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Ethics and Chemical Regulation: The Case of REACH

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Abstract:

In this paper, I investigate how the Precautionary Principle led to the creation of a European chemical regulation known as REACH and I demonstrate how the ethical principle continues to exert a direct and dynamic influence on the development and evolution of this new regulation. I query the extent to which REACH actually manages to implement the principle and outline significant challenges that remain in order for ethical decision-making strucutres to be streghtened. The case of REACH thus acts as a suitable study to reflect upon the relationship between ethical considerations and chemistry.

Key-words: REACH, Precautionary Principle, Chemical Hazards and Risks, Uncertainty, Regulation.

1. Introduction

The worldwide use of chemicals has increased dramatically in recent decades, driven mainly by increased economic development in various sectors including industry, agriculture, food processing and distribution, drugs, cosmetics, and transport (Pollak 2011). Consequently, people are exposed to a larger number of chemicals of both natural and man-made origins - leading to concerns regarding potential unintended and harmful effects both on human health and the environment. These unplanned effects may have immediate, acute, as well as severe 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, emissions arising from the use of such 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 not only on its specific composition, but also on the composition of other chemicals with which it is mixed and its relative proportion within such a mixture or solution. A number of other factors also complicate the determination of health risk. These include, firstly, 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; secondly, the type of exposure: the manner in which the hazardous chemical enters the body determines how the material may travel through the body and affects organs or systems [2]; thirdly, 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; and lastly, the effect depends upon the physical and chemical interactions developed between the chemical and the body. In many situations, if not most, relatively safe chemicals may become toxic or even deadly if the dose is high enough, whereas highly toxic chemicals may be used safely if exposure is kept relativly low. All chemicals are thus toxic at some level of dosage, and may produce harm if the exposure is sufficiently great. The actual health risk of a chemical is therfore a function of the toxicity of the chemical and of the actual dosage (or exposure) someone has of that chemical.

The `regulation' of chemicals refers to the legislative intent of national and international agreements, strategies, and conventions to define and standarize local policy regarding chemicals as well as to set exposure or emission limits. For example, the Strategic Approach to International Chemicals Management (SAICM) [3] was adopted at the International Conference on Chemicals Management, which took place in Dubai in February 2006 and gathered both state governments and intergovernmental and non-governmental organizations. The SAICM regulation defines a policy framework covering the risk assessments of chemicals and the harmonization of labeling practices, while also tackling issues regarding obsolete and stockpiled products. Another international chemical regulation - the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) [4] - which proposes harmonized hazard awareness indicators such as labels and safety data sheets, was adopted by the United Nations Economic Commission for Europe in 2002. This system aims to ensure for the better protection of human health and the environment during the handling of chemicals, including during their transportation and use. Chemicals are classified within the regulation based upon their potential hazard. While governments, regional institutions, and international organizations are the primary audiences for the GHS, the policy also contains sufficient context and guidance for industry leaders who will ultimately be implementing the requirements which have been adopted.
On a more specific regional context, 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]. The act does not address issues regarding waste produced as byproducts of chemical manufacturing, as did the Clean Water and Air Acts before it, but instead, attempts to exert direct governmental control over which types of chemicals could, or could not, be used in the actual use or production. Neither does the TSCA regulation require chemical companies to perform risk assessments on new chemicals. By contrast, the new European chemical regulation, called the `REACH Regulation' — an acronym that I will clarify in this paper — requires chemical companies that produce at or above a level of 1 metric ton per year to conduct a risk assessment, and demands for a chemical safety assessment to be carried out for *all* chemicals produced from companies that produce more than 10 tons per year. Requiring companies to propose risk assessments corresponds to an *unprecedented* type of policy regarding chemical regulation. The 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 the concept of the `Precautionary Principle' (PP) is implemented and controlled by case law.

In this paper, I propose to investigate the way this ethical principle has shaped the rise of REACH, and how it continues exerting a directive and dynamic influence on the development and the evolution of the new European chemical regulation. I shall also query the extent to which REACH *actually* implements the principle. In brief, the REACH legislation acts as a useful case study in order to reflect upon the relationship between ethical considerations and chemical regulation, and to investigate the type of role ethics plays within the development of such regulations.

I shall first scrutinize chemical hazards and risks in order to highlight the ethical problems they raise. I shall then introduce the different types of environmental chemical policies which have been implemented so far while identifying their basic assumptions concerning nature, science, and the relationships between humankind and nature. Third, I shall provide historical developments about: (1) the integration of the Precautionary Principle in European environmental law; and (2), its consequences not only over the European chemical regulation implemented prior to REACH, but also over the emergence of the REACH regulation itself. Fourth, I shall introduce the basic characteristics of REACH before discussing, in the final section 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 ethical issues within chemistry. The word `risk' encompasses different meanings depending on the context of use. Most definitions are based on 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. An example of such a decision being made using probability intervals is when a meteorologist says: “the probability of rain today is between 0.5 and 0.7” (Peterson 2009). The EU regulation on food law and food safety defines risk as a function of the probability of an adverse health effect and 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, 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, corresponding to the legal definition proposed by the European Agency for Safety and Health at Work in the framework of Directive 98/24/EC of April 7th 1998 regarding 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 the 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, a hazard is defined as an `intrinsic' property of a chemical agent whereas risk is a 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; but 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 act. 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 to set up new methods of determining the toxicity of a mixture of chemicals. I am also aware that the 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.*, it 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 of nanochemistry. Chemical molecules and materials also need to be defined by their selective capacity to interact with one another within a precise context. Consequently, the knowledge we have about them can only be partial 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, our insistence)

As a discipline, chemistry is a permanent source of new unknowns, which justifies our paying of 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 regarding chemicals and the actual possibility for chemists to produce a safer and greener chemistry thus engages 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 at the same time a dump for waste produced by resource exploitation, maintaing that 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 Ruthenberg (2016) and Fjelland (2016) have pointed out in the first series of papers published within this special issue on ethical case studies of chemistry, several human tragedies and environmental disasters have begun to highlight to us that nature, and human health, cannot be represented as `some thing' capabable of enduring unbridled developments. Incidents 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 shown otherwised.

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 assisted in the reparation of 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 feasability, 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 and can often lead to problems assigning clean-up costs to liable parties, especially when

environmental effects become widely diffused 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*. The situation no longer remains under human control. 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. However, 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 out. Therfore, 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. Anticipating environmental policy

The situation changes 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 it is the case for PCBs [12] and DDT [13] on biological life or for CFCs on the ozone layer, to quote but a few examples, could not be understood until these substances have 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, among them are: (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 manisfestation (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 insufficiently 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".

Notwithstanding the fact that this kind of policy is new, Precaution and the PP are very often considered to be just a contemporary form of 'prudence': this word being synonymous with *Phronēsis* in Aristotle's *Nicomachean Ethics* (Bourg & Schlegel 2001, Andorno 2004). However, this 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 causes are not stable or 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 case 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 from 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 from 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's 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, and 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 meaning "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. The paper paved the way for an anticipatory type of environmental policy and referred to land degradation caused by acid rain, calling for *precautionary actions* to protect and take 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 within the 1992 Helsinki Conventions on the Protection and Use of Transboundary Watercourses and International Lakes, and in another agreement 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 where there is reason to assume that a substance or energy introduced, directly or indirectly, into the marine environment may cause

harm to human health or 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 anticipating types of environmental measures, and constitute a step towards the implementation of the new anticipating 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:

> 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. (Law 95-101, article 1, our translation, [14])

This law, which clearly only belongs to 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 produced a judgment in relation to 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 `anticipating turn', which includes both environmental care and sanitary safety.

Two main texts have formalized and clarified this `anticipating 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 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 anticipating 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, while taking into account scientific progress and a society's change of concerns; (4) the choice of measures based on the consideration of potential benefits and costs of 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 (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 anticipating 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: "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." (Article 1, [17]) 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 the other harmful substances in anti-fouling systems (Heyvaert 1999). The sixth amendment to the Council Directive on the classification, packaging, and labelling of dangerous substances, which established an EU-wide notification procedure for newly marketed substances, meaning

substances placed on the market since 1981, was intended to increase knowledge of the effects of substances and thereby 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).

As 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 quatities 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 since risk assessments had only been drafted for a very small number of existing substances pursuant to EC legislation on existing substances, and none had been adopted, maintaining the current approach was unlikely to tackle the problem of existing substances with the view to achieving an appropriate limitation of all risks posed by these substances to health and the environment (Winters 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 Chemical 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 that I propose to describe in the following part of my paper.

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; the date on which approximately 30.000 substances are expected to be 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).

We can read on the REACH website that: “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 immediately 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 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”. I would like to show how those objectives are included in the different steps of the process.

5.1 Registration

Registration concerns chemicals (substances and products) intended for the market, provided their level of production exceeds 1 tonne/year/producer; with the knowledge that a large number of specific products do not fall under under the realms of REACH. As a matter of fact, chemicals used in biocides, agriculture, and cosmetics are excluded from REACH, since they are covered by existing specific legislation (Heyvaert 1999, 2008). Quantities below this threshold of any specific substance are exempt from the registration requirements, as are substances used for research and development purposes only.

The information requirements depend on, and vary greatly with, tonnage level. The standard details 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 of more than 10 tonnes/year/producer,

proponents should present a chemical safety report providing the results of toxicity tests and *defining appropriate management measures apt to guarantee a safe use*. Concerning the persistent, bio-accumulating and toxic (PBT) characteristics of substances and products, the information required is reinforced by requesting an exposure assessment and a risk characterisation.

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) inquiry used 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) [18]. Evaluation comprises of 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 proposals made by the registrant 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 prioritised 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. The objective is to request further information from the registrants of the substance to verify the suspected concern, if necessary.

In the case of an autoritative request for further information, registrants can comment 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-examine 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 a further 30 days to propose further amendments. This iterative procedure thus involves all actors at the EU level in order to increase the probabilities of making the optimal decision. To understand how the procedure works, I ask our readers to refer to a document [19] produced in 2014 by ECHA, which concerns the case of Octocrilene. This substance, 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 and to set up the precise methodological framework in which the research should be carried out.

A final point to bear in mind is that the selection of the substances to be assessed is the result of a preliminary identification process undertaken 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, with the first decisions been finalised in the fall of 2013.

5.3. Authorization

The authorization of chemicals is based on evaluation, with a specfiic authorization being required depending on the level of danger and the quantities involved. A key regulatory outcome of the evaluation process could be the imposition of restrictions on the manufacture, supply or use of a substance. Evaluation may also lead to a substance being added to the priority list for authorization, or to a proposal for the substance’s classification or labelling to be changed. 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, where no viable alternative exists. In such a case, authorizations containing 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 solely by the commission, considering 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. Bearing all this information in mind, I can discuss to what extent REACH implements the PP, and reflect upon how ethics and this regulation could be further and better related to one another. To do so, I shall refer to the eight criteria previously identified (pp. 12-13).

6. REACH and the Implementation of the Precautionary Principle

Article 1(3) of REACH clearly claims the application of the PP [20]:

> 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 previolsy listed criteria numbers 2, 3 and 5, and are compatible with numbers 1 and 6.

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 must be taken into account (criteria 3). A crucial point which remains in compliance with a precautionary approach is that authorizations are subject both to periodic review and conditions (criteria 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 the compliance with criteria number 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 shape of the substitution of 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 fall under the authorization procedure follows the Precautionary Principle objectives: REACH clearly states that the aim of the regulation 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).

If the "safer alternatives option" seems good in theory, it turns out to be much more difficult than was anticipated 10 years ago. An example are the brominated flame retardants: all substitutes with as good efficiency as existing flame retardants also contain a similar risk of impact. Unfortunately, alternatives with similar technical properties often incur similar hazards. Therefore if REACH encourages chemists to search for safer alternatives, a fact which remains consistent with, if not a consequence of, its precautionary nature, the current results must be discussed in a more balanced way.

In addition, Godards (2013) underlines the point that the huge shift of responsibility for producing the relevant data on risks to business firms, that are directly interested in putting their products on the marketplace, is a source of tension with the Precautionary Principle's requirement to set up an independent and transparent expertise, away from the control vested interests. In this respect, the current form of REACH does not implement the PP fully, and additional improvements are necessary ethically speaking, especially concerning the *full* respect of criteria 7.

Furthermore, Hansen *et al.* (2007) regret that stakeholders are not systematically involved in the different stages of registration, evaluation, and authorization, and that the opportunity given to the public to comment on risk assessment and socio-economic analyses are not precisely articulated within the decision-making process; a situation, which, once again, is a source of tension with the PP, and especially with criteria 8. This situation is a plea for improving the debate between citizens and scientists, and for changing the way we consider science, public opinion, and their relationship. This question will be, at least partly, resolved, thanks to education. Deliberative democracy is not a reality, but an aim that remains to be reached.

7. Concluding remarks and perspectives

REACH reinforces the important role expertise plays within political decision-making, and establishes a platform for cooperation in the assessment and management of the compounded,

serious, and irreversible risks faced under *scientific uncertainty*. This is achieved by means of PP integration into the EU law. While efforts remain to be made in order for REACH to better implement the Precautionary Principle, especially concerning the compliance with criterias 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 in achieving improvements to: (1) carry out the safer option, (2) speed the whole procedure, and (3) increase the whole number of substances taken into consideration by REACH. Nevertheless, this regulation is a guide for action; a guide mainly underpinned by the PP.

In addition to the points already discussed in this paper, REACH enhances research in toxicology and ecotoxicology, and poses challenges to the existing frameworks for chemical safety evaluation. As a matter of fact, it calls for further studies about long-term effects and prolonged exposure at very low concentrations. To address this situation, researchers are discussing alternative procedures using inherent characteristics of substances, and amplifying 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, [21]) for, among many purposes, 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. As a matter of fact, it enables us to avoid animal suffering and to protect life. Moreover, new kinds of methods are emerging. The `Integrated Testing Strategy' (IST) can be described as combinations of test batteries covering relevant mechanistic steps and organized in a logical, hypothesis-driven decision scheme, which is required to make efficient use of generated data and to gain a comprehensive information basis for making decisions regarding hazard or risk (Ahlers *et al.* 2008). Another new framework, the `Adverse Outcome Pathway' (AOP), portrays existing knowledge concerning the link between a direct molecular intiating event and an adverse outcome at a biological level of organization relevant to risk assessment (Ankley *et al.* 2010). In brief, we are living through a thorough change in the way we rationalize ecotoxicological assays, and REACH is among the springs of this change due to the PP plea for a long-term, continuous, and adaptive approach to environmental measures. It is the consequence of the ethical demand to act in a proportionate, balanced, and pragmatic way before any disaster should occur.

However, while REACH demands the protection of the environment, it does not define what we really want to 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, an ethical reflection is necessary, and why it is so urgent*. We have an important opportunity for interaction between society and science; *all the citizens*, among them are scientists, defining what they want to protect and how much they are willing to pay for it — weighing the costs of either use or non-use of a chemical/product — while science and technology provide 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 played by 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 and the effects usually appear quickly 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: www.saicm.org.

[4] A presentation of GHS is available at: https://www.unece.org/fileadmin/DAM/trans/.../ghs/ghs.../ST-SG-AC10-30-Rev4e.pdf.

[5] A presentation of TSCA is available at: https://www.epa.gov/laws.../summary-toxic-substances-control-act.

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

[7] A presentation of REACH is available at https://osha.europa.eu/fr/legislation/directives.

[8] Chlorofluorocarbon (CFC) is an organic compound that contains 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] Primarily prescribed as a sedative or hypnotic, it was used against nausea to alleviate morning sickness in pregnant women. Shortly after the drug was sold in West Germany, between 5,000 and 7,000 infants were born with phocomelia (malformation of the limbs). Only 40% of these children survived.

[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 3,000 kilos of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD).

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] Dow Chemical (India): 20000 people killed and 200000 disabled persons because of the gaz of Methyl isocyanate used as a chemical intermediate for the production of insecticides and herbicides.
[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 — dichloro-diphenyl-trichloroethane — was developed as an insecticide in the 1940s, and was widely used during World War II to combat insect-borne diseases.
[14] The text of the Barnier law is available at: https://www.legifrance.gouv.fr.
[15] European Commission. *Communication on the Precautionary Principle*, Brussels, 2 February 2000. European Council. 'Resolution of the Council on the Precautionary Principle', in *Conclusions of the Presidency, Nice European Council*, Annex III, Nice, 7-9 December 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] The information is available at: www.pops.int/documents/convtext/convtext_en.pdf.
[18] The information is available at: https://www.echa.europa.eu/regulations/reach.
[19] The information is available at: https://echa.europa.eu/documents/10162/eb4c9d66-9639-4fa8-8441-207d5047332b.
[20] The information is available at: www.reachonline.eu/REACH/EN/REACH_EN/article1.html.
[21] 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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