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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

European Union Strategy for Endocrine Disruptors

Replacing the Community Strategy for Endocrine Disruptors from 1999

(Text with EEA relevance)

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1. BACKGROUND

Through the 1990's concerns mounted on the possible negative human health and environmental impacts caused by endocrine disruptors, which are substances having the ability to interfere with functioning of a hormonal system. This concern was driven by the fear that exposure to endocrine disrupting chemicals not only could cause chronic diseases in the individuals exposed, but also in their children, their children's children and could thereby have an impact at population level, both in humans and in wildlife.

As a response to this growing concern the European Commission developed and adopted in 1999 a Community Strategy for Endocrine Disruptors (the 1999 Strategy)[1] aiming at increasing our understanding of endocrine disruption, making information available to public, developing test methods to identify them and beginning to address their risks arrising from endocrine disruption. The Commission recently carried out a critical review of the 1999 Strategy[2] which concluded that the understanding has significantly increased over the last 15 years, that the test method development had however been less successful, that the implementation of the 1999 Strategy including legislative action has not been sufficiently focused and coherent and that the risk management of endocrine disruptors has not been sufficiently addressed.

Unfortunately the increased knowledge about endocrine disruption has only confirmed many of the original worries flagged in the 1990's and has even added new ones. It is therefore the more unfortunate, that the 1999 Strategy did not deliver on the expectations regarding test method development and risk management.

This Communication sets out a new strategy replacing the 1999 Strategy and is accompanied by the Commission's review of the 1999 Strategy and by the Commission's Recommendation[3] defining and establishing horizontal criteria for the identification of endocrine disruptors applicable across all relevant EU legislation.

2. STATE OF THE SCIENCE

A number of authoritative reports are now available setting out the current state of knowledge in relation to endocrine disruptors and forming the scientific basis for this Communication. In

[1] COM(1999) 706 final of 17.12.1999. *Community Strategy for Endocrine Disrupters - a range of substances suspected of interfering with the hormone systems of humans and wildlife*.
[2] SWD(2013) XXX. *Critical Review of the 1999 Community Strategy for Endocrine Disruptors*
[3] Commission Recommendation on defining criteria for endocrine disruptors.

2012 UNEP/WHO[4] published an update of its comprehensive review from 2002[5]. In 2011 the Commission published an extensive review prepared under contract by Professor Kortenkamp et al[6]. A recent report from the EEA[7] looks at the possible long-term consequences of endocrine disruptors and the EFSA[8] and the Joint Research Centre of the European Commission[9] have recently published important position papers on critical issues relating to identification of endocrine disruptors.

The state of the science is well summarised by a number of quotes from these reports.

Box 1. Endocrine disruptors affect wildlife

"There is sufficient evidence to conclude that adverse endocrine-mediated effects have occurred in some wildlife species"

Quote: WHO State of the science of endocrine disrupting chemicals 2002 report.

Box 2. Endocrine disruptors play a role in human diseases

"Human and wildlife health depends on the ability to reproduce and develop normally. This is not possible without a healthy endocrine system."

"The speed with which the increases in [endocrine-related] disease incidence have occurred in recent decades rules out genetic factors as the sole plausible explanation. Environmental and other non-genetic factors, including nutrition, age of mother, viral diseases and chemical exposures, are also at play, but are difficult to identify."

"[Endocrine disrupting chemicals] have the capacity to interfere with tissue and organ development and function, and therefore they may alter susceptibility to different types of diseases throughout life. This is a global threat that needs to be resolved."

"Together, the animal model data and human evidence support the idea that exposure to endocrine disrupting chemicals during foetal development and puberty plays a role in the increased incidences of reproductive diseases, endocrine-related cancers, behavioural and learning problems, including ADHD, infections, asthma, and perhaps obesity and diabetes in humans."

"Exposure to endocrine disrupting chemicals could impair the health of our children and their children."

"An important focus should be on reducing exposures by a variety of mechanisms. Government actions to reduce exposures, while limited, have proven to be effective in specific

[4] WHO/UNEP (2012). *State of the Science of Endocrine Disrupting Chemicals—2012*. Geneva, Switzerland, United Nations Environment Programme/World Health Organization.

[5] WHO (2002). *Global Assessment of the State-of-the-Science of Endocrine Disruptors*. Geneva, Switzerland, World Health Organization, International Programme on Chemical Safety. Developed by the WHO through the International Programme on Chemical Safety (IPCS), a joint programme of WHO, UNEP and the International Labour Organization..

[6] Kortenkamp et al. (2011). *State of the Art Assessment of Endocrine Disruptors*. Prepared under Project Contract Number 070307/2009/550687/SER/D3 of the European Commission.

[7] EEA (2012). *The impacts of endocrine disruptors on wildlife, people and their environments. The Weybridge +15 (1996–2011) report*. EEA Technical report No 2/2012, ISSN 1725-2237.

[8] EFSA (2013). EFSA Journal 2013;11(3):3132.

[9] JRC (2013). *Key scientific issues relevant to the identification and characterisation of endocrine disrupting substances - Report of the Endocrine Disrupters Expert Advisory Group*. EUR 25919 EN;

cases (e.g. bans and restrictions on lead, chlorpyrifos, tributyltin, PCBs and some other POPs)."

"Internationally agreed and validated test methods for the identification of endocrine disruptors capture only a limited range of the known spectrum of endocrine disrupting effects. This increases the likelihood that harmful effects in humans and wildlife are being overlooked."

UNEP/WHO 2012 report: State of the science of endocrine disrupting chemicals – Summary for Policy Makers.

The scientific evidence therefore concludes that endocrine disruption does occur in the enviornment and that endocrine disruptors contribute to the increased incidence of endocrine-related deseases observed in humans and the environment in Europe over the last decades. Such deseases are severe and can be hereditary. Current regulatory test methods for identifying safe levels of exposure to endocrine disruptors are insufficient, as they can not detect many relevant effects.

3. THE POLICY RESPONSE

The policy response to the mounting evidence confirming the initial concerns on endocrine disruptors has been multiple and at national, EU and international levels.

Endocrine disruptors are of a similar regulatory concern as Carcinogens, Mutagens and Reproductive Toxicants (CMRs), Persistent, Bioaccumulative and Toxic substances (PBTs) and very Persistent and very Bioaccumulative substances (vPvBs). Therefore, the Commission and the EU co-legislators have introduced legislative obligations linked to endocrine disruptors in the legislation governing water[10] in 2000, industrial chemicals[11] in 2006, plant protection products[12] in 2009 and biocides[13] in 2012. Through the three latter regulations the EU has introduced a policy of phasing out endocrine disruptors similar to the existing Union policies regarding CMRs, PBTs and vPvBs already broadly implemented in Union legislation.

In its conclusions of 11 June 2012 on setting the framework for a Seventh EU Environment Action Programme the Council[14] urged the Commission *"to ensure the continuation and enhancement of policies to protect human health and the environment by addressing"* inter alia "*endocrine disruptors, based on scientific achievements, including in all relevant EU legislation with the aim of reducing exposures to endocrine disruptors and protecting human health and the environment, in particular children".*

[10] Directive 2000/60/EC establishing a framework for Community action in the field of water policy

[11] Regulation (EC) 1907/2006 on the Registration, Evaluation and Authorisation of Chemicals identifies endocrine disruptors as Substances of Very High Concern (SVHCs) and places an obligation on the Commission to review by 1 June 2013 how such substances are assessed under Authorisation

[12] Regulation (EC) 1107/2009 on Plant Protection Products introduces a phase out obligation for endocrine disruptors, establishes temporary criteria for identifying endocrine disruptors and sets a deadline of end 2013 for developing criteria.

[13] Regulation (EU) 528/2012 on Biocides introduces a phase out with exemptions obligation for endocrine disruptors, establishes temporary criteria for identifying endocrine disruptors and sets a deadline of end 2013 for developing criteria.

[14] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/130788.pdf

The European Parliament, in its own initiative report on the protection of public health from endocrine disrupters of 14 March 2013[15], *[c]onsiders, on the basis of an overall assessment of the state of knowledge, that the precautionary principle, in accordance with Article 192(2) of the Treaty on the Functioning of the EU (TFEU), requires the Commission and the legislators to take adequate measures to reduce short- and long-term exposure of humans to endocrine disrupters where necessary, while undertaking a much greater research effort to improve the state of the scientific knowledge on the impact of endocrine disrupters on human health"*. The European Parliament made a number of calls for action. This Communication also constitutes the Commission's response to the European Parliament.

Several Member States (Austria, Belgium, Denmark, France and Sweden) have initiated national action against specific endocrine disrupting chemicals, thereby resulting in obstacles to the functioning of the internal market.

In order for the new strategy to contribute to the European Union's efforts to meet the 2020 goal established at the World Summit of Sustainable Development[16] "*to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment*", the new strategy should deliver on its objectives by 2020.

4. THE OBJECTIVES OF THE 2020 STRATEGY

Objective I. To minimise exposures to humans and the environment from endocrine disrupting chemicals giving particular attention to exposures occuring during critical windows of development of an organism (exposures to foetuses, during pregnancy and to off-spring);

Current policies provide insufficient protection to human health and the environment. Considering the level of evidence for occurrence of adverse effects in the enviornment and in humans as a consequence of exposure to endocrine disruptors, the severity of the effects observed and the inability of current regulatory tes methods to detect many of them, the overall objective of the new strategy must be to minimise exposure to endocrine disruptors. The most sensitive window of exposure to endocrine disruptors of living organisms is pre-natal and during the development of the organism, so special attention must be given to minimising exposures during these critical windows.

Objective II. To promote the substitution of endocrine disrupting chemicals where technically and economically feasible alternatives exist;

The prefered route to minimising exposures is substitution, by alternative technologies or less hazardous substances, where such alternatives exist.

Objective III. To protect the internal European market and avoid unnecesary barriers to trade by ensuring a horizontal legislative approach to controlling endocrine disruptors and by strenghthening consumer and worker confidence;

[15] European Parliament resolution of 14 March 2013 on the protection of public health from endocrine disrupters (2012/2066(INI)).

[16] Plan of Implementation of the World Summit on Sustainable Development, A/CONF.199/20, Paragraph 22, Johannesburg, September 2002

Several Member States have taken unilateral action on endocrine disrupting chemicals, thereby impeding on the functioning of the internal market. The new strategy should counter this tendency by seeking EU measures where justified and necessary, thereby strengthening the functioning of the internal market.

Objective IV. To further improve the scientific understanding in policy relevant areas regarding endocrine disruptors.

The state of the science reports conclude that further research is necessary to deepen our understanding and hence enable improving our prevention policies. In line with the recommendations of the EEA[17] such research should be focused on areas where the investment provides best returns and not in areas where deeper understandning would not lead to better policies.

5. TURNING OBJECTIVES INTO ACTION

Exposures to endocrine disruptors can be minimised by ensuring that such substances are first identified and then the exposures reduced. Identification involves applying (testing) information to criteria. As the current regulatory test methods have limitations in detecting effects induced by endocrine disruption, endocrine disruptors can only be identified if new regulatory test methods for detecting the remaining effects are continuously developed and then applied. Objective I therefore necessitates that:

1. the *horizontal criteria are applied* (see section 6.1) to all relevant pieces of legislation, thereby ensuring a harmonised and horizontal approach to identifying endocrine disruptors across all relevant legislation;
2. the gaps between the effects of endocrine disruption and what can be identified by current *test methods* (see section 6.2) are filled, thereby improving the ability to identify endocrine disruptors;
3. the *regulatory information requirements* (see section 6.3) related to endocrine disruption are reviewed and, where necessary, updated, thereby improving the ability to identify endocrine disruptors;
4. *regulatory action* (see section 6.4), be it improved implementation or additional measures, is taken to minimise exposures to identified endocrine disruptors.

When doing so particular attention should be given to legislation which regulates exposures to endocrine disruptors of humans during the critical windows of development, *i.e.* during pregnancy and during development until maturity, and exposures to wildlife impeding population development.

The objectives on substitution (Objective II) and preservation of the internal market (Objective III) are met by establishing endocrine disruption as a regulatory class similar to the established priority classes of CMRs, PBTs or vPvBs and subjecting them to similar policies. The mechanisms of reversal of burden of proof (having economic operators demonstrate safety) creates substitution pressures and a level playing field for economic operators, thus supporting the internal market.

Objective IV, improving relevant scientific knowledge, can be met through continued investments in improving the *science* base (see section 6.5), where this is likely to improve regulatory decision making. This would require additional research into improving our understanding of chemical toxicity due to endocrine disruption, improving our access to

[17] EEA (2013). *Late lessons from early warnings: science, precaution, innovation*. EEA Report No 1/2013, ISBN: 978-92-9213-349-8

scientific information, developing biomonitoring programmes and finally further developing testing methods for the identification and assessment of endocrine disruptors for regulatory purposes.

The *communication* (see section 6.6) to the public should continue and should be targeted particularly to those groups able to prevent exposure during critical windows of development, *i.e.*, pregnant women and parents.

The *information exchange* on implementation of the strategy (see section 6.7) should benefit from and contribute to international efforts, for example those of the OECD and SAICM, aiming at maximising efficiencies and regulatory consistency and should take place with broad stakeholder involvement.

6 THE 2020 ACTION PLAN

6.1 Apply the Horizontal Criteria

Target: Ensure horizontal identification of endocrine disruptors and harmonised approach across legislation

The starting point for an effective EU strategy is the application of horizontal criteria for identification of endocrine disruptors across all relevant pieces of legislation. To aid in the uniform application of the criteria and avoid duplicative work, a list of identified (suspected) endocrine disruptors should be established.

Without such horizontal criteria, the identification of endocrine disruptors become inconsistent and confusing, leading to variable and unpredictable outcomes, to possibly diverging conclusions under different pieces of legislation and undermining the credibility of this strategy. In order to ensure that the application of the criteria serves its purpose the guidance document accompanying the criteria should be periodically reviewed in light of the scientific developments.

Action 1: By 2014, the Commission, supported by the relevant Commission Scientific Committees and agencies, will develop a guidance document accompanying the horizontal criteria for identification of endocrine disruptors detailing how to interpret results of test methods in relation to identification of endocrine disruptors using the horizontal criteria.

Action 2: From 2013 onwards, the Commission will compile a list of endocrine disruptors and suspected endocrine disruptors identified through the application of the criteria in the sectoral legislation. A substance on the list should then be recognised horizontally across EU legislation, thus avoiding the need to re-evaluate a substance under different pieces of legislation.

Action 3: By 2018 and every 5 years thereafter, the Commission will review and if necessary revise the guidance document accompanying the horizontal criteria for identification of endocrine disruptors with the goal to adapt it to technical and scientific progress.

6.2 Improve Regulatory Test Methods

Target: Improve availability of appropriate test methods for identification and assessment of endocrine disruptors

There is a significant gap between known effects of endocrine disruptors and the effects current regulatory test methods can identify. Current test methods only cover the oestrogen

and androgen pathways, so for example there is a lack of test methods covering the full lifetime exposure from in utero to death and the investigation of early life or in utero exposure on cancer incidence in adult or aged animals. It is currently also not possible to identify the particular sensitive life stages, the impacts on menopause, mammary tumours, metabolic syndrome or insulin resistance.

The OECD is the recognised body for developing internationally agreed test methods. Development of test methods by the OECD not only ensures international acceptance and reduction in barriers to trade, it also provides the European Commission and Member States annual cost savings of over €150 million[18]. The EU and its Member States should therefore ensure that priorities as regards test method development are agreed as well as appropriate funding allocated to fully support the implementation of this strategy. Member States and the Commission must therefore step up efforts and make available resources for the development of these test methods under the auspices of OECD.

Action 4: By 2014, based on the needs for the implementation of the EU legislation and for the application of the horizontal criteria for identification of endocrine disruptors and based on the latest scientific findings, the Commission will in cooperation with Member States set priorities for the next 7 years for the development of appropriate test methods under OECD auspices.

Action 5: The effort of the Commission and Member States, including active participation of their independent experts, for the validation of these test methods at the OECD needs to be considerably increased in comparison to the resources made available over the last 10 years, to ensure by 2020 the necessary battery of ED test methods is available.

6.3 Improve Regulatory Information Requirements

Target: Amend existing data requirements in the chemicals *aquis* to address endocrine disruption

The data requirements set out in current EU legislation to assess the safety of chemicals should be evaluated to ensure they appropriately cover the information necessary for identification of endocrine disrupting properties. In some cases (e.g. under the plant protection products regulation or the biocides regulation), previously compliant data may be deemed not to cover endocrine sensitive endpoints or the information available may not have been appropriatly assessed for endocrine disrupting activity. In such cases it would be appropriate to carry out a new assessment, new testing or data collection.

Maximising the use of all available data requires a horizontal approach, including the use of data published in peer-reviewed literature for the hazard and risk identification of endocrine disruptors. Relevant well documented studies should be given equal ranking in hazard and risk assessment as studies performed according to good laboratory practice rules and used in a weight of evidence approach.

[18] OECD 2010. Cutting costs in Chemicals Management. http://www.oecd.org/env/ehs/47813784.pdf

Action 6: By 2014, the Commission will make proposals for inclusion of all OECD test methods developed for identification of endocrine disruptors into the Test Methods Regulation[19]. When new test methods become available, these methods will be included without delay in the Test Methods Regulation.

Action 7: By 2014, the Commission, supported by the relevant Commission Scientific Committees and agencies, will develop a guidance document aiming to increase use of academic studies in regulatory risk assessment. The guidance document will specify information necessary to consider studies of sufficient reliability to be used in regulatory risk assessment. This guidance should be broadly disseminated to all the scientific community and to the editors to promote reporting data in a way that enables their use in regulatory risk assessment.

Action 8: By 2015, the Commission will review and if necessary make proposals for updating data requirements under the chemical *acquis* dealing with protection of human health and the environment from chemical exposure (including under the legislation with specific provisions on endocrine disruptors already incorporated such as REACH, the plant protection products regulation or the biocides regulation) to ensure that the relevant endocrine endpoints are tested and that sufficient data are generated to enable the application of the horizontal criteria. If new specific provisions for endocrine disruptors are included in legislation, , the data requirements should be adapted as soon as the provisions are incorporated.

Action 9: By 2015, the Commission will ensure that for re-authorisation of substances suspected to be endocrine disruptors (e.g. based on in vitro screening or QSAR), new data is generated using test methods specifically adapted to cover endocrine endpoints.

6.4 Take Regulatory Action

Target: Apply the chemicals *aquis* to the fullest

Existing legislation offers an important possibility to reduce the exposure of humans and the environment to endocrine disruptors. Endocrine disruptors under REACH may be identified for authorisation or restriction and suspected endocrine disruptors for evaluation. Under the plant protection product and biocide regulations, exposure to suspected endocrine disruptors can be further reduced during the regular re-authorisation of active substances or after an evaluation of active substances due to new safety concerns. It is important to accelerate the use of the current chemicals *aquis* to minimise the exposure to endocrine disruptors.

Action 10: By 2014, ECHA will be requested by the Commission to screen the REACH registration database, utilising for the screening exercise experts nominated by the Member State Competent Authorities to identify potential endocrine disruptors and to subject by 2015 the identified substances to the appropriate evaluation action under REACH (dossier evaluation or substance evaluation) or proposing by 2015 to the Commission or Member States the appropriate regulatory action (restrictions or authorisation).

Action 11: By 2016, ECHA (on request by the Commission) and Member States will prepare the appropriate dossiers for restrictions or authorisation for those substances

[19] Regulation (EC) 440/2008 on Test Methods.

proposed by ECHA under the previous action.

Action 12: By 2014, the Commission will review if the Chemical Safety Report and the Safety Data Sheet under REACH need to be amended in order to require registrants and suppliers of substances and mixtures to assess if the substance they are registering or supplying fulfils the criteria on endocrine disruptors.

Action 13: The Commission will request ECHA and EFSA to screen by 2014 all approved biocides and pesticides, respectively, to identify potential endocrine disruptors and to create a list of potential endocrine disruptors. ECHA and EFSA will utilise for the screening exercise experts nominated by the Member State Competent Authorities.

Action 14: The Commission will trigger the review of all active substances approved under the Biocidal Product Regulation and Plant Protection Product Regulation that are potential endocrine disruptors, which are due for regular review after 2016, and for which there are indications of significant concerns about their safety or for which there are indications that achieving the objectives established in the Regulations is compromised.

Target: Allow for risk assessment of combined exposure to endocrine disruptors

Humans and the environment are exposed to mixtures of chemicals at the same time. Knowledge about whether substances act by similar mode of actions informs the decision about the choice of the risk assessment methodology to be applied. Therefore, to allow a risk assessment of combined exposure to endocrine disruptors, it is necessary to identify and record endocrine disrupting hazard of a chemical even if it is finally regulated based on other properties or risks.

Action 15: By 2014, the Commission, Member States and Agencies, where possible, will identify and record for a substance subjected to a regulatory process also endocrine disrupting properties to facilitate risk assessment of combined exposure.

Target: Augment the chemicals *aquis* where necessary

The water framework directive, REACH, the plant protection products regulation, the biocidal products regulation and the Commission proposed revision of the legislative framework for medical devices already contain specific, but diverging, requirements for endocrine disruptors all aiming at reducing exposure of humans and the environment to endocrine disruptors. As pointed out in the review of the 1999 strategy, the remainder of the chemicals *aquis* dealing with protection of human health and the environment from chemical exposure does not contain specific provisions as regards endocrine disruptors and thereby represent a gap in minimising exposure of humans and the environment to endocrine disruptors. It is therefore necessary to address the diverging application of current provisions and where necessary fill the gaps where no provision currently exist.

Action 16: By 2016, the Commission will review and if necessary make proposals for amending the water framework directive, REACH, the Regulation on Plant Protect Products and the Regulation on Biocidal products with the aim to achieve a coherent approach to addressing endocrine disruptors and the application of the horizontal criteria.

Action 17: By 2016, the Commission will review the chemicals *aquis* dealing with protection of human health and the environment from chemical exposure with a view to

achieve a coherent approach to minimising exposures to endocrine disruptors and the application of the horizontal criteria whilst respecting the objectives set out in each piece of legislation. This regulatory review will assess if chemicals are properly examined for their potential endocrine disrupting effects, if endocrine disruptors are identified and if the exposures are minimised.

Action 18: By 2016, the Commission will make legislative proposals, where necessary and appropriate, to amend the chemicals *aquis*.

6.5 Target research efforts

Target: Streamline the scientific knowledge for risk assessment and risk management of endocrine disruptors

The science on endocrine disruptors is rapidly developing, with new exposure data and new effect data being generated daily. It is necessary to ensure that data generated by the scientific community becomes readily available and accessible to risk assessors and managers minimising the time necessary for the uptake of new information. It is also necessary to ensure a regular exchange of information among scientists from various fields (such as e.g. toxicologists, ecotoxicologists, endocrinologists, paediatricians, gynaecologists, etc.) and between academic scientists on one side and regulatory scientists and risk managers on the other side.

Action 19: The Commission will operate and promote the use of a publicly accessible web portal on endocrine active substances developed to become a "one stop shop" for hazard data on endocrine active substances.

Action 20: The Commission will develop, operate and promote the use of a publicly accessible information platform for chemical monitoring data to become a one stop shop for chemical monitoring data in Europe.

Action 21: The Commission will ensure that hazard and exposure data generated by the scientific community through projects supported by the EU budget are reported [to the respective information platforms] in a uniform format that allows efficient and transparent use. Member States funding authorities and agencies will equally be invited to participate.

Action 22: The Commission will organise bi-annually a conference on endocrine disruptors with participation of academic scientists from all relevant fields, risk assessors and risk managers of chemical products.

Human biomonitoring is an important tool for the estimation of exposure of humans to chemicals. Harmonised protocols for comparable human biomonitoring across the EU was developed in two recent research projects COPHES[20] and DEMOCOPHES[21]. There is also a need to use the tool developed in such projects to obtain a realistic estimate of human exposure to endocrine disruptors.

[20] www.eu-hbm.info/cophes
[21] www.eu-hbm.info/democophes

Action 23: Member States, in cooperation with the Commission, will ensure that regular human biomonitoring campaigns across EU include endocrine disruptors among the chemicals to be monitored and that the results of such campaigns are made publicly available through an information platform for chemical monitoring data.

Target: Increase support for research and development to address data and knowledge gaps

Research remains essential in understanding the phenomenon of endocrine disruption, particularly when it comes to understanding the mechanism, the assessment of exposure to endocrine disruptors and the establishment of causal links between exposure to substances and adverse effects in humans and wildlife. Research is also essential for developing tools for hazard and exposure assessment of endocrine disruptors.

Despite the significant increase in scientific knowledge over the past 14 years, two major policy relevant scientific uncertainties persist: do substances having an endocrine disrupting mode of action have a *threshold* below which exposures will not lead to adverse effects? and are effects at *low doses* predictable based on the data generated at higher dose exposures?

The UNEP/WHO report and statements from the Endocrine Society do expect the answers to these two questions to be 'no'. Given the status of the coverage of current available regulatory test methods the conclussion is 'in practice no'. Further research is therefore needed into these two issues, but also into the better understanding of the mechanisms from chemical exposure.

Action 24: The Commission will reinforce the research in the area of endocrine disruptors in the European Union's framework programme for research and innovation Horizon 2020[22] by doubling the budget for this area as compared to FP7. The priorities for research should include the broader topics of exposure assessment and identification of substances with endocrine disrupting properties, test method development and human epidemiology, but also specific topics as existence of thresholds and low-dose effects regarding endocrine disruptors.

6.6 Improve Communication

Target: Provide information to the public and ensure targeted awareness raising

The general public and particularly vulnerable groups should be informed about the possible risks associated with the use of every day products. Since it has been recognised that particularly exposure to endocrine disruptors during pre-natal and postnatal development until puberty and during maternity are critical, there is a need to consider developing appropriate information for pregnant women and parents. The most efficient way of informing this population may be via medical doctors.

[22] http://ec.europa.eu/research/horizon2020/index_en.cfm

Action 25: Member States will prepare appropriate information addressing the possible risks of endocrine disruptors in various developmental stages and providing advice to vulnerable groups on how to minimise those risks. The distribution should be targeted via interest groups, e.g. via gynaecologists, paediatricians and family doctors. The Commission will provide a platform for coordination of preparatory work and for exchanging experiences and information between Member States.

6.7 Ensure information exchange

Target: Ensure information exchange and coordination on endocrine disruptors across legislations with involvement of stakeholders when implementing the strategy

To ensure a coherent and harmonised approach to endocrine disruptors across legislation reflecting all points of view, a forum is required for an information exchange among all players involved including Member States, NGOs and industry. Where appropriate the Commission will ask the Commission's Scientific Committees and regulatory agencies for formal input when scientific advice is needed.

Action 26: The Commission will establish a regular working group of Commission Services, EU agencies, Member States and stakeholders under the Union's strategy for endocrine disruptors to provide a forum for information exchange, oversee the implementation of the strategy and to coordinate issues on endocrine disruptors.

Target: Continue supporting international work and information exchange when implementing the strategy

Information exchange and cooperation with partners from outside the EU is crucial in order to achieve a high level protection of environment and human health in today's globalised world, an efficient use of resources worldwide and regulatory convergence reducing barriers to trade. Financial support to OECD for the work on endocrine disruptors should continue. The EU and its Member States should support financially and ensure expert participation in international work on endocrine disruptors under the Strategic Approach for International Chemical Management (SAICM). Further, UNEP and WHO activities in this field should continue to be supported.

Action 27: The Commission and the Member States will continue supporting international work on endocrine disruptors, in particular that of the OECD, SAICM and WHO/UNEP.