Endocrine Disrupting Chemicals

Call-for-Action

The Danish Ecological Council

April 2012

The Ecological Council
Tomorrows environment is created today

Endocrine Disrupting Chemicals Call-for-action

The Danish Ecological Council calls upon the EU to:

- **Strengthen the regulation of EDCs in REACH.** If it is decided not to make a REACH revision in 2012-13, but only a review, it must be substantiated that a safe regulation of EDCs can be provided within the present REACH-text - by changing annexes (comitology), guidelines and procedures.
- **Establish criteria for EDCs based on hazard and not potency.** Alongside that, a higher number of accepted test methods for EDCs should be integrated in EU legislation. But the criteria should not be restricted to endpoints covered by existing test methods.
- **Expedite controls on EDCs and eliminate/reduce exposures**. Chemicals with ED properties should be subject to authorization or restriction as soon as possible. If authorization is chosen, it must be the full procedure, not "adequate control".
- **Implement elimination of exposure as a goal because of the likely mixture and low dose effects.** Given the additive effects of chemicals, when exposure occurs to several substances at low dose levels, the goal should be to eliminate exposure to chemicals with ED properties, whenever possible.
- **Ensure the use of the precautionary principle** with regard to the identification of, and controls over, chemicals with ED properties, without awaiting results of further research. However, research must continue in parallel in order to improve our understanding of EDCs.
- **Support and expand existing substitution databases, or create an EU-funded and -based substitution database.** The database should be easily accessible and provide information on substitution procedures, with detailed steps.
- **Increase transparency regarding chemical data provided by companies.** Once in the public domain, this data can assist green innovation in the chemicals sector, by informing consumers, who can encourage substitution of hazardous chemicals with safer alternatives.

Moreover, The Danish Ecological Council calls upon the member states to:

- **Use instruments like green taxes, green public procurement and eco-labelling** more actively to eliminate the use of EDCs.

The EU has recognized the threat that endocrine disrupting chemicals (EDCs) pose to human health and the environment, but so far regulation has been very limited. Unless action is taken, exposure to EDCs will continue to increase, with human exposure arising through a wide range of everyday products including cosmetics, food packaging, furniture, clothing, and electronic products. Many of these consumer items have beneficial uses, but unfortunately some may have unwanted properties that leach out into the environment and/or can be absorbed by the human body. Thus, it is of the utmost urgency that safer alternatives, which do not derail our hormone systems, are found.

EDCs can enter the environment by a number of ways, including

direct emissions:

- direct, deliberate releases to land, water or air by industries using or producing chemicals pesticides and other chemicals used in farming
- discharges from sewage treatment plants or pulp mills
- accidental spills and releases

indirect emissions:

- everyday use of chemicals and pharmaceuticals by the public in their homes (EDCs are leaching out from e.g. TVs, mobile phones, soft furnishings, beddings, PVC flooring and shower curtains and are consequently found in ordinary household dust)
- indirect release to land or water from urban and rural run-off of storm-water and the emissions of vehicles.

Wildlife and human health harm

Wildlife and the human population are now exposed to many EDCs such that it is important to eliminate, or at least minimize, the use of chemicals with such hazardous properties at source.

The body of evidence showing that EDCs may contribute to health and environmental problems is growing. Numerous animal and wildlife studies provide good reasons for concern. EDCs interfere with the hormone systems of living creatures and it is our hormones which control many biological functions, including reproduction and metabolism. Hormones also play a key role during development in the womb, such that if exposure occurs during this sensitive time window, long term irreversible consequences can result. For example, EDCs have been increasingly linked to a range of health problems including altered brain development giving rise to behavioral and cognitive or attention deficit disorders[1,2], cancers (particularly including breast, prostate and testicular cancer)[3,4], diabetes[5], reproductive disorders[6], and impaired fertility[7] in wildlife and/

1 Ishido et al., 2007, Mesencephalic neurodegeneration in the orally administered bisphenol A-caused hyperactive rats. Toxicol Lett., 173:66-72

2 Jurewicz and Hanke, 2011, Exposure to phthalates: Reproductive outcome and children health. A review of epidemiological studies. International Journal of Occupational Medicine and Environmental Health, 24:115-141

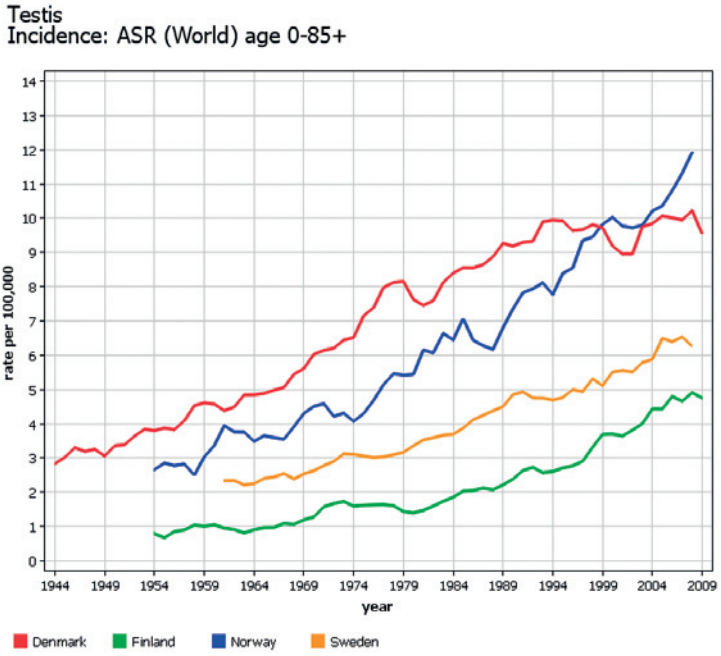
3 Soto and Sonnenschein, 2010, Environmental causes of cancer: endocrine disruptors as carcinogens. Endocrinology, 6:363-370

4 Jenkins et al., 2007, Prenatal TCDD exposure predisposes for mammary cancer in rats. Reprod. Toxicol., 23:391-396

5 Lim et al., 2008, Association of Brominated Flame Retardants with Diabetes and Metabolic Syndrome in the U.S. Population, 2003-2004. Diabetes Care, 31:1802-1807

6 Markey et al., 2005, Long-term effects of fetal exposure to low doses of the xenoestrogen bisphenol-A in the female mouse genital tract. Biol Reprod. 72:1344-1351

7 Cohn et al., 2003, DDT and DDE exposure in mothers and time to pregnancy in daughters. Lancet, 361:2205-2206



NORDCAN © Association of the Nordic Cancer Registries (10.4. 2012)

or humans[8]. Animal studies have raised the alarm, but because of the many chemicals that are potentially involved, identifying the precise chemicals involved in the adverse trends in male reproductive health and hormone related cancers etc. in the population at large is a very challenging task. There is therefore a need for reliable biomarkers of effect and better data on exposure levels.

In addition, wildlife has been adversely affected. What is probably still the best documented example is the masculinisation of sea snails[9] (and several other animal species[10,11]) caused by the antifouling agent tributyltin (TBT). Today there is a worldwide ban on the use of TBT, but since this chemical is very persistent, it doesn't degrade and so remains in the environment for a very long time, and thus, still even today strongly affects the ecosystem. In order to avoid future disasters like this, it is important to identify and avoid EDCs before they are introduced to the market or used in production processes. There are also many other examples, particularly in polluted areas, of the feminization of male vertebrate wildlife species, including fish, birds, reptiles and mammals[12].

Opportunities in REACH legislation

The current legislation has many gaps and shortfalls, including a limited number of accepted test methods for EDCs.

It is important to get EDCs included in each step of the REACH-regulation; registration, evaluation, authorization, restriction, and classification and labeling. Substances with strong indication of ED-properties should furthermore be the object to either authorization or restriction.

An important part of REACH is the authorization scheme, where Substances of Very High Concern (SVHC) can only be marketed for specific use that is authorized by the EU. First a substance with specified undesirable properties which make it a SVHC can be included on the candidate list after which it may be brought forward for the authorization procedure (Annex XIV). Chemicals with ED properties can therefore be subject to this authorization procedure once they have been

8 Damstra et al., 2002, Global Assessment of the State-of-the Science of Endocrine Disrupters. WHO/I PCS/EDC/02.2. World Health Organization/International Programme on Chemical Safety, Geneva

9 Santos et al., 2005, New insights into the mechanism of imposex induction in the dogwhelk Nucella lapillus. Comp Biochem Physiol., 141:101-109

10 Revathi and Munuswamy, 2010, Effect of tributyltin on the early embryonic development in the freshwater prawn Macrobrachium rosenbergii. Chemosphere, 79(9):922-7

11 Guo et al., 2010, Effects of tributyltin (TBT) on Xenopus tropicalis embryos at environmentally relevant concentrations. Chemosphere, 79(5):529-33.

12 Lyons G (2008) Effects Of Pollutants On The Reproductive Health Of Male Vertebrate Wildlife - Males Under Threat. A CHEM Trust publication available at: http://www.chemtrust.org.uk/documents/WildlifeUnderThreat08fullrepFINAL.pdf

accepted onto the candidate list as SVHCs. The Commission shall review the conditions for granting authorizations to chemicals with ED properties under REACH by June 2013. Currently they can be authorized if it is judged that there is "adequate control" of the risks, but the 2013 review provides the opportunity to subject them to more stringent controls and only allow them to be authorized if there is no suitable alternative and their socio-economic benefits outweigh the risks.

Back in 2006 when REACH was adopted, there was an intense discussion whether EDCs should be included in the authorization scheme. In the end, a compromise had been reached that EDCs should be included, but only on a case by case basis[13], and moreover, EDCs with a threshold for effects were only subject to the less stringent procedure for authorization, called the "adequate control" route to authorisation. But "adequate control" is a very weak regulation, and substances with endocrine disrupting (ED) properties should be object to the full authorization procedure and not just "adequate control".

Restriction on manufacture and usage should still be used towards chemicals that display properties of concern in terms of human health and the environment, even if they are placed on the candidate list. Therefore, it should also be possible for authorities to provide justification for banning or restricting specific uses if there are strong indications of a chemical having ED properties.

One challenge is that EDCs have very different effects depending on when exposure occurs during our lifetime. A healthy adult who is not affected by a certain EDC does not necessarily imply that a foetus or a newborn is not affected. Furthermore, endocrine disruption is not one effect, but a mechanism that can lead to many different effects. And effects differ from high exposure levels to low concentrations of the same chemical. Finally, it is important to bear in mind the mixture effects that have been found in scientific studies where chemicals at dose levels which individually show no effects, have been shown to have health effects when they occur at the same levels in a mixture[14].

1. EDC criteria

If a substance has endocrine properties, the absence of precise scientific knowledge of how it exerts its effects (mechanisms of action) should not hinder or impede the regulation of such a chemical. Thus, it is important that the criteria are not restricted to chemicals for which there is absolute proof that they exert adverse effects as a consequence of an endocrine disruption mechanism of action. Moreover, the criteria should not be restricted to endpoints covered by existing test methods; such that it should be considered how new knowledge can be easily included when available.

Furthermore, it is important to adopt hazard-based criteria which do not include any potency thresholds for the identification of EDCs. This is because it is the time of exposure rather than the dose that seems to be most important with regard to the effects of EDCs.

The criteria should apply across all relevant EU legislation.

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13 REACH regulation, Article 57(f)

14 Kjaerstad et al., 2010, Mixture effects of endocrine disrupting compounds in vitro. Int. J. Androl., 33(2):425-433. A similar Call for Action paper on mixture effects will be issued by the Ecological Council during spring 2012

2. Test methods/Biomarkers of effect

There is a need for a comprehensive review and strategy to get better screens and tests in use in EU to identify chemicals with ED properties. To date there are far too few internationally accepted test methods designed for testing ED properties. There is an urgent need for additional (and/or modification of existing) test methods that can reveal the full range of consequences of exposure to EDCs during the developmental period.

Furthermore, REACH requires data sharing in order to eliminate unnecessary animal testing, and companies should be careful to abide by this requirement. Where companies do need to test on animals, they must first announce their intentions to the European Chemicals Agency (ECHA) to see if any other company or academic centre has already carried out such tests. If no one has, and only if experts judge that the test is really needed, they are given a license to test. However, increased transparency is needed in order to make this rule more effectively reduce unnecessary animal testing.

3. Implement elimination of exposure as a goal

Given the likely mixture- and low dose effects it is important to reduce overall total exposure to EDCs by making use of existing EU legislation to phase-out and substitute EDCs, and to at least minimize exposure as far as possible.

To increase incentives for industry to substitute, it is important to reduce the economic costs for businesses or create the necessary incentives. Learning from the experience of others can play an important part in this. A useful resource can become the international Internet portal www.subsport.eu (Substitution Support Portal), which will be launched in May 2012. This portal is a source of both information on alternative substances and technologies, and of tools and guidance for substance evaluation and substitution management. There is an urgent need to increase awareness of this portal in companies in order to make real progress on substitution.

It is furthermore very important that the EU achieves the goal, set by the European Commission, of getting 136 substances on the REACH candidate list by 2012 and to have all relevant currently known SVHC on the candidate list by 2020. The Swedish NGO ChemSec has published the SIN list 2.0 of now 378 substances, which applies to the official criteria of being included in the EU candidate list. It also includes many substances with ED properties. At the World Summit on Sustainable Development the European Union committed to the goal of minimizing the adverse impacts of man-made chemicals on human health and the environment by 2020. Janez Potocnik, European Commissioner for Environment, has said that the SIN list 2.0 should indicate to industry the substances the European Commission (EC) would take into consideration for being included in the candidate list. This is a good starting place and it is important that the EC continues to work diligently to ensure that all chemicals of high concern are listed on the candidate list, soon leading to inclusion on

the list of substances subject to authorisation (Annex XIV of REACH). However, even if the Commission would take its own commitment seriously, there is a problem with the timeline set considering all the timelines involved. Listing "relevant known" substances of high concern on the candidate list by 2020 has indeed a good impact in terms of advanced warning for industry, information generation within the supply chain and towards consumers, but it does not entail a legal obligation to substitute. Substitution will only happen for certain once the substance is listed on Annex XIV and its sunset date is reached. So far it has taken more than two years to get only six candidate list substances onto the Annex XIV authorisation list, with an extra three to four years allowed to sunset the substances. This suggests that "all relevant currently known" SVHCs should be on the list by 2014/2015 if they are to be substituted by 2020.

Furthermore we call upon Member States and ECHA to ensure that the dossiers for chemicals which are nominated for inclusion on the candidate list not only specify the CMR (carcinogenic, mutagenic or reprotoxic) or PBT (persistent, bioaccumulative and toxic) properties, but also specify their ED properties, where relevant. If a chemical is included on the candidate list based not only on their CMR or PBT properties but also on ED properties, it may have a bearing on the granting of the authorization, particularly in future if EDCs are blocked from the adequate control of the risk route.

4. Need for coherent EU legislation on EDCs

EDCs are regulated under many different legislative instruments e.g. REACH, ROHS[15], biocides, cosmetics, toys, workers protection and pesticides. The new Plant Protection Products Regulation (PPPR) (applying from 14 June 2011) will require the phase out of pesticides with ED properties that may cause adverse effects unless there is negligible exposure, and furthermore, brominated flame retardants are restricted by the Toy Safety Directive and ROHS. In order to ensure safety for humans and the environment in all aspects of chemical exposure, coherent legislation is needed.

To ensure coherence, a safeguard clause could be formulated, which ensure that bans through other sector legislation should always be allowed, provided that the EDC criteria used are the same, or a ban under one legislative framework should also mean a ban under other legislation as well.

In order to increase consumer safety and to simplify the obligations of companies, there is a need for the forthcoming criteria to identify chemicals with ED properties, to apply across all legislative texts where EDCs are covered. Such criteria need to be precautionary and should therefore not require a high burden of proof, in order that such chemicals can be regulated in a timely manner.

5. Authorisation

For EDCs, we consider that authorisation should only be possible for limited periods of time, not exceeding 24 months, and only if no safer alternatives are available.

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[15] The directive on electric and electronic equipment

If it is decided only to make a REACH review (article 138:7) and not a revision of REACH, it must in other ways be ensured that also EDCs, that are considered to have a threshold, are blocked from the adequate control of the risk route to authorization. It is also important that an authorisation is frequently reviewed to avoid cases where EDCs remain on the market even though a safer alternative has been developed.

Recently, 4-tert-octyl phenol was included in the update of the Candidate List, as it was identified as a SVHC because of its ED properties and evidence of probable serious effects to the environment which give rise to an equivalent level of concern as the other chemicals subject to authorization (which are CMRs, Persistent, Bioaccumulative, and Toxic (PBTs) or very Persistent and very Bioccumulative (vPvBs) substances).

6. Implement a classification and labelling (C&L) system for EDCs

Giving due regard to the criteria that are developed to identify chemicals with ED properties, the EU should implement a classification and labeling (C&L) system for such chemicals. C&L is important in relation to hazardous substances that are *not* banned or substituted, because C&L provides a visible warning to the user - professional or private consumer.

Classification criteria will also speed up and facilitate the identification of chemicals with ED properties and its listing to the REACH SVHC candidate list by Member States.

7. Transparency

For all citizens and companies to make informed choices, sufficient information about hazardous chemicals should be publicly available on ECHA's website.

A database like this should contain all endocrine disruption-relevant test data, full access to the Chemical Safety Report and it should be ensured that all peer reviewed and published independent data (such as that generated in academic laboratories) is included.

Further, the database should enable citizens to visualise where these hazardous substances are used (e.g. multi-query search function by article or use category).

8. Act on the basis of the precautionary principle

Alongside that more experiments are being performed to find "the hows and whys", and given the limitations of the internationally agreed test methods, use of the precautionary principle in the decision-making process is critical to ensure reproductive and general hormonal health. The results of non OECD test methods, where these are judged to be reliable, should certainly be taken into account. Moreover, where there is controversy about certain effects, industry should not be given the benefit of the doubt for chemicals with ED properties, particularly as it is suspected that EDCs play a role in the clear adverse trends in health that already exist in the population at large.

9. Action at national level

EU member states should, to a higher degree, integrate environmental considerations into the tax system for a wide range of products and services that adversely affect the environment. There is a need for more green taxes on hazardous chemicals, which have proven to have a positive effect on the amount of hazardous chemicals used in the industry (e.g. a Danish tax on phthalates and soft PVC from 2000, which have led to substitution of phthalates in cables).

Furthermore, providing more information and guidelines to green procurement in the public system would increase the incentive and reduce the challenge and costs of the conversion to less harmful products.

Lastly, it is important that eco-labelling is promoted. Consumers should easily be able to avoid products with hazardous chemicals.

APPENDIX I: EDCs and health effects

Endocrine Society Scientific Statement: Endocrine-Disrupting Chemicals 2009
www.endo-society.org/journals/ScientificStatements/upload/EDC_Scientific_Statement.pdf

List of 800 Potential Endocrine Disruptors
www.endocrinedisruption.com/endocrine.TEDXList.overview.php

Prenatal origins of cancer report
TEDX: The Endocrine Disruption Exchange
www.endocrinedisruption.com/prenatal.cancer.overview.php

BREAST CANCER

Breast cancer and exposure to hormonally active chemicals - An appraisal of the scientific evidence Report produced by HEAL and CHEM Trust
The report provides a review of the scientific evidence that certain chemicals may be implicated in breast cancer, and focuses on the role of hormone disrupting chemicals. It covers early life and multiple chemical exposures. Written by Professor Andreas Kortenkamp, Head of the Centre for Toxicology, School of Pharmacy, University of London, UK. *The report is available in English on* www.chemicalshealthmonitor.org/spip.php?rubrique100

Factors influencing the risk of breast cancer - established and emerging Briefing produced by HEAL and CHEM Trust
This briefing summarizes the key information on all the risk factors and breast cancer with particular focus on the potential role of certain chemicals in the environment. It is written in a language that is accessible to non-scientists and is suitable for the general public and breast cancer suffers. *Available in English, French, Spanish, Italian, German and Armenian*
www.chemicalshealthmonitor.org/spip.php?rubrique100

Breast Cancer - Preventing the preventable Leaflet produced by HEAL and CHEM Trust
This leaflet briefly describes the evidence that hormonally active chemicals may be implicated in breast cancer. Written for sufferers and a wide public audience, the leaflet highlights the risk factors for breast cancer, the views of several scientific groups concerning the role of chemicals, and what people can do to minimize exposure. It also describes the policy actions needed in order to reduce exposures. The leaflet is available in *English, French, Spanish, Italian, German, Czech and Armenian on* www.chemicalshealthmonitor.org/spip.php?rubrique100

No More BPA Report. Report by Breast Cancer UK
The report is available in English on www.nomorebpa.org.uk

'State of the Evidence' on Environment and Breast Cancer. Report by Breast Cancer Fund, USA.
About: www.breastcancerfund.org/media/publications/state-of-the-evidence
The report: www.breastcancerfund.org/assets/pdfs/publications/state-of-the-evidence-2010.pdf

WOMEN'S HEALTH

Girl, Disrupted: Hormone Disruptors and Women's Reproductive Health. *This public report is available in English on* http://healthandenvironment.org/articles/doc/5492

The Falling Age of Puberty in U.S. Girls: What We Know, What we Need to Know. Report for Breast Cancer Fund www.breastcancerfund.org/media/publications/falling-age-of-puberty/

MEN'S REPRODUCTIVE HEALTH/TESTICULAR DYSGENESIS SYNDROME

Male Reproductive Health Disorders and the Potential Role of Exposure to Environmental Chemicals (CHEM Trust).
The scientific report written by Professor Richard Sharpe is available in English on www.chemtrust.org.uk/Male_reproductive_health.php

Men under threat: A referenced briefing on the decline in male reproductive health and the potential role of exposure to chemicals during in-utero development (CHEM Trust)
The briefing is available in English on http://www.chemtrust.org.uk/Press_and_Media.php

Men Under Threat - A leaflet on the decline in male reproductive health, and the potential role of exposure to chemicals (CHEM Trust and HEAL)
This leaflet briefly describes the evidence that hormonally active chemicals may be implicated in the deterioration of male reproductive health. Written for those affected and a wide public audience, the leaflet explains the hypothesis of testicular dysgenesis syndrome (TDS) and how it may be linked to exposure during a male baby's pre-natal development. *Based on the CHEMTrust report Male Reproductive Health Disorders and the Potential Role of Exposure to Environmental Chemicals and can be found on* www.chemicalshealthmonitor.org/spip.php?rubrique118

CANCER

A review of the role of pesticides play in some cancers: Children, farmers and pesticides users at risk? Report published by CHEM Trust. *The report is available in English on* www.chemtrust.org.uk

Reducing Environmental Cancer risk: What We Can Do Now (US Presidents' Cancer Panel Report on Environment & Cancer). In May 2010, the panel advised President Obama "to use the power of your office to remove the carcinogens and other toxins from our food, water, and air that needlessly increase health care costs, cripple our nation's productivity, and devastate American lives." The 240-page report by the President's Cancer Panel is the first to focus on environmental causes of cancer. *The report is available in English on*: http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp08-09rpt/PCP_Report_08

The Environment Cancer and You (Canadian Cancer Society). *The report is available in English on*: www.cancer.ca

Cancer & the Environment: What health providers should know. Factsheet by US Physicians for Social Responsibility available in English on www.psr.org

Living Downstream Community Guide and educational DVD (Coming soon). A guide for educators who wish to use the film in their teaching. Filled with lesson plans, review questions,

key concepts and extension activities, it is designed to encourage critical thinking. Produced in collaboration with teachers and their students. *The DVD and guide are available on* www.livingdownstream.com

Chemicals Health Monitor
Dedicated web pages specific to diseases and environmental factors: including hormone-related cancers such as breast cancer, prostate cancer and testicular cancer. www.chemicalshealthmonitor.org

Collaborative on Health and the Environment

> Working Groups

Breast Cancer Working Group www.healthandenvironment.org/working_groups/br_cancer
Cancer Working Group www.healthandenvironment.org/working_groups/cancer

> Webpages on specific cancers & environmental factors

Breast Cancer: www.healthandenvironment.org/breast_cancer
Prostate Cancer: www.healthandenvironment.org/prostate_cancer
Testicular Cancer: www.healthandenvironment.org/testicular_cancer

OBESITY/DIABETES

Obesogens. Factsheet, Collaborative on Health and the Environment, September 2011.
www.healthandenvironment.org/initiatives/childrens_health/columns_facts
www.diabetesandenvironment.org/

OTHER DISEASES/CONDITIONS

Collaborative on Health and the Environment

> Working Groups

Diabetes-Obesity Spectrum Working Group www.healthandenvironment.org/initiatives/diabetes
Learning and Developmental Disabilities Working Group www.healthandenvironment.org/initiatives/learning
Autism Working Group www.healthandenvironment.org/initiatives/autism_group
Asthma Working Group www.healthandenvironment.org/initiatives/asthma
Neurodegenerative Diseases Working Group www.healthandenvironment.org/initiatives/neuro
Fertility / Reproductive Health Working Group www.healthandenvironment.org/initiatives/fertility
Mental Health www.healthandenvironment.org/initiatives/mh

> Resources

Diabetes-Obesity Spectrum www.healthandenvironment.org/initiatives/diabetes/diabetes_resources

Learning and Developmental Disabilities www.healthandenvironment.org/learning_behavior
Autism www.healthandenvironment.org/autism
Asthma www.healthandenvironment.org/asthma_sci
Parkinson's www.healthandenvironment.org/parkinsons_disease
Endometriosis www.healthandenvironment.org/endometriosis
Birth Defects www.healthandenvironment.org/birth_defects
Cardiovascular www.healthandenvironment.org/cardiovascular

CRITICAL WINDOWS OF DEVELOPMENT

TEDX: The Endocrine Disruption Exchange
www.endocrinedisruption.com/prenatal.criticalwindows.overview.php

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