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THE PRECAUTIONARY PRINCIPLE AND CHEMICAL RISKS

Olivier GODARD

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# The Precautionary Principle and chemical risks

Olivier Godard<sup>1</sup>

January 2012

## ABSTRACT

EU institutions (Commission, Council and Parliament) have adopted the EU doctrine of the Precautionary Principle (PP) in year 2000, whereas the EU is the sole huge region where something called the PP is implemented and controlled by case law. There is nevertheless a huge contrast between this doctrine and other views put forward by stakeholders, specially NGOs, and academic circles. For instance the PP is often confused with a Maximin approach or catastrophism, which are shown to be inconstant standards under uncertainty. Against this background, the links between the PP and the REACH regulation for chemical products are questioned. Beyond common features, it is shown that these normative constructs are no substitutes and that the PP should go on to inspire public action for chemical substances in conjunction with REACH.

## KEYWORDS:

Precautionary principle, Europe, risk management, chemicals, REACH

## JEL CLASSIFICATION:

D81; K32; L65

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The precautionary principle (PP) is a rather new standard of behaviour that public authorities may legitimately use –alternatively should use – when they face scientific uncertainty about possible damages in relation to environmental protection, public health or food safety. It developed as a policy and law concept over the last twenty-five years, mainly in Europe. A key date to this regard is 1992. First, it has been mentioned in the Maastricht Treaty as one of the basic principles governing environmental policy of the European Union. Second it has been given acknowledgement in the international arena under a watered-down format deprived of legal strength as a ‘precautionary approach’; it so became the Principle 15 of the Rio Declaration adopted in June by the Rio Summit.

Both the principle and the approach are relevant to address collective ‘potential risks’ or ‘hypothetical hazards or threats’. These expressions refer both to hazards, the existence of which is scientifically uncertain, being neither proven nor refuted, and to dangers for which, despite their known existence, there is no realistic way to establish credible<sup>2</sup> probabilities for the damage scenarios they may entail. The adjective ‘collective’ means that individual agents are not in a position to control these risks (see Box 1) or hazards by themselves, although they may have some margins to protect themselves against them. A typical case of ascertained collective risks affecting health is influenza. As such environmental risks are ‘collective’ by essence: think of dangerous alteration of the global climate or the depletion of stratospheric ozone.

By contrast ‘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. Scientific uncertainty does not offer the same easiness for precautionary action. This is the reason why, before the mid-eighties, ill-established hazards, dangers and threats were left to on-going research and put aside by safety policies. At the same time, scientific uncertainty is not easily tackled by the business insurance, so that exclusion by insurance companies has during the last decades reinforced the interest in precautionary measures aimed at limiting the chance of damage to crystallise.

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<sup>2</sup> For the readers concerned by the objective foundation of probabilities, let us say that the latter can only be reached either by logical or theoretical analysis, or by statistical observation of repeated events belonging to the same class.

In spite of a general agreement that scientific uncertainty delineates the field of relevance of the PP, very different competing interpretations of what the principle requires as a policy norm have coexisted from the very beginnings and still do today. Yet the European Union and member states have developed a doctrine and fixed it by year 2000 to specify what the PP meant for them and what was rebutted from their understanding. In spite of that, there is no other policy concept still raising so many misconceptions and misunderstandings than the PP: everybody feels legitimate to give the PP a personal content and scrutinize public management to denounce failure of governments to implement his or her own preferred PP. In spite of their divergence, most people refer to the PP, as if one and unique concept of PP was at stake and commonly understood. To this regard the biggest contrast can be found between the EU PP and a catastrophist approach to uncertain hazards. At the same time the logic of compromise at work behind EU statements and rules sometimes led the EU governance maintaining ambiguous wording or contradictory uses of concepts in relation to the implementation of the PP. This will be shown in the context of the REACH regulation addressing chemical hazards.

**Box 1: troubles with the word risk**

The word 'risk' means something different for various people. It has a meaning for insurance companies, such as flood risks or car accident risks. If risk is defined as "a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard", as in article 3 of EU regulation 78/2002 on food law and food safety (European Council, 2002), the expression 'potential risks' is not consistent, since it designates situations for which it is not possible to state an objectively and scientifically established probability. If risk is defined by the stochastic nature of the consequences of an action, with the stochastic range being expressed around a central value, the term 'potential risks' is also inappropriate, since it relates exclusively to the possibility of harm attributable to exposure to a danger. In fact usage and public debate have given a meaning to the word risk which is different from the neutral meaning in decision theory. Ordinary meaning is 'danger', 'possible damage' or 'threat of disaster' with no explicit consideration of probabilities. In this paper I will use the word risk in the most extensive meaning, encompassing both situations called risks and those called uncertainty by decision theory.

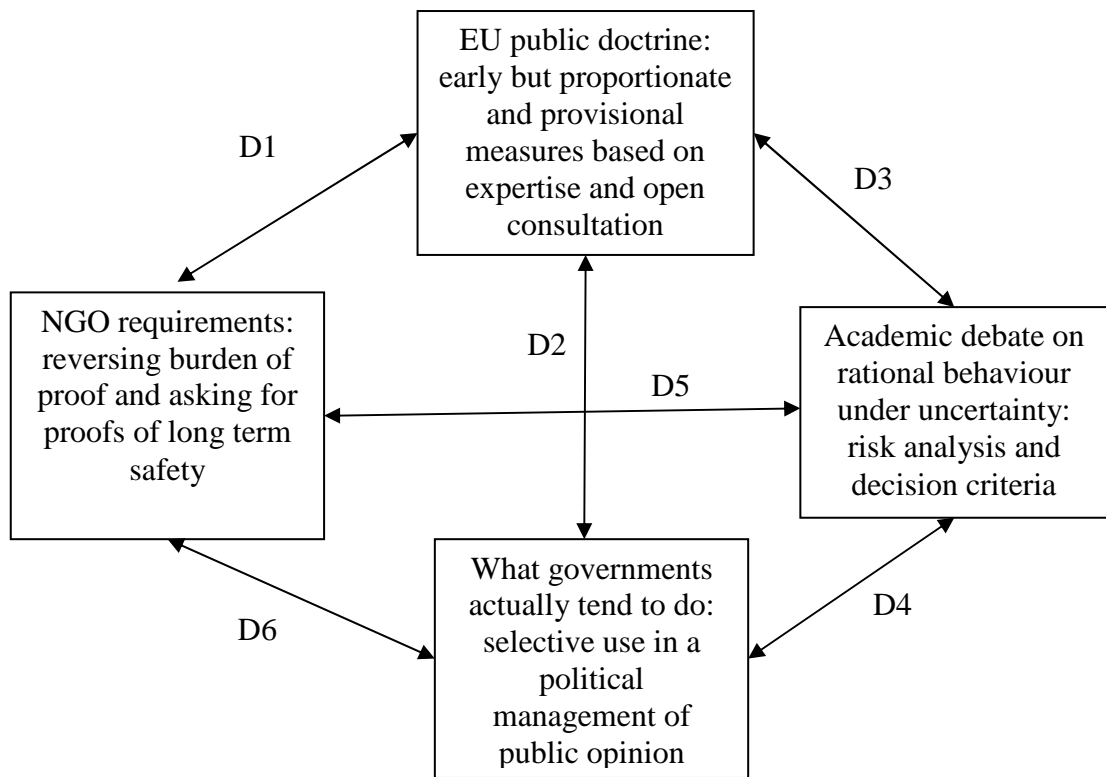
The first purpose of this paper is to introduce the fundamental doctrine of the PP adopted by EU institutions (Commission, Council and Parliament) in year 2000 since the EU is the sole huge region where something called the PP is implemented and controlled by case law. The second is to underline the contrast between this doctrine and other views put forward by stakeholders among NGOs, their companion researchers and some academic fellows. Then I will turn to chemical products, beginning with a question about what the specifics to chemistry may be in relation to science and risks. Eventually I will consider the REACH regulation and wonder to which extent it may be seen a sensible implementation of the PP.

## **1. Discrepancies between the PP as a policy norm, a concept of rational decision theory, and a negotiated political tool**

In the literature there is no agreement on what the specifics in the PP really are. On one side non-governmental organizations and their academic companions take strong positions on the PP as the main leverage to make ruptures with existing risk management and technological development modes but at the price of putting ahead often inconsistent or unreasonable requirements, as will be seen later. On the other side authors grounded in decision theory meet the highest difficulties to catch what the PP really brings as a social and legal norm. We then have to tackle several types of discrepancy between the following poles: first there is the public doctrine, adopted in legal texts and political statements, echoing institutional cultures shaped by history; second there is what activist NGOs ask for regarding risk management; third there is what governments actually do and fourth, there is the academic debate on the PP oriented by researches on rational behaviour under uncertainty.

Figure 1 shows the spread of discrepancies between the four poles identified. By order, the most significant are D1, contrasting the public doctrine and NGO requirements, D2, between the public doctrine and real-life public policies under the pressure –or absence of pressure– of social movements and public opinion, D3 between academic framing of concepts and the EU public doctrine, D5, between the academic recommendations on rational management and requirements of NGOs, and D4 between academic framing and real-life management by governments. It is clear that the discrepancy game turns differently according to the matters involved: GMOs, agricultural chemicals, BSE, climate change, nanotechnologies, etc.

**Figure 1:** mapping the discrepancies raised by the Precautionary principle



Let us give an example of D3. In his recent review articles Charles Vlek (2010a and b) places the examination of the PP in the context of search of a basic rational attitude for complex, ill-defined, uncertain and potentially catastrophic situations. He does not see substantive differences in problems for collective decision making and for individuals in their everyday lives (financial investment, medical treatment, road transport and challenging sports); no attention is either deserved to specific fields of concern, such as environmental and public health protection versus profit-making financial investment: the PP is seen by this author as relevant for every practical domain of action and is discussed as a general standard of rational decision-making, not as an original policy norm valuable for some fields.

This framing is problematic. It so happens that the dominant Bayesian theoretic framework does not admit conceptual distinctions between risk and uncertainty. According to Savage's argument (1954) all probabilities are subjective since they imply some confidence level on the information given by others (scientists, experts) or directly obtained through experience. This way any uncertain situation can be supposedly grasped within a subjective probabilistic framing. At the same time, it is

the decision-theorists' ambition to deliver relevant analyses of policy-making touching uncertain risks, as if policy-making were just an exercise of applied decision theory. Thus, for the academic viewpoint, the PP has difficulty to escape the alternative between either being highly disputable or intrinsically flawed, whenever it takes extreme forms of obligation of abstention before any potential risk (Sunstein, 2005), or rejoin standard criteria developed in probabilistic Bayesian theory. At best the PP is given a psychological foundation in particular attitudes of extremely prudent agents<sup>3</sup> for whom the prospect of getting better knowledge<sup>4</sup> in the future paradoxically induces an increase of immediate precautionary savings compared with a situation of no improvement of knowledge (Gollier, Jullien, Treich, 2000).

At the crossroads of academic literature and more policy-oriented reflection Vlek (2010a, p. 533) identifies three distinctive features of the PP: the inclination to take a pessimistic view of possible outcomes; the proponent's burden of demonstrating the likelihood of safety of new items; a tendency to delay risk-taking until sufficient new information becomes available. He concludes:

“the basic motive for being precautionary lies in the asymmetric presence of possible serious harm or damage vis-à-vis moderate expected benefits” (ibid, p. 535).

He then opposes the PP to the Venture principle (VP) involving uncertain highly attractive benefits with moderate risks of loss. The discussion is interesting, but does not wholly grasp what the PP really is for the EU public doctrine. The three features retained by Vlek are in fact not constitutive of the EU doctrine of the PP: the latter does not ask either to give systematically a premium to the consideration of potential bad outcomes or to reverse the burden of proof; the main idea is an early account of hypothetical risks, which cannot be confused with a systematic delay in risk-taking.

This case is just an example of a more general feature: unfortunately a huge part of academic decision-theoretical literature having the ambition to define and discuss the PP misses their target, or exacerbates peripheral

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<sup>3</sup> Formally the absolute prudence index should be at least twice as high as the index of absolute risk aversion ( $P \geq 2A$ ), knowing that the prudence index is assumed to be expressed by the ratio of the third derivative to the second derivative of the von Neumann-Morgenstern utility function. Note that these derivatives are not observable.

<sup>4</sup> This is the way these authors interpret scientific uncertainty: as a promise of better knowledge to-morrow than today; and the prospect of better knowledge is supposed to increase the uncertainty perceived *ex ante* by very prudent people.



aspects of the PP. This is not to say that they absolutely lack of relevance since they may bring fine arguments against such and such practice of the PP by the authorities or against such and such demand of business circles or NGOs.

The PP brings novelty in risk management but novelty does not lie in the fact that the PP would express a systematically more precautionous attitude, in the ordinary sense, than previous prevention policies for every aspect, for instance by increasing safety margins, focusing on worst-case, or letting decision absorbed by strong aversion to risk. The practical novelty of the PP is to put ill-known and uncertain hazards identified in the field of environmental protection and public health into the domain of public attention and action, especially in cases of threats of huge and irreversible damage.

It first implies a social value choice, considering that environmental protection and human health take precedence over economic profitability when conflicts arise. Secondly it rehabilitates the old (Knight, 1921; Keynes, 1921) distinction between uncertainty and risk, i.e. between hypothetical hazards stricken by uncertainty, which are not amenable to probabilistic calculations, and recognised risks amenable to probabilistic calculations and fitting to the standard concept of prevention. By essence, this distinction between prevention and precaution cannot be understood by Bayesian and Savage's approaches of risk<sup>5</sup>.

This breakthrough being made, the foremost ingredient of the PP is to ask for an early account of possible hazards in spite of scientific uncertainty: authorities should not wait for full scientific certainty and should not use uncertainty as a pretext to postpone measures addressing possible hazards. Thus the main innovation of the PP is to change the time schedule of policies in relation to risks in favour of an early account (Godard, 1997; European Environmental Agency, 2001). At the same time, informed ignorance, i.e. ignorance that remains after having mobilised existing sources of scientific information- or the simple postulated presupposition that "bad effects could happen" are not sufficient to mobilize the PP. This principle is concerned by the cognitive grey zone existing between ignorance about possible risks and well-known risks.

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<sup>5</sup> Economic approaches developed within a Bayesian framework are presented in Kast and Lapied (2004) and Gollier (2004).

## 2. The conceptual context

### *Scientific uncertainty*

Scientific uncertainty delineates the background to the PP. Ascertaining what scientific uncertainty really is raises difficulties of their own for risk managers. It should be confused neither with the when and where uncertainty of contingent events of day-to-day life, such as “when will the next flood touch New Orleans?”, nor with rough ignorance. Scientific uncertainty is not to be confused with a complete lack of information about possible outcomes of a technology but should be seen as a lack of conclusive scientific knowledge about laws, processes, mechanisms, or properties of specific natural phenomena, such as changes of behaviours of substances when they are organized at nanoscale or detrimental processes induced by non-conventional pathogens. Scientific uncertainty is not when you know nothing, but when what you know is not conclusive and remains at the stage of unresolved hypotheses and conjectures, although the latter have been formulated in accordance with standard scientific approaches and empirical observations.

With this background, scientific uncertainty may affect different points of risky situations. We may have uncertainty in the realization of harm: harm is then just a possibility which has been neither dismissed nor proven. We may also have uncertainty in the causes of a given phenomenon: damage to health or a detrimental process affecting the environment is observed, but we do not know for sure which causes it should be imputed to. Both types of uncertainty are derived from insufficient knowledge on the relationship between active causes (a technology, a substance...) and detrimental effects.

Scientific uncertainty constitutes a challenge not only for experts and managers, but also for the legitimacy of public action: welfare state and public action in Europe have been developed on the basis of a rational-legal model for which establishing objectivity of issues is a critical feature for enabling decision-makers to act according to the general interest and obtain confidence and support from public opinion. When facing uncertainty, individual agents may shape beliefs about probabilities of ill-defined events –a catastrophe?-, from a mixture of piecemeal information and personal attitudes and values. It may lead to the formation of subjective opinions regarding riskiness of situations. These psychological constructs are nonetheless deprived of direct relevance as a basis for reasonable public action, except by setting ultimate political limits of social acceptability under a democratic regime in contexts marked by high stakes and strong social controversies.

Indeed policy-making in democracies entails another requirement, that of justifying goals and actions before citizens with the help of diagnoses and arguments which can be shared with most of citizens. A symmetrical obligation to ascertain positions and proposals is addressed to the citizens who make various demands. So both governments and citizens have to justify actions and policies they propose, whereas respective arguments are open to discussion. In that context scientific expertise aims at reaching shared statements which approach objectivity and enlighten decision-making. At stake, the definition of a common world on the basis of which public deliberation may take a reasonable form beyond unavoidable trade-off between interests and between concerns.

Under scientific uncertainty the possibility of citizens to share an objectively determined common world is put in peril and public deliberation becomes difficult, controversial and inconclusive, unless there is an agreement throughout society on how to address hypothetical risks. This critical link between public decision making and objectivity explains the huge role of scientific expertise in public decision making in relation to risks for the environment and health. Unfortunately it is generally ignored by academic work belonging to decision theory due to its individualistic and subjective approach. For its advocates public decision-making only comes to finding appropriate procedures for aggregating consumers' individual preferences or defining how a public decision-maker can manage various sources of information and influences in order to maximize her own utility function (power, career, wealth, honours...).

Since under scientific uncertainty objective probabilistic formulations are not at hand, supplementary points of support have to be found to make reasonable decisions: this need sets the legitimacy of more extended procedures of public debate and dialogue with interested parties in parallel to scientific expertise and normative assessments produced by lawyers, economists and ethicists. With this three-ways approach, the PP clearly calls on a case by case reflection to elicit judgments on proportionate and provisional measures targeting potential dangers or uncertain threats.

### *The PP as a principle*

Principles are beings different from rules and criteria (Godard, 2010): various principles may coexist in spite of contradictory implications; they do not establish a complete order on a set of actions; they are compatible

with different criteria<sup>6</sup> –but not all-. For instance in spite of what is often said (Gardiner, 2006), the PP does not identify with a Maximin criterion. So the question is raised: why are principles useful? Their purpose is to provide a broad base for more precise rules and criteria valuable for particular circumstances; in doing so, they articulate agreed social values and legitimate forms of commitment into action in rather abstract terms. They establish a meaning that gives directions and clarifies existing or proposed institutional procedures. They are a reference point in a coordination process that must accommodate numerous transformations and wide empirical diversity. Eventually, they stimulate change in an existing normative system (de Sadeleer, 2003). Many criticisms addressed to the PP –being vague, unclear and not operational- in fact fault it for being a principle, and not a criterion, which is just nonsense.

### *A conceptual heritage*

Explicit formulation of a PP goes back to the German *Vorsorgeprinzip* in the 1970s. It then combined two main ideas: a) not waiting for the stage of scientific certainty on causal relationships involved before undertaking preventive action designed to limit or avoid environmental threats; b) committing to a long-term, continuous and adaptive approach to environmental measures, by being opportunistic in the use of technological progress to drive ecological modernization of industrial processes.

These two ideas have been somewhat separated by the following history. The second joined the stream of sustainable development, while the first emerged as the PP. Meanwhile both remain compatible and even complementary. As the 2000 Nice Resolution on the PP (see below) states, the PP has to be understood under the light of sustainable development.

In France the 1995 law 95-101 for the strengthening of environmental protection defined the PP in the following terms:

“Absence of certainty, taking account of current scientific and technical knowledge, should not lead to postpone 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”.

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; it then confirmed the PP in substance by reckoning that the

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<sup>6</sup> See Vlek (2010b) for a review of possible decision-making criteria to be used for the implementation of the PP.

authorities were justified in taking health measures without waiting to have full scientific certainty about causal links and the extent of damage. For the first time this decision gave the PP an autonomous legal force in an area other than that of the environment: food and health safety (European Court of Justice, 1998; Gonzalez Vaqué *et al.*, 1999).

Following a request from the European Council and an open consultation process with stakeholders, the Commission released a communication on the PP in February 2000. This key text expounded the doctrine which would inspire the Commission's policy in the field of environmental risks (European Commission, 2000). It places the PP in the context of risk analysis according to agreed international standards, in spite of the fact that risk assessment cannot be conclusive. Concepts of proportionality, coherence and regular revision of measures are stressed, as well as the need for public authorities to organize an independent, competent, multi-disciplinary, transparent and adversarial expertise. On this basis, a "Resolution on the precautionary principle" was adopted by European heads of state and governments at the Nice summit in December 2000 (European Council, 2000), soon followed by a symmetrical statement of the EU Parliament. These convergent documents gave a political legitimacy to a specific, 'proportionate' doctrine of the PP confirming the main ideas already kept by the Rio Statement and the French law.

In 2002, the European regulation 178/2002 on food safety was adopted. It poses a principle in Article 14:

"Food shall not be placed on the market if it is unsafe. Food shall be deemed to be unsafe if it is considered to be (a) injurious to health; (b) unfit for human consumption".

This requirement of safety should be assessed by taking account of normal conditions of use and information given to consumers. It also made the PP one of the pillars of food safety regulation. Article 7 says under the title 'Precautionary principle':

- "1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.
2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the

matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment”.

From this have been drawn specific action and informational obligations for the agrifood business: whenever an operator has suspicion on the safety of food ingredients he bought or of processes or of food products he has put on the market, he has obligations to withdraw the products and inform competent authorities and affected consumers, if it happened that products were already in their hands (European Council, 2002). On the intellectual ground, this regulation already suffered from the inner tension that REACH will most importantly share between the requirement of safety and the state of scientific uncertainty: what is safety in uncertain contexts? How can safety be ascertained under scientific uncertainty?

In March 2005, the French Congress added an Environmental Charter to the French Constitution, giving a constitutional value to the goal of environmental protection and stating that public policies must aim at sustainable development. It refers in Article 5 to the obligations of the public authorities in implementing the PP:

“If the occurrence of damage has the potential to affect the environment in a serious and irreversible manner, even though there may be scientific uncertainty, the public authorities should make sure, by applying the precautionary principle and within the limits of their attributions, that risk assessment procedures are followed and that provisional and proportionate measures are taken in order to ward off the damage”<sup>7</sup>.

This article emphasizes the eminent responsibility of public authorities in organizing the implementation of the PP as well for putting in place appropriate evaluation of risks and for taking appropriate measures which would be proportionate and provisional.

Following a Chemicals White Paper issued by the EU Commission in 2001 (Rogers, 2003), the REACH regulation entered into force in spring 2007. This regulation targets chemical substances not already covered by existing regulations. As said by the acronym this regulation introduces new obligations and procedures aiming at registering, evaluating and authorizing –or forbidding– chemical substances by tens of thousands, since both existing and new chemicals are concerned. Special attention is given to chemicals classified as carcinogenic, mutagenic or reprotoxic

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<sup>7</sup> Unofficial translation from French.

(CMR), or as persistent organic pollutants (POP). 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. This strong formula of 'reversal' is about a lie to the extent that it omits the fact that is not possible to prove the absence of future damage with an incomplete, ongoing science; the proof will be limited to existing tests and stabilized knowledge, without any possibility to dismiss future scientific progress and discoveries on new types of harm. Here is revealed the inherent contradiction of the wording of REACH, which can only be overcome by adding subtle conditions and provisions in the evaluation-authorization process.

### 3. The precautionary principle in the EU doctrine

Two main texts express the PP doctrine of the EU: the Communication presented by the Commission in February 2000 and the Resolution adopted by European heads of state at the Nice Summit in December 2000. These texts have no direct legal force, but delineate a politically legitimated conception which should inspire action by the Commission and across all member states. It should also inspire legal decisions by jurisdictions and in particular the European Court of Justice<sup>8</sup>. This doctrine is summarized in Box 2<sup>9</sup>.

As is synthesised by Rogers (2011), the EU PP adopts five components for screening precautionary actions:

- Proportionality to the chosen level of protection.
- Non-discrimination, in particular in regard to imported products.
- Consistency with similar measures previously taken for known risks, but taking account of scientific progress and change of concerns in the society.
- Choice of measures based on the consideration of the potential benefits and costs or various possible actions, including the no-action option.
- Periodic review of measures in the light of new scientific results.

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<sup>8</sup> To this regard, see Stokes (2008) and Rogers (2011).

<sup>9</sup> See also Klinker et al., (2006).

**Box 2: The EU doctrine on the precautionary principle**

1. The PP is to be applied if the scientific information is inconclusive and there are reasonable grounds for concern that potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection. The possibility of harmful effects on health or the environment has to be identified through procedures scientifically recognized but the preliminary scientific assessment of available facts and scientific results does not enable to determine the risk with sufficient certainty.
2. The PP is to be understood and implemented within a sustainable development perspective.
3. To proceed to an assessment of the risks, the public authority should have an appropriate research framework, drawing in particular on scientific committees and relevant scientific work; public authorities are responsible for organizing risk assessment, which should be conducted independently and transparently on a multidisciplinary basis; open debate and adversarial procedures should be enhanced. The assessment of the risk should allow the mention of minority views in public reports.
4. Civil society should be implicated and particular attention should be paid to consulting all interested parties at the earliest possible stage.
5. The whole spectrum of measures able to achieve the desired protection level should be considered, including the no-action option. The choice of measures should respect the principle of proportionality by taking into account short and long-term risks and by aiming at the high level of protection sought; the least restrictive measures for trade should be sought under the condition that they reach the searched level of protection. Measures should be consistent with those already taken in similar situations, taking account of the most recent scientific developments and the evolving level of protection sought.
6. Measures taken on the basis of the PP should be 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.

***Application field and first order responsibility***

The relevant field of legal application of the PP is limited to the environment, health of animals and plants, human health, food and feed.



The PP applies both to the Commission's policies and actions and to those of the member states. Public authorities stand at the forefront to organize the appropriate implementation of the PP: they are responsible for setting-up scientific assessments and launching dedicated research actions in order to elucidate pending scientific uncertainty. They bear the political responsibility of estimating the right level of acceptable risk though they should remain in line with the EU objective to ensure a high level of protection of health and the environment, and with principles of proportionality and consistency with the measures adopted for other similar situations and with international trade law, with a special mention to the Agreements on Sanitary and Phytosanitary measures (SPS) and on Technical Barriers to Trade (TBT) (Belvèze, 2003).

### *Proportionality*

Proportionality is an important ingredient of the EU doctrine. This word is a clear affirmation that the PP does not embrace catastrophism (see later) as the relevant framing to address hypothetical risks. The PP takes part to a risk management aiming at a high level of environmental and health safety, but its purpose is not to condemn any risk or to guarantee that no damage would ever happen. Moreover, the objective is not to minimize possible damage at any cost. In other words, the PP is a way to organize safe conditions for the development of technologies, not a means to block technological development. At the same time seriousness of envisaged damage may lead to renounce to specific technologies or specific uses, especially when less threatening alternatives are available at a moderate cost.

For EU law, built in favour the free circulation of goods, proportionality includes three key requirements (Gonzales-Vaqué et al., 1999):

- the measure should be appropriate to its objective (notion of efficacy);
- the measure should be necessary in the sense that there are no other measures which are equally effective and less restrictive for international trade;
- there should be a reasonable link between the objective sought and the constraints imposed on the circulation of goods.

Within national contexts of member states, other dimensions of proportionality are relevant. All costs and benefits possibly involved, including those having a moral standing (basic liberties versus safety, for instance) have to be examined for each measure and balanced with the possible seriousness of the damage. To this regard due attention should

be given to the extent and richness of the scientific basis supporting hypotheses of risks, in order to assess scientific plausibility in absence of reliable probabilities (Godard, 2003).

### ***Burden of proof***

Whatever may have been said (Raffensperger and Tickner, 1998; Hansen et al., 2007), the idea of shifting the burden of proof does not belong to the core EU doctrine of the PP. It is an option depending on situations. For example, for food additives, new foods, or drugs, the PP should be just incorporated into existing procedures of administrative authorization prior to being put on the market, without altering the pre-existing rule. For products and processes already on the market and widely used, responsibility of bringing the expected scientific evidence supporting suspicion of harm is placed on the shoulder of third parties or the public authorities who suspect possible unacceptable harm.

In fact, in the context of the PP, the idea of reversing the burden of proof is quite ambiguous and conceals a real shift regarding what is to be proven. Strictly speaking, shifting the burden of proof and asking to prove absolute safety represent a logical impossibility. The scientific proof of the harmlessness of a product, substance or technique definitely cannot be brought when the scientific knowledge involved is neither complete nor fixed and incorporates uncertainty. Numerous authors have emphasized this impossibility. Some sources of uncertainty may be reduced with research, experience and time; others reflect intrinsic incompleteness of knowledge. Hence, the movement launched by the PP asking for an early account of risks does not consist in shifting the burden of proof but in moving public management of risks away from the concept of scientific proof and keeping the latter at bay, whatever should be proven, damage or safety. Naturally, this does not mean that public management should ignore scientific knowledge. The contrary is true: the PP asks risk management to be more attentive to science in development and to what constitutes the ordinary course of research (conjectures, hypotheses, ambiguous results, etc.).

When they keep themselves in line with honesty, authors who speak of the reversal of the burden of proof are in fact not aiming at proof of the absence of risk, but at setting up authorization procedures implying for proponents to present results of studies establishing the safety of their products or technologies by using standard tests based on existing knowledge. Such tests cannot dismiss the possibility of future harm in relation to still unknown paths. When activists ask for the proof of absence of risk, with the time horizon being extended to long term effects, it is

quite another thing. Asking for what scientists cannot deliver, they slide into mere political rhetoric and use the argument of reversal of proof as a means to obtain endless moratoriums against targeted products and technologies.

Moreover, assigning to the proponents the responsibility of developing studies and safety tests of the products and technologies they want to put on the market is not the best means to ensure the credibility and transparency of scientific expertise on risks (Godard, 2005), even if they are competent and honest. Expertise of risks is expected to be independent and to be carried out according to precise multidisciplinary rules, transparency and the principles of adversarial examination and open debate. This cannot be easily done by private business and it anyway meets scepticism of public opinion when expertise and information come from business. How to ensure that information transmitted to public expert committees is not incomplete and truncated?

All this would argue in favour of a separation between the financial burden of studies and the assignment of operational responsibility of scientific tests. The latter should be imputed to independent scientific applied research and tests placed under public and open supervision, which is not the case in the present state of EU regulation. The quality of the review process by public agencies is no substitute for the quality and credibility of primary studies on which public agencies depend.

### *Searching for consistency, an extension of a comparative approach*

The rationale of the PP is not justifying extreme and extravagant measures that would paradoxically be much more demanding and restrictive than those taken for well-documented and evaluated risks. Asking for policy consistency implies to extend the perimeter of assessment to similar cases and thus to comparative approaches. Profiles of several similar risks, some of them being potential and others ascertained, should be compared. An analogous extension will result from the consideration of possible precaution actions, which possibly includes less hazardous alternatives: due to limitations of knowledge and data on possible end-results of introducing new technologies or new products, attention may shift towards the search of substitutes having a priori lower impacts. To this regard some authors propose to substitute a focus on risks (endpoints) by one on intrinsic features of hazards, from risk assessment to hazard assessment. For instance Müller-Herold and al. (2005) suggest to systematically considering the existence of amplifying factors able to transform local damages into large-scale ones, and to use them as filters in an authorization process. According to these views, the PP does not only

ask for considering a whole spectrum of candidate actions to control a given threat of damage, but also to explore the existence of alternatives to the use of suspected technology or products and so avoid risk-risk tradeoffs (Hansen et al., 2007).

### *Taking risks to improve knowledge and reduce uncertainty*

Far from catastrophism, the PP should be able to accept activities suspected of creating health or environmental risks, even when such risks are poorly understood, but with progressive commitment and a special side-programme of observation in order to identify first signs of emerging damage and to learn about the presumed risks. This is one of the paradoxes created by the PP: it may be necessary to take risks in order to check the very existence of those risks and get knowledge on them<sup>10</sup>. This commitment is linked to the key conceptual component of the PP which refuses any complacent acceptance of initial scientific uncertainty: the PP should not be the ultimate rationale of risk management but the one which organizes the transition to a state of better knowledge of risks, allowing to go from precaution to prevention. The early consideration of risk hypotheses should be supplemented by specific programs aiming at reducing and possibly eliminating this uncertainty. In that, the PP is different from the sort of instrumentalisation of scientific uncertainty in the service of the interests of stakeholders who use debate on the management of potential risks to improve their social positions or power.

## **4. The dead-end of catastrophism**

The PP asks for an early account of potential or hypothetical threats in spite of remaining scientific uncertainty. It also asks for proportionate and provisional measures. Is well thought-out precaution possible if done early? Are we not faced by a basic contradiction between the obligation to act early and the search for a cost-efficient action? If we want to prevent that hypothetical risks become real damage, are we not obliged to take measures based on worst case scenario, which would make no difference between known risks and potential risks, between prevention and

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<sup>10</sup> Decision theory confronted with irreversibility has shown the existence of three types of irreversibility: those affecting the set of possible actions, those concerning the real consequences on the environment or human health; those affecting future knowledge and information. There are actions which bring new information and actions which forbid gaining new insights on possible risks. If expected knowledge and information are very important, the best choice may be to commit to the potentially risky action that will bring them.

precaution? All these questions turn around the same issue: to control hypothetical risks, is it not necessary to embrace a catastrophist framing?

In its full conceptual development, catastrophism can be characterized by the combination of three ideas (Godard, 2006): (1) tackling an uncertain context by focusing on the worst case scenario; (2) deciding, by convention, to consider this scenario as certain if no action is undertaken; (3) choosing the forms and intensity of preventive action necessary to block the realisation of this scenario.

There are several types of catastrophism, from the most respectable philosophical work of Hans Jonas (1984) to confused, vulgar and inadvertent ones. None of them can be defended since all of them are stricken by theoretical inconsistency or non-sense.

### *Catastrophism and Hans Jonas's Responsibility Principle*

The point of departure of Hans Jonas's thinking is the huge threat that the power of modern technology poses for the future existence of humanity. Hence the idea of a new responsibility for the future. Jonas also bears a specific view of technology: technology is only controllable in its beginnings and first steps of development and diffusion; subsequently technology spreads through society and becomes an autonomous, unmanageable force. Action to control technology at its beginnings is the only possibility to safeguard the future of humanity from anticipated catastrophes. In order to be well-adjusted, control of technological impacts should be based on scientific forecasting<sup>11</sup> but also on imagination and sensibility applied to possible future consequences of technology. This is what Jonas calls 'heuristics of fear'. What is important for him is to distinguish technologies that may have direct and indirect apocalyptic impacts on the existence of humanity from the other ones. Avoiding apocalyptic risks is, to Jonas' view, the sole and unique moral categorical imperative: such risks must be eliminated, whatever the probabilities involved and whatever the expected benefits of the technological development under scrutiny. To this regard, reversing the Cartesian position<sup>12</sup>, the mere possibility of an apocalyptic risk should be considered

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<sup>11</sup> Jonas underlines the new moral status given to what he calls 'futurology', a future-oriented science dedicated to the identification and assessment of possible effects of technological developments in relation to the environment and human essence.

<sup>12</sup> Jonas wrote: "To establish the indubitable truth, we must, according to Descartes, hold everything that in one way or another may be put into doubt as equivalent to a proven falsehood. Here, on the contrary, we must treat that which can certainly be put into doubt, as long as it is possible - once we're dealing with a possibility of a certain kind - as

as a certainty at the moment of profiling prevention measures intended to eradicate this type of risks. For non-apocalyptic risks, ordinary risk management considering costs and benefits of technology is acceptable, which would admit the possibility for some damage to become reality: individuals have the right to put their own existence at risk, not the right to put the existence of humanity at risk. According to the heuristics of fear, if a technology incorporates a chance of causing apocalyptic harm, even indirectly or far in the future, it should be refused and banned.

The value of the new maxim depends on the capacity of risk managers to ascertain at an early stage which technologies are potentially apocalyptic and which ones are not. If the possibility of apocalyptic outcomes cannot be dismissed on the basis of scientific investigations, it should be categorized as ‘certainly apocalyptic’ according to Jonas. This position is flawed and reveals inner contradictions in the thought of Jonas. The structural incapacity of scientific knowledge to embrace the spread of technology’s effects, on which Jonas bases the argument in favour to his “heuristics of fear”, means that the possibility of an apocalyptic outcome can never be ruled out. Since Jonas excludes any reference to the idea of probability, all technological developments should be said potentially apocalyptic, whatever the plausibility involved in that qualification (Godard et al., 2002; Godard, 2003). And any technological development should be banned at their outset because of their risks.

Against his formal distinction between apocalyptic and ordinary risks, the Jonas’s maxim would entail a paralysis of human action. Even if we can accept many of his premises, the model of action he puts forward leads to a logical and practical dead-end. Furthermore, this radical conception would give rise to a false sense of security, since paralysis of innovation would maintain humanity in dependence of existing technologies, whereas many of them were at the source of the present environmental crisis. The PP should definitely put aside the “guilty if not proven innocent” position inspired by Jonas since innocence cannot be proven.

### *The vulgar catastrophism*

There is no much to say about the vulgar catastrophism, which is just an extension of Jonas’ maxim to all possible threats to the environment and human health, which Jonas considered as highly irrational. The aim of the PP cannot be to eradicate at source any possible risk. It still remains a

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a certainty with respect to our decisions”. Here the ‘possibility of a certain kind’ referred to an apocalyptic outcome.

meta-decision of choosing which potential risks can be taken and accompanied by proportional and provisional measures regularly revised in view of experience and progress of knowledge, and which potential risks should not be taken. Such meta-decision cannot be taken by using the general slogan of reversed proof of safety.

A weak form of vulgar catastrophism is to ask for a policy choice minimizing the possible damage across several technological options, with no consideration given to costs and scientific plausibility. After John Rawls and for a different matter, Gardiner (2006) defended this Maximin rule in specific contexts where potential gains are negligible and alternative courses of action are unacceptable. These are very particular conditions and certainly not a general model of situations of potential risk management. Furthermore the value of this rule evanishes in contexts where all possible outcomes have not been identified and it is impossible to define a closed set of outcomes. In the latter case, the game space is not bounded and the logic of Maximin cannot be deployed. It will get stuck on indecision because of a race to the bottom and levelling of all options by the worst: what should you do, if apocalypse is the possible end-result of each alternative?

### *The involuntary catastrophism: the earliness-seriousness artefact*

There is a certain type of risk assessment, apparently supported by ethics or common sense goodwill, which triggers an involuntary catastrophism. It is so because of a pure artefact resulting from an inverse relation between the earliness in considering hypothetical risks and their image of seriousness (Godard, 2003, 2006): the initial justification of the PP is that because of seriousness and irreversibility of possible damage resulting from suspected risks, early preventative action should be taken. The inversed relation would be that because of earliness of consideration, any risk comes to being suspected of potentially having apocalyptic consequences, then deserving the strongest prevention measures. This artefact may impose itself whatever the risk of concern. The underpinning logic is the following: the more a risk is considered early on regarding the level of scientific achievement, the greater the number of hypotheses and conjectures that are not yet proven to be wrong, the more the set of possible scenarios will include catastrophic outcomes and the greater the envisaged technology will be perceived as dangerous, and the more this risk will call for severe and restrictive measures. One then ends up with the same aporetic result as with Jonas's maxim.

The biased assessment procedure giving rise to these unexpected aporetic effects rests on two statements chosen as 'axioms' which look

attractive and sound at first sight. The first requires that the public appraisal of a collective risk only considers possible damages, without giving a look at possible benefits for society. The underlying rationale is that the principle of basic freedom acknowledged to entrepreneurs assigns them the role of appraising the benefits of their projects or technical innovations; public responsibility is thus limited to making sure that these initiatives do not generate unacceptable damage for the society<sup>13</sup>. The second axiom basically takes up Jonas's position, in requiring, in the name of the future, that a non-invalidated possibility be treated as a certainty. By combining these two axioms is sufficient to trigger the earliness-seriousness artefact.

To find a way-out of this deleterious artefact it is necessary to reverse the content of the two axioms. First, risk assessment should also take into account the various social benefits of technical developments, without confining itself to potential damage. Next, it is essential to differentiate risk hypotheses according to their degree of plausibility and scientific consistency: a hypothesis still lacking of any empirical and theoretical support should not be treated the same way as a hypothesis strongly supported by scientific inputs but still not established according to the views of a majority of competent scientists.

## 5. The specifics with chemical risks

Chemistry is an 'impure science', since it intrinsically mixes the quest for knowledge with technological applications. As Bensaude & Simon (2008) put it:

"chemistry serves as the archetypal techno-science, unable to restrict itself to the high-ground of pure theory, but always engaged in productive practice".

The industrial production of chemicals has been a major new source of environmental disruption since WWII, allowing for industrializing agricultural production with intensive use of energy and chemical inputs but also for a mass usage of plastic products and packaging (Milton & Farvar, 1972). Residues of pesticides have come to the forefront as a huge threat for human health through the contamination of food and we find traces of industrial chemicals in every sample of water in the world. The

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<sup>13</sup> This principle does not apply in the area of drugs and medical products, where on the contrary risk-benefit analysis has been adopted by medical circles as the right assessment framework. But in that case, as well benefits as risks of damage are related to health impacts and do not directly embrace considerations of commercial benefits of drugs companies.



pervasive diffusion of chemicals is all the more striking that most of substances 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 recently invented by chemistry; it is the most common feature of chemicals that have been disseminated for several decades in the atmosphere, in waters and in soils. Threat is already there and we did not know much about it. For these threats, we are very far from an early account of risks.

Another feature of chemistry, as a science, is that it produces new substances and not only knowledge on the existing material world. New substances introduce new properties difficult to anticipate and difficult to catch in all their possible consequences. So the development of chemistry is a permanent source of new unknowns. With biochemistry, the new challenge is nowadays to reach synthetic life. The heritage of the alchemical tradition is still there. As said by Schummer (2001),

“With every production of a new substance, the scope of nonknowledge 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.”

Due to the mass number of new chemical substances introduced in ecosystems, this creative process entails an increasing unpredictability of environmental changes. Creating a new substance and putting it on the market come to generating new unpredictable potentials of harm to the environment and public health, increasing difficulties of a prior control of these harms. This is a legitimate source of concern: chemistry is a major cause which renders our world unpredictable. There is not better justification for submitting the products of chemistry's innovation to rigorous procedures of public control and to place those procedures under the flag of the PP.

## 6. REACH and chemicals

### *An outline*

Following a 2001 White paper, the European regulation REACH (Registration, Evaluation and Authorization of Chemicals) came into force on 1 June 2007. It was the outcome of a six-year chaotic deliberation process animated by markedly opposite positions putting on balance public health, environmental quality and industrial competitiveness. Elizabeth Fisher (2008) sees in that process a ‘perfect storm’ due to the convergence of three components: a radically innovative approach regarding new information duties of business both in bearing the burden

of safety studies and in disseminating information to all stakeholders alongside the supply chain; the rewriting of the conditions of access to the market by making registration an absolute condition to obtain a 'licence to operate' in order to achieve sustainable development; the spread of impacts on multiple jurisdictions within and outside the EU.

This regulation echoed several concerns in relation to, respectively, the health and environmental impacts of toxic substances, the lack of knowledge about effects of most chemicals having been put on the market and disseminated into physical environments, the incapability of governments to inform and run a timely control of thousands of chemical substances and last but not least, the lack of incentives for safer and greener chemicals due to the previous regulation's focus on new substances from 1981.

The REACH regulation consists of three main components:

1. Registration of all chemicals (substances and products) intended to the market, be they 'new' or 'old', provided that their level of production exceeds 1 tonne/year/producer. The procedure asks producers and importers to bring information allowing to identify the substances in terms of properties and usages and specify envisaged levels of production and sales. For substances produced or imported by more than 10 tonnes/year/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. In particular this document should test the persistent, bioaccumulating and toxic (PBT) characteristics of substances and products. In that case information needs are reinforced by asking for an exposure assessment and a risk characterisation.
2. Evaluation is conducted by member states according to guidelines and criteria elaborated by the new European Chemical Agency. It is supposed to check the quality of testing and data delivered by proponents but also to determine which regulatory status will be given to candidate chemicals. A specific attention is given to substances and products that should be classified as dangerous. On the basis of their evaluation, member states present proposals of classification to the European Agency who examines them with the help of three committees (risk assessment; socio-economic, and member states) before making ultimate proposals to the Commission.
3. Authorization of chemicals is based on evaluation. Depending on dangerousness and quantities involved, a specific authorization is needed. Restrictions or complete ban of certain chemicals may result if they cannot be used safely and this usage is not essential. A key point is the following: proponents should establish that a safe use of their chemicals can be reached. Dangerous products should be unauthorized for being unsafe,

unless it is demonstrated that the benefits for society are higher than possible harm to public health and the environment. In that case authorisations with restrictions in scope and time can be delivered.

A first deadline for the registration of chemicals was November 2010 with the registration of chemicals produced by more than 10000 tonnes/year. 4300 substances have been registered before this deadline. Deadlines for other categories are forecast for 2013 and 2018. Priority for examination and decision of authorisation has been given to substances of very high concern (persistent, bioaccumulative, toxic, mutagen, carcinogen and reprotoxic).

### *An assessment under the light of the PP*

REACH has often been presented, especially by the Commission (Rogers, 2003; Fisher, 2008), as an application of the PP in the specific field of use and dissemination of chemicals. It is true that article I(3) of the REACH regulation presents the new rules as being 'underpinned by the precautionary principle'. At the same time supporters of radical conceptions of the PP have expressed their doubts on the precautionary content of REACH. This is the case of Hansen et al. (2007).

These authors begin by expressing their regret that REACH refers to the 2000 Communication of the Commission, which is not a right expression of the PP to their eyes: a) it adopts a too restrictive understanding of scientific uncertainty, as if scientific research and improvements of scientific methods will suffice to make them disappear; b) it sets the PP in the framework of a standard risk assessment and confirm the separation between risk assessment and risk management in spite of the pervasive presence of value judgements in risk assessment, what is generally called the 'framing of expertise'; c) it expresses a defensive, reactive approach filtering technologies and products but insufficiently promotes the search of safer alternative solutions. Regarding REACH, they regret that regulating authorities would have to demonstrate the existence of a risk and proof indications of its severity before they can decide restrictions. This requirement goes on imposing the burden of proof on the shoulders of public bodies, which is contradictory with the conceptions that the authors have of the PP. They acknowledge the shift of responsibility for the collection of data and the performing of tests but consider it to be insufficient for a full implementation of the PP. Last, they regret that involvement of stakeholders is not systematic at the different stages of registration, evaluation and authorisation and the opportunity given to the public to comment risk assessment and socio-

economic analyses is not precisely articulated with the decision-making process.

I suggest a more balanced assessment. Several features fit well to the PP's rationale. First REACH confirms that we do not have to be afraid by uncertainty. Uncertainty is not a legitimate motive to postpone safety regulation. It is possible to discriminate between chemicals on the basis of an evaluation considering a mix of possible impacts and inherent characteristics of substances. It is clear that chemicals are exposed to be regulated before any harm is observed, confirming the PP's focus on earliness –for new substances. Then it will be necessary to remain alert to avoid both false negative and false positive since, as Vlek (2010b) puts it:

“the required level of evidence for precautionary action cannot be fixed but should depend on the prior probability or plausibility of harm and the seriousness of possible false-positive versus false negative decision consequences” (p. 564).

Secondly, like the PP, REACH reaffirms the key role of scientific expertise for evaluating riskiness and safety of chemicals. Regulation is not expected to break-up with the quest of scientific objectivity but to be based on as sound scientific assessment as possible and to submit it to comments of stakeholders<sup>14</sup>. REACH also shows no complacency towards uncertainty, since the bulk of this regulation is to oblige business to gather and share huge amounts of data relevant for safety. Thirdly, in spite of the principle according to which safety has to be established for a substance to be authorized, REACH does not fall into the trap of catastrophism since in case a chemical product is difficult to substitute and generate important benefits to society, a balance of threats and benefits has to be achieved, which command the subsequent regulatory treatment. This sounds as a partial echo to the core idea of proportionality.

This being acknowledged, it is fair to say that the main purpose of REACH is not to implement the PP. By and large REACH belongs mainly to the universe of prevention based on the concept of proof of safety, just like the 2002 Regulation on food safety, and on standard tests and stabilized science in toxicology and other cousin disciplines. These tests are very useful for direct harm on human health but are not well designed

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<sup>14</sup> To keep-up with the values of rationality and consistency of overall safety policy, it is important not to downgrade the contribution of scientific investigation, and fight against an increasing tendency to design policy responses on the basis of political tactics in response to green NGOs activism, as shown by Nilson (2004) about chemicals in the case of Sweden or Godard (2011) about GMOs in the case of France. Socio-political contexts and their consequences on decision-making are well analysed by Sunstein, (2005) and Lofstedt and al. (2011).

to apprehend new types of effects or systemic environmental risks, as those affecting biodiversity or human health through chemical synergies between various substances traces (Maxim and Spangenberg, 2009). To this regard the literature is searching for proxies and alternative procedures based either on inherent characteristics of substances, amplifying factors of damage or determinants of scale (extent and dissemination of demand for products, safely confined versus open use, etc.) in order to identify filters, thresholds and screening conditions (Klinke et al., 2006) by non arbitrary methods.

Another source of discrepancy with the PP is the shift to business of the operational burden of studying environmental and health impacts of chemicals and getting primary data on safety. It is a risky gamble from the viewpoint of spread and quality of studies since all short-term incentives delivered by the search for profit push business neither to realize all investigations and tests that would have been made under a public control, nor to transfer all relevant information to public authorities and other stakeholders, including consumers and the public. There is anyway an issue of credibility: it is not possible to have business firms making or controlling safety studies in the name of responsibility and to ask at the same time an independent, pluralist and transparent expertise on risks, as does the PP. It is certainly useful to involve business in care for risks imposed to society but the PP certainly asks for a more diverse source of studies and data than those disseminated by firms interested to put their products on the market. Secondary assessment and check by public agencies can be no substitute for controlling primary sources of information and steering the primary impulse of focused scientific research.

A last point concerns the conception of the regulation. The PP puts forward a new philosophy of preventive action which conceives the precautionary measures as provisional, flexible and paying attention to the development of empirical and scientific knowledge, without impairing the future by irreversible commitments or irreversible prohibitions; such measures should be periodically revised accordingly. REACH does not fit well with this fluid approach to precautionary actions<sup>15</sup>, since its aim is to obtain quasi once-for-all classification of substances and, for the supposedly most dangerous ones, to decide their definitive eviction. This may be explained by the mass of substances to register and evaluate, and the necessity to make-up for years of negligence regarding the impact of chemicals already disseminated into the environment. Therefore it means

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<sup>15</sup> It should be noticed that it is the ingredient of the PP that case law of the European court of justice tends to disregard (Rogers, 2011).

that a specific and distinct role should be maintained for the PP in the field of chemicals regulation, in parallel to REACH.

## 7. Conclusion

Although the PP has been introduced in the European landscape twenty years ago, its content is still fiercely debated. Discrepancies between concepts and between concepts and achievements are striking. In spite of absence of consensus the EU has adopted a public doctrine of the PP in year 2000 which gives precious landmarks of a 'proportionate' concept. Earliness, proportionality and reversibility of precautionary actions thus strongly mark that the PP does not embrace a catastrophist viewpoint. Chemicals are on the frontline of the quest for environmental and health safety because of their specific features of novelty. As a discipline, chemistry is a permanent source of new unknowns, which justify a special attention to the risks potentially raised. In Europe the REACH regulation shares important components with the PP, such as the necessity to take measures without waiting for full scientific certainty and to bet on scientific expertise to enlighten policy choices in parallel to consultation of stakeholders. At the same time the huge shift of responsibility of 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 PP requirement to set up an independent and transparent expertise, far from vested interests. REACH is also much more rigid than is expected from precautionary actions under the PP. All this suggests that the PP should continue to be trusted a role aside the bigger administrative programme of registration and evaluation of chemicals driven by REACH. To this regard the PP should be kept as a lighthouse to enlighten the developments of green chemistry.

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