

## Future Problems of Novel Substances: The EU Perspective

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### Abstract

This review starts with an overview of the state of the art of public health and environmental policies in the European Union (EU) and seeks to examine the response of EU to emerging issues posing environmental and public health risks. In this context, EU plays an important role since a wide variety of regulatory references have been introduced on the use and marketing of hazardous compounds by the EU Commission. A broad range of evidence-based scientific measures to protect human health and the environment is available due to the joint commitment of researchers and legislators. Some examples of achievements that have resulted in improved environmental protection and increased health for populations are also shown, together with future perspectives.

**Keywords:** Commission; Perspectives; Human health; Environmental care; Re-emerging health threats

### Understanding Emerging Environmental and Public Health Threats and Policies

Since both public safety and environmental protection are European Union priorities, a goal of many public regulatory programs is the protection or enhancement of human health and the environmental care. Today numerous infectious diseases such as Ebola, HIV/AIDS and others, pose a substantial threat throughout the world, anyway, global health concerns cannot be limited to infectious diseases, since there are several other sources of emerging or re-emerging health issues which could pose unacceptable risks to public health and the environment.

The fast technological development over the last century, together with economic development, social structure changes and human behaviour has also resulted in an increasing variety of problems, including climate change, land degradation, freshwater depletion, waste products overload with consequences that are difficult to predict, but which are capable of posing irreversible risks to human health and the ecosystem on unprecedented spatial and temporal scales [1]. Anyway, problems could arise not only from emerging but also evolving and re-emerging health threats, which have been around for decades or centuries but have come back in a different form or a different location, or sometimes just old problems that have never been really or properly solved.

Governments not only must address present but even anticipated problems that might pose a serious threat to public health operating in a complex world with an increasing number of scientific discoveries brought about by researchers and scientists. Anyway, latest scientific discoveries are not in themselves enough to improve public health and protect the environment, since a broad range of evidence-based scientific measures is required. It is a complex scenario: on the one hand researchers making new discoveries, on the other legislators that have to create or modify laws to be further implemented and enforced. A good question would be if it is really possible to find fast and, preferably, simple solutions to the numerous complex emerging environmental and public health threats.

Good research is always been the basis for the development of public health practice and policy since it helps to identify risk factors for existing, evolving and re-emerging health threats, as well as the impact of disease control and the promotion of preventive measures. Anyway, to achieve successful public health interventions it is

fundamental to put into practice the on growing body of knowledge. It is generally stated that research on public health is at a good quality and quantity level, but the translation from research results to policy and practice is lacking. As Gro Harlem Brundtland, the former director-general of WHO (World Health Organization), clearly stated: "Good science is the basis of good public health, but the challenge we face is to translate the best science into public policy." (International Conference celebrating the 400<sup>th</sup> anniversary of Public Health Services in Norway, 16 June 2004).

The gap between research on one side and policy on the other is due to several factors. A better interaction between policy and research, which moreover not always focuses on actual policy questions, means that researchers should learn to translate their research findings into recommendations for the solution of practical or policy problems, but also legislators should be trained to translate policy problems into research questions and to interpret research results. It seems that the solution has already been found, thus it must only be put into practice to solve the problem. But it is not so simple, since there is something more we have to consider. Science-based discoveries do not lead to instant claims but need to be further and deeply investigated in order to give objective and reliable results. Law is not as progressive, it has to come to a definitive conclusion within a limited period of time, thus needs clear and detailed information which are not always available immediately after the discovery of a new issue.

### EU Legislation: Better Safe than Sorry

EU legislation is no exception in this regard. In a considerable number of cases, legislators had to deal with the question of how to evaluate, often conflicting, scientific data. Since languages of law and science differ considerably, in order to transmit the results of science in legal form a "translation" of the language of science is needed.

A comprehensive description of the vast EU environmental,

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health and safety laws and regulations enacted is beyond the scope of this paper, moreover the modern world is a large and highly complex international network of connections and exchanges, therefore decisions taken in fields apparently distant from, or not even related to, human health or environmental care, in unpredictable ways might result in adverse consequences. Selected examples of serious public health and environmental threats are herein provided since it is a more effective way to give a simple and easily understandable picture of the current state of the art. The next paragraphs provide an overview of the substantive EU legislation enacted to respond to emerging and re-emerging environmental and public health threats, as well as describe the European Union's executive and regulatory agencies that took an active role into scientific or technical know-how development.

Underneath the complexity of EU legislation there is a basic principle that is adopted by EU member states as a guiding principle. This Principle enables rapid response in the face of a possible danger to human, animal or plant health, or to protect the environment therefore is invoked in EU regulatory affairs over a wide range of topics, but most often when environmental or health danger is at issue. When scientific and objective data do not permit a complete evaluation of the risk, Member States should apply the Precautionary Principle. The recourse to this principle could also be used to stop distribution or order withdrawal from the market of products likely to be hazardous. In 2002 the European Commission issued a Communication on the Precautionary Principle, which applies "where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection" and "the risk is still considered too high to be imposed on society, in view of chosen level of protection" [2]. It might look like just common sense instead than a revolutionary idea but it is evident how it poses challenges to business, as it is in strict contrast with economic liberalization on which the international trade regime is designed; indeed this simple principle already generated several trade controversies e.g. concerning genetically modified foods [3].

Not only human health but also protection of the environment is a well-established policy in the European Union starting in 1967 with the first European Community Directive concerning classification, packaging and labelling of dangerous substances [4]. The European Parliament approved REACH (Registration, Evaluation, Authorisation and Restrictions of Chemicals) regulation on December 2006, to guarantee the free movement of chemical products but at the same time to protect human health and environment. EU environment policy has developed a solid legal framework which contributes to pursuit the objectives of the European Environmental Policy set in the Article 191 of the Treaty of the [5] Functioning of the European Union: "preserving, protecting and improving the quality of the environment; protecting human health; a prudent and rational utilization of natural resources; promoting measures at international level to deal with regional or worldwide environmental problems" [6].

As reported on the European Commission website: "As a result, of broad range of environmental legislation put in place by the European Union over the past decades, air, water and soil pollution has significantly been reduced. Chemicals legislation has been modernised and the use of many toxic or hazardous substances has been restricted" [7].

With this said, the question is: how safe are we today? In order to try to answer this question it could be useful to take a look at the way EU has dealt with past cases and emerging issues posing environmental and public health threats.

## Asbestos: An Old Problem which is Still an Issue

Asbestos is one of the leading causes of occupationally related deaths in the twentieth century [8]. Deaths from asbestosis are a legacy of exposures to asbestos in the past. The total number of male deaths from pleural mesothelioma in Western Europe has continued to increase during the last decade of the 20th century, from approximately 7550 in 1985-1989 to 9550 in 1995-1999. Even if recent articles showed that the number of asbestos-related mesothelioma deaths during 1995-2029 in Europe is likely to be lower than the previously estimated 250 000, [9] anyway the deaths from other asbestos-related cancers, along with female asbestos-related deaths and deaths in Eastern Europe, were not included in the calculation thus it is not unreasonable to predict that 500 000 Europeans will die from these avoidable diseases, as emerged from the "Europe's Asbestos Catastrophe" conference which took place in Brussels on September 2012 [10]. Thus, the incidence of this quite old problem in industrialised countries has still to reach its maximum level in the next future, between 2010 and 2020 [11].

Asbestos, which is a naturally occurring set of silicate minerals forming thin fibrous crystals, is very commonly found in nature [12]. Since it is suitable for multiple uses, because of its desirable physical properties such as: resistance to heat and to many chemicals, sound absorption, average tensile strength, resistance to fire, heat, electrical and chemical damage, and, last but not least, affordability, it has been largely used worldwide since ancient times.

Despite asbestos and its related health problems are not new to the general public, anyway the recognition of its dangerousness is fairly recent, dating back to the 1960s. However, the medical community's knowledge about the dangers of asbestos extends almost a hundred years [13]. The large scale asbestos industry began in the mid-19th century and the use of asbestos became increasingly widespread towards the end of the 19th century [14]. The recognition of its toxicity started with a first diagnosis of a fatal case in 1899 by Dr. Montague Murray [15] and, even though this evidence did not create a widespread interest, the discovery of numerous early deaths and lung problems in asbestos-mining towns during the 1920s allowed medical knowledge about asbestos hazards to grow substantially, as did the industry itself. In 1924 a worker in the leading British asbestos firm factory died and the pathologist Dr W. E. Cooke indicated that the extensive fibrosis in the lungs was "originated from asbestos [dust] and were, beyond a reasonable doubt, the primary cause of [...] death", moreover he was the first to give this disease a name calling it "asbestosis" [16]. Following Cooke's report, between 1928 and 1929, thanks to several separate medical publications and a government enquiry into the effects of asbestos dust and the subsequent report that was presented to parliament on 24 March 1930, it was concluded that the development of asbestosis was irrefutably linked to the prolonged inhalation of asbestos dust [17]. It is now recognized that there are three major diseases associated with inhalation of asbestos fibres which are: asbestosis, lung cancer and mesothelioma. Asbestosis is a pneumoconiosis a fibrosis of the lungs, caused by an invariably occupational, exposure to asbestos. Though not always fatal, it is a degenerative condition which is incurable. Another highly malignant, painful and fatal asbestos-related cancer the "mesothelioma", was only identified in the late 1950s. This tumour may take decades to appear (sometimes over forty years) but once the disease develops it can kill within a year. The main cause of mesothelioma is asbestos dust, even after a relatively limited exposure [18].

A first list of occupational diseases was formulated in 1962 [19], in which asbestosis (with or without lung tuberculosis or cancer)

was listed in the category 'occupational diseases by inhalation' thus there was the recognition of the right to be compensated. The first legislative initiatives at European level date from the late 1970s [20], followed by numerous others. An important Council Directive was the 76/769/EEC that introduced restrictions on the marketing and use of certain dangerous substances and preparations, which represented an important new legal feature to move 'gradually to a complete ban' on certain dangerous substances including asbestos [21].

As a result of asbestos well documented dangerousness its trade and use have been restricted or banned in many countries. In particular asbestos has been banned in the European Union for several years since the Directive 1999/77/EC that prohibits the use of asbestos in the EU by 1 January 2005 at the latest, [22] which, anyway, provided specific exceptions. Although the ban did not require removal of asbestos that was already in place, the European Parliament resolution of 14 March 2013 on prospects for abolishing all existing asbestos, "calls on the Member States to move forward with the phasing-out of asbestos in the shortest possible timeframe" [23]. Anyway, since asbestos use continues in certain countries, due to the international market, imported materials that may contain asbestos could be potentially spread worldwide. About this we must consider Section 8 of REACH regulation which details the restriction on certain dangerous substances that pose an unacceptable risk to human health and the environment [24]. These restrictions limit or ban the manufacture, the placing on the EU market or the use of certain substances, preparations and articles. Restrictions apply to all manufacturers, importers, downstream users and distributors of a substance if the manufacture, use or placing on the market of this substance is included in REACH-Restrictions List (Annex XVII). The level of restriction can be divided into two main categories: restrict the use or existence in certain products or restrict all uses (i.e. totally prohibited), such as asbestos.

Since the results of first pioneering medical studies (in the early 1900s), a long time has passed since asbestos-related cancers became better recognized and an even longer one to formulate provisions and regulations. Even allowing for the long latency of asbestos-related diseases, it seems that there was plenty of advance warning of the dangers. It was said that the political deliberations were strongly influenced by lobby groups but it's also true that the possible loss of jobs in the industry was also a strong argument [25]. Whatever were the causes to this slow spring into action, it is evident that the result of this waiting has been a human and financial burden; with not calculable costs in terms of suffering and that earlier actions would have saved many of these costs. Asbestos offers a lesson that is relevant to numerous other agents that could have long-term hazardous impacts.

## Endocrine Disrupting Compounds (EDCs): An Emerging Issue

Bio-persistent xenobiotic (man-made) organic micro pollutants are today ubiquitous in the environment (air, water, soil, and biota). Among other xenobiotic persistent chemicals continuously released in the water-soil compartments, endocrine disrupting compounds (EDCs) are able to interfere in various ways with hormonal functions of animals and humans causing numerous problems, therefore there is a raising concern on their potential impact [26].

EDCs related issues came to light only with recent advancements in chemical analysis at trace levels based on modern analytical techniques, allowing for the effective detection of micro pollutants at trace levels ( $\mu\text{g}$ ,  $\text{ng}$  or lower) [27]. Despite the extensive data on potential hazards of xenobiotic compounds released in the environment, the effects

of EDCs on wildlife and humans are still not fully understood. The increasing number of new preparations commercialized on yearly basis, the lacking knowledge on fate and transport phenomena, the long term (chronic) effects related to continuous low-level exposure, the simultaneous presence of low level compounds that may lead to an increase of the environmentally available dose with possible synergistic effects, are all factors that may lead to underestimate the potential hazard from these xenobiotic persistent substances.

There is a vast number of compounds already known as EDCs, which show very different molecular structures but possess a common disrupting mechanism of action onto the endocrine system. Since EDCs represent a broad class of compounds, therefore, it is more convenient to cluster them into three main groups: pharmaceuticals, personal care products and pesticides, which possess similar chemical structure and show comparable features and performance.

As previously mentioned, on December 2006 the European Parliament approved REACH regulation, this EC Regulation entered into force on 1 June 2007 and replaced over 40 already existing directives and regulations. The rationale behind this change was to create a single and more effective system applicable to all chemicals which was needed since "the previous system often proved itself to be incapable of identifying risks posed by many chemicals and was slow to act when risks were identified", as clearly stated on the official website of the European Union [28]. This Regulation is the result of a wide-ranging fundamental overhaul of EU chemical control legislation based on the protection of human health and the environment, which aims to improve the knowledge of the hazards and risks associated with existing and new chemicals. Compared to the previous legislation, it introduces an important new feature: the reversal of the burden of proof, which places on chemicals manufacturers and importers the obligation to ensure and demonstrate the safety of chemicals produced and/or marketed. Thus, in compliance with REACH there must be a registration process of "old" and "new" chemicals which is made following a process of sharing and generating information, before the supply to the European market. This complex legislation is very strict into the regulation of chemical substances but, since at the same time wants "to maintain and strengthen the competitiveness and innovative capacity of European chemical industry" therefore provides a phased implementation over a decade with various deadlines for registration determined by volume and hazard of compounds [28].

On 16 July 2014 was elaborated a paper presented to the Competent Authorities for REACH and CLP (Classification, Labelling and Packaging) regulations containing the EU executive's final conclusion on authorisation and safe thresholds of EDCs. European Commission decided to evaluate applications for "authorisation" (under REACH) of EDCs on a case-by-case basis, and recognized that safe threshold levels can exist [29].

Substances of Very High Concern (SVHCs) are defined as substances that may have serious and often irreversible effects on human health and the environment. As foreseen by REACH, a specific procedure will be followed to decide when the substances should be included in the list of substances subject to authorisation (Annex XIV of the REACH Regulation). The steps of the authorisation procedure include the identification of a substance as an SVHC, the inclusion in the Candidate List of Substances of Very High Concern and, finally, the eventual inclusion in the Authorisation List. The Candidate List (updated at 16 June 2014) contains 155 substances.

The REACH regulation (Title X) has also established the European Chemicals Agency (ECHA) in order to manage and implement the

technical, scientific and administrative aspects of the regulation. REACH allows companies to submit an application to ECHA requesting an authorisation for specified uses the SVHC substance (on its own, in preparations and articles), included in the Authorisation List (Annex XIV of REACH).

## Conclusion

The rapid industrial, technological and economic development in Europe and in the rest of the world, has created numerous benefits, although unfortunately it has brought not only wealth and opportunity but moreover a strong impact on society, ecosystems and environment. A greater interdependence among technological and global progress, demographic growth, and economic advancement has contributed to increase the complexity of the factors that can affect human health and represent a threat to our environment. Managing this complexity is a challenge that not only EU but the whole world has to face.

The race to innovate and the need for speed which characterize modern world also promoted the development and progress of science in such a way that more data, more information and more knowledge are available. Anyway, science has limitations in dealing with the complexity of the real world since this increasing complexity has resulted in more intangibles and less predictability. Therefore, even if the understanding of environmental and health risks has advanced greatly, still large uncertainties remain of possible dangerous impacts of novel technologies and substances.

The necessity of strong evidence of risk before implementing preventive action required by policy-makers, often resulted in unreasonable lengths of time before a decision and thus a preventive action was taken. There are some past cases when this waiting for a convincing proof of harm was too long and has resulted in irreparable mistakes, such as those related to asbestos. The waiting for definitive evidence has come at a high price, not only because of the financial costs but also for the costs in terms of human lives, without considering the irremediable chains of events which have led to enormous long-term social, economic and environmental repercussions in terms of health damage.

In order to ensure the benefits of progress not precluding present and future generations an adequate standard of living together with a clean and healthy environment the European Commission published a White Paper called "Together for Health". Since health is recognized as "a value in itself and a precondition for economic prosperity" and thus "needs to be supported by effective policies and actions in Member States, at EC level and at global level", a first and comprehensive EU strategy called "Together for health" was adopted in 2007, in order to set out a coherent framework and to give direction to Community activities in health. This White Paper is part of the EU's growth strategy for the coming decade which is called "Europe 2020". This EU strategy sets several ambitious objectives to be reached by 2020, underpinned by concrete actions at EU and national levels.

The future of EU environmental policy relies on the 7th Environment Action Programme (EAP) which entered into force in January 2014 and will guide European environment policy until 2020. This program identifies several priority key objectives for the EU: healthy people ("safeguard the Union's citizens from environment-related pressures and risks to health and wellbeing"), healthy environment ("protect, conserve and enhance Union's natural capital"), more sustainability and prosperity ("turn the Union into a resource-efficient, green, and competitive low-carbon economy"). In order to deliver on these goals a better implementation of legislation, better information by improving

the knowledge base, more and wiser investment for environment and climate policy, and full integration of environmental requirements and considerations into other policies are foreseen.

But EAP goes further 2020, since it also has a vision of the EU by 2050 which includes "an innovative, circular economy where nothing is wasted and where natural resources are managed sustainably, and biodiversity is protected, valued and restored in ways that enhance our society's resilience" and images that the "low-carbon growth has long been decoupled from resource use, setting the pace for a safe and sustainable global society."

It is now up to the EU institutions and the Member States to ensure it is implemented, and that priority objectives set out are met by 2020.

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