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Children´s special health vulnerability to environmental hazards and REACH

Introduction

EPHA Environment Network (EEN) advocates protection of the environment as a means to improving the health and well being for European citizens. Launched in 2004, it represents 3-5 million European citizens and brings together groups that want to ensure that health is at the centre of environment issues.

Member groups include NGOs specialising in public health, environment-related health conditions and women's environmental and health concerns and associations representing health care and environmental professionals. One of EEN's key objectives is to bring health expertise to the environment policymaking process. This involves exploring the complex linkages between health and the environment in order to provide policy makers with a clear image of the wider perspective.

EEN has supported calls for REACH to:

1.Phase out the use of hazardous chemicals, only allowing their continued use if no safer alternatives are available and their use is essential to society
2.Strengthen registration procedures to close the existing gap in safety information for chemicals produced in 1-10 tonne per annum quantities.
3.Ensure that industry information receives an **independent quality audit**
4.Require chemicals used in **imported articles** to undergo the **same information requirements** as those in EU-made articles, so as to protect consumers and avoid distortion of competition
5.Make sufficient **information** on chemicals **publicly available** so that downstream users, retailers and consumers can find out which chemicals are contained in the products they purchase and make their own risk judgements.

But consider that issues related to the health of vulnerable populations has not been considered adequately in the current REACH proposal and needs clarifying in the legal text itself in order that any Technical Guidance Documents produced by the Commission have clear direction.

Because:

- **Children** are physiologically different from adults. The younger the child, the greater the difference. This affects the uptake of substances in the body, the distribution through tissue, metabolisation by enzymes and excretion from the body.

- **Children**, per unit of body weight, are more heavily exposed, to environmental hazards, they drink more water, eat more food, breathe more air, absorb more toxics than adults (in most cases). Young children crawl a lot and often put their hands and all kinds of objects in their

mouths.

- **Children** are open to longer term risks because of early exposure, particularly before birth, or continual exposure, they have their whole lives ahead of them and may develop chronic diseases that take several decades to appear.

- **Children** are more susceptible to long-term and inter-generational effects of bio-accumulation. Toxics are stored up and passed to our children and grandchildren through the placenta and breast feeding.

The **World Health Organisation**[1] has stated that we need to establish child-focused protective policies based on better knowledge of biological susceptibility, of socio-economic and psychosocial determinants of environmental exposure to health hazards.

All European **Environment and Health Ministers** have signed the **Children´s Environment and Health Action Plan**[2] in Budapest stating that they *´will aim to reduce the proportion of children with birth defects, mental retardation and developmental disorders, ... and ... childhood cancers by: (a)* ***passing and enforcing legislation*** *and regulations and implementing national and international conventions and programmes to:*
i) ***reduce exposure of children and pregnant women*** *to hazardous chemical, physical and biological agents to levels that do not produce harmful effects on children´s health;*
iii)ensure appropriate information on and/or ***testing for effects on health of developing organisms of chemicals****, products and technologies before their marketing and release into the environment;´*

Also signed back in 1997 a declaration of **Environment Ministers of the G8**[3] on children´s environmental health stated *´that national policies should take into account the specific exposure pathways and dose-response characteristics of children when conducting risk assessment and setting protective standards´*

The **Intergovernmental Forum on Chemical Safety**[4] (IFCS) including 125 Governments, IGOs, NGOs and Industry recommended *´When assessing the protection of children, consideration should be given to chemical exposures that can occur during preconception, throughout gestation, infancy, childhood and adolescence. ..... Governments should, when setting acceptable levels or criteria related to chemicals, take into consideration the* ***potential enhanced exposures and/or vulnerabilities of children****.´*
Indeed CEFIC´s position on **Children Health & Environment** states:
´Industry has a responsibility to be actively involved in reducing the uncertainties and making the risk assessment process as robust as possible.´ and supports *´Focus(ed) research and chemical evaluation programmes on answering questions about possible unique susceptibilities and exposures of children to natural and synthetic substances´*

How does this relate to REACH?

So does REACH go some way to answering and solving the following questions:

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[1]World Health Organization & European Environment Agency: Environment issue report No29, Children´s health and environment: A review of evidence. ISBN 92-9167-412-5, EEA Copenhagen, 2002.
[2]World Health Organization, Fourth Ministerial Conference on Environment and Health, Budapest, Hungry, Children´s Environment and Health Action Plan for Europe, EUR/04/5046267/7, 25 June 2004.
[3]Environment Leader´s Summit of the Eight, 1997. Declaration of the Environment Leaders of the Eight on Children´s Environmental Health, Miami FL, 5-6 May 1997.
[4]Central European Journal Occupational and Environmental Medicine, 2003, Volume 9 Special Issue, p.S64 Intergovernmental Forum on Chemical Safety Working Group, Protecting Children from Harmful Chemical Exposures: Chemical Safety and Children´s Health, Recommendations of the Forum IV, Bangkok, Thailand, 1-7 November 2003.

- Do the REACH risk assessments consider the unique vulnerabilities and susceptibilities of children and include children´s exposure patterns at different times of development?

- Are children´s exposures and environment-related health conditions assessed in different geographical areas, as well as in different populations?

- Will REACH take into account child or reproductive specific toxicity and exposure?

- When child – or – reproductive – specific toxicity data or exposure data are insufficient, is an extra margin of safety employed or the substance disallowed for use until such data are available?

REACH states

Step 4: Identification of Derived No-Effect Level(s)
Annex 1.4.1 Taking into account the available data and the exposure scenario(s) in Section 5 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. Workers, consumers and humans liable to exposure indirectly via the environment and possibly for certain sub-populations (e.g. Children, pregnant women) and for different routes of exposure. .....When establishing the DNEL, the following factors shall, inter alia, be taken into account:
(i) the uncertainty arising, among other factors, from the variability in the experimental data and from intra – and inter-species variations;
(ii) the nature and severity of the effect;
(iii) the human population to which the quantitative and/or qualitative information on exposure applies.

While chemical substances may produce the same types of effects in adults and children, these can occur at different exposure levels. In addition, substances can result in effects that are unique to children, and that are associated with adverse effects on the development of organs or organ systems.

In particular, effects on the development of the nervous system and the immune system may remain unnoticed. This may also apply to effects resulting from endocrine disruption. Changes which are most likely to remain unnoticed are those resulting from exposure during development that only emerge in later life.

It is unclear to what extent the lack of this relevant data about development toxicity is offset by the traditional uncertainty factor for variations in vulnerability between individuals. This means that it is also unclear whether the calculations of DNELs will always provide adequate protection for children, including unborn children, in periods of heightened vulnerability during the course of their development.

Furthermore, effects involving aspects such as behaviour, learning ability, motor skills, immunity or fertility are difficult to identify. Research has shown that some substances can have an adverse effect on the development of children. Examples are PCBs, dioxins and lead.

Improvements are required to existing research protocols. In particular, studies of reproduction toxicity involving several generations of laboratory animals should be designed on broader lines, to allow for the identification of any effects on the development of the nervous system, immune

system and endocrine-regulated processes of development. If this standard research yields an indication that there may be an adverse effect on the development of organisms, there should be follow-up research into the specific problem.

For example the use of genomics (proteomics and metabolomics) may lead to better understanding of mechanisms of toxicity, and individual genetic susceptibilities, which in turn would lead to better risk assessment information regarding susceptible populations, co-mixtures of chemicals and low levels of exposure.

If, on the basis of all available data and in the absence of adequate research or follow-up research, there is reasonable cause for supposing that developing organisms are more vulnerable than adult organisms, an additional uncertainty factor in addition to the factors traditionally used would surely be appropriate when calculating the DNEL.

Please see recommendations for amendments below:

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EEN´s proposed amendments to REACH.

Therefore, EEN considers that the following amendments are essential to protect our children from chemicals that are potentially hazardous to their health. (underlined being introduced text, struck out being deleted text).

In **Preamble:**
Whereas:

(4)To preserve the integrity of the internal market and ensure a high level of protection for human health, especially the health of workers and other vulnerable groups, and the environment, it is necessary to ensure that substances manufactured in the Community comply with Community law, even if they are exported.

(5)..... identified a number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field and a failure to protect public health and the environment in a precautionary manner.

(52) To ensure a sufficiently high level of protection for human health, in particular to vulnerable populations, and the environment, substances with properties of very high concern should be treated in a precautionary manner which requires enterprises using them to demonstrate to the granting authority that the risks are adequately controlled. .....

(89) Resources should be focused on substances of the highest concern. A substance should therefore be added to Annex I of Directive 67/548/EC ~~only~~ if it meets the criteria for classification as a carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, ~~or~~ as a respiratory sensitiser, or recognised as a possible threat to human health or the environment.

Article 3
Definitions
New

30. Vulnerable populations means susceptible humans including neonates, infants, children, women and men prior to conception, pregnant women, nursing mothers, the infirm and immune compromised, elderly, individual genetic susceptibilities and other identified groups of concern.

Article 57
The granting of authorisations

~~2. An authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII is adequately controlled in accordance with Annex 1, section 6, and as documented in the applicant´s chemical safety report. The Commission shall not consider the following:~~
~~(a) risks to human health and the environment of emissions of the substance from an installation for which a permit was granted in accordance with Council Directive 96/61/EC[49];~~
~~(b) risks to and via the aquatic environment of discharges of the substance from a point source governed by the requirement for prior regulation referred to in Article 11(3) and legislation adopted under Article 16 of Directive 2000/60/EC of the European Parliament and of the Council[50];~~
~~(c) risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC[51], Council Directive 93/42/EEC[52] or Directive 98/79/EC of the European Parliament and of the Council[53].~~

3. ~~If an authorisation cannot be granted under paragraph 2, a~~An authorisation may be granted only if there are no alternative substances or technologies, and if it is shown that the socio-economic benefits outweigh the risk to ~~human health or~~ the environment **and human health, especially including vulnerable populations,** arising from the use of the substance and if measures to minimise exposure are put in place ~~if there are no suitable alternative substances or technologies~~.
.....

N.B. For article 57 the bold underlined indicates the amendment for children´s health – while the others are proposed to be amended (by deletion for example) to consider the matter of substitution.

Article 65

Introducing new and amending current restrictions

1.When there is an unacceptable risk to ~~human health or~~ the environment or human health, especially including vulnerable populations and exposures to mixtures, arising from the manufacture, use or placing on the market of substances, which needs to be addressed on a Community-wide basis, Annex XVI shall be amended in accordance with the procedure referred to in Article 130(3) by adopting new restrictions, or amending current restrictions in Annex XVI, for the manufacture, use or placing on the market of substances on their own, in preparations or in articles, pursuant to the procedure set out in Articles 66 to 70.

Annex I

1. Human Health Hazard Assessment
1.4 Step 4: Identification of Derived No-Effect Level(s)

1.4.1 Based on the outcomes of steps 1 to 3, a Derived No-Effect Level(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the available data and the exposure scenario(s) in Section 5 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. Workers, consumers and humans liable to exposure indirectly via the environment) and possibly for ~~certain sub-populations~~ vulnerable populations ~~(e.g. Children, pregnant women)~~ and for different routes of exposure. A full justification shall be given specifying, *inter alia*, the choice of the data used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. If more than one route of exposure is likely to occur, then a DNEL shall be est~~g~~ablished for each route of exposure and for the exposure from all routes combined. When establishing the DNEL, the following factors shall, *inter alia,* be taken into account:

(i) the uncertainty arising, among other factors, from the variability in the experimental data and from intra – and inter-species variations;
(ii)the nature and severity of the effect;
(iii)the human population to which the quantitative and/or qualitative information on exposure applies.
(iv) particular susceptibilities of vulnerable populations;
(v)any indication of non-standard effects, especially where the mode of action remains unknown or insufficiently characterised;
(vi) possible co-exposures to other chemicals;
(vii) uncertainties regarding the quality of data and overall confidence in the database;

Article 112
Harmonisation of classification and labelling

1. Harmonised classification and labelling at the Community level ~~shall~~ may from the entry into force of this regulation ~~only~~ also be added to annex 1 of directive 67/548/EEC as well as to directive 1999/45/EC. ~~For classification of a substance as carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, or as a respiratory sensitiser.~~ To this end, member states Competent authorities may submit proposals to the Agency for harmonised classification and labelling in accordance with Annex XIV.