

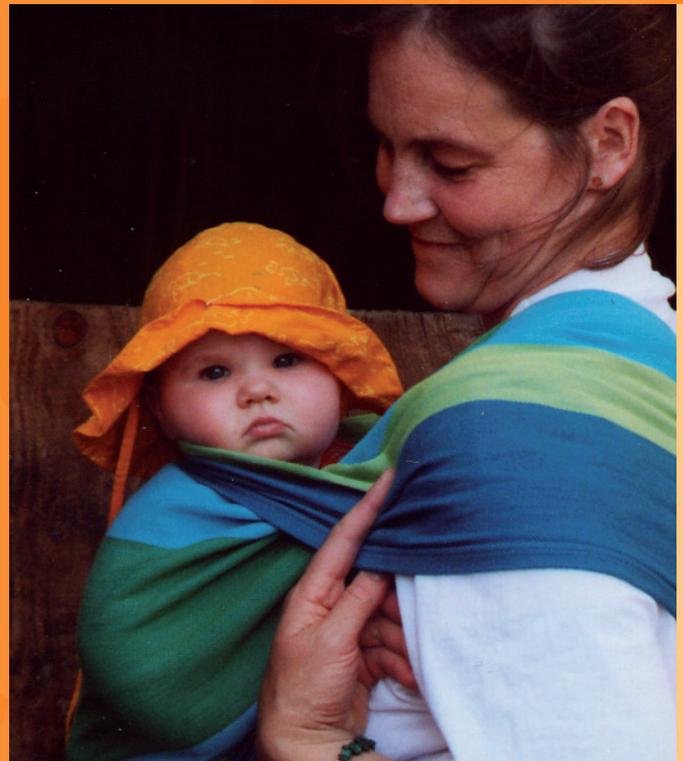
**Author**  
Sylvia Altamira

# Safeguarding future generations:

## Developmental harm of children caused by exposure to hazardous chemicals in daily life

Overview and EU Policy Recommendations  
on Pesticides, Toys, Cosmetics and REACH

16.10.2008



**WECF** | Women in Europe for a Common Future

WECF Germany  
Sankt Jakobs Platz 10, 80331 Munich  
Phone: +49-89-2323938-0  
Fax: +40-89-2323938-11

WECF The Netherlands  
PO Box 13047, 3507 LA, Utrecht  
Phone: +31-30-23 10 300  
Fax: +31-30-23 40 878

WECF France  
BP 100, 74103 Annemasse Cedex  
Phone: +33-4-50490738  
Fax: +33-4-50499738

# **Safeguarding future generations:**

## **Developmental harm of children caused by exposure to hazardous chemicals in daily life**

Overview and EU Policy Recommendations  
on Pesticides, Toys, Cosmetics and REACH  
16.10.2008



Women in Europe for a Common Future | **WECF**

# 1. Introduction

Exposure to very low doses of hazardous substances can cause harm to the foetus, infant and child during vulnerable periods of development. The results are irreversible and can be multi-generational.

One such example regards exposure to some phthalates, which during certain months of pregnancy, can potentially result in hypospadias (a deformation of the penis). Another example regards low-level exposures to neurotoxic pesticides during pregnancy, which can lead to impaired brain development and a range of other problems. Children are not only exposed to one chemical, but a combination of hazardous chemicals, during early development. While the combined effects are only beginning to be understood, these “chemical cocktails” ending up in children’s bodies, are already suspected of being linked to cancer, diabetes, learning and behavioural disorders and other diseases later in life.

Scientists state that there is a great health risk for children, and that preventive actions need to be taken quickly. Current European legislation and proposals for Pesticides, Toys, Cosmetics and Chemical do NOT adequately protect the developing foetus, infant and child.

Children’s exposures to hazardous chemicals and substances must be prevented now.

Taking into account that:

- Studies indicate that it is not only the dose of the chemical or substance that is important, but also the *timing* of the exposure.
- “Exposure to certain chemicals and substances during early foetal development can cause brain injury at doses much lower than those affecting adult brain function”<sup>1</sup>
- “The blood-brain barrier, which protects the adult brain from many toxic chemicals, is not completely formed until about 6 months after birth.”<sup>2</sup>
- Knowledge regarding the causes of learning and developmental disorders implies an ethical duty and responsibility to act to protect children’s health and well-being.<sup>3</sup>

It is imperative that decision-makers take some time to understand the implications of this complex issue and take precautionary measures to prevent unnecessary exposures. There is too much at stake for our children to wait.

---

<sup>1</sup> P Grandjean, PJ Landrigan, *Developmental neurotoxicity of industrial chemicals*. [www.thelancet.com](http://www.thelancet.com) Vol 368 Published online November 8, 2006 DOI:10.1016/S0140-6736(06)69665-7 1

<sup>2</sup> P Grandjean, PJ Landrigan, *Developmental neurotoxicity of industrial chemicals*. [www.thelancet.com](http://www.thelancet.com) Vol 368 Published online November 8, 2006 DOI:10.1016/S0140-6736(06)69665-7 1

<sup>3</sup> *Scientific Consensus Statement on Environmental Agents Associated with Neurodevelopmental Disorders. Collaborative on Health and the Environment*. Feb, 2008. pg.16

*...there is clear scientific evidence that exposure to environmental chemicals during different developmental stages can result in a number of adverse outcomes in children and have resulted in an increased incidence of certain childhood diseases. (World Health Organisation-WHO)*

## 1. 2 Developmental Harm: What is it?

Developmental harm refers to the impact that environmental pollutants such as hazardous chemicals<sup>4</sup> can have on embryonic, foetal and infant development. These impacts can have lifelong negative effects on the health of the individual.

“We know that development is susceptible to disruption by environmental factors<sup>5</sup>.” It is no longer an issue up for debate. In Roman times, lead was first recognised to cause miscarriages and infertility in men and women<sup>6</sup> (it was in their drinking water and food, as they used it for making their pipes and kitchen utensils). Today, lead it is still found in house dust around the world.

Do we really need centuries to pass before deciding to take precautions that are just plain common sense?

Studies indicate that it is not only the dose of the chemical that is important, but also the *timing* of the exposure. “The periods of embryonic, foetal and infant development are remarkably susceptible to environmental hazards. Toxic exposures to chemical pollutants during these *windows of increased susceptibility* can cause disease and disability in infants, children and across the entire span of human life.”<sup>7</sup> Even very low doses of these chemicals can cause developmental harm during those vulnerable periods. The results are irreversible and can be multi-generational. Test protocols already exist to test reproductive, neuro-developmental and immune toxicity, but they are not routinely used and do not cover the full range of developmental effects.

Policy makers are now faced with some tough questions....

- What are they going to do about it?
- Where do they draw the line?
- How much more proof is needed before they will take action?
- Who will protect these vulnerable groups if they do not?
- What is the societal cost of inaction?

---

<sup>4</sup> The hazardous chemicals and substances referred to in this report include – but are not limited to: Carcinogenic, Mutagenic and Reprotoxic (CMR 1,2 and 3), endocrine (hormone) disrupting substances, Persistent Bio accumulative and Toxic (PBT), very Persistent and very Bio accumulative (vPvB), Neurotoxins, non-classified dangerous chemicals and nano-substances.

<sup>5</sup> Quote by Lou Guillette, PhD, Howard Hughes Medical Institute, see footnote 6.

<sup>6</sup> Schwartz, Jackie M., MPH and Woodruff, Tracey J., *Shaping Our Legacy: Reproductive Health and the Environment*, University of California, San Francisco, September 2008. pg.3. Quote by Lou Guillette, PhD, Howard Hughes Medical Institute.

<sup>7</sup> The Faroes Statement, *Human Health Effects of Developmental Exposure to Chemicals in Our Environment*, Faroes Islands 2007.

*“The periods of embryonic, foetal and infant development are remarkably susceptible to environmental hazards. Toxic exposures to chemical pollutants during these windows of increased susceptibility can cause disease and disability in infants, children and across the entire span of human life.”ii (Faroes Statement)*

### **1.3 Health Impacts: Range from impaired brain development to deformed sexual organs**

“Research definitively shows that environmental agents such as lead, mercury, manganese, arsenic, PCBs, alcohol, toluene, tobacco smoke and many pesticides are capable of disrupting human brain development, resulting in negative impacts on the functions controlled by the brain. Additional environmental chemicals and pollutants, other solvents and other heavy metals have been shown to disrupt brain development in animal studies and are suspected of having similar effects in humans.”<sup>8</sup>

Additional potential health effects linked to chemical exposures in our everyday lives, include things like:

- reproductive disorders,
- impaired immune systems,
- breast and prostate cancers,
- effects on metabolism
- behavioural abnormalities
- inflammatory diseases<sup>9</sup>

Unfortunately, this is very likely just the tip of the iceberg.

### **1.4 Who is at risk?**

When it comes to exposures, embryos, children, adolescents and pregnant women are all vulnerable groups.

Pregnant women can unknowingly pass on their body burden of hazardous chemicals to their developing foetus. The foetus grows up to become a child with varying amounts of hazardous chemicals in his/her system. These chemicals can wreak havoc on foetal and childhood development, resulting in children with a wide range of health problems, including developmental disorders decreased organ functions and impaired brain function.

---

<sup>8</sup> *Scientific Consensus Statement on Environmental Agents Associated with Neurodevelopmental Disorders. Collaborative on Health and the Environment. Feb, 2008. pg.9.*

<sup>9</sup> *Such as arthritis, diabetes, thyroiditis and Crohn’s disease.*

Some of the health effects are obvious, requiring immediate medical attention, such as hypospadias<sup>10</sup>. Others are more subtle and harder to pinpoint, or only become apparent later in life, such as a slight decrease in brain function and IQ, Attention Deficit Disorder, a decrease in reproductive capacity or premature or delayed puberty.

“During foetal development, the placenta offers some protection against unwanted chemical exposures, but it is not an effective barrier against environmental pollutants. For example, many metals easily cross the placenta, and the mercury concentration in umbilical cord blood can be substantially higher than in maternal blood. The blood-brain barrier, which protects the adult brain from many toxic chemicals, is not completely formed until about 6 months after birth.”<sup>11</sup> In fact, the brain continues to develop during early childhood and therefore remains vulnerable.

Children take in more pollutants and hazardous chemicals in relations to their size than adults and the effects can be much more harmful as they are still developing. (See further explanation below.)

- Environmental exposures start early: preconception, during gestation (*in utero* exposure), via breast milk, infant formula and then through contact with the environment.
- For their body weight, children eat and breathe more than adults, thus a small exposure translates into a big dose.
- Their organ systems, particularly the nervous system, are forming and are thus more susceptible to the effects of chemicals.
- Young children are prone to hand-to-mouth behaviours that expose them to higher levels of ambient chemicals.
- Children rely on adults to ensure that they develop in an environment in which they can reach and maintain their full potential.<sup>iii</sup>

Ensuring that safety standards protect the most vulnerable groups will in fact ensure that the entire population is protected.

---

<sup>10</sup> Hypospadias is a defect of the baby's penis, where the urethra exists on the underside rather than at the tip.

<sup>11</sup> P Grandjean, PJ Landrigan, *Developmental neurotoxicity of industrial chemicals*. [www.thelancet.com](http://www.thelancet.com) Vol 368 Published online November 8, 2006 DOI:10.1016/S0140-6736(06)69665-7 1

*Protection of children is at the core of the sustainability of the human species. It should be a priority of all countries and international and national organisations to provide safe environments for all children and reduce exposure to environmental hazards...iv(WHO Report)*

## **1.5 Basic Human Rights: Children have the right to a healthy environment**

Children have the right to a safe environment in which to grow, whether that environment is the uterus or later in their homes, villages or cities. They also have the right to be protected from evident harm. It is the responsibility of society, policy makers and indeed all adults, to protect the environment so that it can be a healthy place for current and future generations to live and grow.

“There is growing recognition that ethical, legal and social considerations play a crucial role in public and child-health decision making that involves conflicts between individual, corporate, human rights and social-justice goals. Knowledge of the causes of learning and developmental disabilities implies an ethical duty and responsibility to act to protect children’s health and well being.”<sup>12</sup>

### **Protecting Children’s Basic Human Rights – What can I do?**

- Policy makers must take the lead by enacting policy that protects human development and health.
- Business leaders should invest in the safest possible chemicals, processes and products. Protecting their own children, as well as their future workforce is good common sense.
- Parents can assist this by using their purchasing power to support greener products and their vote to demand legislative measures.
- Scientists and scientific institutions should prioritise research on prevention of harm to human development and health and should receive the budgets needed for independent research.

We all have a responsibility to help bring about the needed changes and we all stand to gain by achieving this goal.

---

<sup>12</sup> *Scientific Consensus Statement on Environmental Agents Associated with Neurodevelopmental Disorders. Collaborative on Health and the Environment. Feb, 2008. pg.16*

*Within the human brain lies our capacity to learn, talk, read, calculate, memorise, conceptualise, organise, pay attention, utilise motor skills, interact socially and behave appropriately. We cannot reach our full potential with a damaged brain or nervous system. v (Scientific Consensus Statement-t CHE)*

## 1.6 The Cost

It is a difficult and complex task to truly and accurately quantify the cost of NOT protecting developmental health: e.g. costs in lost lives, lost quality of life, loss of IQ points and losses in human and workforce potential. However, it would be useful for decision makers to have quantifications of those costs.

Some attempts at limited cost calculations for certain environment related childhood diseases have already been made. Two examples below:

<p><b>Europe: 16 Billion Euros related to 4 childhood diseases.</b> A study conducted in the Imperial College of London tried several approaches to figuring out the financial side of four childhood diseases attributed to environmental factors. They looked at lead poisoning, asthma, ADHD and autism in Europe and estimated that the costs for 2005 were over 16 Billion Euros.<sup>vi</sup></p>	<p><b>United States: 77 Billion USD cost of special education services</b> In children, developmental, learning, attention and behavioural problems can cause tremendous challenges for the affected children, their families and communities. Consequences include psychological and economic costs associated with learning delays, aggressive or otherwise inappropriate behaviour, school dropout, teen parenting, substance abuse, unemployment, welfare dependency and involvement with juvenile and adult criminal justice systems. Attempts to calculate the costs of these childhood "morbidity" have only recently been undertaken (20, 21). Providing special education services to students with disabilities amounted to \$77.3 billion, or an average of \$12,474 per student in 1999-2000, almost twice the cost per regular education student, which is almost 22 percent of the 1999-2000 total spending on all elementary and secondary educational services in the US (22) (for additional information see the Center for Special Education Finance (CSEF) at <a href="http://www.csef-air.org/">http://www.csef-air.org/</a>).<sup>vii</sup></p>
-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

A Study commissioned by the European Parliament (September 2008) asserts that based on initial economic analysis, the potential benefits of withdrawing hazardous pesticides can be significant. The study also highlights the need for more economic studies. "An extensive body of scientific work has found statistically sound evidence of strong associations between exposures to pesticides as a group and to specific substances. However, robust economic analyses of the actual costs of chronic exposures are still missing." IP/<sup>13</sup>

<sup>13</sup> "The benefits of strict cut-off criteria on human health in relation to the proposal for a Regulation concerning plant protection products" STUDY IP/A/ENVI/ST/2008-18 PE 408.559

*The "Barker hypothesis," conceived by a British scientist in 1992, says human foetuses are "programmed" for diseases by their early environment. The scientists [at the Faroes Conference] concluded that this is now well-documented for toxic exposures by a large collection of animal experiments and some human data. viii*

## 2. The Science

In the last 10 years there have been many new insights into the foetal origins of disease.

Many studies, reports, scientific consensus statements and conferences have come to the same conclusions about children's environmental diseases, namely: **we are confronted with an extremely serious problem, which can impact millions of children and many generations, and therefore preventive action needs to be taken quickly. Current proposals for restricting chemicals exposure by children are not at all sufficient.**<sup>14</sup>

Three documents based on extensive scientific evidence are discussed below: The Faroes Statement, the Ramazzini Statement and the report published by the WHO, Principles For Evaluating Health Risks In Children Associated With Exposure To Chemicals.

### 2.1 Faroes Statement

An international conference with the world's leading environment and health scientists was held in May 2007 on the Faroe Islands. The conference reviewed the latest research on "developmental programming caused by environmental chemical exposures." More than 120 scientific papers provided new insights regarding the effects that exposures to hazardous chemicals, metals and environmental pollutants can have on embryonic, foetal and infant development.

The chemicals referred to are in common use. They are found in most European homes, neighbourhoods and workplaces. They are present in the air, soil, food, consumer products and building materials. They can affect the reproductive system, immune system and brain development.

---

*Policy Department Economic and Scientific Policy, commissioned by the European Parliament Sept 08.*

*This study was requested by the European Parliament's Committee on the Environment, Public Health and Food Safety. (Ref to contract: IP/A/ENVI/FWC/2007-057/C1/SC2)*

*<sup>14</sup> Examples include but are certainly not limited to, the more than 120 reports presented at the Faroe Conference, and all the references cited in this paper.*

Highlighted in Faroes Statement	Related Health Effects
Neuro-toxics	Impaired brain development
Endocrine disruptors	Animal research shows links to reproductive abnormalities, metabolic disorders (e.g., diabetes and cancers)
Phthalate esters	Testicular cancer, poor semen quality and hypospadias.
Polychlorinated or polybrominated biphenyls dichlorodiphenyltrichloroethane compounds	May affect puberty development and sexual maturation at adolescence, highly immunotoxic.
Bisphenol A	Breast or prostate cancer
Vinclozoline (fungicide)	Cancer

\* Prenatal or early postnatal chemical exposures may be linked to asthma, allergic sensitisation or greater susceptibility to infections.<sup>15</sup>

Studies indicate that it is not only the dose of the chemical or substance that is important, but also the *timing* of the exposure. Even very low doses of these chemicals can cause developmental harm during vulnerable periods of development. The results are irreversible and can be multi-generational. Test protocols already exist to test reproductive, neuro-developmental and immune toxicity, but they are not routinely used and do not cover the full range of developmental effects e.g. on energy metabolism.

**Three important aspects:**

1. The mother’s chemical body burden will be shared with her foetus or neonate.
2. Susceptibility to a wide range of adverse effects is increased during development, from preconception through adolescence, depending on the organ system.
3. Developmental exposures to environmental chemicals can lead to life-long functional deficits and disease.<sup>16</sup>

**Recommendations in the Faroes Statement:**

- Studies on the aetiology [causes or origin] of human disease need to incorporate early development and characterise appropriately the factors that determine organ functions and subsequent disease risks.
- Cross-disciplinary approaches and improved communication needs to be stimulated among scientific disciplines and between scientists and policy-makers.
- Environmental chemical exposure assessment should emphasize the time period of early development.
- Mixed exposures need to be considered in a life-course approach to disease.

<sup>15</sup> *The Faroes Statement, Human Health Effects of Developmental Exposure to Chemicals in Our Environment, Faroes Islands 2007*

<sup>16</sup> *idem*

- Risk assessment of environmental chemicals needs to take into account the susceptibility of early development and the long-term implications of adverse programming in a variety of organ systems.
- Preventive efforts are needed- the embryo, foetus and small child are highly vulnerable populations and need to be protected against toxic exposures to environmental chemicals.
- Prevention should not await definitive evidence of causality when delays in decision-making would lead to the propagation of toxic exposures and their long-term harmful consequences.

## 2.2. Principles for evaluating health risks in children associated with exposure to chemicals (WHO Report)

*Adverse effects in children may result from exposure prior to conception (paternal and/or maternal), during prenatal development, or postnatally to the time of full maturity.<sup>17</sup>*

This report contains the collective views of an international group of experts. According to the report, “Environmental factors play a major role in determining the health and well-being of children. Accumulating evidence indicates that children, who comprise over one third of the world’s population, are among the most vulnerable of the world’s population and that environmental factors can affect children’s health quite differently from adults’ health.”

A small sample of the issues highlighted:

- There is a need to expand risk assessment paradigms to evaluate exposures relevant to children from preconception to adolescence, taking into account the specific susceptibilities at each developmental stage.
- The full spectrum of effects from childhood exposures cannot be predicted from adult data.
- The special vulnerability of children should form the basis for development of child-protective policies and risk assessment approaches. A lack of full proof causal associations should not prevent efforts to reduce exposures or implement intervention and prevention strategies.
- The need to design and implement cohort studies of pregnant women, infants, and children with longitudinal capture of exposures at critical windows and sensitive health end-points along the continuum of human development. Efforts to recruit couples prior to conception are needed to address critical data regarding peri-conceptual exposures and children’s health.
- We need to determine which exposure reductions will have the greatest overall impact on children’s health.

This report clearly supports the need for extra protection of vulnerable groups and calls upon the active participation of all sectors of society.

---

<sup>17</sup> (Faustman et al., 2000; Selevan et al., 2000).

## 2.3 Collegium Ramazzini Statement – The Control Of Pesticides In The European Union, A Call For Action To Protect Human Health

The Collegium Ramazzini is an international scientific society that examines critical issues relating to occupational and environmental medicine. Their statement stems from the growing body of evidence that links exposure to hazardous pesticides to adverse impacts on human health.

In their statement they state that: “the annual application of synthetic pesticides to food crops in the EU exceeds 140,000 tonnes. This amount corresponds to 280 grams per EU citizen per year. More than 300 different pesticides are known to contaminate food products sold in the EU. One out of twenty food items exceeds the current EU legal limit for an individual pesticide. Over 25% of fruits, vegetables, and cereals are known to contain detectable residues of at least two pesticides. Processed food and baby food are also commonly contaminated.”

They urge the EU to adopt strong legislation to protect public health and the environment against adverse effects of pesticides.

In regard to the proposed Regulation on the placing of plant protection products on the market, the Collegium makes the following recommendations:

- Apply stringent “cut-off” criteria as hazard triggers to eliminate the most hazardous pesticides from food products and the environment
- Approve substances for use in the cultivation of food and feed only if they are not carcinogenic, mutagenic, or toxic for reproduction (categories 1, 2, and 3 under the provisions of the current Directive 67/548/EEC)
- Likewise, no substance should be approved, if it is considered to be endocrine disrupting, or causing developmental neurotoxicity or immunotoxicity
- Any derogation or dispensation from this legislation should be granted only when residues of the active substance concerned in food and feed can be assured to remain below the limit of determination using the most sensitive method; and
- The EU should support the development and implementation of safer and more effective ways to manage pests.

## 3. Legislation

The EU is currently adapting or implementing legislation in 4 areas which can directly impact the increase or decrease of developmental disorders in Europe.

1. Pesticides
2. Toy
3. Cosmetics
4. Chemicals/REACH

The accumulating evidence regarding the developmental effects of exposures to hazardous chemicals in our every day environments, make it of extreme importance that policy makers take it into account when setting safety standards in the legislation. Information regarding the current state of affairs in each policy area and the suggested policy priorities related to developmental disorders are highlighted below.

### 3.1 Pesticides

Revision of Regulation on Authorisation of Plant Protection Products 91/414/EEC & Framework Directive on Sustainable Use of Pesticides

According to the European Parliament website, the “purpose is to establish a framework for achieving a more sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment in a way that is consistent with the necessary crop protection.”

The wording above seems to imply a willingness to make a compromise regarding the protection of human health. When it comes to “proper crop protection” and “proper child protection,” it is imperative that the protection of the child comes first.

Safer alternatives already exist. Legally requiring the use of safe chemicals and/or methods will greatly stimulate the use of existing alternatives and research on additional methods.

Given the accumulating evidence linking exposure to hazardous pesticides to human health problems, it is very important that new or adapted EU policies on pesticides prioritise the protection of our most vulnerable groups.

A study commissioned by the **European Parliament** states:

*The special vulnerability of children argues **for extreme caution** with respect to **developmental neurotoxicants**. Strong associations have been found between neurological problems in children and exposure to pesticides during critical periods of brain development. Recalling the decades it took to gather sufficient evidence of the neurotoxic effects of lead to bring about policy action, and noting the accumulating evidence concerning impacts of neurotoxicant and immunotoxicant pesticides, the developmental neurotoxic and immunotoxic parameters also appear to be warranted.<sup>18</sup>*

A Precautionary Approach is certainly warranted; while strict regulations can later be relaxed if found unnecessarily stringent, harm to countless developing foetuses and children cannot be reversed.

The pesticides Action Network, has issued the following specific recommendations regarding policy needs.

#### **Regulation on Authorisation of Plant Protection Products**

- Crucial to set strict 'cut off' criteria to give clear signal to industry and to remove the worst pesticides from foods; cut-off criteria should be
  - neurotoxin
  - immunotoxin
  - hormone disrupting
  - carcinogenic, mutagenic, reprotoxic
- Ensuring mandatory substitution of hazardous pesticides with safer alternatives, when available;
- Cumulative and synergistic effects must be included in all risk assessments.
- Authorisation to be decided on Member States level and not on "zone level" clustering Members states in an absolute artificial way;

#### **Framework Directive on Sustainable Use of Pesticides:**

- Making Integrated Pest Management mandatory (IPM), and giving priority to non chemical treatment and setting concrete principles (Annex V);
- Set up pesticide use reduction targets;
- No pesticide spraying in public areas including schools and hospitals;
- A ban on aerial spraying across the European Union

WECF supports their recommendations and would like to add:

It is essential that **Developmental Neurotoxins and Immunotoxins** are included as cut-off criteria.

According to a study commissioned by the European Parliament, "The cut-off criteria will provide additional protection for farmers and their families. Farmers, agricultural workers and their children are at higher risk of incurring health problems

---

<sup>18</sup> "The benefits of strict cut-off criteria on human health in relation to the proposal for a Regulation concerning plant protection products" STUDY IP/A/ENVI/ST/2008-18 PE 408.559  
Policy Department Economic and Scientific Policy, commissioned by the European Parliament Sept 08.

due to long-term exposures to pesticides. The fact that the people responsible for producing Europe's food must carry this disproportionate risk and the subsequent costs, needs to be balanced against any risks of increased food production costs due to reduced availability of certain pesticides."<sup>19</sup>

A November 2006 study in the Lancet concluded that up to one in six children could have developmental disabilities resulting from exposures to at least 200 unregulated chemicals, most of which are pesticides. Studies show, that if the brain has been affected during early childhood, it will never be able to recuperate. The costs for additional care of children with learning and behavioural disorders are increasing everywhere in the EU and the US.

WECF believes that is essential that the text as proposed in the first reading on Pesticides of the European Parliament is maintained:

3.6.6. An active substance shall only be approved if, on the basis of the assessment or other available data and information including a review of the scientific literature, it is not considered to cause a risk of **developmental neurotoxic or immunotoxic** properties in humans, taking into account exposure during embryonic/foetal life and/or during childhood as well as likely combination effects. Such active substances may only be approved if the exposure of humans to that active substance in a plant protection product, under realistic conditions of use, is negligible, as the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance concerned on food and feed do not exceed the limit of determination using the most sensitive methods.

### 3.2 Toys

Proposal for a Directive of the European Parliament and of the Council on the Safety of Toys<sup>20</sup>.

The current European toy safety directive is 20 years old. The European Commission DG Enterprise presented a proposal for the revision of this toys directive on 25.01.2008, "Proposal for a Directive of the European Parliament and of the Council on the safety of Toys". On 6.6.2008, Marianne Thyssen (rapporteur of the IMCO Committee) presented a report with proposed changes to the Commission proposal. Considering the recent toy scandals, rapid technological developments in the toy industry, and the increasing amount of toy imports from countries with lower environmental and safety standards (75% of toys on the market in Europe originate in China), this revision is urgently needed.<sup>21</sup>

---

<sup>19</sup> "The benefits of strict cut-off criteria on human health in relation to the proposal for a Regulation concerning plant protection products" STUDY IP/A/ENVI/ST/2008-18 PE 408.559  
Policy Department Economic and Scientific Policy, commissioned by the European Parliament Sept 08.

<sup>20</sup> COM(2008)9-2008/0018/COD

<sup>21</sup> Women In Europe for A Common Future, Position Paper, 2008, European toy safety directive –will children really be safe from hazardous chemicals in toys?

We live under the presumption that toys bought in Europe are safe for our children. However, massive recalls of toys in the EU (made by well known producers) show that this is not the case. In 2007 the highest percentage of recalls were toy products.

Some points to consider:

- Toys bought in the EU can contain a number of highly toxic chemicals or allergens.
- 90% of the toys on the EU market are imported.
- The CE mark is misleading as it does not give any guarantee regarding the presence of toxic substances and is not controlled.
- To date no common European labelling system exists that enables parents to make informed choices and avoid potentially harmful toys.

**WECF recommendations comprise three main points:**

1. **Total ban on all categories of CMRs in all toys and toy parts**
2. **Total ban on other known very hazardous substances such as endocrine disruptors, Persistent Bioaccumulative Toxic (PBT), very Persistent very Bioaccumulative (vPvB), neurotoxins, and nano-substances**
3. **Total ban on all allergens, fragrances and sensitisers in all toys**

Rationale for points raised above:

**Carcinogenic, Mutagenic and Reprotoxic chemicals (CMRs)**

Children suck on toys... even those that contain extremely carcinogenic substances, as studies in France, Germany and Sweden have shown. Some substances are so toxic that there are no 'lowest limit values' for safe contact<sup>22</sup>. One example is nitrosamine found in rubber giraffes for babies in France. While chemists handle nitrosamin with great precaution (gloves and masks) it is an ingredient in some toys which babies suck on.

It is essential to ensure that there are no loopholes in the directive to allow ANY CMR's into toys. No loopholes, no exceptions. CMR 3's are suspected to be carcinogenic, mutagenic and reprotoxic for humans, and are regularly moved to the CMR 1 category. Allowing CMR-3's would allow formaldehyde in toys, which the World Health Organisation already classifies as one of the most dangerous carcinogens.

There is no acceptable reason for industry to argue that they absolutely need to put CMR's into toys. No parents want toys that can be harmful for their children. In the cases where there is not a substitute for the CMR, then a new design is needed.

Children often use toys in other ways than they were originally intended. Any toy can become a teething object or be put into the mouth, carried around next to the skin, or slept with. Toys can break and children have the habit of swallowing small things. Thus, no inner or outer part of a toy should contain substances of concern. While referring to other legislation in this directive, references should be made to the food and cosmetics legislation.

---

<sup>22</sup> See consumer product tests by Stiftung Warentest Germany (test 9/2008) Ökotest Germany (11/2007 & 12/2007), 60 Million de Consomateurs France (test 353)

### Other known Hazardous Chemicals

Dr. Henrik Leffers from the National University Hospital in Copenhagen presented data on the devastating effects of phthalates on baby boys, leading to malformation of the genitals and testicular cancers resulting from mothers who were exposed to phthalates. They tested the speed at which body creams (containing only 2% phthalates) entered into the mother's blood, and found that it enters extremely fast. What can be expected of babies sucking on toys, which can contain up to 40% phthalates?

The fact that Phthalates can penetrate the skin means that children can be exposed just by touching the toys. They can also inhale Phthalates, which are released from the plastic. All known hazardous chemicals and substances that are already suspected to be hazardous, but are not yet classified (including nanosubstances) should be excluded entirely from toys. This should be clarified in the first part of the directive and specified in annex II.

### Fragrances

Fragrances are not essential in toys; they are used for marketing purposes. Considering that there is an increase in allergies from fragrances (more than half a million in Germany already<sup>23</sup>) and that even so-called "natural" fragrances can cause allergies depending on the type of exposure and the dose. WECF asks for a ban on ALL fragrances and sensitizers from toys.

### WECF calls for following amendments to the proposed Toys Safety revision<sup>24</sup>:

#### Amendment 80/ Proposal for a Directive/ Recital 16

Whereas the proposed amendment suggests that 'risk-analysis based' restrictions should be imposed on carcinogenic and other toxic substances, we propose that only a total ban can safeguard children from these known very toxic substances. In addition, we propose that additional hazardous chemicals such as endocrine disruptors, PBTs, vPvBs and neurotoxins, should be banned in toys.

#### Amendment 93/ Proposal for a directive/ Annex II – part III – point 3

We welcome the intention of this amendment to offer more protection to children by making the wording more rigorous, but it should go further, to a total ban on CMRs in toys, bearing in mind that there are no safe levels for these substances. The reasoning for banning them in any part of a toy is that any part of any toy could, in theory, be broken apart and become accessible to a child.

#### Amendment 94/ Proposal for a directive/ Annex II – part III – point 4

We agree with the proposal that CMRs of categories 1, 2 and 3 should be treated in the same way, as indeed they all present a risk to children's health. However, we propose a **total ban** on the use of these substances in toys. There is no reason why known highly toxic substances should be used in children's toys. Our key principle is that the safety of children is paramount. It is simply inadmissible that products, which are sold to promote children's enjoyment and development, should directly endanger their health by containing known hazardous substances, and no exemptions or excuses can be accepted.

<sup>23</sup> Federal environmental agency: Research study of circulation of environmentally determined contact allergies with focus on the private sector, 2004

<sup>24</sup> COM(2008)9-2008/0018/COD

Amendment 96/ Proposal for a directive/ Annex II – part III – point 5 a (new)  
And Amendment 97/Proposal for a directive/ Annex II – part III – point 6 a (new)

We welcome the tougher stance of this amendment. However, we propose to extend the provisions of the food packaging directive as well as the cosmetics directive to **all toys**, regardless of whether they are designed to be put in the mouth or come into contact with the skin or not. The reality is that young children put everything in their mouths, including toys designed for younger children as well as any older siblings' toys to which they have access. Children sleep next to toys with lengthy periods of skin contact, and chew or nuzzle them. Therefore it is imperative that all toys are safe for children's use, including putting them in their mouths.

Amendment 98/ Proposal for a directive/Annex II – part III – point 7  
Based on the scientific evidence that fragrance allergies, once acquired, can never be overcome, we propose that all fragrances and sensitisers be banned from toys. There is no need for these substances in toys, and there are clear health reasons for banning them.

### 3.3 Cosmetics

#### Simplification of the Cosmetics Directive 76/768/EEC

The EU is currently recasting EU legislation cosmetic products.

The purpose is to:

1. Remove legal uncertainties and inconsistencies in cosmetic legislation
2. Avoid divergences in national transpositions
3. Ensure that cosmetic products placed on the EU market are safe.

The cosmetics directive has been amended 55 times. The goal now is to merge them into one legal text while making some important changes. These changes include: introducing a set of definitions, updating the glossary of ingredient names, setting out the requirements for cosmetic product safety assessments in terms of content, strengthening in-market control (regards imports), introducing a new CMR (carcinogenic, mutagenic or reproductive toxin) regime, and more....

It is very important that in the simplification process, the directive continues to adopt a hazards based approach. This is crucial if we value the health of consumers, workers and children. While the current CMR ban in the current Cosmetics Directive ensures that classified chemicals will not be used in cosmetic products, there are ingredients in cosmetics already suspected to be CMR's but not yet classified.

There is also a need for more studies regarding chronic exposures and the cumulative and combined effects from daily use with specific attention to developmental effects.

Research by the University Hospital in Copenhagen<sup>25</sup> shows that many hazardous substances currently used in cosmetics, such as the phthalate DEP, can enter directly

---

<sup>25</sup> *Why is Infertility Growing in Europe?* Henrik Leffers, Niels E. Skakkebaek, Niels Jørgensen, Katharina Main, Anna-Maria Andersson, Ewa Rajpert-De Meyts, Anders Juul, University Department of Growth & Reproduction, Rigshospitalet, Copenhagen Presentation at the European Parliament, 3 September 2008

into the blood stream, and remain there for 48 hours. Cosmetics are often applied daily, so the user has constant high levels of these hazardous chemicals in their bloodstream. Pregnant women unknowingly pass these chemicals straight to their developing child.

The phthalate research shows that exposure to the phthalates DEHP (banned from use in cosmetics as is DBP) DEP and DBP<sup>26</sup> can lead to a number of serious, lifelong defects of the reproductive organs for the developing child. In baby boys, it is linked to a feminisation of the male reproductive organs, as well as the development of testicular cancer later in life.

As the cumulative effects of hazardous substances on children's and women's health are shown to exist, but are not yet quantified, for all combinations, the precautionary principle should be applied, by making sure no hazardous chemicals are used in cosmetics.

## **WECF Policy Priorities**

### **CMR exemptions:**

- Any exemptions to the CMR ban should only apply to newly classified substances, be time limited and include a mandatory requirement for the company to submit a substitution plan.
- Any product containing an exempt CMR should be labelled as containing an ingredient, which has been classified as a CMR.
- CMR 3's should be subject to the same safety assessments as CMR's 1 and 2.
- Substances suspected of being CMR's should be withdrawn from cosmetics until proven safe.

### **Ethanol and denaturants:**

In accordance with EU regulations,<sup>27</sup> highly hazardous substances, such as phthalates, are known to be used as denaturants in ethanol. Phthalates should never be used for denaturalisation because of their endocrine disrupting effects. Denaturants should not contain any CMRs, PBTs, vPvBs<sup>28</sup>, neurotoxins or other known- but not yet classified- hazardous substances.

- Harmonisation is required throughout the EU and denaturants must be assessed individually under the cosmetics directive.

### **Nanotechnology**

Certain ingredients used in cosmetics such as anti-aging creams and sunscreens can be as small as an atom, or "nano-sized".<sup>29</sup> They are already being used in a wide

<sup>26</sup> DEHP (Di(2-ethylhexyl) phthalate), DEP (Diethyl phthalate), and DBP (Di-n-butyl phthalate).

<sup>27</sup> Commission Regulation (EC) No 849/2008 of 28 August 2008

<sup>28</sup> PBT (Persistent, bio accumulative and toxic), vPvB (Very persistent and very bio accumulative).

<sup>29</sup> A nanoparticle is defined as anything at the scale of 100 nanometres or less.

variety of applications including textiles and cosmetics with little regard for potential impacts on health and the environment.<sup>30</sup>

Nanoparticles can technically pass through the skin into the body and research has shown that some of them can be toxic to human tissue. Due to their size, they have different properties and are more toxic than larger molecules of the same substances, thereby requiring different health and safety assessments. They can also penetrate blood and brain cells, thereby posing a threat to the developing foetus and to children's health.

Products that enter the body are required to be classed as medicines, yet some cosmetics can do just that and are called "cosmeceuticals" by the industry. If a product has drug properties, it must be assessed like a drug. However this is not yet the case with ingredients like nanoparticles.

- All products containing nanomaterials including those currently on the market should be labelled for consumer information.
- Full safety testing is needed prior to any nanoparticle ingredient use.
- The data gaps on nanotechnology need to be filled and a definition added to the directive.
- Nanomaterials should be treated as new chemicals from a risk assessment point of view under REACH. • A precautionary approach to all nanoparticles should be taken, in consumer products as called for by the European Trade Union Confederation (ETUC).<sup>31</sup>

### 3.4 Chemicals Legislation – REACH

The new EU policy on chemicals entered in to force in June 2007. According to the International Chemical Secretariat (ChemSec), "The success of REACH will depend on a prompt, effective process for identifying the most hazardous chemicals on the European market and replacing them with safer alternatives."

ChemSec explanation of the authorization process and the Candidate List:

The procedure for dealing with the most hazardous chemicals, and a cornerstone of REACH, is a process called Authorisation - a requirement for the producers or importers of the most hazardous substances to obtain a special permission before placing them on the market. At the heart of the Authorisation process is a "Candidate list" of chemicals that meet the criteria of "Substances of Very High Concern" (SVHC) defined in the legislation, such as those that may cause cancer or persist in our bodies and the environment for long periods of time. Connected to this list is a requirement for companies to provide information to consumers concerning the presence of these substances of very high concern in consumer products. In 2009, the European Chemicals Agency will make a first recommendation of priority substances, which will subsequently require an authorisation for continued use.<sup>ix</sup>

<sup>30</sup> *Nanoscience and nanotechnologies: opportunities and uncertainties. Royal Society 2004.*  
<http://www.nanotec.org.uk/report/Nano%20report%202004%20fin.pdf>

<sup>31</sup> *ETUC wants precautionary principle applied to nanotechnologies - [www.etuc.org/a/5159?var\\_recherche=nano](http://www.etuc.org/a/5159?var_recherche=nano)*

Once a chemical is on the candidate list, EU consumers have the legal right to know/question retailers as whether or not they are present in their consumer products. This “right to information” about chemicals on the list, is another reason that it is important to get chemicals of concern onto the list as soon as possible.

To date all 27 EU member states have committed to establishing a list of substances of very high concern (SVHCs) (i.e. chemicals that cause cancer, birth defects, and other serious health effects and which persist in the environment and accumulate in our bodies). However, only 16 chemicals have been officially nominated for the list so far. This is unacceptable, considering the fact that many official EU lists specifying different hazardous chemicals already exist.

The International Chemical Secretariat has spearheaded a joint effort by public interest organisations, including WECF, to compile a first list of chemicals of “high concern”. This SIN List (Substitute It Now) includes 267 chemicals and substances, which meet the REACH criteria. The aim of the joint effort was to “push for strict implementation of EU chemical legislation, and to provide guidance to European authorities, companies and consumers for taking action on the listed chemicals.” The Sin list is available at: [www.chemsec.org](http://www.chemsec.org)

REACH implementation and future reviews will directly impact human exposures to hazardous chemicals. It is important that sufficient attention be given to substances known/or suspected of causing developmental disorders, while comprising the candidate list of SVHCs. The speed at which REACH will be implemented and hazardous substances restricted or phased out, is very important, as each year more and more children are paying the price with their health.

**Table: Policy Recommendations to Protect Children’s Developmental Health**

<b>Policy Area</b>	<b>Priorities/Needs</b>	<b>Timeline</b>
<p>Pesticides</p> <p>Revision of Regulation on Authorisation of Plant Protection Products &amp; Framework Directive on Sustainable Use of Pesticides</p>	<ul style="list-style-type: none"> <li>• Mandatory substitution and strict cut-off criteria to remove the worst pesticides from foods:               <ul style="list-style-type: none"> <li>– Carcinogenic Mutagenic Reprotoxic (CMR1,2)</li> <li>– Endocrine Disrupting Chemicals (EDC),</li> <li>– Developmental Neurotoxins</li> <li>– Immunotoxins</li> </ul> </li> <li>• Cumulative and synergistic effects must be included in all risk assessments</li> <li>• Parliament proposed “no spray zones” in public areas including schools and hospitals</li> <li>• Set up pesticide use reduction targets</li> </ul>	<p>06/10/2008 - Consideration of draft recommendation for second reading (ENVI Committee)</p> <p>10/10/2008 - Deadline for amendments</p> <p>04/11/2008 - ENVI Vote</p> <p>01/2009 (est.) - Plenary vote</p>
<p>Toys Directive</p>	<ul style="list-style-type: none"> <li>• Prohibition of all CMRs (category 1,2 and 3) without any exemptions.</li> <li>• Prohibit other known hazardous chemicals               <ul style="list-style-type: none"> <li>– EDCs including phthalates and Brominated Flame retardants (BFRs)</li> <li>– PBTs</li> <li>– vPvBs</li> <li>– Neurotoxins and Immunotoxins</li> <li>– Nanosubstances</li> </ul> </li> <li>• Ban of all fragrances and sensitizers</li> </ul>	<p>10/07/2008 – ENVI: Opinion vote</p> <p>10/16/08 - ITRE</p> <p>11/06/08 – IMCO: Rep. vote</p> <p>12/01/08 - Council</p> <p>16/12/08 - Plenary vote (est.)</p>
<p>Cosmetics Directive</p>	<ul style="list-style-type: none"> <li>• Should continue to adopt a hazards-based approach and substances suspected of being CMR’s should be withdrawn until proven safe.</li> <li>• Exemptions to CMR ban should <u>only</u> apply to newly classified substances, be <u>time limited</u>, and include a <u>mandatory</u> requirement for the company to submit a substitution plan.</li> <li>• A precautionary approach to all nanoparticles in consumer products. No safety data, no market!</li> <li>• All products containing nanomaterials including those currently on the market to be labelled for consumer information</li> </ul>	<p>05/11/2008 - EP: report scheduled for adoption in committee, 1st or single reading.</p> <p>01/12/2008 - Council: debate or examination expected.</p> <p>16/12/2008 - EP: probable part-session scheduled by DG Presidency, 1st reading.</p>
<p>REACH</p>	<ul style="list-style-type: none"> <li>• Review of the criteria for identifying PBT and vPvB substances (taking into account real world daily exposures and vulnerable groups.)</li> <li>• Increase compulsory information submitted for low volume chemicals (1-10 tonnes/year)</li> <li>• Endocrine disruptors, as classified in the EU, should automatically be considered SVHCs.</li> <li>• REACH gives the consumer the right to ask retailers whether there are SVHCs present in the goods they buy. REACH should use the same definitions as RoHS - 0,1% of each homogenous material, not the entire goods.</li> </ul>	<p>PBT review</p> <p>12/01/08 - Completed by the COM</p> <p>01/09 - Comitology vote</p> <p>01/09-04/09 - Parliament scrutiny</p>

## 4. Conclusion

International concern is increasing as scientific evidence continues to mount, indicating that even low level exposures to hazardous substances and chemicals (common in our every day lives) are harming human health.

The foetus, pregnant woman and child are of particular concern as “the periods of embryonic, foetal and infant development are remarkably susceptible to environmental hazards. Toxic exposures to chemical pollutants during these *windows of increased susceptibility* can cause disease and disability in infants, children and across the entire span of human life.”<sup>32</sup>

Legislative formulation or implementation must take into account the susceptibility of early human development and the long-term implications that result from organs systems being harmed, keeping in mind that some of the impacts may not become apparent until much later in life.

Important points to consider include:

- The timing of the dose is important
- Much of the harm is irreversible
- The harm can be multi-generational
- Preventive action (to protect from harm) is important and urgent
- Personal and societal costs are enormous.
- The increase of diseases such as learning, behavioural and immune disorders, cancer, diabetes and obesity are linked to a combination of causes, including chemical exposure during development

Although even more studies are needed in order to fully understand this complex issue, we are hearing repeated warnings from the scientists and medical doctors not to wait for all the additional studies to be completed, but to take preventive action now.

There is already enough evidence to show that the health and development of vulnerable groups are in need of protection from exposures to hazardous chemicals. In order to achieve this, policy makers must adopt a precautionary approach and enact protective measures. Our future depends on it!

---

<sup>32</sup> *The Faroes Statement, Human Health Effects of Developmental Exposure to Chemicals in Our Environment, Faroes Islands 2007.*

---

<sup>i</sup> *Summary WHO Report August 2007*”, *Environmental Health Criteria 237, Principles For Evaluating Health Risks In Children Associated With Exposure To Chemicals*.

<sup>ii</sup> *The Faroes Statement, Human Health Effects of Developmental Exposure to Chemicals in Our Environment, Faroes Islands 2007*

<sup>iii</sup> *Scientific Consensus Statement on Environmental Agents Associated with Neurodevelopmental Disorders. Collaborative on Health and the Environment. Feb, 2008. pg3.*

<sup>iv</sup> *Summary WHO Report August 2007*”, *Environmental Health Criteria 237, Principles For Evaluating Health Risks In Children Associated With Exposure To Chemicals*.

<sup>v</sup> *Scientific Consensus Statement on Environmental Agents Associated with Neurodevelopmental Disorders. Collaborative on Health and the Environment. Feb, 2008.*

<sup>vi</sup> *Sally Hutchings and Lesley Rushton , (Lesley Rushton is quite conservative )Estimation of the burden of childhood disease in Europe due to environmental risk factors, Imperial College London. 2007 (draft)*

<sup>vii</sup> *Scientific Consensus Statement on Environmental Agents Associated with Neurodevelopmental Disorders Collaborative on Health and the Environment. Feb, 2008. pg 5*

<sup>viii</sup> *Marla Cone, Times Staff Writer, Scientists warn: Common chemicals pose danger for fetuses, May 25, 2007*

<sup>ix</sup> *Chemical Secretariat, The Reach SIN\*List (Substitute it Now) A Tool for Phasing out Chemicals of High Concern, 3 July 2008.*