

# What will new EU chemicals legislation deliver for public health?

The regulation of chemicals is not achieving a very high level of health protection. Statistics linking ill health to workplace exposure make this abundantly clear, with thousands of people affected. It is estimated that 27,000 people suffer from work related skin disease in Britain annually,<sup>1</sup> and 156,000 people report occupation related breathing or lung problems.<sup>2</sup> Other work related illness include at least 1,500 -2,500 asthma cases per year,<sup>2</sup> and an estimated 6,000 cancer deaths<sup>3</sup>.

## THE PROBLEM

The bulk of chemicals on the market have never been properly tested and assessed for safety. Although the extent to which every day exposure to chemicals adds to the current disease burden in the general population is not known, research clearly suggests that chemicals may play a role in some allergic reactions,<sup>4,5,6</sup> cancers,<sup>7,8</sup> birth defects,<sup>9,10</sup> and adverse effects on male reproductive health, sperm counts,<sup>11,12,13</sup> and fertility.<sup>14</sup> Chemical exposures have also been implicated in a plethora of other conditions including endometriosis,<sup>15,16</sup> diabetes,<sup>17</sup> obesity,<sup>18</sup> neurodegenerative conditions,<sup>19</sup> immune system effects<sup>20</sup> and adverse effects on brain function.<sup>21,22</sup>

Adults may be relatively insensitive, but exposure of the foetus to remarkably low levels of certain contaminants may de-rail development and lead to disease or functional deficits showing up later in life.<sup>23,24,25</sup> Unfortunately therefore, exposure to certain chemicals may prevent the next generation from reaching their full potential. For example, research already suggests that due to exposure in the womb, the brain development of thousands of children in Europe has been affected by background levels of man-made chemicals called PCBs.<sup>26,27,28</sup> These chemicals were banned many years too late to prevent such effects. Similarly, past experience with asbestos and the ozone-depleting chlorofluorocarbon chemicals, bears unwelcome testimony to the need to shorten the time period between research showing that certain chemicals can cause harm and effective

regulatory action. This is an area where the voice of the medical professions could certainly play an important role. That said the ideal situation would be to ensure adequate prior testing and a regulatory framework that prevented hazardous chemicals from being used in harmful situations.

The role of contaminants in early life in causing altered gene expression and function is now coming under the spotlight in the study of epigenetics, and this has the potential not only to escalate the concern about exposure to certain chemicals<sup>29,30,31,32</sup> but also to revolutionise our understanding of inheritance itself.

## REACH CAN BRING HEALTH BENEFITS

It is hoped that new EU legislation to control chemicals, which entered into force in June 2007, will remedy the dearth of information on the hazards posed by chemicals.<sup>33</sup> The REACH Regulation (which stands for the Registration, Evaluation, Authorisation and Restriction of Chemicals) will require safety data to be collected for chemicals traded in quantities greater than 1 tonne per year, with more testing being required for chemicals traded in larger volumes.

One of the pillars of REACH is that it involves a shift in responsibilities. In the future, the chemical manufacturing industry itself must provide the data and assess its chemicals, with some checks being done by the Regulatory Authorities.

Concerned about their costs and future global competitiveness, the chemical industry lobbied hard during the negotiation of the REACH legislation, as a result of which the proposed toxicity testing requirements were greatly reduced. It is not easy to find the right balance between the costs to industry and the costs of adverse health effects or environmental damage from insufficient regulation. Nevertheless, in the UK it is estimated that for REACH to 'break even' only 18 cancer deaths a year would have to be prevented.<sup>34</sup> All too often, the costs to industry of impending legislation take centre stage, because these costs are more obviously linked to the regulatory action, whereas health benefits may take several years to become apparent. Yet, it is relatively easy to see for example, where one UK National Health Service Trust is required to pay substantial compensation to staff sensitised by latex or glutaraldehyde, how much cheaper it would have been to substitute articles or formulations containing these chemicals with safer alternatives.<sup>35</sup> Indeed, some years ago allergy costs throughout Europe were estimated at a massive 29 billion euros (around £19.5 billion) a year.<sup>36</sup>

### WHICH CHEMICALS ARE CAUSING CONCERN?

Under REACH, the worst chemicals can be subject either to restrictions or the so-called authorisation process. If a chemical is subject to the authorisation process, then industry must make a case for its continued use, and only those uses which are specifically authorised can continue. Authorisation can be applied to the so called '*substances of very high concern*', which include (a) carcinogens, (b) mutagens, (c) reproductive toxicants (collectively called CMRs), (d) persistent, bioaccumulative and toxic substances (PBTs), (e) very persistent and very bioaccumulative chemicals (vPvBs), and (f) chemicals of equivalent concern, such as those with endocrine disrupting properties, 'for which there is scientific

evidence of probable serious effects...'. This latter clause has been a focus of debate, as it has been argued that having to provide evidence that serious effects are probable is too high a burden of proof.

Persistent and bioaccumulative chemicals are considered to be substances of very high concern because if harm does come to light the persistence of these compounds means that exposure cannot be stopped. Furthermore, as these substances bioaccumulate in the body's fatty tissues they can be passed from mother to baby *in-utero* or during breastfeeding.

Perhaps one of the most useful elements of REACH is that a candidate list is to be drawn up of those chemicals which meet the criteria for being subject to authorisation in advance of the formal authorisation procedure. In some cases, this will undoubtedly lead industry voluntarily to replace those chemicals.

Whether an authorisation to use a '*substance of very high concern*' is granted depends on certain factors. The PB(T) chemicals that are drawn into the prior authorisation procedure can only be used if the socio-economic benefits outweigh the risk and there are no safer alternatives. However, some carcinogens (Cs) and mutagens (Ms), and many reproductive toxicants (Rs), and chemicals of equivalent concern (such as chemicals with endocrine disrupting properties) can be authorised if industry can show that the risks they pose are adequately controlled. This should effectively mean that exposures are very tightly controlled and well below thresholds for effects. However, there is considerable debate about the potential for long term, low dose effects, and whether there are indeed safe thresholds for exposure for some of these substances.

Unfortunately, risk assessment will typically still be based on a single substance approach, despite the fact that research clearly shows that many chemicals, particularly those that have common mechanisms of action or have mechanisms of action that converge, can act additively.<sup>37</sup> Chemicals which damage membranes or protective barriers may also increase the likelihood of damage due to other chemicals.<sup>38</sup> This means that while exposure to some potentially harmful chemicals can be below their individual thresholds for harmful effects, exposure to many such chemicals in our environment, even at low levels, may collectively cause harm to susceptible individuals.<sup>39,40</sup> It might therefore be better to require industry to substitute them with safer alternatives, if they are available, instead of relying on exposure to be controlled to a level below that known to cause effects for that single substance. Ongoing concern surrounding this issue is such that REACH stipulates that there must be a review of how chemicals with endocrine disrupting properties are dealt with within 6 years.

Scores of scientists have already signed a declaration saying that for a few chemicals, such as those known to mimic oestrogen or block androgen hormone action, scientific uncertainty should not delay action to reduce exposures and risks.<sup>41</sup> Moreover, the Standing Committee of European Doctors (CPME), representing 2 million doctors across Europe, has written to the Commissioners of the EU to demand "the substitution of hazardous chemicals whenever and wherever safer alternatives are available".<sup>42</sup> The REACH law obliges all applications for an authorisation to include an analysis of alternatives and a substitution plan where a suitable alternative exists. However, it is doubtful whether this will really deliver safer substitutes because industry can still gain an authorisation by showing that the risks for the single substance in question are adequately controlled.

## HOW TO JOIN IN THE DEBATE

Studies are continually emerging which point to the role of chemical exposures in various aspects of ill- health, particularly when exposure occurs during susceptible 'windows' in early life. New resources are available to help those working in the health sector to develop a greater understanding of the potential role of chemicals in disease, and to enable their input into REACH implementation discussions.

Several web sites are recommended, including those of the Brussels-based Health and Environment Alliance (<http://www.env-health.org/>), the US Collaborative on Health and the Environment (<http://www.healthandenvironment.org>), and Environmental Health News ([www.EnvironmentalHealthNews.org](http://www.EnvironmentalHealthNews.org)).

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**CHEMICALS  
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**Chemicals Health Monitor** aims to improve public health by ensuring that key scientific evidence on the links between chemicals and ill-health are translated into policy as quickly as possible. The strategy involves fostering dialogue, sharing perspectives and greater collaboration between policy makers and governments on the one hand and scientific researchers, medical and health professionals, patient groups, environmental organizations and the public on the other. We work to highlight the compelling scientific basis for added controls over certain chemicals; and encourage EU policies that are precautionary and participatory, especially with regard to the implementation of REACH, and the substitution of hazardous chemicals. The project was launched by the Health and Environment Alliance (<http://www.env-health.org/>) in collaboration with other partner organisations across Europe in March 2007. <http://www.chemicalshealthmonitor.org>

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