# Ethics and Chemical Regulation: The Case of REACH

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**Abstract**: In this paper I look at the way the Precautionary Principle shaped the rise of REACH, and how it is still exerting a directive and dynamic influence on the development and the evolution of this new European chemical regulation. In it I also query the extent to which REACH actually implements such an ethical principle, and I outline significant challenges that remain to be addressed for making ethical decision-making stronger in such regulation. The case of REACH is thus used in order to reflect upon the relationships between ethical considerations and chemistry.

**Keywords**: *REACH, precautionary principle, chemical hazards and risks, uncertainty, regulation*.

## 1. Introduction

The use of chemicals has been increasing, mainly due to the economic development in various sectors including industry, agriculture, food processing and distribution, drugs, cosmetics, and transport (Pollak 2011). As a consequence, people are exposed to a large number of chemicals of natural and human-made origins. The trouble is that chemicals may have unintended and harmful effects both on human health and the environment. They may have immediate, acute effects, as well as chronic long term consequences.[1] Chronic, low-level exposure to various chemicals may result in a number of adverse outcomes, including damage to the nervous and immune systems, impairment of reproductive function and development, cancers, and organ-specific damages. In addition, environmental emissions arising from the use of chemicals vary in impact, depending on both the properties of the chemical at stake and the purposes and methods of its use.

The hazards associated with a chemical depend on its nature, the other chemicals with which it is mixed, and its relative proportion in the case of a mixture or a solution. Furthermore, the effects of exposure to a chemical are

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dependent on many factors. First, the amount of the particular chemical being present inside the body: the dose of a chemical that a person receives is dependent on the concentration of the chemical and on the frequency and duration of the exposure. Second, the type of exposure: the way the hazardous chemical enters the body determines how the material may travel through the body and affects organs or systems.[2] Third, the effect depends upon the physical and chemical interactions developed between the chemical and the body. Last but not least, the susceptibility of the individual receiving the dose: each person's body will react differently upon exposure – exposure to a hazardous material may affect one person more than others. In most situations, relatively safe chemicals may become toxic if the dose is high enough, and even potent, whereas highly toxic chemicals may be used safely if exposure is kept low enough. All chemicals are thus toxic at some dose and may produce harm if the exposure is sufficient, but all chemicals produce their harm under prescribed conditions of dose or use. The actual health risk of a chemical is thus a function of the toxicity of the chemical, and of the actual dose (or exposure) someone has to that chemical.

The 'regulation' of chemicals is the legislative intent of a variety of national laws and international initiatives such as agreements, strategies, or conventions. These international initiatives define the policy of further regulations to be implemented locally as well as exposure or emission limits. For instance, the Strategic Approach to International Chemicals Management (SAICM)[3] was adopted at the International Conference on Chemicals Management, which took place in February 2006 in Dubai, gathering state governments and intergovernmental and non-governmental organizations. This regulation defines a policy framework which covers risk assessments of chemicals and harmonized labeling up to tackling obsolete and stockpiled products. Another recent international chemical regulation, namely the Globally Harmonized System of Classification and Labelling of Chemicals (GHS),[4] proposes harmonized hazard communication elements, including labels and safety data sheets. It was adopted by the United Nations Economic Commission for Europe in 2002. This system aims to ensure a better protection of human health and the environment during the handling of chemicals, including their transportation and use. The classification of chemicals is based on their hazard. While governments, regional institutions, and international organizations are the primary audiences for the GHS, it also contains sufficient context and guidance for those in industry who will ultimately implement the requirements which have been adopted.

Concerning regional regulations, I could refer, for instance, to the US Toxic Substances Control Act (TSCA) of 1976 which shaped the mandate of the Environmental Protection Agency (EPA) to protect the public from unreasonable risk of injury to health or the environment by regulating the

manufacture and sale of chemicals.[5] This act does not address waste produced as byproducts of manufacturing, as did the Clean Water and Air Acts before it. Instead, TSCA attempts to exert direct government control over which types of chemicals could, or could not, be used in actual use and production. This regulation does not require chemical companies to perform risk assessments on new chemicals. By contrast, the new European chemical regulation, namely the 'REACH Regulation' – an acronym that I will clarify below – requires chemical companies that produce at or above the level of 1 metric ton per year to conduct a risk assessment, and demands the conduct of chemical safety assessments for *all* the chemicals produced from the companies that produce more than 10 tons or more per year. Requiring companies to propose risk assessments corresponds to an *unprecedented* type of policy for chemical regulation. This new policy has only been developed within the framework of the European Union hitherto, and reaches its culmination within the context of REACH. Indeed, the EU is the sole large region where something called the 'Precautionary Principle' (PP) is implemented and controlled by case law.

In this paper, I look into the way this ethical principle shaped the rise of REACH, and how it is still exerting a directive and dynamic influence on the development and the evolution of this new European chemical regulation. I also query the extent to which REACH *actually* implements such an ethical principle. In brief, the REACH legislation is the case study analyzed here in order to reflect upon the relationships between ethical considerations and chemical regulation, and especially how ethics is involved and plays a role in this kind of regulation.

To do so, I first scrutinize chemical hazards and risks and highlight the ethical problems they raise. I then introduce the different types of environmental chemical policies that have existed so far while identifying their basic assumptions concerning nature, science, and the relationships between humankind and nature. Third, I narrate the historical developments of: (1) the integration of the Precautionary Principle in European environmental law; and (2) its consequences not only over the European chemical regulation implemented before REACH, but also over the emergence of the REACH regulation itself. Fourth, I introduce the basic characteristics of REACH before discussing, in the last part of this paper, how REACH implements and differs from the Precautionary Principle. In doing so, I shall outline significant challenges that remain to be addressed for making ethical decision-making stronger in such regulation.

## 2. Ethical Implications of Chemical Hazards and Risks

Chemical hazards and risks are central when addressing the ethical issues in chemistry. The word 'risk' nevertheless encompasses different meanings depending on the context of its use. Most definitions of risk are based on a probability calculation. According to decision theory – the theory of rational decision making – a decision is said to be made 'under risk' if the relevant probabilities are available and 'under uncertainty' if they are unavailable or only partially available, *i.e.*, expressed with probability intervals, as it is the case, for instance, when a meteorologist says: 'the probability of rain today is between 0.5 and 0.7' (Peterson 2009). The EU regulation of food safety defines risk as a function of the probability of an adverse health effect and weighted by the severity of that effect (European Council 2002). Risk can also be defined by the stochastic nature of the consequences of an action,[6] with the stochastic range being expressed around a central value, whenever a random variable intervenes. By contrast, the ordinary meaning is 'danger', 'possible damage' or 'threat of disaster', and comprises no explicit consideration of probabilities.

In this paper, I shall use the word 'risk' in its legal sense, the one that corresponds to the legal definition proposed by the European Agency for Safety and Health at Work in the framework of the Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents. The objective of this Directive is to lay down minimum requirements for the protection of workers from risk to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving 'chemical agents'. The article 2 of this Directive provides many definitions closely related to REACH Regulation:[7]

> 'Chemical agent' means any chemical element or compound, on its own or admixed, as it occurs in the natural state or as produced, used or released, including release as waste, by any work activity, whether or not produced intentionally and whether or not placed on the market.
>
> 'Hazard' means the intrinsic property of a chemical agent with the potential to cause harm.
>
> 'Risk' means the likelihood that the potential for harm will be attained under the conditions of use and/or exposure.

According to this Directive, hazard is thus defined as an 'intrinsic' property of a chemical agent whereas risk is a relational notion related to the probability that the potential for harm will be attained *under the conditions of use and/or exposure*. In fact, risk is the *probability* that the exposure level is higher than the minimum level of toxicity.

In practice, most chemicals have not been duly tested for their environmental and health impacts beyond light toxicity tests. The 'unknown' is not only a feature of new molecules or materials recently invented by chemistry; it is the most common feature of chemicals that have been disseminated for several decades in the atmosphere, in water, and in the soil. As a matter of fact, chemical bodies are context-sensitive, and the ways in which they act upon the world always depend on the physical and chemical context in which they are. It is impossible for a chemist to give an *exhaustive* description of the chemical character and future behavior of chemicals. No one could have been able to predict that chlorofluorocarbons (CFCs),[8] such as chlorodifluoromethane, could cause ozone depletion from the basic knowledge of its composition, structure, and from what chemists already know about the chemical reactions involving this kind of substance.

I do not mean, of course, that it is impossible for chemists to describe chemical bodies using their composition and their internal structure only, as if they were in isolation. This strategy is often a very efficient way to produce new chemicals, or to explain a certain type of reactivity within a chemical reaction. I know how hard toxicologists and ecotoxicologists are working for setting up new methods to determine the toxicity of a mixture of chemicals. I am also aware that risk assessment of chemicals is a complex task which involves multidisciplinary teams, and that any model, as well as any biological test, is limited by its applicability domain, *i.e.*, can only answer the questions that have been asked. But the composition and the internal structure of a substance can change depending on what surrounds it, as it has been known for a long time by chemists in the case, for instance, of acid or oxidative properties, and as it is more than ever the case in nanochemistry. Chemical molecules and materials also need to be defined by their selective capacity to interact with one another within a precise context. As a consequence, the knowledge we have about them can only be open and provisional (Llored & Sarrade 2016). The philosopher of chemistry Joachim Schummer draws our attention to the fact that science does not create knowledge only; it also transforms the world and produces 'the unknown':

> [w]ith every production of a new substance, the scope of non-knowledge increases tremendously, by the number of undetermined properties of the new substance as well as by all chemical reactivities of the already existing substances with the new one. [Schummer 2001, p. 110]

Following this line of reasoning, Godard adds:

> New substances introduce new properties that are difficult to anticipate, with possible consequences that are difficult to fully comprehend […]. Due to the massive number of new chemical substances that are being introduced into ecosystems, this creative process entails an increasing unpredictability of environmental changes. The creation of a new substance and putting it on the

> market generate a new unpredictable potential for harming the environment and public health, increasing the difficulties associated with the control of these harms. This is a legitimate source of concern: *Chemistry is a major factor in making our world unpredictable*. [Godard 2013, p. 87, my emphasis]

As a discipline, *chemistry is a permanent source of new unknowns*, which justifies our paying special attention to the risks it potentially raises for us, and for other forms of life. The chemists Paul Anastas and Tracy Williamson assert:

> With knowledge comes the burden of responsibility. Chemists do not have the luxury of ignorance and cannot turn a blind eye to the effects of the science in which we are engaged. Because we are able to develop new chemistries that are more benign, we are obligated to do so. [Anastas & Williamson 1996, p. 1]

Anastas and Williamson put emphasis on the ethical commitment to which chemists cannot but subscribe. In the same vein, Schummer adds:

> it is very likely that any new substance can be used to cause harm. Thus, we may expect that our chemist, while being unable to foresee the particular case of harm, knows well about the high probability of possible harm. Therefore, the knowledge argument turns to the contrary and does not help to excuse our chemist. (Schummer 2001, p. 112)

The incompleteness of our knowledge about chemicals and the actual possibility for chemists to produce a safer and greener chemistry thus engage the whole community of chemists from an ethical standpoint. Before studying the REACH Regulation, I would like to introduce the three kinds of chemical policies which have been proposed so far.

## 3. Kinds of Environmental Policies and their Basic Assumptions

For over a century industrial societies have considered nature to be both a rich reserve of resources and a dump for the waste produced by resource exploitation. Nature would always be able to eliminate production and consumption residues. In other words, the possibility of eventual regeneration has always been assumed. However, as Kleindorfer & Kunreuther (1987), Ruthenberg (2016), Fjelland (2016), and Eckerman & Børsen (2018), to quote but a few authors, have pointed it out, several human tragedies and environmental disasters – as for instance in the late 1950s and early 1960s in West Germany with thalidomide,[9] in Seveso (10 July 1976),[10] or in Bhopal (3

December 1984)[11] – have illustrated that nature, and human health, cannot be represented as 'something' able to endure unbridled developments.

In response to this situation, three main policies for environmental protection have been successively proposed. Each of them depends on particular representations of what nature and science are; representations which, in turn, underpin the ways in which humankind *ought to* or *must* behave with respect to nature (de Sadeler 2002). In fact, the process which leads from one kind of policy to another could be termed 'superposition' rather than 'succession', since the stabilization of a new kind of policy does not necessarily imply the elimination of previous ones.

## 3.1 Curative environmental policy

According to the 'curative kind' of policy, nature can no longer cure itself: it should be helped to repair the damage inflicted upon it. Following this perspective, what has been polluted *can* be cleaned up; what has been destroyed *can* be restored; and what cannot be safeguarded *can* be replaced, be it by natural processes or through human intervention. Everything occurs *as if* the situation were totally under human control. Moreover, and for reasons of equity and feasibility, public authorities ought to apportion the economic cost of such intervention by requiring polluters to pay the cost of cleaning up after pollution and destruction. The 'polluter-pays principle' thus creates the economic conditions for reparation (de Sadeler 2002). This policy nevertheless implies *a posteriori responses* to a social problem: knowing that assigning clean-up costs to liable parties can become highly problematic, especially when environmental effects become too diffuse or reparation proves too costly, as is often the case with chemicals.

## 3.2. Preventive environmental policy

The situation changes from a curative to a 'preventive type' of policy as soon as damages become *irreversible*, such that reparation is simply impossible. This schema rests on the idea that science can determine with *certainty and precision* what level of damage will compromise the restoration of ecosystems and their species. But we can only prevent what we understand; it is difficult to prevent a problem that is not understood, and even more difficult to prevent the unknown, which is very often caused by the release of chemicals into the environment as we have previously pointed it out. As a consequence, a preventive policy assumes that science is able to find a precise solution to any kind of problem (de Sadeler 2002). This is the reason why prevention usually addresses *known risks* for which a full risk assessment, leading to quantitative estimates of exposure of various groups and estimates of expected damage, can be delivered. As such, prevention is highly demanding in terms of

knowledge and information but, being based on rather precise estimates, offers a rational basis for policies, for coverage by social security institutions and for the business of insurance companies (Godard 2013).

## 3.3 Anticipatory environmental policy

The situation changes again with the emergence of a new type of risk, *i.e.*, *potential risks* or *hypothetical hazards or threats*. The destructive effects of chemical substances, as for instance PCBs[12] and DDT[13] on life and CFCs on the ozone layer, could not be understood before these substances had been produced and released into the environment. *In this case, the relevant question is not about how to prevent assessable, calculable, and certain risks, but rather about how to anticipate risks suggested by uncertainty, plausibility, and probability*. Uncertainties can be related to different factors, including: (1) the geographical scope of the potential for damage (*e.g.* chemical pollutants in the marine environment); (2) the temporal duration of chemicals (low levels of chemical contaminants exert impacts which are difficult to detect in short-term laboratory tests, but which can show up in the next generation because of the persistence of chemicals in the environment); (3) the duration of its manifestation (*e.g.* the impact of greenhouse gases on climate); and (4) the reversibility or irreversibility of this manifestation (*e.g.* the ozone layer depletion). This new kind of risk is characterized by the difficulty of identifying and quantifying causal links between a multitude of potential hazards (such as various types of emissions) and specific adverse effects (for example desertification). At this stage, scientists are largely dependent upon analogies or computer simulations to assess suspected risks (Godard *et al.* 2002, de Sadeler 2002).

This is the context in which a new 'anticipatory environmental policy', based on the Precautionary Principle, is emerging. Such a principle is about collective, potential, uncertain, and hypothetical threats. Not only has damage not yet occurred, but there is no irrefutable proof that it will occur at all. Notwithstanding this situation, a key-idea is that *uncertainty should no longer delay the adoption of measures intended to anticipate environmental degradation*. Precaution serves to prevent delay under the pretext that the 'true nature' of risks is not known and will be *fully* determined later. Conversely, it serves to brake hasty action, by urging delay in executing projects whose risks are considered to be insufficiently well-identified. Reaching this goal requires a change in our perception of time: today's choices must also reflect a still uncertain future (de Sadeler 2002). Recourse to the Precautionary Principle is therefore justified by considering the long term effects despite and beyond the presence of uncertainty. The REACH regulation, as we shall see, belongs to this third category. This type of policy is new in the context of

chemical regulation, and seems to better address the specific situation of chemical hazards related to the 'unknown' implied by the release of chemicals into the environment. As Godard (2013, p. 87) states: "There is no better justification for submitting products derived from innovation in the field of chemistry to rigorous procedures of public control, and to place these procedures under the flag of the Precautionary Principle".

## 3.4 Precaution versus *phronēsis*

Notwithstanding the fact that this kind of policy is new, precaution and the PP are often considered to be just a contemporary form of prudence, synonymous with *phronēsis* in Aristotle's *Nicomachean Ethics* (Bourg & Schlegel 2001, Andorno 2004). But that is not the case. I claim that understanding their differences enables us to understand the specific ethical situation of our time. In his *Nicomachean Ethics*, and especially in the Sixth Book, Aristotle first deals with the knowledge of things whose originative causes are invariable – the principles of scientific knowledge, or *epistēmē* –, and focuses his attention on the fact that invariable causes can be replicated under similar circumstances, *i.e.*, satisfy the requirements of scientific stability and universality. He then points out how the knowledge that guides art and action differs from *epistēmē*. To do so, he refers to situations within which human beings have to make a decision when the causes are not stable and universal, but, are, by contrast, context-dependent and never fully known – as is typically the case with chemicals if we draw a parallel with our present study. Aristotle calls *phronēsis* the special type of wisdom relevant to practical decision of this kind (Dunne 1993, Birkholm 2016). This wisdom requires an ability to discern *how*, *when* – the opportune moment to act, *i.e.,* the *kairos* in Aristotle's terminology –, and *why* one may act despite the inderterminacy of the situation. *Phronēsis* is thus related to decision-making and action in cases of inderterminacy and uncertainty.

To better understand how *phronēsis* differs from precaution, we have to bear in mind the additional distinction drawn by Aristotle between *poiésis* and *praxis*. *Poiésis* encompasses art, technology, and the activity of production in the broadest sense of the term. It is related to the means we use in order to satisfy our needs and desires, independently of any moral reflection about the possible *bad* consequences that this use of means may have upon other people. To make this idea more concrete in the domain of chemistry, *poiésis* could be related to the production of chemicals in order to satisfy our need for transportation, independently of the consideration of the bad health impact of gasoline. That is the reason why, according to Aristotle, *poiésis* should be complemented with *praxis,* which is about the capacity we have, as human beings, to explore *with caution* not only ourselves, but also the city we

live in. *Praxis* is thus related to political action within a particular community, and *phronēsis* means to take care both of ourselves *and* the *polis* – the city state in ancient Greece.

By contrast, Precaution and the PP are not about ourselves and the city only: they are related to decision-making and action in order to take care of the Earth and Humankind understood as a universal interrelated whole. They are not only about us or our relatives, or about the cities or countries to which we belong. They are also about future generations, and the right they have to live in good conditions. This idea is well captured by Jonas' famous sentence (1984, p. 11): "Act so that the effects of your action are compatible with the permanence of genuine human life", and is clearly related to the decision we have to make considering the long term consequences of our actions upon the Earth. The objects both of precaution and the PP are humankind – present and future –, other forms of life and future ecosystems, and the Earth. They are global, and not local only. Following this line of reasoning, the aim of precaution, as we shall see in the EU context, is related to the defense of a sustainable development thanks to which humankind both *preserves nature and creates* '*new natures*', almost in the ancient sense of birth and growth of a being – *phusis* and *perì phuseôs* in ancient Greek.

Precaution and the PP involve collective agents such as States, institutions, and 'the public', and call for a *deliberative form of democracy* in which all stakeholders have *the same right* to take part in the decision-making about science and technology. Deliberations on science and technology involve a whole set of ethical values concerning humankind, the Earth, ecosystems, democracy, honesty in science, fair trade, animal suffering, human well-being, which co-exists with a pragmatic representation of science according to which uncertainty does not mean the defeat of science and truth, but does mean the opportunity for the sciences and technologies to articulate different kinds of expertise and interests. It is from within this growing network of ethical values that the third kind of policy has emerged. And it is also in this context that the PP has been integrated into the European legislation. Having grasped some crucial differences between prudence and precaution, I can now study how and why the gradual integration first of precautionary measures and then of the PP into the European legislation fosters the transition from the preventive to the anticipatory type of environmental policy in the EU context, and why the PP has become a crucial principle around which REACH revolves.

## 4. The Precautionary Principle in European Environmental Law and European Chemical Regulation before REACH

In 1972, The United Nations Conference on the Human Environment held in Stockholm, Sweden, defended the 'ALARA Principle' – the acronym means 'As Low As Reasonably Achievable'. This radiation safety principle is based on the minimization of radiation doses and aims to limit the release of radioactive materials into the environment.

In 1976, the government of West Germany published the paper 'Vorsorgende Umweltpolitik' with the view to framing German Environmental Policy in the long run. This paper paved the way for the anticipatory type of environmental policy. It referred to land degradation caused by acid rain, and called for *precautionary actions* for protecting and taking care of natural resources. It first defended the idea that *waiting for scientific certainty before undertaking preventive action is all but acceptable*. It also pleaded for a long-term, continuous, and adaptive approach to environmental measures. The basic idea was to remain opportunistic in the use of technological progress to drive an ecological modernization of industrial processes (von Moltke 1987).

In the 1980s, North Sea Conferences called for 'precautionary approaches'. The Precautionary *Principle* appeared, for the first time, in the field of marine pollution, for instance within the 1992 Helsinki Conventions on the Protection and Use of Transboundary Watercourses and International Lakes, and in another dedicated to the Protection of the Marine Environment of the Baltic Sea Area. In line with the German *Vorsorgeprinzip*, the contracting Parties of the Helsinki Conventions aimed to take preventive measures when there is reason to assume that a substance or energy introduced, directly or indirectly, into the marine environment may cause harm to human health and marine ecosystems, even when there is no conclusive evidence of a causal relationship between inputs and their alleged effects (article 3(2)). North Sea Conferences encompass preventive and anticipatory types of environmental measures, and constitute a step towards the implementation of the new anticipatory type of policy. In the same vein, and still in 1992, The Rio de Janeiro Earth Summit gave the Precautionary Principle a worldwide public audience while the writers of the Maastricht Treaty focused their attention both on this principle and on preventive actions.

In France, the 1995 Barnier Law for the strengthening of environmental protection defined the Precautionary Principle in the following terms:[14]

> Absence of certainty, taking account of current scientific and technical knowledge, should not lead to postponing the adoption of effective and proportionate measures aimed at averting the risk of serious and irreversible damage to the environment, at an economically acceptable cost.

This law, which clearly belongs to the anticipatory environmental policy, focused on the concepts of proportionality, coherence, and regular revision of measures, as well as on the need for public authorities to organize an independent, competent, multi-disciplinary, transparent, and adversarial expertise (Godard 2013).

In May 1998, the European Court of Justice issued a judgment on the 'Mad Cow Disease' case between the UK government and the Commission. The judgment stated that the authorities were right in taking health measures without waiting to have full scientific certainty about causal links and the extent of damage. This decision gave the Precautionary Principle an autonomous *legal force* in an area different from that of the environment, *i.e.*, food and health safety (European Court of Justice 1998). In this respect, it epitomized an 'anticipatory turn', which includes both environmental care and sanitary safety.

Two main texts have formalized and clarified this 'anticipatory turn', *i.e.*, the way the Precautionary Principle is understood and used at the European Union level: (1) the Communication presented by the Commission in February 2000, and (2) the Resolution adopted by European heads of state at the Nice Summit in December 2000.[15] This Resolution clearly states that *measures taken on the basis of the Precautionary Principle should be continuously re-examined in the light of the development of scientific knowledge*. To this end, follow-up of the effects of decisions should be implemented and further research should be carried out *to reduce the level of uncertainty*. According to Rogers (2011), five crucial points have to come into focus in order to understand how the EU gives sense to precautionary actions and implements the anticipatory environmental policy:

(1) The proportionality to the chosen level of protection;
(2) The non-discrimination of the procedure, in particular in regard to imported products;
(3) The consistency with similar measures previously taken for known risks, but taking account of scientific progress and change of concerns in the society;
(4) The choice of measures based on the consideration of the potential benefits and costs or various possible actions, including the no-action option; and
(5) The periodic review of measures in the light of new scientific results.

In addition, Klinke *et al.* (2006) emphasize three additional points in order to understand how the Precautionary Principle is understood and used in Europe:

(6) The principle is implemented within a *sustainable development perspective* in line with the Brundtland Report (World Commission on Environment and Development 1987);[16]
(7) Public authorities are responsible for organizing risk assessment, which should be conducted *independently* and *transparently* on a *multidisciplinary basis*; and
(8) Civil society should be implicated and particular attention should be paid to *consulting all interested parties at the earliest possible stage*.

We have now understood how the PP has been integrated into the EU legislation as an active open-ended process of decision-making, how it has been defined in this cultural context, what it contains in terms of aims, commitments, and ethical values, and in what types of purpose it takes part. The situation is now clearer on how and why the gradual implementation of the PP has fostered the transition from the preventive type of environmental policy to the anticipatory one. I can now briefly describe the European Chemical Regulation that was in force prior to REACH, and the role played by the Precautionary Principle in the implementation of this later regulation.

Recognizing the risk posed by persistent organic pollutants (POPs) to human health and the environment, the 2001 Stockholm Convention on POPs laid down a precautionary approach as its main objective:[17]

> Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants.

As a consequence, Precaution guided the listing procedure for new POPs. In addition, the 2001 London International Maritime Organization Convention on the Control of Harmful Anti-Fouling Systems on Ships, which prohibited the use of harmful organotins in anti-fouling paints used on ships, established a precautionary mechanism to prevent the potential future use of other harmful substances in anti-fouling systems (Heyvaert 1999). The sixth amendment to the Council Directive on the classification, packaging, and labeling of dangerous substances, which established an EU-wide notification procedure for substances introduced on the market since 1981, was intended to increase knowledge of the effects of substances and thereby to facilitate subsequent decision-making. Since 1982, producers and importers of new substances have been obliged to notify the competent national authority about, and provide full information on, any substance that has been introduced on the market. Moreover, the Seveso Directives already put the onus of continuously collecting and updating safety information on operators of dangerous industrial plants, leaving national public authorities with the role of assessing the performance of those private assessors (Fleurke & Somsen 2011).

Because procedures apply to new substances *only*, most chemicals have never been assessed in terms of their harmful effects on health and the environment (Bro-Rasmussen 1998). In order to fill the information gap concerning chemicals introduced on the market before 1981, the Council Regulation envisaged a system of evaluation and control of the risks posed by *existing substances*: any community importer or producer of an existing substance in quantities exceeding 1,000 t/year must submit data on the ecotoxicity and environmental fate and pathways of that chemical to the Commission. In June 1999, the Council nevertheless stated that, because risk assessments had only been drafted for a very small number of existing substances pursuant to EC legislation, and none had been adopted, the current approach is unlikely to achieve an appropriate limitation of all risks posed by these substances to health and the environment (Winter 2000).

To remedy this situation, the European Commission adopted, on 13 February 2001, a *White Paper* setting out the strategy for a future Union Policy for Chemicals (Rogers 2003). The main objective of the new strategy was to ensure a high level of protection for human health and the environment in the light of the Precautionary Principle, while ensuring the efficient functioning of the internal market and stimulating innovation and competitiveness in the chemical industry (Santillo *et al.* 2000). This *White Paper* then led to the REACH Regulation.

## 5. REACH Basic Characteristics

Following the Chemicals White Paper agenda, the REACH regulation entered into force in spring 2007 and will be gradually implemented until 2018, when approximately 30.000 substances are expected to have been included in the whole procedure. REACH targets chemical substances which have not previously been covered by existing regulations. The acronym of this regulation introduces new obligations and procedures aiming at registering (R), evaluating (E) and authorizing (A) – or restricting the production of, and even forbidding – chemical substances (CH). According to its website:[18]

> REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals.

Ethical and economic objectives are thus put forward and intertwined within this regulation; they follow the often called 'No data, no market' line.

Special attention is given to chemicals classified as carcinogenic, mutagenic or reprotoxic (CMR), and to POPs. A second central plank of REACH is the principle of substitution: if safer alternatives exist, certain dangerous substances – the 'Substances of Very High Concern' (SVHC) – must be phased out. Whereas previously chemicals could only be banned if proven to be dangerous, REACH requires EU industry and importers to prove that each substance intended for the market is safe for human health and the environment. This is what is sometimes referred to as 'reversal of the burden of proof'. Those objectives are included in the different steps of the procedure.

## 5.1 Registration

Registration concerns chemicals (substances and products) intended for the market, provided that their level of production exceeds one ton per year and producer. Many specific products are not registered under REACH. For instance, chemicals used in biocides, agriculture, and cosmetics are excluded from REACH, because they are covered by other legislation (Heyvaert 1999, 2008). Quantities below the threshold are exempted from the registration requirements, as are substances used for research and development only.

The information requirements depend on, and vary greatly with, tonnage level. The standard information that has to be submitted by each registrant consists in a 'technical dossier' made up of information pertaining to the identity, classification, intended use(s), produced or imported quantities, physical properties, and toxicological and ecotoxicological information of the substances. For substances produced or imported in quantities of more than 10 tons per year and producer, proponents should present a chemical safety report giving the results of toxicity tests and *defining appropriate management measures apt to guarantee a safe use*. For persistent, bio-accumulating and toxic (PBT) characteristics of substances and products, an exposure assessment and a risk characterization is required.

Registration is based on the 'one substance, one registration' principle. This means that manufacturers and importers of the same substance have to submit their registration *jointly*. The requirement to share information is a fundamental aspect of REACH. In so doing, registrants of the same substance can *reduce registration costs* and *avoid unnecessary testing, especially on vertebrate animals*. There are two mechanisms for data sharing: (1) substance information exchange forums used for existing substances that have been pre-registered; and (2) inquiries for new substances or existing ones that have not been pre-registered.

## 5.2 Evaluation

Evaluation is conducted by member states according to guidelines and criteria elaborated by the new European Chemical Agency (ECHA).[19] Evaluation comprises three different steps:

(1) *The compliance checking* during which ECHA examines any registration dossier to verify if the information submitted by registrants is compliant with the legal requirements.
(2) *The report evaluation* during which ECHA assesses the registrants' proposals concerning the animal tests they envisage in order to prevent unnecessary animal testing. To do so, ECHA invites third parties – *public* consultation – to submit scientifically valid information or studies addressing the substance and hazard endpoints in question on its website.
(3) *The substance evaluation*, undertaken by national competent authorities, on substances that have been prioritized for potential regulatory action because of concerns about their hazardous properties. Member States evaluate certain substances to clarify whether their use poses a risk to human health or the environment and request further information from the registrants to verify the suspected concern, if necessary.

In the case of a request for further information, registrants can comment on it within 30 days and update their dossiers with information relevant to the concern or fill the data gaps detailed within the draft decision. The evaluating Member State or ECHA re-examines the comments and updated dossiers and may amend the draft decision accordingly. The other Member States and ECHA, in the case of substance evaluation, then review the updated draft decision and the registrants' comments, and have 30 days to propose further amendments. This iterative procedure thus involves all the actors at the EU scale in order to increase the chance of making a good decision. As an illustration of the procedure, I refer to a document produced by ECHA in 2014 on octocrilene.[20] This substance, which is mainly used in cosmetics and personal care products, was suspected of causing long lasting harmful effects to aquatic life. The document was published so as to demand further research according to a precise methodological framework.

The selection of the substances to be assessed is the result of a preliminary identification made by Member states and ECHA. The list of these substances is used to define the Community Rolling Action Plan (CoRAP), which indicates substances for evaluation by the Member States in the next three years, and which is updated each year in March. It was set up for the first time in 2012, and the first decisions were given in the fall of 2013.

### 5.3 Authorization

Authorization of chemicals is based on evaluation. Depending on the level of danger and the quantities involved, a special authorization is needed. A key regulatory outcome of evaluation could be the imposition of restrictions on the manufacture, supply, or use of a substance. Substance evaluation may also lead to a substance being added to the priority list for authorization, or to a proposal to change the classification and labeling. Dangerous products are banned, unless it is demonstrated that the benefits for society are higher than the possible harm to public health and the environment, as long as no viable alternative exists. In that case authorization with restrictions in scope and time can be delivered. In the case of SVHC, for instance, the obligation rests with firms to furnish proof that risks posed by this category of substances are either 'adequately controlled', or to show a 'socio-economic need for their continued use'.

The final decision is made by the Commission, taking into account the opinion of ECHA. If risks are shown to be 'adequately controlled', then the Commission must grant authorization. If it is impossible to contain the risks fully, the Commission, involving the European Parliament and Council, may grant authorization, depending on the severity of the risk and the viability of alternatives.

The following Section discusses to what extent REACH implements the PP, and reflects upon how ethics and this regulation could be further and better related to one another by referring to the eight criteria of Section 4.

## 6. REACH and the Implementation of the Precautionary Principle

Article 1(3) of REACH clearly claims the application of the PP:[21]

> This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

Precautionary elements that indeed underpin REACH include: (a) providing a continuous supply of data; (b) risk assessments for substances used in certain volumes; (c) shifts in the burden of proof; (d) the requirement to search for safer alternatives; and (e) provision concerning review and monitoring. Those five points conform to the criteria 2, 3 and 5, and are compatible with the criteria 1 and 6 of Section 4.

Moreover, Annex I contains general guidelines for assessing substances and preparing chemical safety reports, and reflects the Precautionary Principle by insisting that information gaps be acknowledged, and that – in addition to scientifically established risks – 'potential effects' of substances have to be taken into account (criterion 3). A crucial point which remains in compliance with a precautionary approach is that authorizations are subject both to periodic review and conditions (criterion 5), including monitoring (Fleurke & Somsen 2011). The authorization list is also provisional and can be amended over time. Furthermore, the Commission eventually has the power to suspend the authorization pending the review. Nevertheless, it remains to be seen how compliance with criterion 1, related to proportionate measures, could be improved further within the evaluation step, and especially within the iterative procedure involving all the actors at the EU scale.

In addition, innovation, in the form of substituting hazardous chemicals by safer alternatives, is a crucial element of precautionary thinking in Europe, even if such a shift is costly and introduces heavy discrimination between industries, depending on their importance and domains of activity. The substitution requirement for substances that falls under the authorization procedure follows the Precautionary Principle objectives: REACH clearly states that the aim of REACH is to encourage, and in certain cases, to ensure that substances, technologies, and engineering processes of high concern are eventually replaced by less dangerous ones if suitable economically and technically viable and sustainable alternatives are available (criteria 4, 6).

However, while the 'safer alternatives option' is good in theory, it turns out to be much more difficult than was anticipated 10 years ago. For instance, all the efficient substitutes for brominated flame retardants have a similar risk of impacts. Unfortunately, the same technical properties often incur the same hazards. Thus, if REACH encourages chemists to search for safer alternatives, which is consistent with, if not a consequence of, its precautionary nature, the current results have to be discussed in a more balanced way.

In addition, making companies, which have a vested interest in marketing their products, responsible for producing the relevant risk data is a source of tension with the Precautionary Principle requirement to set up an independent and transparent expertise (Godards 2013). In this respect, the current form of REACH does not implement the PP fully, and additional improvements are necessary ethically speaking, and especially concerning the *full* respect of criterion 7.

Furthermore, stakeholders are not systematically involved in the different stages of registration, evaluation, and authorization; and the opportunity given to the public to comment on risk assessment and socio-economic analyses are not precisely articulated within the decision-making process (Hansen

*et al.* 2007). That is, once again, a source of tension with the PP, particularly with criterion 8, and calls for improving the debate between citizens and scientists, and for changing the way we consider science, public opinion, and their relationships. The issue may be, at least partly, resolved by education. Deliberative democracy is not a reality, but an aim that remains to be reached.

## 7. Concluding Remarks and Perspectives

REACH reinforces the weight of expertise in political decision-making. It also requires these two areas to interact so as to face the challenges posed by the compounded, serious, and irreversible risks they must assess and manage under *scientific uncertainty*. It can do so because of the PP integration into the EU law. Even if efforts still need to be made in order for REACH to better implement the PP, especially concerning compliance with criteria 1, 7 and 8, we should bear in mind that the 'Community Rolling Action Plan' is recent, and that the road will remain long and difficult: (1) to carry out the safer option, (2) to speed the whole procedure, and (3) to increase the number of substances taken into account by REACH. However, the regulation is a guide for action, mainly underpinned by the PP.

In addition, REACH enhances research in toxicology and ecotoxicology, and poses challenges to the existing frameworks for chemical safety evaluation. It calls for further studies about long-term effects and prolonged exposure at very low concentrations. To address this situation, researchers discuss alternative procedures using inherent characteristics of substances, and amplify factors of damage or determinants of scale in order to identify filters, thresholds, and screening conditions (Klinke *et al.* 2006). They also use Quantitative Structure-Activity Relationship models (QSAR models)[22] for assessing the bioaccumulation of chemicals.

The recourse to vertebrate animals for testing has gradually been reduced thanks to *in vitro* and *in silico* assays, which, despite the huge efforts that remain to be made in this area, is, in itself, a very positive outcome from an ethical standpoint. It enables us to avoid animal suffering and to protect life. Further new kinds of methods are emerging. The 'Integrated Testing Strategy' (IST) is a combination of test batteries covering relevant mechanistic steps and organized in a logical, hypothesis-driven decision scheme, which makes efficient use of generated data and gains comprehensive information for making decisions on hazards or risks (Ahlers *et al.* 2008). Another new approach, the 'Adverse Outcome Pathway' (AOP), links events at the molecular level to adverse outcomes at the biological level of organization rele-

vant to risk assessment (Ankley *et al.* 2010). In brief, the way we rationalize ecotoxicological assays is thoroughly changing. REACH is among the sources of this change because of the PP plea for a long-term, continuous, and adaptive approach to environmental measures. It demands to act in a proportionate, balanced, and pragmatic way before any disaster occurs.

Although REACH requires the protection of the environment, it does not clearly define what we should protect. The concept of environment is too loose and multifarious, and does not refer to a 'fixed reality', but, by contrast, to a 'time-evolving reality'. *This is the reason why, beside technical and scientific research, ethical reflection is necessary, and why it is so urgent*. There is an important need for interaction between society and science, such that *all citizens*, including scientists, define what they want to protect and how much they are willing to pay for it – weighing the costs of both use and non-use of a chemical/product – while science and technology offer solutions. It is also a matter for all citizens to define political, cultural, and economic priorities and values (Berthoud 2014).

In parallel with the growing role of the precautionary and anticipatory type of policy in chemical regulation, we are witnessing the ongoing recasting of the operational, symbolic, conceptual, technical, and normative frameworks of chemistry fostered and carried out by green chemists (Llored & Sarrade 2016). Sustainability and the Principle of Precaution are becoming the tenets of chemical innovation, especially in Europe. The widespread reference to eco-conception, waste recycling, and life cycle analysis, in publications is a clear indicator of this ethical trend in contemporary chemistry. It nevertheless remains to be seen whether such an ethical challenge could turn out to be compatible with an economic system based on consumption, competition, and individualism. This is one of the reasons why future chemists should keep their mind strongly open to ethics.

## Notes

[1] Acute toxicity results from a single, short exposure; the effects usually appear briefly and are often reversible. Chronic toxicity results from repeated exposure over a long period of time.

[2] Local injuries involve the area of the body in contact with the hazardous material; they are typically caused by reactive or corrosive chemicals, such as strong acids, alkalis, or oxidizing agents. Systemic injuries involve tissues or organs unrelated to, or removed from, the contact site when toxins have been transported through the bloodstream.

[3] A presentation of SAICM is available at http://www.saicm.org.

[4] Online available at http://www.unece.org/trans/danger/publi/ghs/ghs_rev05/05files_e.html; accessed 22 August 2017.

[5] A presentation of TSCA is available online at http://www.epa.gov/chemicals-under-tsca, accessed 22 August 2017.

[6] A stochastic event or system is one that is unpredictable due to the influence of a random variable.

[7] The text of REACH is available online at http://ec.europa.eu/environment/chemicals/reach/reach_en.htm, accessed 22 August 2017.

[8] Chlorofluorocarbon (CFC) is a group of compounds that contain only carbon, chlorine, and fluorine. The most common representative is dichlorodifluoromethane (Freon-12). Many CFCs have been widely used as refrigerants, propellants (in aerosol applications), and solvents.

[9] Thalidomide was originally introduced as a non-barbiturate hypnotic, but withdrawn from the market due to teratogenic effects. For more details, see Ruthenberg 2016.

[10] Strange skin diseases suddenly appeared on people's faces one Saturday in 1976. Nobody knew at first that the nearby chemical plant had exploded and released a cloud of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) (Kleindorfer & Kunreuther 1987, p. 5). The accident resulted in the creation of the European Community's Seveso Directive, called 'Seveso I', in June 1982, which was followed by the directive 'Seveso II', instructing common guidelines for the chemical industry and giving new standards for safety and public insight.

[11] Union Carbide (India): between 3,000 and 10,000 people were killed and between 100,000 and 200,000 disabled, because of a gas leakage of methyl isocyanate used as an intermediate for the production of insecticides and herbicides. For more details, see Eckerman & Børsen 2018.

[12] PCBs (polychlorinated biphenyls) are human-made chemicals first produced in the late 1920s. They were used as cooling fluids in electrical equipment and machinery because of their durability and resistance to fire.

[13] DDT (dichlorodiphenyltrichloroethane) was developed as an insecticide in the 1940s, and was widely used during World War II to combat insect-borne diseases. For more details, see Børsen & Nielsen (2017).

[14] Law 95-101, article 1, my translation [available online at https://www.legifrance.gouv.fr/eli/loi/1995/2/2/ENVX9400049L/jo/texte, accessed August 23 2017].

[15] European Commission 2000, European Council 2000.

[16] A sustainable development is a development that meets the needs of the present without compromising the ability of future generations to meet their own needs. (World Commission on Environment and Development 1987).

[17] Article 1, p. 4 [online available at http://www.wipo.int/edocs/lexdocs/treaties/en/unep-pop/trt_unep_pop_2.pdf, accessed 22 August 2017].

[18] Quoted from https://echa.europa.eu/regulations/reach/understanding-reach, accessed 24 August 2017.

[19] See https://www.echa.europa.eu/regulations/reach, accessed 22 August 2017.

[20] 'Decision on substance evaluation pursuant to article 46(1) of regulation 46(1) of regulation NO 1907' [online availabe at: https://echa.europa.eu/documents/

10162/13628/corap_sev1_228-250-8_dec_final_public_2796_en.pdf/, accessed 22 August 2017].

[21] See http://www.reachonline.eu/REACH/EN/REACH_EN/article1.html.

[22] QSAR models relate physico-chemical properties or theoretical molecular descriptors of chemicals to a biological activity of the chemicals. They quantify a supposed relationship between chemical structures and biological activity in a data-set of chemicals.

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