independent research. The Parliament also recommends that the Commission initiates an investigation into the number of endocrine-disrupting substances and the quantity of EDs which humans and wildlife are exposed to, including an investigation into the quantities of EDs in foodstuffs.?

Public health: endocrine disrupters, consequences on human and animal health

PURPOSE: to establish the first report (2001) on the progress made on the implementation of the Community Strategy concerning endocrine disrupters. CONTENT: a key short-term action of the Community Strategy is the establishment of a priority list of substances for further evaluation of their role in endocrine disruption. During 2000, a candidate list of 553 manmade substances and 9 synthetic/natural hormones has been identified. The candidate list has been divided into three separate groupings of substances depending on the level of information available, and a priority list of actions has been developed in order to further evaluate the role of these substances in endocrine disruption. Actions, timeframes and groupings of substances are presented in Annex 1 of this Communication. Regarding other short-term actions, the Commission is planning a European workshop on endocrine disrupters to organise with the sponsorship of the Swedish Ministry for Environment, Swedish National Chemicals Inspectorate (KEMI), OECD, WHO and the European Environment Agency. The workshop will take place on 18-20 June 2001 in Sweden and will focus on monitoring, research and development, test methods/testing strategy and international cooperation. The Commission has also held meetings with WHO and the US EPA during 2000 with a view to enhancing international cooperation. The Commission and Member States continue to participate in the OECD Endocrine Disrupter Testing and Assessment Task Force, which was set up in 1998 with the goal of developing agreed test for endocrine disrupters. The latest estimates are that agreed test methods for human health would be available in 2002 while tests for environmental effects are expected in the timeframe of 2003 to 2005. Furthermore, under the 5th Community Framework Programme for R&D (1999-2002), research into endocrine disruption has been prioritised in the latest revisions of the relevant work programmes. In addition, dedicated call for research proposals on the health and environmental implications of endocrine disrupters was published in May 2001 with a budgetary envelope of 20 MEURO. Finally, regarding legislative action, the proposed revision of the General Product Safety Directive proposes, inter-alia, a simplification of conditions and procedures for urgent measures at Community level. In addition, the issue of endocrine disrupters is addressed specifically in the context of new and existing legislation in the field of water policy and in the recent White Paper on a strategy for a future chemicals policy. Moreover, the report indicates that the year 2001 will be dedicated to the further evaluation of the role of the candidate substances in endocrine disruption, with first priority given to those substances with evidence of ED or potential ED which are neither restricted nor currently being addressed under existing Community legislation. The evaluation will include the identification of specific cases of consumer or ecosystem exposure which might warrant special consideration from a consumer and environmental policy point of view in the short-term. Equally, priority will be given during 2001-2002 to gathering data on a range of candidate ED substances and to launching a series of research projects aimed at filling the gaps in knowledge and understanding of the phenomenon of endocrine disruption. In addition, the Commission invites the Member States to speed up the current risk assessment process for existing substances and plant protection products which appear on the ED candidate list and which are being addressed under existing Community legislation.?

Public health: endocrine disrupters, consequences on human and animal health

Following the adoption by the Commission of a Communication on a "Community Strategy for Endocrine Disrupters" in December 1999, the Council invited the Commission to report regularly on the progress of the work in this field. The first progress report was adopted in June 2001. A second progress report summarising the implementation of the Strategy during the period 2001-2003 was adopted in October 2004. This is the third progress report on the implementation of the Strategy during the period 2004?2006. It describes the developments that have been made in terms of activities on prioritising substances for further investigation, stimulating research, agreeing test methods or adapting legislation.

The "Community Strategy for Endocrine Disrupters" contains activities for the short, medium and long term. The short and medium term actions focus on gathering scientific data on "candidate substances" with a view to prioritising testing, guide research and monitoring efforts and to identify specific cases of consumer use and ecosystem exposure. The long-term actions focus on review and possible adaptation of policy and Community legislation.

In view of the fact that "endocrine disruption" is not a toxicological endpoint per se, but is a class of many mechanisms of action that may lead in different species to various types of effects which may result in adverse consequences on humans and ecosystems, the key short term action is the establishment of a priority list of substances for further evaluation of their endocrine disrupting effects. This prioritisation work started in the year 2000. Some 600 chemical substances ("candidates") have been screened, evaluated and a preliminary priority list established. This work was completed at the end of 2006.

The preliminary priority list of substances for further evaluation is not a negative list of substances but is meant to provide a basis for gathering further data on the endocrine disrupting effects of those substances and for their subsequent evaluation. Between 2000 and 2006 the Commission had three studies conducted on identification and evaluation of substances.

In total 575 substances were investigated over the past six years as to their endocrine disrupting (ED) effects. In terms of prioritisation, it was found that, out

of this number, 320 substances showed evidence or potential evidence for ED effects, while in total, 109 substances were not retained in the priority list, either due to insufficient data on ED effects or insufficient scientific evidence. 147 substances have been excluded from evaluation as they were identified as double entries, mixtures or of doubtful relevance.

An assessment of the legal status of the substances with evidence or potential evidence of endocrine disrupting effects showed that the majority of them are already subject to a ban or restriction or are addressed under existing Community legislation, although for reasons not necessarily related to endocrine disruption.

As regards medium-term actions, the Commission and Member States continue to participate in the OECD - Endocrine Disrupter Testing and Assessment Task Force (EDTA), which was set up in 1998 with the goal of developing agreed test methods for endocrine disrupters. It is hoped that the agreed test methods for some environmental and human health effects will be finalised in 2007. Furthermore, endocrine disrupters were addressed under the 5th (FP5? 1998-2001) and 6th (FP6? 2002-2006) EU Research Framework Programmes and will also be addressed under the 7thFramework Programme of the European Community for Research, Technological Development and Demonstration Activities (FP7 - 2007?2013).

Regarding long term actions, relevant developments since 2004 are the adoption of the regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), formally adopted on 18 December 2006; the proposal for a directive setting environmental quality standards for priority substances under the water framework directive (2006); and the proposal for a regulation revising Directive 91/414/EC on plant protection products (2006).