Considerations on the application of the Precautionary Principle in the chemicals sector

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Abbreviations

List of abbreviations

ALARA	'As low as reasonably achievable'
BAT	Best Available Techniques
BPA	Bisphenol A
CBA	Cost Benefit Analysis
CFI	Court of First Instance
CLP	Classification, Labelling and Packaging
ChemSec	International Chemical Secretariat
CMR	Carcinogenic, Mutagenic and Reprotoxic
CoRAP	*Substances* for the Community Rolling Action Plan
CSA	Chemical safety assessment
DNEL	Derived No Effect Level
ED	Endocrine disruptor
EU FP7	EU Seventh Framework Programme
ICJ	International Court of Justice
IPPC	Integrated Pollution Prevention Control
ECHA	European Chemicals Agency
ECJ/CFI	Court of Justice of the European Communities/ Court of First Instance
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMA	European Medicines Agency
ELV	End of life vehicles
GATT	General Agreement on Tariffs and Trade
ICCA	International Congress and Convention Association
ICJ	International Court of Justice
IUCN	International Union for Conservation of Nature

MEA	Multilateral Environmental Agreements
MOS	Margin of Safety
NOAEL	no observed adverse effect levels
NOEL	no-observed effect level
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, bioaccumulative, toxic
PIC	Prior Informed Consent
PNEC	*Predicted no-effect concentration*
POP	Persistent organic pollutants
PP	Precautionary principle
PPP	Plant protection product
(Q)SAR	Quantitative structure-activity relationship
RAC	Committee for Risk Assessment
RAPEX	EU rapid alert system for non-food dangerous products
RAR	Risk Assessment Report
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemical substances
ROHS	Restriction of Hazardous substances
SIN List	Substitute It Now
SEAC	Committee for Socio-economic Analysis
SVHC	Substances of very high concern
t	tonnage
TEC	Treaty establishing the European Community
TFEU	Treaty on the functioning of the European Union
WTO	World Trade Organisation
WTO AB	Appellate Body
WTO SPS	Sanitary and Phytosanitary Measures Agreement

Figures

1. Introduction

This Final Report intends to serve as a practical tool for officials involved in chemicals regulation considering the application of the precautionary principle within the regulatory decision-making process in chemicals legislation.[1] Application of the precautionary principle requires *inter alia* taking decisions on what is considered an "acceptable" level of risk for society, identifying gaps in knowledge that result in uncertainty concerning the nature of a potentially unacceptable risk, and managing that risk in the face of uncertainty.

Applying the precautionary principle (PP) in the context of chemicals regulatory decision-making can present numerous challenges. These challenges are partly due to the specific nature of (regulating) chemicals, and the more general nature of the precautionary principle. The Commission Communication on the precautionary principle, issued in 2000,[2] provides general guidance but these are not tailor-made for the application of the precautionary principle to chemicals. In the meantime, significant legal and practical developments in the field of chemicals regulation and application of the precautionary principle have occurred at the EU and national level.

The starting point in preparing this report is nonetheless the 2000 Commission Communication on the precautionary principle. The project team has also considered how the precautionary principle has been further elaborated and applied in the case law of the European Court of Justice and the Member States, as well as in the academic literature. Their review of the current state of the art on application of the precautionary principle (both in case law and literature) has then been linked to technical knowledge of the chemicals regulatory decision processes.

Additional valuable input was provided by the legal specialists and regulatory authorities who participated in a day-long workshop in May 2011 organised in the context of the preparation of this report. These experts contributed their insights and experiences to date on the use of the precautionary principle in chemicals control decisions, and made many practical suggestions concerning the content and structure of these considerations.

This report provides a logical framework for applying the precautionary principle in the chemicals regulatory field. The aim is to help regulators work through the process of considering whether a substance or mixture presents the combination of concern and uncertainty about possible harmful consequences such that precautionary measures of control should be taken.

Section 2 of the report provides a brief history on how the precautionary principle emerged, including early examples of the precautionary approach. It discusses the differences between prevention and precaution, and when to apply the two distinct concepts.

Section 3 presents an overview of the main points covered by the 2000 Commission Communication. It also looks at subsequent case law from the European Court of Justice as well as lessons learned as detailed in the academic literature. More detailed guidance from ECJ case law is provided in Section 5 as well as in Annex 1.

Section 4 reviews some of the stages in taking regulatory decisions on chemicals, including the essential elements of risk assessment, and considers examples of how the precautionary principle has been applied to particular substances. The substance case studies provided in Annex 2 provide

[1] This report has been prepared as part of the study *Technical assistance related to the precautionary principle in chemicals regulations* (ENV.D.3/SER/2010/0083rl) carried out for DG Environment of the European Commission by Milieu Ltd, together with the Asser Institute and PACE.
[2] COM(2000)1.

concrete examples of some of the practical and political issues that may arise in considering whether to apply precautionary risk management measures.

On the basis of this background, Section 5 then presents a series of logical steps for the process of considering whether a substance or mixture is a candidate for the application of a precautionary control measure. The framework is intended to help the regulator work through the issues that should be considered in determining whether the information available indicates the potential for harmful effects yet at the same time cannot fully demonstrate the risks or possible consequences.

Finally, Section 6 discusses additional issues that need to be taken into account in the process of when and how to apply the precautionary principle within the regulatory decision process. These include documentation of the scientific evaluation as well as public consultation and stakeholder involvement.

As noted above, Annex 1 provides brief synopses of European Court of Justice case law and key legal points from those rulings organized according to the Section 5 logical framework. Annex 2 consists of six case studies on different substances where the precautionary principle has already been applied or may be applied in the future. Annex 3 provides a literature list for further reading, whereas Annex 4 summarises the outcomes of the consultative workshop on considerations to include in the decision-making process when applying the precautionary principle. Finally, Annex 5 provides a list of relevant ECJ cases.

2. Background on the Precautionary Principle

a. A brief history

The precautionary principle ('*Vorsorgeprinzip'*) formed one of the leading principles of German environmental law from an early moment on. At the outset, no clear distinction was made between prevention of regular risks that science can quantify and precaution against potential risks that science cannot (yet) quantify (an issue that will be discussed under point 2c below). Germany introduced the principle as an environmental policy principle to the international scene at the North Sea Conferences:

- Bremen Declaration 1984: *"damage to the marine environment can be irreversible or remediable only at considerable expense and over long periods and that, therefore, coastal states and the EEC must not wait for proof of harmful effects before taking action."*
- London Declaration 1987*: "in order to protect the North Sea from possible damaging effects of the most dangerous substances, a precautionary approach is necessary which may require action to control inputs of such substances even before a causal link has been established by absolute clear scientific evidence."*
- The Hague Declaration 1990: *"will continue to apply the precautionary principle that is to take action to avoid potentially damaging impacts of substances that are persistent, toxic and liable to bioaccumulate even when there is no scientific evidence to prove a causal link between emissions and effects."*

In line with the broad German interpretation of '*Vorsorge'* no clear distinction was made between prevention and precaution in the 1984 Declaration. As of 1987, the focus became mainly precaution as a means of avoiding potential risks in situations of scientific uncertainty.

Other early examples of a precautionary approach can be found in various places, for instance:

- 1980 IUCN World Conservation Strategy advises to "*keep in mind that in spite of present knowledge, what we know about the biosphere, ecosystems and their interrelationships is less than what we do not know. Consequently, it is often difficult to accurately predict the effects of human actions. Gaps in knowledge should be filled where possible, the report continued, but in the meantime risks should be reduced."*
- 1982 World Charter for Nature (adopted by UN General Assembly) demands that activities which are likely to cause irreversible damage to nature shall be avoided; and activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed.

A precautionary approach can be identified in a number of binding international instruments, notably the 1985 Vienna Convention for the Protection of the Ozone Layer (mentioning 'precautionary measures' and the need to take measures against adverse effects 'likely to result' from human activities which are 'likely to modify the ozone layer') and the subsequent 1987 Montreal Protocol, which played an important role in the emerging climate change regime. The 1992 UN Framework Convention on Climate Change put it as follows:

> *"The parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost. To achieve this, such policies and measures should take into account different socio-economic contexts, be comprehensive, cover all relevant sources, sinks and reservoirs of greenhouse*

gases and adaptation, and comprise all economic sectors. Efforts to address climate change may be carried out cooperatively by interested parties."

The prevention principle was included in the EC Treaty in 1987 through the Single European Act, and the precautionary principle followed suit when the Treaty of Maastricht entered into force in 1993. In the year 2000, the Commission issued its Communication (2000)1 on the precautionary principle (PP). The PP was also laid down in many pieces of secondary European law, notably in Annex IV of the IPPC Directive, where it is prescribed that the principle is to be taken into account when determining the Best Available Techniques (BAT) when issuing permits to an installation. The Water Framework Directive (notably where the identification of priority hazardous substances is concerned), decisions regarding phthalates (discussed in Annex 2), and numerous other pieces of legislation also take the PP into account.

The European Court of Justice interpreted older pieces of legislation, like the Habitats Directive, in line with the PP. In addition, non-environmental legislation was interpreted in the light of the PP, with the help of the integration principle that nowadays can be found in Art. 11 TFEU (formerly Art. 6 TEC). The ECJ case law and guidance that can be drawn from it are discussed further in Annex 1.

Where chemicals are concerned, the PP was also incorporated in a number of directives and regulations. REACH refers to the principle several times in its preamble and assures in Article 1(3) that the Regulation is "underpinned by the precautionary principle". Regulation 1107/2009 concerning the placing of plant protection products on the market contains a reference to the PP in Article 1(4):

"*The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.*"

At the initiative of European Parliament, the new Biocides Regulation is to contain the following text in Article 1a: "*The purpose of this Regulation is to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market, making available on the market and use of biocidal products, whilst ensuring a high level of protection of both human and animal health and the environment. The provisions of this Regulation are underpinned by the precautionary principle, the aim of which is to safeguard the health of humans, animals and the environment*."[3] Contrary to the Plant Protection Products Regulation, the possibility for Member States to apply the PP is not expressly mentioned.

b. WTO, Codex Alimentarius and the Precautionary Principle

As explained in the 2000 Communication, the PP has also found its way into the law of the World Trade Organization (WTO), albeit with numerous conditions attached to it. The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) defines precaution in Art. 5(7) as follows: *"In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by*

[3] Source: http://register.consilium.europa.eu/pdf/en/10/st17/st17474-ad01.en10.pdf. EP had proposed a slightly different text : "*The purpose of this Regulation is to ensure a high level of protection of both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market and use of biocidal products. The provisions of this Regulation are underpinned by the precautionary principle, in order to ensure that active substances or products placed on the market do not have harmful effects on humans, non-target species and the environment. Special attention shall be paid to protecting children, pregnant women and the sick*." Source: http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2010-0333

other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

The WTO, established in 1995, did not embrace the PP as firmly as the EU. Attempts at strengthening the role of the principle, for instance through the WTO Committee on Trade and Environment, have remained obstructed due to limited political consensus. The WTO Agreement does aim at sustainable development, and the PP is often seen as an essential principle to achieve sustainable development. Principles can form an aid to interpretation (US – Shrimp case) so the principle can in theory serve as a means of interpretation of WTO law.

The SPS Agreement is the only place in the WTO law where a situation of scientific uncertainty is regulated. Taking precautionary measures against potential risks falling under the SPS regime means that these measures – in as far as relevant scientific evidence is insufficient - need to meet the strict, cumulative conditions set out in Article 5(7) SPS Agreement. In the Beef Hormones dispute, it became clear that the Panels and Appellate Body (AB) were not willing to interpret the other provisions of the SPS Agreement in the light of a general precautionary principle, and required the EC to perform specific, adequate risk assessments for the hormones it suspected of being a potential hazard to human health.

The option of invoking Article 5(7) SPS (a provision incorporating the PP according to the Appellate Body) was not explored any further in this case, probably because the EC did not invoke the provision that allows only for provisional measures (the EC ban was in the form of a regular directive). The Appellate Body did add that the risk to be evaluated under Article 5(1) "is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die." Where the possibilities to use this interpretation of Article 5(1) end and the need to follow the route of Article 5(7) begins is still to be determined. In the EC – Asbestos dispute, the AB added that "responsible and representative governments may act in good faith on the basis of what, at a given time, may be a divergent opinion coming from qualified and respected sources."

The WTO does not set its own product or substances standards; this is left to the WTO parties. Where such national standards are derived from the standards set up in international standards setting organisations like the Codex Alimentarius, they are presumed to be in conformity with WTO law. If a WTO party wishes to introduce precautionary standards that are stricter than Codex standards, the hurdles are high. The SPS Agreement differentiates between national measures based on international standards, guidelines and recommendations and other, stricter national measures. The first type of measures is clearly favoured, as may be seen in Article 3(3) SPS Agreement which demands that WTO Members "shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3." According to Article 3(2), such measures shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.

Article 3(3) of the SPS Agreement explains that measures which are stricter than international standards, guidelines or recommendations are only allowed if there exists a scientific justification for them (situation 1) or if they are established in accordance with the provisions of Article 5 (situation 2). Both for situations 1 and 2, it is stipulated that the stricter measures have to be in conformity with the other SPS Agreement provisions. In a footnote, it is explained that for the purposes of this specific provision on situation 1, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of the Agreement, a member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection. As for the second situation, compliance with the provisions of Article 5 of the SPS

Agreement is made obligatory. This article deals with risk assessment and the determination of appropriate levels of protection. Among other things, it contains the specific provision on precautionary measures in Article 5(7) discussed above.

Although Codex standards in themselves are voluntary, the reference to them in WTO agreements increased their significance considerably. The EU tried in vain to introduce the PP in the key Codex documents. The latest attempt focused on the 'Working Principles for Risk Analysis for Food Safety for Application by Governments' of 2007.[4] The "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[5]"do not refer to the PP, notably due to resistance from the side of the USA.

Nevertheless, in the part on risk assessment it is explained that "[p]recaution (*sic*) is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow the Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard." It is also explained that "[c]onstraints (*sic*), uncertainties and assumptions have an impact on the risk assessment" and that they "should be explicitly considered at each step in the risk assessment and documented in a transparent manner. Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable."

The Principles for the risk analyses of foods derived from modern biotechnology (CAC/GL 44-2003) supplement the Codex Working Principles for Risk Analysis. Where risk assessments are concerned, it underlines the need for using 'sound science' and 'science-based risk assessment methods', while allowing the gathering of data for risk assessments from 'other interested parties'. In the part on risk management, it is recommended that risk managers "should take into account the uncertainties identified in the risk assessment and implement appropriate measures to manage these uncertainties." The PP is not specifically mentioned as a reason for doing so.

Recommendation: Where EU regulators are contemplating using the PP in cases with an international trade law aspect (notably because it can hinder the import of substances), they need to ensure that any precautionary measure will need to be based on a specific risk assessment (as far as possible) for the substance at stake. There is some room for manoeuvre in the direction of qualitative reasoning and the use of minority opinions offered in the case law of the Appellate Body, notably in the EC-Asbestos, EC-Hormones and EC-Biotech cases. If it is a SPS matter, it will need to be explored whether the measure can be tailored to the cumulative conditions set out in Article 5(7) SPS Agreement (allowing only provisional measures that need to be reviewed within a reasonable period of time).

c. Distinguishing between the prevention principle and the PP

The *prevention principle* was included in the EC Treaty through the Single European Act in 1987. The *precautionary principle* was added by the Treaty of Maastricht in 1993. The fact that they were put side by side (rather than having the precautionary principle replace the prevention principle) already indicates that the two principles have a different meaning, although they are related.

[4] www.codexalimentarius.net/download/standards/10751/CXG_062e.pdf.

[5] Adopted by the 26th Session of the Codex Alimentarius Commission, 2003; Codex Alimentarius Commission Procedural Manual; Thirteenth edition.

Some argue that a distinction between prevention and precaution is irrelevant, since they both deal with risks and uncertainties.[6] However, it is important to point out that some risks can be calculated/ quantified while others cannot. The latter can be called potential risks. The Communication explained that the PP only applies to potential risks, i.e. risks that cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inconclusive nature of the scientific data.[7] If a risk can be quantified, the prevention principle rather than the PP applies and risk managers can use the data to decide on whether or not to adopt measures, and if so, what these measures will be. The 'uncertainty' in such cases concerns the question *when* damage will occur, but not the chance *whether* damage will occur.

Both in cases where risks are quantifiable and where they are not, the aim also laid down in the EU Treaty is to ensure a high level of protection, and ensuring that available scientific and technical data are to be taken into account. Where the PP is concerned, an evaluation should show that the desired high level of protection of the environment or a population group could be jeopardised. Absence of an established causal relationship, a quantifiable dose/response relationship or a quantifiable evaluation of the probability that the potential risk would materialise should not be used as a reason for inaction. Of importance is the manner in which scientific and technical data as far as possible are to be gathered, and a risk assessment as far as possible is to be carried out, without demanding for a minimum amount of quantified risks.

For risk assessment of chemicals, it will be important to decide whether the risks at stake can be determined with sufficient certainty (and explain how robust the findings are), or whether (some parts of) the risks cannot be determined. In the latter case, reporting on the uncertainties will facilitate risk manager's tasks.

d. Definitions of the Precautionary Principle

Critics of a precautionary approach often stress that the principle is too vague and undefined. They point at different definitions, quoting authors promoting stronger or weaker versions of the PP. Although extensively discussing various aspects of the PP, and thus clarifying how to use it, Communication (2000)1 does not provide a definition and was attacked for lacking to do so.[8]

According to the Commission, the absence of a definition does not necessarily lead to legal uncertainty. It would be more important to understand the circumstances under which the precautionary principle may be used than to provide a static definition. The Commission submitted that, like other general notions contained in the legislation, such as subsidiarity or proportionality, it is for the decision-makers and ultimately the courts to flesh out the principle.[9] However, as will be demonstrated in Annex 1, although the ECJ and the Court of First Instance (CFI) brought about some clarity in precautionary matters, the European judiciary has not clarified the terms of application of the PP in much detail. Hence, the judiciary's role in defining the precautionary principle within the EU has not brought about the results expected a decade ago when the Communication was formulated.

At the international level, the lack of an accepted definition probably contributed to the reluctance of courts and tribunals to accept the principle as a binding rule of international customary law or as a general principle of international law. The International Court of Justice (ICJ), for instance, only

[6] See for instance J.B. Wiener, The real pattern of precaution, p. 530, in: J.B. Wiener, M.D. Rogers, J.K. Hammitt and P.H. Sand (eds.), *The reality of precaution. Comparing risk regulation in the United States and Europe,* RFF Press / Earthscan, Washington / London 2011.

[7] Note that COM(2000)1, p. 13 talks of insufficiency or "inclusive" nature of scientific data; also looking at other language versions (German: "nicht eindeutiger"), this should be "inconclusive".

[8] For instance by the U.S. Food and Drug Administration and U.S. Department of Agriculture, *A U.S. Government submission to the Committee on General Principles of the Codex Alimentarius Commission for the committee's April 10-14, 2000 meeting*.

[9] COM(2000(1), p. 10.

proclaimed that the prevention principle forms such a rule in the case between *Argentina* v. *Uruguay* of 20 April 2010. The ICJ pointed out that the principle of prevention, as a customary rule, has its origins in the due diligence that is required of a State in its territory. It is "every State's obligation not to allow knowingly its territory to be used for acts contrary to the rights of other States" (*Corfu Channel (United Kingdom* v. *Albania), Merits, Judgment, I.C.J. Reports 1949*, p. 22). A State is thus obliged to use all the means at its disposal in order to avoid activities which take place in its territory, or in any area under its jurisdiction, causing significant damage to the environment of *another* State. This Court has established that this obligation "is now part of the corpus of international law relating to the environment" (*Legality of the Threat or Use of Nuclear Weapons, Advisory Opinion, I.C.J. Reports 1996 (I)*, p. 242, para 29)."[10]

Claims that the PP would bring about a reversal of the burden of proof were dismissed: "while a precautionary approach may be relevant in the interpretation and application of the provisions of the Statute, it does not follow that it operates as a reversal of the burden of proof."[11]

Although the ICJ does not reject the idea of interpreting treaty provisions in the light of the precautionary approach (rather than the PP), for now it has refrained from accepting the PP as a binding rule of international customary law. It is to be added that the cases that it did decide on, including this one, all seem to be cases in which there was little or no scientific uncertainty at stake. The case between Argentina and Uruguay, for instance, concerned difference of opinions on the harmfulness of pollution from a paper mill. Still, even a decade after the Communication was adopted the PP still does not seem to form "a full-fledged and general principle of international law" as confirmed by the WTO agreements.[12]

Given the absence of guidance on the definition of the PP by ECJ/CFI case law, or case law from other courts or tribunals at the international level, it would contribute to the development of the principle if the Commission opted to include a definition of the precautionary principle in future general or more specific guidelines, for instance for an area such as chemicals regulation. By looking at some of the existing definitions and the differences between them, a proposal for such an EU definition of the PP can be made.

In the previous section, definitions of PP as established in the North Sea Declarations from 1984, 1987 and 1990 and in the 1980 World Conservation Strategy were already quoted. The 1987 declaration focuses on the 'most dangerous substances', whereas the 1990 declaration centres on substances that are 'persistent, toxic and liable to bioaccumulate'. The Strategy focuses on activities posing a 'significant risk'.

An early definition of the PP that became very well known can be found in Principle 15 of the Rio Declaration adopted in 1992. It reads as follows: *"in order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".* This definition encompasses a 'hurdle' of damage that is either serious or irreversible, and concentrates its scope on the protection of the environment.

The principle found its way into numerous MEA's, for instance in the 2000 Cartegena Protocol, where Article 11(10) explains that "*lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food*

[10] Para. 101.
[11] Para. 164.
[12] COM(2000)(1), p. 11.

or feed, or for processing, in order to avoid or minimize such potential adverse effects." Although it can be argued that the element "environmental degradation" used in the Rio Declaration also encompasses human health, it is definitely better to make this explicit in order to avoid discussion. Hence the Cartegena Protocol and Regulation 1107/2009 on plant protection products, both mentioning risks to human health next to environmental concerns, form examples that should be followed when defining the PP.

It follows from the examples cited above that there are indeed various definitions of the PP. At the same time, the notion that these different versions are not compatible with one another must be rejected. Just like the prevention principle is made operational in a wide variety of manners, notably according to the issue regulated, the PP will also vary depending on the issue at hand. In both cases, the measures to avoid the damage need to be proportionate. Societies make choices based on the available means and information, and do not aim at averting all risks or striving for a 'zero risk' society. Rather, reasonable choices are made, based on science as far as possible.

In cases where science can accurately predict what damage to the environment or human health can occur because of activities or substances, the choice remains to be made whether regulatory action will be taken or not, and if so, how stringent the measures will be. If the chance is high that the damage will occur, and that damage is considerable (for instance affecting the health of a large part of the population), and costs of measures are reasonable, it is likely that preventive measures will be introduced. If on the other hand the chance is low, and the resulting damage not serious or irreversible, while the costs of taking preventive measures are high, it is less likely that preventive measures will be taken.

Riding bikes without helmets could serve as an example here. The activity produces the risk of serious injuries to an average amount of persons involved in accidents each year. The risk can be calculated, as can the costs and benefits of a solution chosen in Sweden, namely making it obligatory to wear a helmet when cycling. It will be up to the regulator in other countries to say whether this preventive measure would be proportionate, considering the benefits in terms of the average number of persons suffering less injuries each year (does an average of one cyclist losing his or her life per year in case no helmets are prescribed amount to serious damage for society?) and a boost in sales for bicycle equipment sales, as opposed to the costs (notably for cyclists and for enforcement).

Similarly, in cases of scientific uncertainty, the estimated likelihood of the damage actually occurring forms a factor to take into account, as do the costs of precautionary measures and the seriousness or irreversibility of the potential damage. If a substance is suspected of being carcinogenic, and it is widely used, there is a good argument to be made that its use is to be restricted. If on the other hand the use is already very restricted and potential damage therefore limited, the need for precautionary measures seems smaller.

It is interesting to note that the Communication does not propose a threshold like 'serious' or 'irreversible' damage. Instead, the Communication opted for a wide interpretation of the principle, without fixed thresholds - except for one instance.[13] Almost all of the references to potential risks in the Communication refrain from mentioning the seriousness or irreversibility of the damage to be avoided. Instead, on several occasions the Commission stressed that it is the official aim of the Community to strive for a high level of protection where the environment and human health are concerned. Limiting the application of the precautionary principle to serious or irreversible damage was felt to be not in line with that aim.

A specific barrier of seriousness or irreversibility of damage is not formulated in the Communication nor in the case law of the ECJ, although in practice following a precautionary approach is accepted

[13] COM(2000)1, p. 16 mentions "serious consequences" of non-action as a reason to investigate precautionary measures. Note that the Communication also quotes Principle 15 of the Rio Declaration and article 3 of the UNFCCC, in which seriousness does form a condition – without specifically endorsing this aspect of those versions.

especially when the potential damage is serious (for instance where human health or protected nature areas are at stake). The Communication and subsequent developments allow for a wide scope of application of the PP under EU law, encompassing the protection of the environment as well as the protection of human health. A definition could thus be:

> *In particular, where there are threats of serious or irreversible damage, lack of full scientific certainty about the properties and effects of chemical substances shall not be used as a reason for not taking or postponing cost-effective measures to protect the environment and human health.*

3. Commission Communication (2001)1 and later developments

a. The main points of the Communication

The 2000 Commission Communication on the precautionary principle remains the most definitive source of guidance on application of the PP within the Union. By following this approach, the Commission wants to ensure that the PP is only used in cases where this is called for, and avoid unwarranted recourse to the PP as a disguised form of protectionism. In addition, the Commission points out that decision-makers are constantly balancing the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health. "Finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent actions can be taken, requires a structured decision-making process with detailed scientific and other objective information".[14]

The Communication does not deal specifically with application of the PP in the context of chemicals, but it does set out numerous guidelines that are of particular relevance for chemicals, notably because it places the PP within the realm of dealing with risks. The Communication calls for a structured approach to risks which comprises of three elements: risk assessment, risk management and risk communication. The PP is to be used especially in the risk management phase ("The PP is particularly relevant to the management of risk")[15].

As far as the preceding risk assessment phase is concerned, the Commission is of the opinion that risk evaluators are to apply a prudential approach rather than the PP. The PP is to be applied in particular in the risk management phase by decision-makers who consider that the chosen (high) level of protection may be in jeopardy but where scientific uncertainty precludes a full assessment of the risk.[16] In such a case, decision-makers need to be made aware of the degree of uncertainty attached to the results of the evaluation of the available scientific information.

Before deciding on taking action or not, the Communication underlines that it is necessary to complete as far as possible a risk assessment, consisting of four components: 1) hazard identification, 2) hazard characterization, 3) appraisal of exposure and 4) risk characterization. Annex III of the Communication provides further detail concerning these four components:

> Ad 1) Hazard identification is described as "identifying the biological, chemical or physical agents that may have adverse effects." It is explained that "[a] new substance or biological agent may reveal itself through its effects on the population (illness or death), or on the environment and it may be possible to describe the actual or potential effects on the population or environment before the cause is identified beyond doubt."
>
> Ad 2) Hazard characterisation means "determining, in quantitative and/or qualitative terms, the nature and severity of the adverse effects associated with the causal agents or activity." At this stage, the Commission explains, "a relationship between the amount of the hazardous substance and the effect has to be established", adding that sometimes, the relationship is difficult or impossible to prove, for instance because the causal link has not been established beyond doubt.[17]
>
> Ad 3) Appraisal of exposure consists of "quantitatively or qualitatively evaluating the probability of exposure to the agent under study." Apart from information on the agents

[14] COM(2000)1, p. 8.
[15] Ibid., p. 3.
[16] Ibid., p. 12
[17] Ibid., p. 28.

themselves (source, distribution, concentrations, characteristics, etc.), there is a need for data on the probability of contamination or exposure of the population or environment to the hazard.

Ad 4) Risk characterisation corresponds to the qualitative and/or quantitative estimation, taking account of inherent uncertainties, of the probability, of the frequency and severity of the known or potential adverse environmental or health effects liable to occur. It is established on the basis of the three preceding and closely depends on the uncertainties, variations, working hypotheses and conjectures made at each stage of the process. When the available data are inadequate or non-conclusive, a prudent and cautious approach to environmental protection, health or safety could be to opt for the worst-case hypothesis. When such hypotheses are accumulated, this will lead to an exaggeration of the real risk but gives a certain assurance that it will not be underestimated.

b. Summary of subsequent ECJ case law

From the EU judiciary's case law it is difficult to derive precise indications on the way in which the PP is to be applied by the EU regulators. At the same time it is worth noting that no case law was identified in which precautionary EU measures were found to be too precautionary (note that the same does not hold true for precautionary measures adopted by the EU Member States, where a multitude of judgments confirmed that not enough proof was presented to warrant national precautionary measures, for instance C-41/02 *Commission* v *Netherlands*). Further one case was identified in which an EU measure was judged to be not precautionary enough, namely T-229/04 *Sweden* v *Commission*.

In case T-229/04 *Sweden* v *Commission*, the CFI annulled the decision to include paraquat as an active substance under Directive 91/414, *inter alia* because of procedural irregularities in the assessment of this substance. The Commission's conclusion that "there is no indication that paraquat is neurotoxic" (para 103) was judged to be not satisfying the required procedural requirements laid down in the relevant regulation, because there were in fact indications of a possible link between paraquat and Parkinson's disease, but these were not investigated: the examination of the dossier submitted by the notifier did not contain an assessment of the literature concerning this possible link. Furthermore, a Guatemalan study whose results on effects of the substance on humans had been extrapolated to address the situation in the EU should have lead to the conclusion that a more precautionary approach was warranted (para 180). Finally, studies on the effects on animals (showing a significant risk) were not taken into account (para 228-242). These reasons brought the CFI to the conclusion that the level of proof brought about not only enabled the EU institutions to adopt a precautionary measure, but also an obligation for the EU to do so.

In the other cases investigated for this study, including *Afton Chemical* C-343/09, *Gowan* C-77/09, *S.P.C.M.* C-558/07, *Bayer Crop Science* T-75/06, *Solvay Pharmaceuticals* v. *Council* T-392/02 and *Pfizer Animal Health* v *Council* T-13/99, the courts indicated that the very wide discretion of the EU decision maker stood in the way of finding precautionary decisions to be in violation of EU law. Still, some indications on the way in which risk analysis should be conducted and risk management decisions are to be prepared (notably the way in which scientific advice can be used) can be derived from the case law of the EU judiciary.

In general, review by the EU judiciary is limited to verifying whether the exercise of such powers has been vitiated by a manifest error of appraisal or a misuse of powers, or whether the regulator has manifestly exceeded the powers of its discretion (see for instance *S.P.C.M.* C-558/07 and *Pfizer Animal Health* T-13/99). In such a context, the EU judiciary is of the opinion that it "cannot substitute its assessment of scientific and technical facts for that of the legislature on which the Treaty has placed that task" (case C-343/09 *Afton Chemical* on the fuel additive MMT, para 28).

The fact that risk assessments actually showed risks to be acceptable did not stand in the way of adopting precautionary measures according to the EU judiciary. The same holds true for situations in

which a risk assessment could not yet be carried out due to the absence of test methodologies (case C-77/09 *Gowan* on the pesticide fenamirol; see the substance case study on fenamirol in Annex 2). In several cases, these circumstances did not stand in the way of the adoption of precautionary measures aimed at protecting human health and/or the environment.

The judiciary did point out that Community institutions must be able to show that in adopting a precautionary act they actually exercised their discretion, which presupposes the "taking into consideration of all the relevant factors and circumstances of the situation the act was intended to regulate" (C-343/09 *Afton Chemical*, para 34).

In other legal regimes, notably that of the WTO, the European Court of Human Rights and to a certain extent in Germany and the Netherlands, examples of a more extensive judicial testing can be found:

- In the Netherlands, in cases of uncertainty the judiciary concentrates on due care and careful reasoning.
- In Germany, it has been argued that the considerable degree of leeway that authorities have in regulating risks needs to be compensated by formal requirements: the more leeway, the more careful the assessment needs to be, *e.g.,* setting up of a risk council, documentation of all stages of the procedure, stating the reasoning used extensively including the scientific basis and remaining uncertainties, and publication.
- In the WTO, each substance for which restrictions are to be introduced must be assessed separately; precautionary measures may only be adopted as provisional measures, the Panels and the Appellate Body look into the scientific reasoning in much more detail and ask experts from both sides to explain. In the EC-Beef hormones dispute, the fact that the individual hormones had not been subjected to a risk assessment was one of the reasons why the European precautionary measures were judged to be violating WTO law.
- In the first case in which the European Court of Human Rights made active use of the PP, *Tătar v Romania* nr 67021/01 of 27 January 2009, Romania was said to be obliged under Article 8 of the Convention (right to family life) to adopt precautionary measures to protect the complainants against health problems that might be caused by a gold mine where a sodiumcyanide spill occurred but activities were allowed to continue after the accident. The absence of scientific certainty and technical knowledge about the occurrence of damage as a result of the mining activities cannot stand in the way of adopting effective and proportionate measures aimed at preventing serious and irreversible damage.

Several commentators have expressed their concern about some of the precautionary measures adopted by the EU institutions, and have argued that the ECJ and the General Court (former CFI) should adopt a more active approach in testing such measures. They sometimes point at the way in which the ECJ approach differs from the much less restrictive way in which WTO Panels and its Appellate Body test the validity of trade restrictive measures. Also, the absence of a genuine cost-benefit analysis when adopting precautionary measures is criticized, as is the ECJ's reasoning that human health always takes precedence over economic concerns (*Pfizer* case); in reality, human health does not always take precedence.

4. Stages in taking regulatory decisions on chemicals

> *Application of the precautionary principle is part of risk management, when scientific uncertainty precludes a full assessment of the risk and when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy.*
>
> *--2000 Communication, p. 3*

The Communication sets out that the PP should only be applied in the event of a potential risk, if it cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inconclusive nature of the scientific data. It stresses that a scientific evaluation of the potential adverse effects (risk assessment) should always be undertaken based on the available data (hazard identification, hazard characterisation, estimation of exposure and risk characterisation). This should lead to a conclusion on the possibility of the occurrence and the severity of a hazard's impact on the environment, or health of a given population including the extent of possible damage, persistency, reversibility and delayed effect and to a description of the remaining uncertainties that helps the decision makers in the risk management phase.

Risk assessment is an integral part of the process of control found in much of the EU chemicals control legislation, though there is also a second type of regulatory action where no explicit risk assessment is required and ensuring safety is reliant on establishment of essential safety requirements and European technical standards. In the second type of regulatory regime, the regulators have already identified some of the risks associated with the product (hence the essential safety requirements) and the risk management measures are aimed at making the essential requirements operational and/or achieving compliance with the essential requirements, including the development of technical standards, verification procedures, etc.

Integral risk assessment/ risk management	**No explicit risk assessment; risk management only or secondary assessment only after implementation of essential requirements**
• REACH, and the chemicals legislation preceding REACH • Plant Protection Product Directive/Regulation • Biocidal Products Directive/Regulation • Food and feed safety legislation (food additives, flavours, food contact materials, food enzymes, nutrients, plus parallel legislation for feed) • Human and veterinary medicines • Cosmetics • Detergents	• Construction Products Directive • Packaging and Packaging Waste Directive • IPPC

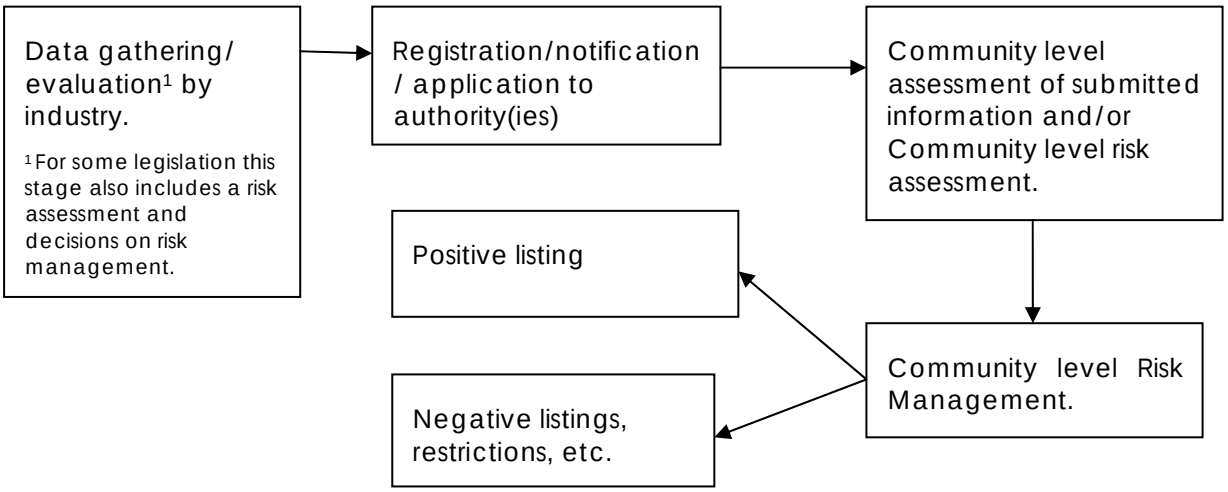
For the first type of regulatory action, the type of risk assessment carried out will depend on the particular legislation that covers the use(s) of the substance. Within the applicable legislative requirements, for instance for industrial chemicals under REACH, for biocides under the Biocidal Products Directive or Plant Protection Products (PPP) under the PPR Regulation or for chemicals used

in food or feed, the data required and the manner in which risk assessments are carried out (such as the number of required tests to be carried out or the bodies responsible for the risk assessment) can also differ. This is particularly notable in REACH where the requirements depend on the annual volumes of the chemical that are manufactured or imported per year. This is not a major factor in other legislation where risk assessments are required.

In addition to EU risk assessment requirements there is also the dimension of risk assessments carried out under other international and national programmes, such as the ICCA: Voluntary Global HPV initiative or OECD risk assessments. These have to be taken into account in developing the EU assessment, and this may require a further iteration of any EU risk assessment to include any relevant findings from the international work.

For the first type of regulatory action mentioned above, Figure A shows the main stages that can normally be identified, as reflected in a number of different legislative acts:

Figure A: Main stages in decision-making in chemicals regulation



Note that in most chemical legislation, the party seeking to place a substance on the market must produce data on the properties of the substance. The legislation then relies on regulatory authorities to assess that information and take the main decisions if needed. In reversing the burden of proof as to a substance's safety for a particular use, REACH also requires industry to assess the data it has gathered and to implement and recommend risk management measures for all substances manufactured/imported starting from 1 tonne/year.[18] Under REACH the regulatory authorities then carry out further data evaluation, risk-assessment and risk management for selected substances, as needed.

1. In relation to the schema depicted in Figure A, the **data gathering/evaluation stage** is where the entity with interests in the chemical (registrant/applicant) obtains information on the substance, often according to a specific scheme (e.g. Plant Protection Products Regulation, Food and Feed Improvement Agents and REACH Annexes VI-XI). The legislation may or may not require a risk assessment, to be carried out by the registrant/applicant based on the information gathered for the intended uses of the substance and details of any necessary risk management implemented on site, or recommended to customers. If the registrant/applicant cannot demonstrate that the substance can be controlled, it may be at this stage that the registrant/applicant judges that the substance is of serious concern and withdraws their interest in the substance. REACH is a good example of this as the reversed burden of proof implemented by the legislation specifically requires such a risk

[18] The consequence of the reversal of the burden of proof is that REACH primarily relies on the safety assessment carried out by manufacturers/importers.

assessment and risk management regime. However, it should be noted that the risk assessment and risk management is only related to the quantities manufactured or imported by the registrant/applicant and not to the total amount on the Community market so the risk management measures implemented or recommended can never be presumed to be adequate to eliminate the total risk for the substance.

2. The next **registration/notification stage** is where the data and, if required, a risk assessment are submitted to an authority by the registrant/applicant. The Authority could be a Member State authority or a European Authority (e.g. ECHA, EFSA, EMA or the Commission).

3. After the data is submitted comes an **evaluation stage**, during which the authority(ies) assess(es) the information. Not all substances may be subject to evaluation under some legislation, e.g. under REACH at least 5% of substances will be subjected to dossier evaluation. This assessment may include evaluation of the hazard data for its completeness and quality. The appraisal of the risk assessment may look at the appropriateness of its conclusions and the uses it covers to assess the degree of concern. If not revealed earlier, it is normally at this stage that any serious impact that the substance has will be revealed and any further information requirements decided. The need for risk management, or additional risk management, will also be an output of this stage. This stage could also cover assessment of the classification of the substance by the registrant/applicant.[19]

4. The **risk management stage** is where different Community risk management options are implemented such as positive listing, e.g. approval of a plant protection product active ingredient or food/feed improvement agent, or a negative listing, e.g. REACH restrictions. Sometimes there is a direct link to risk management from an evaluation outcome e.g. CMR 1A and 1B leading to a consumer use restriction for substances and mixtures, and in other cases the decision is taken on a case-by-case basis. This case-by-case assessment often leads to conditions that must be followed for positive listings as well as for derogations from negative listing.

[19] It is noted that in practice, the assessment of the classification in the evaluation stage is limited, as there are other processes under the CLP Regulation once established that harmonised C&L is necessary.

Figure B: Key decision points in chemicals regulation (sectoral legislation)

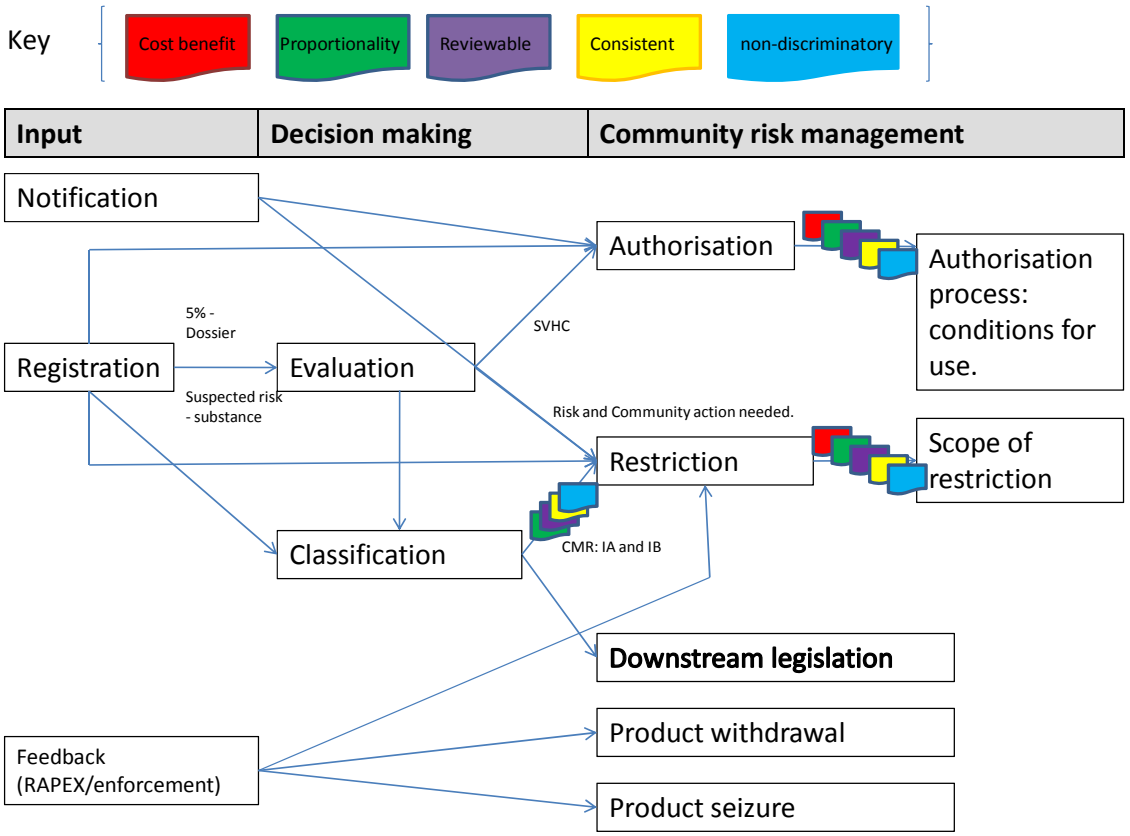


Figure B provides a more detailed overview of these main key decision points in chemicals legislation (data gathering/evaluation stage, registration/notification stage, Community risk management stage), that are considered to be applicable for a number of different sectors of legislation including REACH. In addition this figure shows where the five elements of the PP (proportionality; non-discrimination; consistency; examination of the benefits and costs of action or lack of action; examination of scientific developments) are implemented in the legislation. For example, the REACH authorisation process includes a socio-economic assessment (SEA) as part of the application and is assessed by ECHA's SEA Committee. This would fulfil the cost benefit principle and is represented by the red box in the diagram above. Likewise the authorisation is reviewable (represented by the purple box). This information is important to take into consideration if the relevant legislation is utilised to implement the PP, e.g. subject the substance to authorisation.

The following tables set out the stages as implemented under REACH and also detail a number of uncertainties that may arise which authorities will need to address:

Stage 1: Data gathering/evaluation

REACH process	Uncertainties	How dealt with?
Registrant • Gathers available information on substance and assesses quality. • Carries out gap analysis against relevant testing annexes (VII-XI).	• Appropriate information not identified or existing information of low quality. • Gap analysis is carried out wrongly • Uncertainties with respect to	• Dossier can be examined by ECHA under Dossier Evaluation.

REACH process	Uncertainties	How dealt with?
	available data not identified.	
• Fills gaps with information (Annexes VII-VIII) or proposes further testing (Annexes IX-X)	• Correct test carried out/proposed with appropriate conditions?	• All test proposals assessed by ECHA under Dossier Evaluation.
• Carries out Chemical Safety Assessment (based on information gathered) for all identified uses (if substance manufactured/imported > 10 tonnes).	• Information may be limited dependent on tonnage and thus information requirements may not identify relevant hazards or are not sufficient for a comprehensive risk assessment. • Identification of key studies, correct assessment factors, correct DNELs/PNECs, correct exposure measurements and correct risk characterisation ratio.	• Dossier can be examined by ECHA under Dossier Evaluation or risks from the substance can be further explored under substance evaluation.
• Implements identified risk management measures and recommends such measures to their customers.	• Risk management measures may not be sufficient for the registrant or not properly implemented by the downstream users.	• Dossier evaluation can assess the Chemical Safety Assessment and request more information. • MS can assess suitability and enforce the implementation of ES on the ground. • Substance evaluation can assess the potential risk on a Community level.

This first stage of data gathering/evaluation is likely to be the initial point at which uncertainties with respect to the information available are identified. For example, there might not be sufficient data for certain end-points (due to the requirements of the tonnage band); where a Chemical Safety Assessment is required, the absence of data should be considered and if judged necessary, a testing proposal submitted to ECHA (Annex I. Para 0.5). In addition, consideration of further testing might also be needed depending on the tonnage band.

However, it is always possible that hazards may be missed for a substance, for example where a particular test is not required at the particular tonnage level the substance is manufactured or imported at. In addition, limited information might be available on the basis of which it is not suitable to carry out a comprehensive risk assessment; even though this was the decision taken by the co-regulators.

Box: Limitations on the amount of data available for certain substances under REACH

Under REACH, only a minimum amount of data needs to be produced for non-prioritised[20] low-volume substances[21] which, according to Breitholz a.o. 2010, p. 86, "*will not be sufficient even for an initial characterization of inherent properties*". This is likely to be the majority of such substances. Even for volumes between 10 and 100 t, only acute toxicity tests are required with micro alga, a micro-organism and a fish species plus a chronic test with fish. Only for substances produced above 1000 t, population / reproduction tests are demanded.

It has been previously mentioned that it is at this stage that Industry judges that the substance is of serious concern and withdraws their interest in the substance or one of its uses e.g. when considering the use of a downstream user they may decide that it cannot be used safely. In addition, as the registrant only considers the risk management related to the quantities manufactured or imported by them, it is possible the risk management implemented or recommended is not robust enough. Again this is a consequence of the decisions of regulators.

Stage 2: Registration/notification/application to authority(ies)

REACH process	Uncertainties	How dealt with?
• Registrants submit dossier to ECHA for substances with information and if m/i $\geq$ 10 tonnes a CSA.	• None: ECHA completeness check is administrative only i.e. all fields in dossier filled.	• ECHA rejects registration if dossier incomplete (note: this is not a compliance test)

If ECHA determines that the registration dossier does not include all the information required, the registrant will be given a certain period of time for completing the dossier; if this is not done ECHA will reject the registration as incomplete.

[20] Substances are not prioritised unless it is predicted that they are likely to meet the criteria for category 1 or 2 classification for carcinogenicity, mutagenicity or reproductive toxicity or the criteria in Annex XIII; or substances with dispersive or diffuse use(s) for which it is predicted (i.e. by application of (Q)SARs or other evidence) that they are likely to meet the classification criteria for any human health or environmental effects endpoints (REACH Annex III).

[21] Substances manufactured or imported between 1 and 10 t per year.

Stage 3: Assessment of information/ hazard identification, based on the information, and risk assessment

REACH process	Uncertainties	How dealt with?
ECHA • Examines all testing proposals under Dossier Evaluation	• Correct testing determined	• Conformation of testing or correct test required.
• Selects at least 5% of dossiers for each tonnage level for closer examination (substances opted out of joint registration, low volume substances without full dossiers or substances in the CoRAP are prioritised; in addition enforcement information will be taken into account)	• All relevant requirements correctly fulfilled	• Further information required or substance proposed for restriction/authorisation.
• Substances that are considered as a risk to human health or the environment can be selected for Substance Evaluation on the basis of a dossier evaluation (e.g. due to the cumulative tonnage of the registered substance) or on the basis of any other appropriate source).	• Information and risk management correct for substance as a whole	• Further information required or substance proposed for restriction/authorisation

Note that in stage 3 the regulatory authority (in this case ECHA) checks the information to verify whether the information is sufficient for the further evaluation or whether additional information is needed (the scope of the compliance check is to verify the conformity with REACH requirements, as opposed to substance evaluation).

ECHA checks all testing proposals to ensure unnecessary animal testing is not carried out and also checks a certain number of the dossiers submitted to ensure compliance with the registration requirements. In addition, information on substances can be gathered from all the dossiers and other sources to clarify a suspicion of a risk. These mechanisms can be used to clarify questions on hazard or risk and their conclusions could be that there is a risk that cannot be dealt with by the prevention principle.

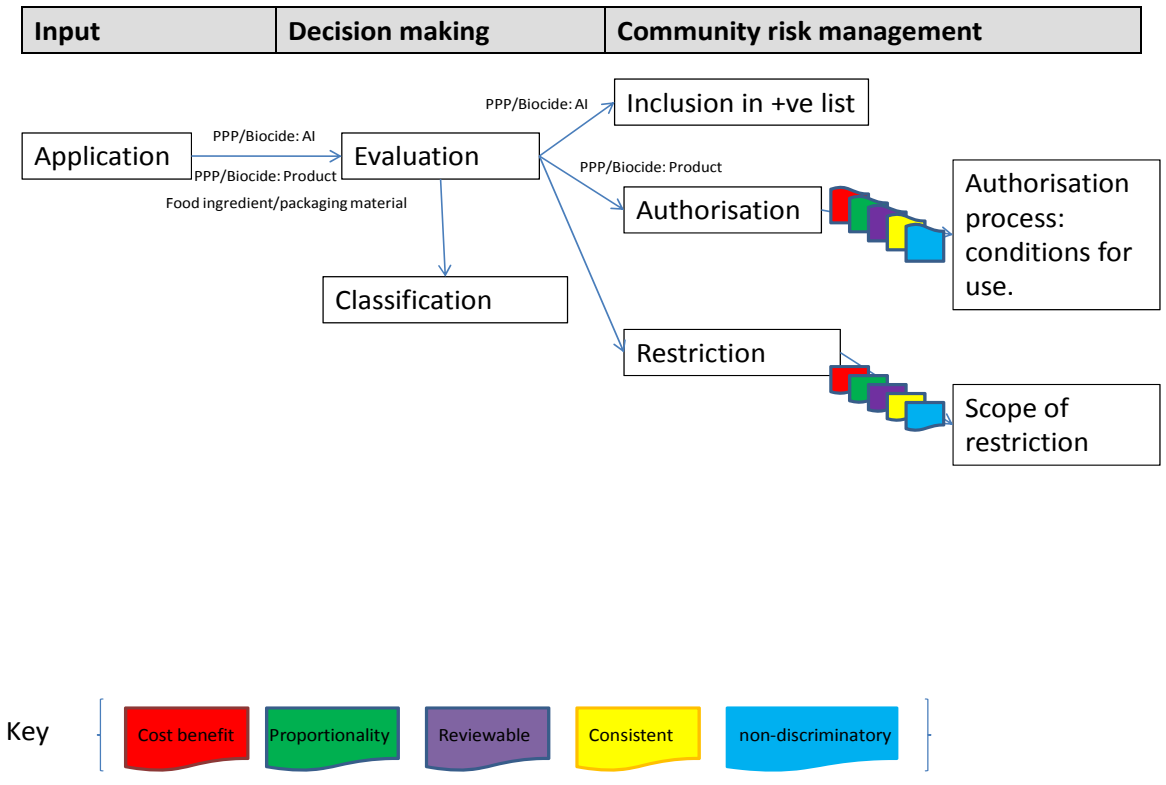
Stage 4: Risk management

REACH process	Uncertainties	How dealt with?
Positive listing		
• Substance to be authorised (allowed) for certain uses: o Substances of very high concern included on the candidate list. o ECHA recommend substances from the candidate list for Annex	• Identification of SVHC. • Identification of risk v benefits.	• Substances identified through a MS Committee procedure. • Risk and benefits are assessed by RAC and SEAC.

REACH process	Uncertainties	How dealt with?
XIV. o Applicants apply for certain uses. o ECHA Risk Assessment and Socio-economic Assessment Committees give an opinion. o Commission decides on authorisation or not.		
Negative listings		
• Substances to be restricted (banned) for certain uses: o ECHA Risk Assessment and Socio-economic Assessment Committees give an opinion. o Commission decides on restriction.	• Identification of the risk or benefits.	• Risk and benefits are assessed by RAC and SEAC.

The main decision points illustrated above in Figure B also apply to a number of different sectoral legislation. Figure C is given as an example to show how regulatory decisions taken for chemicals added deliberately to food for a technological purpose (food improvement agents) have similar decision points. This general scheme also applies to plant protection substances, biocides, cosmetics, food contact materials, etc.

Figure C: Key decision points in chemical regulation (food improvement agents)



In the case of new food improvement agents such as food additives the different stages are further briefly described as has been done for REACH above, also identifying where uncertainties arise and how these are dealt with.

Stage 1 and 2: Data gathering/application to authorities

Process	Uncertainties	How dealt with?
Applicant • Assembles a technical dossier with the required information on substance, including quality check.	• The content of the technical dossier is not absolutely defined under the legislation and the relevant guidance (unlike REACH). There may be data gaps or data quality issues and arguments can be put forward by the applicant as to why certain endpoints should not be addressed . • EFSA compliance check	• The dossier will always be examined by EFSA following a request from the Commission and any uncertainties regarding data gaps or robustness of the data will be addressed by a request to the applicant for further information.

For a new substance, uncertainties at this first and second stage of data gathering/application/ evaluation relate to the interpretation by the applicant of the guidance regarding the content of the technical dossier, and the subsequent decision by EFSA regarding the completeness of the information before the full risk assessment is carried out (EFSA compliance check). For existing additives that are

to be subject to a re-evaluation, uncertainties at this stage of data gathering are much greater, since there is no one applicant or responsible entity linked to a particular substance already on the market, and data gathering is carried out by EFSA itself, based on existing evaluations and newly published information, together with "calls for data". Relevant information may be missed, or may be present in company files but not submitted in response to the "calls for data".

Stage 3: Assessment of information/ hazard identification and risk assessment (evaluation)

Process	Uncertainties	How dealt with?
EFSA • Carries out a risk assessment on each substance submitted by an applicant for "authorisation"	• Data gaps in the information submitted and uncertainties regarding the essential nature of the missing information • Uncertainties regarding the estimated exposure to the substance • Differing opinions between risk assessors (within EFSA and outside) regarding the nature of the toxicological risks • The risks identified require new test methods to fully characterise the risk	• Decision may be made to request the applicant to provide the missing information . • Refinement of exposure assessment as far as possible • Harmonisation of risk assessment terminology and approaches. Open consultation/debate regarding the outcome of the risk assessment between EFSA risk assessors and external risk assessors having different opinions • Development of new test methods and agreement between risk assessors on their interpretation

On the basis of the risk assessment, EFSA reaches a conclusion regarding the degree of risk to human health of the substance when used as intended. This may be that the substance is of very low risk (can be used "quantum satis" in all foods), is of low risk if used as intended (in a certain range of foodstuffs at a certain level) or presents an unacceptable risk if used as intended. Since "use as intended" translates into assessment of exposure, which is one of the key uncertainties in any risk assessment, considerable uncertainties arise concerning the outcome of the risk assessment, which can be challenged by others. Uncertainties also arise (as shown above) because of differing opinions between risk assessors regarding the nature of the toxicological risks or regarding the need for further data on certain endpoints, requiring new test methods to fully characterise the risk. These points have been discussed elsewhere in this report and are well illustrated in the case studies on Phthalates, Fenamirol, Bisphenol A.

Stage 4: Risk management

Process	Uncertainties	How dealt with?
• ***Positive listing (Substance authorised for use and placed on a positive list with or without conditions of use)***		
• Substance of very low concern authorised for use without restrictions on conditions of use • Substance of low concern allowed* for certain uses and at certain levels: • Substances of high concern (unacceptable risk) not placed on the positive list [22]	• Authorisation without limitations (quantum satis) makes exposure assessment almost impossible • Relies on active policing. • None	• General move away from quantum satis authorisation • Active enforcement policy .

Difficulties in applying the logic and consequences of the key decision points

The key decision point models illustrated in Figures A, B and C are useful for hazards and risks that are known and can be managed under the relevant EU legislation. However, certain risks are more difficult to fit within these models. For example, for some end points, e.g. immuno- and neurotoxicity, the risk assessment is still in an infancy stage so a complete risk assessment is not always possible. These may be issues to be identified by an authority for further initiatives.

It is also often the case that current hazard identification and qualification tools are not suitable for some risks. For example, in relation to endocrine disruptors, the discussion on identification tools has been on-going for many years; in 1996 OECD set up a Special Activity on Endocrine Disrupter Testing and Assessment with the objectives of, amongst other things, developing new and revised existing Test Guidelines to detect endocrine disrupters. This work is still on-going. The lack of available test methods and assessment techniques is often an issue in applying the Precautionary Principle, such as in the case below[23]:

Box: The case of Fenamirol

Fenamirol is a potential endocrine disruptor (ED) but the relevant assessment report under Directive 91/414/EEC (Plant Protection Products), carried out by the UK, assessed that the substance would fulfil the safety requirements of the Directive. The Scientific Committee on Plants concluded that the effects of Fenarimol on male fertility as demonstrated in rats were relevant for human risk assessment. There was no scientific consensus on the exact extent of the risk due to the lack of test methods and a number of Member States raised concerns. Due to the uncertainty over the extent of the risk, the Commission proposed restrictions on the use of the substance because of its ED properties. The European Court of Justice confirmed the use of the PP in this case due to the scientific uncertainty regarding the assessment of the effects on the endocrine system of Fenarimol.

[22] Commission is the ultimate decision-maker on authorisation or not.
[23] See full case study in Annex 2 for further information.

Note that the test data required in European risk assessment procedures primarily follow the OECD test guidelines. New test methods are developed only at a very slow pace (taking some 10 to 15 years), notably because of the process of reaching consensus among a large number of OECD members. Therefore, if improvements to existing test methods are required, e.g. to account for actual conditions in ecosystems rather than mere laboratory conditions or if new test methods (for instance for endocrine disruption, as in the case of Fenamirol) need to be developed, the process of development may often lag behind the identified need. This may cause difficulties in applying the key decision point models illustrated in Figures A, B and C in many chemical risk assessments in addition to the Fenamirol example presented above. A further example is provided by the case study on phthalates (see Section 5 (Framework for applying the PP in regulatory decisions on chemicals), item (f)(2), "*Box: The cases of the phthalates and Bisphenol A***"** and also Annex 2, substance case study on phthalates.

5. Framework for applying the PP in regulatory decisions on chemicals

> *Finding the correct balance so that proportionate, non-discriminatory, transparent and coherent decisions can be arrived at, which at the same time provide the chosen level of protection, requires a structured decision making process with detailed scientific and other objective information.*
>
> *--2000 Communication, p. 3*

This section sets out a series of logical steps, seven in all, for considering if a substance or mixture is a candidate for application of a risk management measure, such as a restriction under REACH, the Directives on Restrictions on Hazardous Substances (RoHS) or End-of-Life Vehicles (ELV), or withdrawal of a Community authorisation (via non-inclusion in a positive list) of a plant protection product, a food improvement agent, etc., based on the precautionary principle. It is intended as a framework for considering whether the information available indicates the potential for harmful effects. At the same time it cannot fully demonstrate the risks or possible consequences to ensure that the process followed in such cases warrants policy outcomes and interested parties and the public involved are convinced that decisions are sound.[24] It is in such circumstances that it may be deemed necessary to take precautionary measures. The seven steps are as follows:

a. Has a potential negative effect been identified?
b. Has a scientific evaluation of the substance been carried out?
c. What are the uncertainties concerning the nature or probability of the possible harm?
d. What are the options available for controlling the risk of possible harm?
e. Do the options for risk management measures meet the five elements of the precautionary principle?
f. Process for reaching decisions
g. Is there a plan for reviewing the actions taken if new scientific knowledge emerges?

For each step, specific guidance is provided concerning the various elements that should be considered, starting with an excerpt from the 2000 Communication, referring to developments in smart regulation (notably COM(2010)543 where subsection e is concerned[25] and the Communications on consultation COM(2002)704 and on the use of expertise COM(2002)713), and summarizing ECJ case law where appropriate. Additional ECJ case law is set forth in Annex 1, organized according to the seven logical steps.

Each step stresses the importance of documenting the analytical process, including both the evidence and the uncertainties, in order to give confidence to the decision-maker that the recommendation to apply the precautionary principle is appropriate.

[24] COM(2002)713 on the use of expertise by the Commission.
[25] COM(2010)543 is entitled "Smart regulation in the European Union" and discusses developments in "getting legislation right" in order to deliver on the Europe 2020 Strategy (COM(2010)2020) objectives on smart, sustainable and inclusive growth. It deals *inter alia* with consultation and impact assessment and the promotion of evidence-based policy making, and stresses that efforts on new legislation should match efforts to manage and implement existing legislation, ensuring that it delivers intended benefits and amending it in the light of experience (p. 3).

a. Has a potential negative effect been identified?

> *The precautionary principle is relevant only in the event of a potential risk, even if this risk cannot be fully demonstrated or quantified or its effects determined because of the insufficiency or inclusive nature of the scientific data. It should however be noted that the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions.*
>
> *--2000 Communication, p. 13*

The case law of the ECJ makes it clear that the starting point for applying the precautionary principle is the identification of potentially negative consequences for health or the environment. It is not sufficient to make a generalised presumption about a putative risk (*Comm. v France, C-333/08)*. Likewise, the risk may not be purely hypothetical. Rather, the risk of a negative effect must be "adequately backed up with scientific data" (*Pfizer Animal Health, T-13/99).*

A negative effect, i.e a hazard, is normally identified through one of the following mechanisms:

- Regulatory risk assessment (under those streams of legislation involving integrated risk assessment/risk management such as REACH[26]) reveals a risk that can be characterised to some extent based on the results of available studies.
- Epidemiological studies looking at causes of effects in certain populations (case control studies) or looking for effects that may occur in certain populations over a period of time (cohort studies).
- Monitoring in the environment or biomonitoring to detect the presence of a certain chemical, either from routine monitoring or because of a public interest campaign, plus associated information that this presence of the chemical can have adverse consequences.

In determining if the effect that has been identified is adverse or not, the chemical will normally undergo further testing (either animal or alternative) in order to attempt to refine the hazard identification step. Whether identified as a result of the preliminary testing or following additional testing, the effect can be either well characterised or there may still be a lack of clarity or uncertainties about the effect or its interpretation. In the latter case, the uncertainties over the effect need to be examined and a decision taken on the characterisation of the effect.

In addition to the identification of the adverse effect, the seriousness of the effect should also be considered. "seriousness" may be viewed as a composite of known or considered irreversibility of the effect, knowledge regarding the consequences of the effect (e.g. carcinogenicity) or lack of knowledge regarding the consequences of the effect (e.g. potential mutagenic effects or endocrine-disrupting effects in the human population).

The Communication states that:

> *When decision-makers become aware of a risk to the environment or human, animal or plant health that in the event of non-action may have serious consequences, the question of appropriate protective measures arise. Decision makers have to obtain, through a structured approach, a scientific evaluation, as complete as possible, of the risk to the environment, or health, in order to select the most appropriate course of action.*

However, there is no discussion of the actual degree of seriousness of the risk, or of the consequences of any risk, which is necessary to initiate the PP in the Communication (seriousness is mentioned only once in the text – see above under 2d). It is clear though from the identified case-law and in particular the specific case studies examined (Annex II) that the risk of the occurrence of serious damage is usually the initiator of the precautionary principle. The risks considered in the substance case studies

[26] See also the Plant Protection Products Regulation, Biocidal Products Directive/ Proposed Regulation, food and feed safety legislation (food additives, flavours, food contact materials, food enzymes, nutrients, plus parallel legislation for feed), human and veterinary medicines, cosmetics, detergents.

(see Annex 2) were related to carcinogenicity, endocrine disruption (twice) and developmental effects in children; all these are potentially serious effects where the Court agreed that the PP had been correctly applied. Therefore, although it cannot be deduced that the PP only applies where a potentially serious risk is identified, the burden of proof necessary to justify such application may be lower.

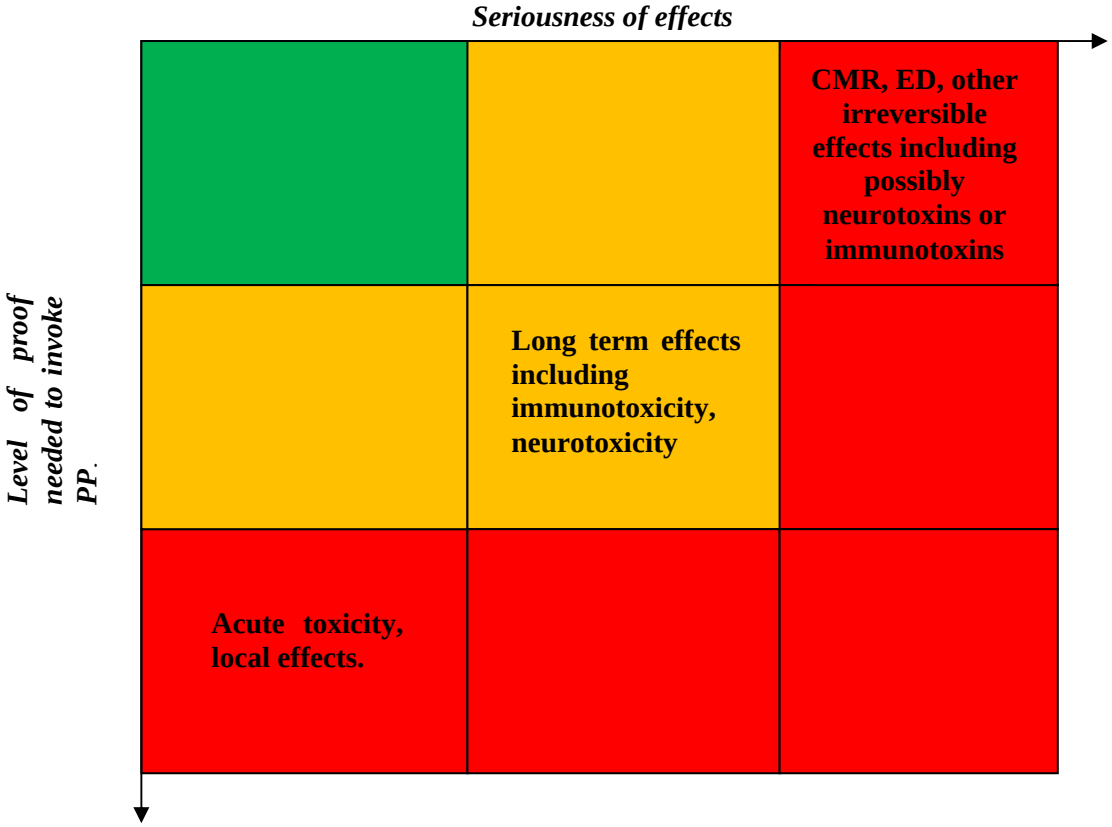
Box: The case of nickel compounds

The Specialised Experts (an expert Committee providing advice to the Commission on classification of CMR substances within the framework of Directive 67/548/EEC) had concluded that nickel sulphate and nickel chloride should be considered as human carcinogens (Carc. Cat. 1), based on epidemiological results following inhalation exposure that demonstrated a causal association between human exposure to the substances and the development of lung cancer. The Specialised Experts also agreed that nickel nitrate and nickel carbonate should be classified as Carc. Cat. 1, despite the absence of strong epidemiological evidence. Despite challenges regarding whether the assessment of the intrinsic properties of the nickel carbonates had been adequate, the classifications were upheld by the ECJ, reflecting the seriousness of the effect, carcinogenicity.

Initially there was extensive debate regarding the potential seriousness of the effects in the case of the substances producing endocrine disruption (fenamirol and phthalates) and developmental effects in children (bisphenol A) used as case studies in this report. However, there is now general scientific acceptance that these effects should be regarded as serious and the PP has been applied in reaching regulatory decisions.

Therefore it is likely in the future that potential risks arising from hazards such as carcinogenicity, mutagenicity, reproductive toxicity or endocrine disruption will continue to be the type of effects where the PP will be invoked. This is due to the potential consequences of the risks and the population exposed (especially vulnerable populations) and this will also likely be true of a number of less well understood risks, such as neurotoxins and immunotoxins. For example, the PP is often invoked in discussions on the potential risk related to some nano materials.[27] In these and other cases, factors such as irreversibility, PBT and long-term effects may be taken into account.

[27] See for instance Dr. E.M. Vogelezang-Stoute, dr. J.R. Popma, dr. M.V.C. Aalders and mr. J.M. Gaarthuis, *Regulering van onzekere risico's van nanomaterialen. Mogelijkheden en knelpunten in de regelgeving op het gebied van milieu, consumentenbescherming en arbeidsomstandigheden*, .



In the case of a lower level of hazard, more indications that there is a potential risk are required; this relationship cannot be exactly quantified (if only because potential risks to which the PP applies per definition cannot be quantified) and will always need to be assessed on a case-by-case basis.

b. Has a scientific evaluation of the substance been carried out?

> *Risk assessment consists of four components - namely hazard identification, hazard characterisation, appraisal of exposure and risk characterisation (Annex III). The limits of scientific knowledge may affect each of these components, influencing the overall level of attendant uncertainty and ultimately affecting the foundation for protective or preventive action. An attempt to complete these four steps should be performed before decision to act is taken.*
>
> *--2000 Communication, p.14*

The Commission stresses in its 2000 Communication that application of the PP does not come in the place of 'sound science'. A scientific evaluation is always called for, and an assessment of risk "should be considered where feasible" (p. 14). The scientific evaluation should show that the desired level of protection of the environment or a population group could be jeopardised. Absence of an established causal relationship, a quantifiable dose/response relationship or a quantifiable evaluation of the probability that the potential risk would materialise are not to be used as reasons for inaction. Indeed, potential consequences of inaction are to be assessed.

The scientific evaluation is assumed to be a risk assessment since the Communication refers to the four components of risk assessment: hazard identification, hazard characterisation, appraisal of exposure and risk characterisation. If the evaluation and/or risk assessment can show that there is sufficient data and evidence, the risk management decisions can be based on the prevention principle, rather than on the PP.

Although the elements of risk assessment are well known, not all legislation requires all of these components. For example, the Detergents Regulation requires assessment of the biodegradability of surfactants used in cleaning agents, but not exposure assessment. This means that if a substance of concern was covered by such an act, a complete risk assessment will not have been carried out. As a result, a risk assessment might need to be carried out according to the requirements of another type of legislation.

The Communication explains that the limits of scientific knowledge may affect each of the four components of risk assessment, influencing the overall level of attendant uncertainty and ultimately affecting the foundation for protective or preventive action. It notes that an attempt to complete these four steps should be performed before a decision to act is taken. Although some may argue that a minimum or sufficient level of scientific evidence would need to exist before precautionary measures could be introduced,[28] the Communication does not formulate any such condition. It merely indicates that reasonable grounds for concern should be identified. The ECJ confirmed that no such condition needs to be taken into account by constantly stipulating that the regulators do not have to wait for the reality and the seriousness of risks to be fully demonstrated.[29]

It is difficult to define "reasonable grounds of concern" in general terms or criteria that can be applied in every case since the specifics of each case are likely to differ because of the uncertainties involved. However some factors could include indications of:

- hazards to vulnerable populations (e.g. children, pregnant woman or the elderly) rather than to healthy adults;
- problems identified in standard tests or in robust epidemiological studies, as opposed to non-standard tests or in epidemiological studies in small populations;
- emerging risks not fully addressed by existing risk assessment methodology, e.g. nanotechnology;
- particular characteristics of the risk (e.g. potential effects are known to be irreversible);
- nature of the risk (e.g. carcinogenic, mutagenic and/or reprotoxic effects).

Where there are reasonable grounds for concern over the possibility of severe or irreversible damage to health or the environment, the lack of full scientific certainty should not be an obstacle to triggering actions to gather and assess additional data.[30]

In any case, it should also be borne in mind that the difficulty in setting a minimum level of scientific evidence is compounded by the 'normal' scientific uncertainties in risk assessment.

[28] CEFIC, Position paper on the precautionary principle, 8 December 1999. The paper suggested that Principle 15 of the Rio Declaration would require that there is a sufficient likelihood that damage would occur before the PP comes into play, although that Principle does not contain any indication of such a condition.
[29] See for instance Case 77/09, para 73 and 74 and the earlier case law quoted there.
[30] For an example of the general acceptance of this principle, please see Nokia Environment strategy http://www.nokia.com/environment/strategy-and-reports/substance-and-material-management.

Box: The example of Bisphenol A

Bisphenol A (BPA) was the subject of a comprehensive Risk Assessment Report (RAR) under the Existing Chemicals Regulation EC (No) 793/93 which showed that there was a need for further information and/or testing in relation to developmental toxicity and effects on endocrine disruption. Studies conducted using low doses (in the µg/kg range) had shown variable and conflicting effects of BPA on endpoints relevant to development and endocrine function that caused concerns. Subsequent risk assessments including those by EFSA emphasised that there was an absence "of an established causal relationship, a quantifiable dose/response relationship or a quantifiable evaluation of the probability that the potential risk would materialise" but concerns continued to be expressed. These concerns eventually led to a restriction of BPA in infant feeding bottles despite the outcome of the scientific evaluations (see Annex 2 for further information).

The first two elements of hazard assessment/characterisation are often the areas where uncertainty occurs (see further discussion in Section 5c) which leads to uncertainty whether there is a risk; this could be due to a lack of data but also to a disagreement over the effect itself; is it an effect that is relevant for humans, is the quality of the studies adequate, are the correct internationally recognised studies used?

In some cases, the uncertainties in the assessment can be resolved by gathering further information, e.g., if the quality of the test or the relevance of the test method is questioned, then a new test could address the situation. However, there are cases where further testing is unlikely to resolve the situation e.g. a new carcinogenicity test will take two or more years to provide an answer and the uncertainties in this type of study would likely not lead to definitive result.

For certain effects it is not possible to carry out a quantitative assessment of effects; for non-threshold effects, such as carcinogenicity caused by genotoxic carcinogens, it is not possible to determine a no effect level, so a qualitative assessment is normally all that is possible. This type of qualitative assessment can also be used in cases where insufficient information is available to reach a decision on a potential risk.

c. What are the uncertainties concerning the nature or probability of the possible harm?

The implementation of an approach based on the precautionary principle should start with a scientific evaluation, as complete as possible, and where possible, identifying at each stage the degree of scientific uncertainty.

--2000 Communication, p. 4

The nature of uncertainty related to the process of risk assessment is essential in determining whether the Precautionary Principle will be invoked. Scientific uncertainty results usually from:

- the variable chosen,
- the measurements made,
- the samples drawn,
- the models used (relying on animal models to establish potential effects in man), and
- the causal relationship employed.

It may also arise from a controversy on existing data or lack of some relevant data. These can be dealt with by incorporating aspects such as:

- using body weight ranges to make inter-species comparisons;
- adopting a safety or assessment factor in evaluating an acceptable daily intake to account for intra- and inter-species variability; the magnitude of this factor depends on the degree of uncertainty of the available data;
- not establishing a safe level of exposure for substances recognised as genotoxic or carcinogenic;
- adopting the "ALARA" (as low as reasonably achievable) level as a basis for certain toxic contaminants. [31]

However, in some situations the scientific data are not sufficient to allow one to apply these aspects in practice. It is in situations like these that decision-makers face the dilemma of having to act or not to act.

The ECHA Guidance on the Information Requirements and the Chemical Safety Assessment (IR/CSA) states that there are uncertainties at each stage of the CSA process (hazard assessment, exposure assessment and risk characterisation), which is true of all classic risk assessments:

- Hazard assessment: the degree of uncertainty in the measure of (no) effect;
- Exposure assessment: the degree of uncertainty in the exposure estimate (predicted or based on measurements);
- Risk characterisation: the degree of uncertainty in the risk estimate.

These uncertainties could be due to descriptive errors (e.g. wrong or incomplete information), aggregation errors (e.g. approximations for volume and time), errors of assessment (e.g. choice of the wrong model), and errors of incomplete analysis (e.g. overlooking an important exposure pathway).

The IR/CSA guidance states that the amount of input required in an uncertainty analysis, and the importance of its contribution, will depend on the specific circumstances; little uncertainty analysis is needed for a substance which has a full data set, few dangerous properties, minimal exposure and a risk characterisation ratio (RCR) which is significantly less than 1.

In many recent uncertainty studies, the difference between variability and uncertainty in the risk assessment is emphasised.[32]

Uncertainty can be caused by limitations in knowledge (e.g. limited availability of empirical information), as well as biases or imperfections in the instruments, models or techniques used. An example is an emission estimate that is based on a reasonable-worst case assumption. The limited knowledge about this factor could be improved (and uncertainty decreased) by site-specific knowledge or measurements. This matters because the real emission (and associated exposure) can differ from the presumed worst-case emission. Consequently, as the quality of data and models improves, the amount of uncertainty decreases. Thus, uncertainty can be reduced by developing an improved knowledge base.

Variability, on the other hand, refers to variation that exists in the real world. It is an inherent property of a system that cannot actually be reduced by further information. There are various sources of variability such as:

[31] ALARA is mentioned in Communication 2000(1) at p. 15, but the Scientific Committee on Health and Environmental Risks (SCHER) has pointed at disadvantages of the ALARA principle. In a 2009 report it stated that ALARA forms a "valuable tool to generally reduce exposure" but also that "it may create problems for risk communication" (SCHER, *Risk assessment methodologies and approaches for genotoxic and carcinogenic substances*, opinion adopted adopted at SCHER's 27th plenary on 13 January 2009). Furthermore the SCHER has pointed out that "[t]he ALARA principle is not science based and is thus not supported by the SCHER and MOE exposure is recommended."

[32] For instance in Verdonck et al., 2005

- Inter-species variability;
- Intra-species variability (e.g. due to age, sensitivity, physiology, behaviour…);
- Variability in environmental characteristics (e.g. temperature, wind, homogeneity…);
- Variability in time and space.

One of the main differences between uncertainty and variability is the fact that uncertainty is often reducible through further information, whereas variability is not. What can be achieved is the reduction of uncertainty in our knowledge about the actual variability.

There are also other considerations in assessing uncertainties in the risk assessment if the risk assessment does not clearly identifies a risk, i.e. whether there are uncertainties about the consequences of a risk as opposed to uncertainties in the risk assessment.

The important consideration with regards to the precautionary principle is whether the uncertainties are at such a level that the effect is of sufficient clarity that action can be taken. If the uncertainties are low enough then the prevention principle can be invoked.

As explained above in section 2c, the prevention principle applies to situations in which a risk can be described in quantitative terms, whereas the precautionary principle deals with potential risks that cannot be quantified because of the insufficiency or inconclusive nature of the scientific data. Whether prevention or precaution is opted for, in both cases difficult risks will need to be explained to the public and stakeholders. The more uncertainties that remain, the more careful this communication will need to be. As one researcher stated: "Since the mid 1990s levels of trust in policymakers and regulators among European publics have increasingly declined, whilst survey responses suggest that environmental NGOs have scored the highest in terms of trust."[33] It is also worth quoting the Commission White Paper on European Governance adopted in July 2001, in which it was observed that "[i]t is often unclear who is actually deciding - experts or those with political authority. At the same time, a better-informed public increasingly questions the content and independence of the expert advice that is given. These issues become more acute whenever the Union is required to apply the precautionary principle and play its role in risk assessment and risk management."

Guidance on how to communicate information on uncertainties can be found in existing guidelines, such as the ECHA guidance on Information Requirements and the Chemical Safety Assessment. It recommends the following approach when communicating uncertainties:

- *Setup, limitations of approach*
  - Describe what was done (narrative) and why (motivate)
  - Considerations what is and what is not considered
  - Considerations of uncertainty and variability
  - Narrative forms should be used to explain what is not understood as well as identifying what is understood
- *Presentation of methods*
  - Specialist jargon should be avoided whenever possible
  - Novel ideas should be introduced one at a time rather than all at once
  - Explanations should be started with familiar assessment methodologies and subsequently move to unfamiliar assessment approaches
  - For decision-makers, inclusion of a "positive control", the effects of which were already well understood by those involved in the risk analysis process, facilitates communication about new methods (e.g. deterministic and probabilistic side by side)
  - Graphs with frequencies on both axes are generally difficult to understand and communicate to non-experts.

[33] A. Anderson, *Communicating chemical risks: beyond the risk society*, in: Eriksson, Gilek and Rudén (2010), p. 29-44 at 41.

- *Communicating the results of the assessment*
    - Communicating what is not known as well as what is known, and potential uncertainties
    - Use narrative forms backed up with diagrams (where appropriate) to describe the results of assessments and associated uncertainties
    - A concise summary report outlining the main points of the assessment and its key results should be produced
    - A technical report annex to the CSA should be made available for those who wish to examine the details

This approach is entirely adaptable to communicating the results of uncertainties for legislation other than REACH and should be included in the documentation of any application of the PP.

Box: Comparative review of risk terminology by DG SANCO

Clarity of scientific advice is important for public authorities to make the best risk management decisions, which are to be understood and widely supported by stakeholders groups. From that perspective, it is vital that the opinions of scientific committees explain clearly the nature of the risks, their possible impact on humans and the environment and the uncertainty in available scientific information. As a result of the wide variety of terms and phrases used to express risk and uncertainty, DG SANCO initiated a comparative review of the terminology used in concluding sections of 100 opinions issued by the EU's former and current non-food scientific committees and made recommendations for improved approaches to expressing risk and uncertainty. The purpose of the comparative review was to assist the current non-food scientific committees to identify best practices in the expression of complex ideas used in risk assessment. The study resulted in several concrete and practical recommendations in relation to formulations of qualitative and quantitative expressions of risk; uncertainty; statistical significance; missing information; functional separation of risk assessment and risk management; and the definition of risk. [34]

d. What are the options available for controlling the risk of possible harm?

Recourse to the precautionary principle does not necessarily mean adopting final instruments designed to produce legal effects that are open to judicial review. There is a whole range of actions available to decision-makers under the head of the precautionary principle. The decision to fund a research programme or even the decision to inform the public about the possible adverse effects of a product or procedure may themselves be inspired by the precautionary principle.

--2000 Communication, p. 15

If the uncertainties concerning the possible adverse consequences linked to the chemical substance remain at such a level that action should be taken, the next step is to consider the options for action. This section reviews some of the options available. The list of options discussed is by no means exhaustive. Rather, the aim is to provide a starting point for considering the types of measures that might be invoked to limit the risks of possible harm identified so far.

Taking a precautionary decision is difficult because of the need to balance between the purported benefits of the substance and the possibility of unacceptable risks. The process of identifying options

[34] Comparative review of risk terminology, A comparative review of terminology and expressions used by the three non-food scientific committees established by the Commission Decision 2004/210/EC and by their predecessors established by Commission Decision 97/579/EC (repealed by Commission Decision 2004/210/EC), *Final Report,* November 2007.

will need to keep in mind the importance of proportionality as well as effectiveness, which are discussed in the next subsection.

The choice of options will be at least partly informed by the information gathered during the scientific assessment, including the uncertainties analysis. For example, a concern that a substance might be a neurotoxin posing special risks to fetuses, infants or young children could signal that risk management measures should focus on how to limit exposures to women of child-bearing age as well as to children.

In identifying possibilities for precautionary risk management measures, it remains important to document carefully the considerations that may arise in discussing the various options. This documentation will be important in carrying out the review of possible options according to the five elements of the PP (see next step) and in presenting the case for precautionary action to the final decision takers.

Risk management options for chemicals

1. Wait and see (do nothing)
2. Gather more data
3. Disseminate information about the possible risk
4. Require authorisation of uses
5. Establish restrictions or bans
6. Voluntary measures

1. Wait and see. One option is to do nothing for a period of time, to see if any more information becomes available in the meantime that might clarify the uncertainties. This may be the option that is easiest to use, and in certain cases it may indeed be the most prudent approach. At the same time, however, it may be the most difficult to justify to public interest stakeholders.

Obviously, the more serious the concern, the more hesitation should be given to taking a "wait and see" approach. In any case, a conscious decision should be taken, instead of simply letting matters slide. Additionally, the justifications for taking this approach should be carefully documented, and a date set for reviewing the decision in the future with the possibility of taking action if the concern is still unresolved.

2. Gather more information. Another frequently used option is to gather more information, with the aim of reducing at least some of the uncertainties identified during the scientific assessment. However, the use of this option needs to balance with the requirement to gather more information as part of the risk assessment that should already been undertaken. It should be noted that this option is often used in combination with the other risk management options discussed here. It can, for example, be used as a variant of the "wait and see" approach, as justification for delaying a more concrete risk management measure. However, it can also be used in combination with e.g. an authorisation or restriction in order to monitor whether the risk management measure is effective or, alternately, continues to be justified.

A range of information-gathering options are possible. One action could be to provide for targeted research on the hazard identified. The research could focus on testing of specific toxicological endpoints or on development of new sampling and testing methodologies. It might also be important to gather more information related to exposure. This could include bio-monitoring or monitoring of various environmental media, such as ambient air or water, to determine the extent of contamination, if any. It might also involve carrying out forward-looking studies to see how much market demand might arise for a substance and whether usage of the substance might increase to the point where exposure might become a matter of heightened concern. The case study on nanosilver (included in

annex 2) could be an example of an emerging issue where this type of additional information might be important.

Possibilities for funding additional information gathering include seeing if the EU FP7 programme or national funding programmes can finance targeted research. There is also the possibility of asking the JRC or linking with Member State scientific facilities to carry out the primary or practical research needed to resolve the policy question.

On the one hand, such research could be viewed as simply another phase of the risk assessment process. However, certain types of research would certainly be more related to the risk management phase, such as development of scientific criteria and test methodologies for evaluating substances for neurotoxicity. It could also be structured as a risk management measure, e.g., by linking the gathering of additional information to a preset deadline at which point the new data would be assessed and a decision taken concerning any additional action.

For example, if more testing is needed on specific endpoints to determine the extent of the possible harmful side effects, it could be decided to carry out the desired testing and to take a decision concerning any envisioned measures at a cut-off date in the future, especially if the uncertainties about the risk are still too high to invoke the prevention principle. This would serve to avoid undue delays in taking precautionary risk management measures. [35]

3. Disseminate information about the possible risk. As the 2000 Communication notes, a precautionary action can also include a decision to inform about the possible adverse effects. Information dissemination is already used extensively in chemicals regulation through the requirements on labelling of products for hazards under the CLP Regulation and the plant protection and biocidal products legislation, and through the REACH requirements to disseminate information through the supply chain via safety data sheets. The ECHA website also serves as a useful mechanism for disseminating information to the public. In addition, the Prior Informed Consent (PIC) Regulation stands as an example of the use of information dissemination on an international scale.

The REACH Candidate List of substances of very high concern (SVHC), in addition to representing the first step in the REACH authorisation process, also serves an information dissemination purpose. Publication of the Candidate List substances (at this point, 53 substances are on the list) places suppliers of substances, mixtures or articles of such substances under a number of obligations. For example, suppliers of articles which contain SVHCs in concentrations above 0.1% (w/w) must provide sufficient information to allow safe use of the article to their customers and include – as a minimum – the name of the substance. Suppliers wishing to avoid the labelling of articles in this way may aim to substitute to alternatives. In such situations the Candidate List may even serve as an important information source to signal concern about particular substances. Manufacturers and importers of these substances may voluntarily decide to review whether the substance has a long term market and consider alternatives.[36]

A precautionary use of information dissemination could include an information campaign targeting the population with the most access to a substance or with the most potential exposure. Professional users might be one target population. For example, an information campaign concerning a substance found in construction products could target construction companies or unions of workers who might be

[35] Note that a Scientific Commission established by France to review whether risk management measures were needed to control risks from non-ionizing radiation decided to take the precautionary step of requiring inclusion of ear-bud headsets with all sales of mobile phones and to monitor the situation in case further action was needed.

[36] Information dissemination is a tactic frequently used by public interest groups in their efforts to get regulatory action. For example, the International Chemical Secretariat (ChemSec) publishes the so-called "SIN List" (Substitute It Now) which as of May 2011 listed 378 substances considered to meet the REACH Article 57 criteria for identification as SVHCs and which it said should also be on the REACH Candidate List.

exposed to the product at a construction site. The general public might form another target audience, particularly if the concern is related to a substance used in a product marketed to consumers.[37]

The EU-wide alert system known as RAPEX[38] (the Community Rapid Information System for non-food dangerous products) set up under the General Product Safety Directive (2001/95/EC) should be noted here. In general, the task of market surveillance rests with the Member States. In cases where a product is identified as posing a serious risk, the Member State assesses the case on its individual merits and decides which risk management measures may be appropriate. Such measures must then be notified to RAPEX, which sends out alerts to other Member States and the Commission. Note that since Regulation (EC) No 765/2008 entered into force in January 2010, the scope of the RAPEX system has been extended to risks other than the health and safety of consumers (i.e., risk to the environment) and also to professional products.

If the measure involves limiting the marketing or use of a chemical substance or preparation/mixture, the Member State needs to provide relevant data, including an assessment of the risk, in accordance with the risk assessment procedures under REACH.[39] If the serious risk of a product requires urgent action at EU level, a Commission decision may be adopted via the comitology procedure requiring the Member States to ban the marketing of an unsafe product, to recall it from consumers or to withdraw it from the market.

Directive 67/548/EEC on dangerous substances had an interesting example of precautionary labelling. Under Directive 67/548/EEC, new substances placed on the market in quantities of less than one tonne per annum per manufacturer were subject to a reduced notification requirement. The substances were required to be packaged and provisionally labelled in accordance with any dangerous properties, but only in so far as the notifier could reasonably be expected to be aware of those properties. If the substances could not yet be labelled in full accordance with the Directive's requirements, the label was required to bear the warning "**Caution - substance not yet fully tested**". However, this precautionary provision was not carried over to the CLP Regulation which replaced it.

4. Require authorisation for specific uses. The regulatory option of setting in place an authorisation regime is also used extensively in EU chemicals legislation, as already noted in section 4. For example, authorisation has long been required in order to place plant protection products (PPP), biocidal products and food additives on the EU market. The case study on Fenamirol describes how the evaluation of active substances within the framework of Directive 91/414/EEC on plant protection products led to a precautionary decision not to approve Fenamirol for use in PPP because of the possible harmful consequences of such uses.

Specialist legislation for products such as cosmetics and food contact materials, where particular types of risks have already been identified, may also require prior evaluation and approval of certain substances before they can be used in the products covered.

Already mentioned above is the authorisation scheme provided under REACH Title VII for Candidate List substances. The Article 57 criteria for including substances under the REACH authorisation regime – in covering long-term effects such as carcinogenicity and PBT – were agreed having a precautionary approach in mind.

[37] The case study on BPA illustrates how information dissemination – largely through media attention and word of mouth – raised public concern about the use of the substance in plastic baby bottles and led to consumer decisions to take precautionary actions.

[38] Note that Commission Decision 2010/15/EU establishes guidelines for the management of RAPEX, including the notification procedure set up under Article 11 of the General Product Safety Directive.

[39] Annex II of the General Product Safety Directive requires risk assessment in accordance with the risk assessment procedures under Regulation (EEC) 793/93 and Directive 67/548/EEC (predecessors to REACH). Though the information specified is not equivalent to the technical dossier required under REACH, RAPEX guidelines for risk assessment of consumer products refer to the ECHA Guidance on Information Requirements and Chemical Safety Assessment.

However, those criteria also potentially limit the scope of the REACH authorisation scheme. While Article 57(f) is a catch-all provision providing a legal basis for including other substances that may not meet the Article 57(a) to (e) criteria, the use of Article 57(f) for identifying substances for inclusion in Annex XIV is so far untested. In the absence of clear guidance or prior practice concerning how to apply Article 57(f), it may well prove too formidable a hurdle. It thus remains to be seen whether the Article 57(f) criteria can be applied in a precautionary way to substances where there is a high level of uncertainty concerning the possibility of adverse harmful effects, so as to enable them to come under the REACH authorisation scheme.

In any case, bringing a substance under REACH authorisation is a long process that can take as long as four years. First, the substance has to go on the Candidate List. This requires preparation of an Annex XV dossier either by ECHA (upon request by the Commission) or by a Member State, publication of the dossier on the ECHA website with an invitation to all interested parties to submit comments, and, if comments are received, agreement of ECHA's Member State Committee (MSC). If no unanimous agreement is reached by the MSC, a decision is taken by the Commission via comitology. The decision to include a substance in Annex XIV must be preceded by a recommendation from ECHA (which must be consulted with the MSC). The decision must provide for transitional arrangements, including the sunset date (the date after which the placing on the market and use of the substance is prohibited unless authorised) and the latest application date (i.e. date by which manufacturers, importers and/or downstream users must have applied for an authorisation if they wish to continue to place on the market and/or use the substance after the sunset date if an authorisation decision has not yet been taken by then; this date must be set at least 18 months before the sunset date).

This lengthy procedure means that the REACH authorisation regime may not be a suitable instrument to apply when a substance gives rise to a serious immediate concern calling for a precautionary measure. In such cases some kind of "fast track" procedure may well be called for, in which case a ban or other restriction might be a speedier option. Note that such options – like the other risk management options discussed in this section – would need to be reviewed against the five elements of the precautionary principle, such as consistency and proportionality.

5. Establish restrictions or bans. One of the most effective instruments for controlling chemical-related risks is to ban or restrict a particular substance of concern or certain of its uses. EU chemicals legislation provides for a number of possibilities of establishing bans or restrictions for particular substances. For example, the regimes in place for plant protection products as well as for biocidal products allow for the non-approval of an active substance, which amounts to a ban of the use of that substance in the pesticidal product. The Cosmetics Regulation and the legislation on food improvement agents similarly provide for the possibility of including a substance on a negative list.

Wherever possible, Commission policy is to use specialist EU legal instruments to implement a substance-related ban or restriction. For example, the POPs Regulation implements the international bans on certain persistent organic pollutants agreed under the Stockholm Convention, and the Detergents Directive bans all surfactants that do not meet its strict criteria for biodegradability.

Since REACH covers *all* substances and mixtures, its Title VIII regime represents one of the most comprehensive and flexible systems for restricting a chemical. Once a restriction of a substance or its use is included in REACH Annex XVII, that substance – whether on its own, in a mixture, or in an article – shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. Under REACH the classification of a substance as a CMR may lead to its inclusion in Annex XVII as a substance restricted for consumer use products.[40] Other Annex XVII restrictions may serve as complete bans, e.g., asbestos, or apply only to specific uses.[41]

[40] Note that inclusion of a CMR substance in REACH Annex XVII is not automatic. See REACH Article 68(2).
[41] Note that the asbestos restriction entry allows Member States to temporarily derogate from the ban in specific situations.

Amendment of Annex XVII to adopt a new restriction or to amend a current restriction also requires a specific procedure, including preparation of an Annex XV dossier by either ECHA (at the request of the Commission) or a Member State. The dossier is then published on the ECHA website and all interested parties – including stakeholders and the general public – are invited to submit comments within six months. The Committee for Risk Assessment and the Committee for Socio-Economic Analysis have additional time for preparing their opinions. On the basis of the Annex XV dossier and the opinions received, the Commission prepares a draft amendment to Annex XVII, which is adopted through comitology. Though this procedure still takes at least 30 months to set in place, it may be one of the quickest options available to chemicals regulators.[42] As noted above, any risk management option considered would need to be tested against the five elements of the precautionary principle.

6. Voluntary measures. Last but not least, the option of voluntary measures might be considered. Voluntary measures can range from voluntary reporting and monitoring to voluntary restrictions. Examples of voluntary reporting schemes can be found in the efforts by the US, UK, FR, BE, and IT governments to gather information from industry on the numbers and types of nanomaterials placed on the market, and to secure voluntary participation in testing selected nanomaterials of potential concern. An example of a voluntary restriction can be found in the decisions of some companies to phase-out decaDBE from the market in the US[43].

The success of a voluntary measure requires the cooperation of the industry members involved in manufacturing and supplying the substance. However, unless it is possible to secure coverage of most uses of a substance, e.g., those representing 90% of quantities used, voluntary measures may not be sufficient to provide the precautionary control that is considered necessary to control the potential adverse effect of concern.

Other considerations. In the process of looking at various options, it will be important to consider what the consequences of a particular choice might be. A later section looks at five elements that must be considered under EU law, including proportionality, non-discrimination, consistency and cost-effectiveness. However there are other elements that might also be considered. These include:

- **The Smart Regulation initiative.** The Smart Regulation initiative stresses the need to ensure that new legislation is the best possible, based on impact assessments to prepare evidence for political decision-making and to provide transparency on the benefits and costs of policy choices.[44] This involves not only looking at the administrative burdens a measure brings about (and alternatives bringing about less burdens, for instance identified by stakeholders during consultations), but rather at the integrated picture of economic, social and environmental impacts.[45] The issue of alternatives is discussed further below in the section on proportionality.
- **Consideration of alternatives.** Attention should also be paid to the substance, and whether there are alternative substances available in case restriction is considered the most effective option. The concern is that a precautionary restriction on one substance might lead to reliance on another substance posing equal or even more serious risks than the restricted substance. However, requiring a review of alternative substances before taking precautionary measures could lead to considerable delay. If the risk is indeed of significant concern, it might be very important to go ahead with the risk management measure whether or not a suitable alternative has been identified.
- **Building confidence for taking a precautionary decision.** As mentioned earlier in this section, it remains important to document which options have been considered and any strengths or weaknesses identified for particular options. Documentation of the analysis will be important for helping to justify why a particular precautionary measure has been selected.

[42] Reference can be made to the Article 68(2) procedure (fast track restriction procedure).This procedure is however untested.
[43] http://pubs.acs.org/cen/news/87/i51/8751notw12.html.

[45] COM (2010)543 p. 5 and 6.

- **Stakeholder responses.** Many of the options – e.g., the option of disseminating information on product-related risks – could lead to a backlash of pressure from the stakeholders responsible for manufacturing or marketing products using the substance of concern. While this type of pressure should not be a reason in itself for avoiding a precautionary measure, it is a political reality and indeed should be anticipated. This issue is discussed further in the section on public consultation.

e. Do the options for risk management measures meet the five elements of PP?

> *Reliance on the precautionary principle is no excuse for derogating from the general principles of risk management. These general principles include:*
>
> - *proportionality,*
> - *non-discrimination,*
> - *consistency,*
> - *examination of the benefits and costs of action or lack of action*
> - *examination of scientific developments."*
>
> *--2000 Communication, p. 17*

The European Union can only take measures in areas where assigned the responsibility to do so through the primary Treaties. In some areas, it is the sole responsible (exclusive competence), but in most areas competence is shared with the Member States. The regulation of chemicals falls in this category, which brings about the application of the subsidiarity principle – EU measures should only be taken if the EU is better suited to do so than the member states. For all measures taken by the EU (whether they concern an exclusive competence or a shared competence), general rules and principles apply. These include the requirements that such measures must be proportionate, non-discriminatory, consistent, adopted after a cost-benefit analysis, and based on scientific data.

Some of these requirements have been laid down in the EU Treaties (for instance the proportionality principle in Article 5(4) TEU, the duty to take account of available scientific and technical data, and of the potential benefits and costs of action or lack of action, both in Article 191(3) TFEU so applying to EU environmental policy), and some have been expanded upon in various other places, for instance in the Better Regulation regime and in the sphere of formal Cost Benefit Analysis (CBA) of draft Commission proposals and in the Smart Regulation initiative. While paying little or no attention to uncertainties, and instead stressing the need of "evidence-based policy making", it can be assumed that they apply to 'regular' preventive measures as well as to precautionary measures. Where the latter type of measures are concerned, the 2000 Communication sets out some of the issues that can arise when it comes to applying these requirements in situations where potential risks are at stake. This makes sense, as for instance some elements need to be interpreted in the light of the circumstances of uncertainties in order for them to be of use.

The need to carefully consider the elements is especially relevant considering the fact that exactly where decision makers have a broad power of appraisal, abiding by procedural norms and elements like consistency, proportionality etc. become all the more important. This has been confirmed in national case law on precautionary measures, for instance in the Netherlands, and at the European level. In the Pfizer Animal Health case C-13/99, the CFI put it as follows:

"where the Community institutions have such a power of appraisal, respect for the rights guaranteed by the Community legal order in administrative procedures is of even more fundamental importance. Those guarantees include, in particular, the duty of the competent institution to examine carefully and impartially all the relevant aspects of the individual case, the right of the person concerned to make his views known and to have an adequately reasoned decision. Only in this way can the Court verify

whether the factual and legal elements upon which the exercise of the power of appraisal depends were present" (para 14).

What will be done in this part of the report is to summarise the points raised in the Communication for each element, after which additional remarks are presented for each element, based *inter alia* on the literature and case law that was studied, the case studies performed, developments in better / smart regulation (notably COM(2010)543) and the discussions with experts at the consultative workshop of 5 May 2011. In this way, the way in which these elements are to be used in chemicals regulation will be elaborated upon in order to arrive as far as possible at tailor-made recommendations.

1. Proportionality

Communication (2000)1 on proportionality

The 2000 Communication indicates that the envisaged precautionary measures need to make it possible to achieve the appropriate protection level (but not strive for zero risk), and should not be disproportionate to the desired level of protection. The incompleteness of risk assessments can limit the number of options available to risk managers; in some cases, a total ban may not be a proportional response to a potential risk, while in other cases, it may be the sole possible response to a potential risk. Less restrictive alternatives that can "achieve an equivalent level of protection" are to be investigated as well. Such alternatives could encompass exposure reductions, tightening of controls, adoption of provisional limits, recommendations etc. Interestingly enough, it is also stipulated that "[o]ne should also consider replacing the products or procedures concerned by safer products or procedures." "Potential long-term effects need to be taken into account in evaluating the proportionality of measures", the Communication adds.

General remarks on proportionality

The proportionality principle was developed by the European judiciary as a means of testing the legality of Member States and Community action in various areas of European policy. Later on, it was codified next to the subsidiarity principle. Article 5(4) TEU states that "[u]nder the principle of proportionality, the content and form of Union action shall not accede what is necessary to achieve the objectives of the Treaties", while adding that "[t]he institutions of the Union shall apply the principle of proportionality as laid down in the Protocol on the application of the principles of subsidiarity and proportionality." That Protocol stipulates that before proposing legislative acts, the Commission shall consult widely, while adding that in cases of exceptional urgency, the Commission shall not conduct such consultations, and that the Commission shall give reasons for its decision in its proposal.

Proposals are to contain a detailed statement on how they comply with the proportionality principle, and need to "take account of the need for any burden, whether financial or administrative, falling upon the Union, national governments, regional or local authorities, economic operators and citizens, to be minimised and commensurate with the objective to be achieved." This last aspect will be returned to within the discussion on the cost/benefits element below. The Protocol does not offer any further explanation as to what proportionality actually means.

Fortunately, the proportionality of EU measures has been dealt with extensively by the European judiciary. Contrary to the precautionary principle, the meaning of proportionality has been fleshed out extensively in this manner, notably where regular prevention measures are concerned. Normally, the proportionality principle is explained by the ECJ as meaning that the measure in question needs to be necessary and appropriate. They "must not go beyond what is appropriate and necessary for achieving the objectives legitimately pursued by the measure in question, it being understood that, where there is a choice between several appropriate measures, recourse must be had to the least restrictive and that the disadvantages caused must not be disproportionate to the aims pursued." (Joined cases T-125/96 *Boehringer Ingelheim Vetmedica* and *C.H. Boehringer Sohn v. Council* and T-152/96 *Boehringer Ingelheim Vetmedica* and *C.H. Boehringer Sohn v. Commission* 1999 [ECR] II-3427, para. 73).

As for the choice between different appropriate measures, authorities are to compare measures that would reach the same or an equivalent result (a high level of protection of the environment or human health, for instance). In another case, this aspect of the proportionality principle was formulated as follows: "where there is a choice between several appropriate measures, recourse must be had to the least onerous" (Case C-174/05 *Stichting Zuid-Hollandse Milieufederatie a.o.,* para 28; repeated in T-75/06 *Bayer CropScience* para 223 and in C-343/09 *Afton,* para 45; the latter case is discussed more extensively below). In sum, the proportionality of EU measures is to be verified and warranted by:

- examining the suitability of the envisaged measure to (contribute to the) achievement of the objective pursued / reaching the envisaged goal
- examining whether other measures are reasonably available that would be less restrictive
- ensuring that the disadvantages caused by the envisaged measure are not disproportionate to the aims pursued
- documenting the process by providing a detailed statement on how the measure complies with the proportionality principle.

Proportionality of precautionary measures

Ensuring the proportionality of precautionary measures brings about complications for the regulator, but also alleviations. Complications arise in the sense that in cases where the PP applies, risk assessments did not provide definitive answers. Hence, the proportionality of a precautionary decision cannot stem from scientific proof of the necessity of that decision. Alleviations appear in the form of a decreased intensity of scrutiny by the judiciary in complex cases where a broad discretion for the regulator is assumed.

A point frequently brought forward from the side of opponents of the PP is the need to not only look at potential risks of an individual substance, but to also examine the risks that substitutes will bring about, in other words whether substitutes would be less toxic (the deca-BDE was suggested as a case in point here during the consultative workshop). They point at the risk of risk-risk tradeoffs, i.e. creating new risks while solving existing ones. Others point out that this could easily lead to 'paralysis by analysis', that the actual occurrence of risk-risk tradeoffs is scarce and avoidable by sound decision making processes (Hansen a.o. 2008) and that the present system should look more at the question why additional risks should be taken if alternatives are available.

In whatever manner one looks at the issue, the proportionality of regulatory decisions (such as those related to evaluations, authorisations, restrictions, classification and labelling) on chemicals needs to be warranted. Above, the general case law was examined. Here, those cases dealing specifically with the proportionality of precautionary measures are looked at, shedding light on the way in which the EU judiciary deals with these complications when asked to test precautionary measures in the light of this general principle of EU law. These cases concern different aspects of chemical substances used in fuel, pesticides, (the processing of) food, and substances covered by REACH.

In the *Afton* case C-343/09, the legality of the decision to limit the use of a fuel additive suspected of posing a potential risk was discussed by the ECJ. The Court (quoting earlier cases) phrased meeting the requirements of the proportionality principle as follows: "measures adopted by Community institutions do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by the legislation in question; when there is a choice between several appropriate measures recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued" (para 45). It added that with regard to judicial review of these conditions referred, the European Union legislature "must be allowed a broad discretion in an area which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments. The legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institutions are seeking to pursue." In the same case, the fact that the measure was of a temporary nature, combined with the absence of testing methods, brought the Court to conclude that the measure was not violating the proportionality principle / necessity test (para 53 and 55).

Another recent example of a case in which the proportionality of a precautionary measure was scrutinised is the *Gowan* case C-77/09 about the restrictions imposed on fenamirol because of potential risks associated with this pesticide. The ECJ set out that the restrictive measure was suitable for achieving the objectives pursued, as it appears from the procedure leading to the adoption of the contested decision and the recitals in the preamble to the directive at stake, that the Commission endeavoured to strike a balance between the objectives relating to the improvement of plant production, the protection of human and animal health, groundwater and the environment and the interest of the notifier in obtaining the inclusion of the plant protection substance at stake in Annex I to Directive 91/414/EEC on conclusion of the scientific assessment of the risks posed by that substance. Given the concerns on the subject of the potential endocrine disrupting effects of fenarimol and the scientific uncertainty in that regard (notably because further test guidelines to further refine the assessment of potential endocrine disrupting properties were still under development at the OECD level; fenarimol should be subjected to such further testing as soon as agreed OECD Test Guidelines exist), the precautionary restrictions which the contested decision imposes on the use of that substance do not appear unsuitable for the achievement of those objectives, the ECJ found. *Gowan* disputed that the measure at issue was necessary on the ground that the terms of the inclusion of fenarimol amounted to a ban and thus went beyond what was necessary to achieve the intended objectives. In that regard, the Court observed that, although the inclusion of the substance in Annex I was reduced to a period of 18 months, but that time limit did not preclude the possible renewal of that inclusion. Similarly, limiting the inclusion to only those uses which have actually been assessed and judged compliant with the conditions of Directive 91/414/EEC does not prevent other uses being included in Annex I to that directive after a full assessment of them. In those circumstances, and having regard in particular to the wide discretion which the Commission has in this field, the measures restricting the use of fenarimol cannot be considered to exceed what is necessary to achieve the objectives pursued, the Court concluded.

In the case *Bayer CropScience* (T-75/06), the criteria for inclusion of the active substance endosulfan in Annex I to Directive 91/414/EEC were not satisfied according to the Commission. When this decision was contested in court, the CFI found that the measure was proportional because of absence of sufficient information to show that the substance posed no risks. During the evaluation of the active substance, a number of areas of concern (like long term risks and exposure of operators under indoor conditions) remained unsolved. Assessments made on the basis of the information submitted did not demonstrate that it may be expected that, under the proposed conditions of use, plant protection products containing endosulfan satisfy in general the requirements laid down in Directive 91/414/EEC.

In the case *Comm. v France* (C-333/08) the ECJ set out that a Member State must demonstrate that prior authorisation scheme for food processing aids does not go beyond what is necessary to attain the objective (of protecting human health). The chosen means must be "confined to what is actually necessary to ensure the safeguarding of public health" (para 90). More specifically, the Court explained that assessments "may reveal a high degree of scientific and practical uncertainty" and such uncertainty (described as "inseparable from the concept of precaution") "influences the extent of the discretion of Member States and thus has an impact on the means of applying the proportionality principle" (para 91). As long as the risk assessment is not based on purely hypothetical considerations, precautionary measures may be adopted in such circumstances. If potential health risks are suspected to exist only for certain categories of processing aids, the national measures must be "targeted and clearly justified in relation to those categories and must not envisage all processing aids or all foodstuffs in the preparation of which processing aids not entering into those dangerous or suspect categories have been used. It is not sufficient to base justification on potential risks posed by the substances or products subject to authorisation." (para 95). Note that this requirement to investigate specifically certain processing aids (on a case-by-case basis) resembles the reasoning employed by the WTO judiciary in the Beef hormones dispute, where the EU was asked to provide evidence regarding specific individual growth hormones rather than growth hormones in general. The ECJ concluded that the French measure was disproportionate in that it systematically prohibits, without prior

authorisation, the marketing of any processing aids or of any foodstuffs in the preparation of which processing aids lawfully manufactured and/or marketed in other Member States were used, without making any distinction according to the various processing aids or according to the level of risk which their use might potentially pose for health (para 100).

In the *S.P.C.M.* Case C-558/07, the ECJ established that the obligation to register reacted monomer substances which are components of polymers pursuant to Article 6(3) of REACH does not go beyond that which is necessary to meet the objectives of the REACH Regulation. Consequently, taking account of the limited number of potential monomer substances, the 12-year period of validity for a previous registration of substances, as provided for in Article 27 of the REACH Regulation, and the possibility of sharing information in order to reduce costs, the burden deriving from the obligation to register reacted monomer substances in polymers does not appear to be manifestly disproportionate in the light of the free movement of goods on the internal market open to fair competition. The ECJ came to this conclusion considering the political, economic and social choices the legislator needs to make, and in which it is called upon to undertake complex assessments. The legality of a measure adopted in that sphere can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue (para 42).

In the case *Comm. v Spain* (C-88/07), proportionality as well as a showing of necessity required for withdrawal from the market in accordance with the PP: Spain claims that in the current state of scientific research, there is uncertainty as regards the harmlessness of the [medicinal herb] products withdrawn from the market that justifies their withdrawal under the precautionary principle. The ECJ disagrees: Requirement is that there be a detailed assessment, on a case-by-case basis, of the risk to public health which the marketing of a product based on medicinal herbs might entail.

In the *Toolex* Case C-473/98, the proportionality was assumed to exist because of the seriousness of the potential effects. The health and life of humans rank foremost among the property or interests protected by Article 36 of the EC Treaty (now 36 TFEU). Swedish legislation prohibiting use of a chemical substance for industrial purposes and establishing a system of individual exemptions was justified, as it might result in damage to human health. The ECJ took the latest research on the subject into account - indicating a link between exposure to trichloroethylene and the incidence of cancer in humans - and also "the difficulty of establishing a threshold above which exposure to trichloroethylene poses a serious health risk to humans, given the present state of research." These strong indications that trichloroethylene poses a risk to human health led the ECJ to conclude that it sees no evidence that national legislation such as that at issue goes beyond what is necessary to achieve the objective in view, in spite of the fact that the Comm. had claimed the opposite. Swedish measures were proportionate.

Where the proportionality of a measure in the sense of ensuring that the disadvantages caused by the envisaged measure are not disproportionate to the aims pursued, the CFI in the *Pfizer Animal Health* case T-13/99 contemplated that the withdrawal of the authorisation of the antibiotic virginiamycin entailed serious economic consequences for Pfizer, but this "does not mean that it can be described as disproportionate for the purpose of challenging its unlawfulness" (para 460). In the same case it was also stressed by the CFI that the withdrawal of the authorisation of the antibiotic formed a provisional measure subject to the duty of re-examination when discussing the proportionality of the measure at stake. Also worth noting is that the CFI stated that "scientific risk assessment must also enable the competent authority to decide, in relation to risk management, which measures appear to it to be appropriate and necessary to prevent the risk from materialising" (para 163).

Finally, in Joined cases C-453/03, C-11/04, C-12/04 and C-194/04 *Abna a.o.,* the ECJ found the contested measure disproportionate because no serious effect was shown. The question was whether an obligation to indicate precise feed materials contained in compound feedingstuff is justified on the basis of the PP in the absence of a risk assessment, based on scientific studies, which requires that precautionary measure on the basis of a possible correlation between the quantity of feed materials used and the risk of the diseases to be prevented? And proportionate? The ECJ said that the obligation

to provide customers with exact indication of the ingredients of a feedingstuff impacts seriously on the economic interests of manufacturers, as it obliges them to disclose the formulas for the composition of their products, at the risk of those products being used as models, possibly by those customers themselves, and that the manufacturers cannot obtain the benefit of the investments which they have made in terms of research and innovation. This obligation is not justified by the objective of protecting public health, as it is pursued and manifestly goes beyond what is necessary to attain that objective. It must be pointed out, *inter alia*, that this obligation is independent of any problem relating to foodstuff contamination and has to be met only if the customer so requests. Furthermore, it is clear from the explanations provided and from the examples submitted to the Court that the indication, on the labelling, of the percentages within brackets should normally make it possible to identify a foodstuff suspected of being contaminated, in order to assess the degree of danger which it represents in relation to the weight indicated and to decide, if necessary, to withdraw it temporarily pending the results of laboratory analyses, or for the establishment of the traceability of the product by the public authorities concerned.

It can be noted that from the case law discussed here it shows that the ECJ tends to employ a stricter review of the proportionality for national measures than for EU measures. This could be because the national measures are often examined in the light of harmonising EU legislation, so as exceptions to a general regime, and thus need to meet higher hurdles.

Recommendations on ensuring the proportionality of precautionary measures in chemicals regulation

In the field of chemicals regulation, regulators need to ensure the proportionality the precautionary measures they plan to adopt. In order to do so, different aspects of the principle need to be observed that were touched upon in the Communication and the Protocol, and further distinguished and fleshed out by the EU judiciary and discussed in the Smart Regulation initiative. The judiciary tests the proportionality of precautionary measures only marginally, since it assumes that where the EU or Member States undertake complex assessments, the legality of a measure adopted in that sphere can be affected only if the measure is "manifestly inappropriate having regard to the objective which the competent institution is seeking to pursue". Still, some precautionary measures – notably those adopted by national authorities – were considered to violate the proportionality principle where the measure in question was too broad rather than restricted to a case-by-case examination of the potential effects (*Comm. v Spain* C-88/07 and *Comm. v France* C-333/08).

Even when the judiciary only scrutinizes precautionary measures in a marginal way, it remains important to carefully set out the reasons why the regulator has come to the conclusion that its precautionary decision is proportionate. This will contribute to persuading the judiciary that the measure is not manifestly inappropriate having regard to the objective which is being pursued, it will enhance the transparency of the decision making process, and contribute to the acceptance of decisions on controversial issues. The acceptance of precautionary measures entailing restrictions or bans tends to be low with industry, but also in literature growing criticism is voiced about the way in which the European courts test the legality of precautionary measures.

The proportionality of precautionary measures can be demonstrated by setting out in detail in the decision:

- which potential risks are to be averted by adopting the measure;
- the suitability of the envisaged measure to (contribute to the) achievement of the objective pursued / reaching the envisaged goal of averting the potential risks (ensure that a balance is reached between the objectives of issues at stake such as the protection of human and animal health, groundwater and the environment, the improvement of plant protection and the interest of the notifier);
- what potential damage (its potential seriousness and/or irreversibility) these risks could bring about (including damage in the long-term, as the Communication stresses);

- what the estimated probability is that the damage will occur (noting that because of scientific uncertainty it might be hard or impossible to provide more than an educated guess on probabilities at times);
- that the disadvantages caused by the envisaged measure are not disproportionate to the aims pursued (a topic discussed further below under the costs/benefits element);
- which other measures that would be less restrictive on the chemical in question and/or less burdensome were considered but rejected, for instance because they were not 'reasonably available' – because of impracticalities in enforcement for instance - , or because they would not reach the same or a sufficiently equivalent level of protection. Here, it can be added that in the SPS Agreement, a footnote to Article 5(6) explains that the question whether another measure is 'reasonable available' in that context is to be established by taking into account "technical and economic feasibility", and that such an alternative should achieve "the appropriate level of sanitary or phytosanitary protection" and should be "significantly less trade restrictive";
- how comments received during consultations on the issue of proportionality were addressed.[46]

Finally, it needs to be mentioned that the ECJ has occasionally considered that adopting a measure of a temporary nature contributed to the proportionality of precautionary measures (notably in the *Afton* case C-343/09 where a test method was being developed but not yet available, but also in *Gowan* case C-77/09 a *Pfizer Animal Health* case C-13/99), without stating that this is a condition applicable in all cases where precautionary measures are at stake. The topic of temporary versus regular measures is returned to when discussing the element of scientific data and re-examinations below.

2. Non-discrimination

The Communication explains at p. 19 that the principle of non-discrimination means that comparable situations should not be treated differently and that different situations should not be treated in the same way unless there are objective grounds for doing so. Measures taken under the precautionary principle should be designed to achieve an equivalent level of protection without invoking the geographical origin or the nature of the production process to apply different treatments in an arbitrary manner.

From the case law of the ECJ and CFI, the principle of equal treatment or non-discrimination requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (Case C-344/04 *IATA and ELFAA* [2006] ECR I-403, paragraph 95 and the case-law cited). *S.P.C.M. (C-558/07).*

It follows that the decision to restrict the use of a specific additive does not violate the non-discrimination principle in cases where no measures are taken regarding similar additives, if the latter substances are not being used or imported in the EU. In such cases, the restricted substance is not in a situation which is comparable to that of other, similar additives and the European Union legislature is not required to set limits for those other additives.

Thus regulatory decisions on chemicals should not be discriminatory in their application. An element to take into account when deciding on restrictions, for instance, would be the question whether similar substances are also being restricted.

[46]. See p. 10 of the Smart Regulation COM(2010)543 on the 2011 review of the Commission's consultation policy, that is to deal *inter alia* with how to better use the consultation process to collect data and evidence for impact assessments and evaluations.

3. Consistency

Communication (2000)1 on consistency

Measures adopted should be consistent with the measures already adopted in similar circumstances or using similar approaches. Risk evaluations include a series of factors to be taken into account to ensure that they are as thorough as possible. The goal here, the Communication stresses, is to identify and characterise the hazards, notably by establishing a relationship between the dose and effect and assessing the exposure of the target population or the environment. If the absence of certain scientific data makes it impossible to characterise the risk, taking into account the uncertainties inherent to the evaluation, the measures taken under the precautionary principle should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available.

General remarks on consistency

The consistency element can be found in some of the case law of the European judiciary. It has not been codified in EU law. There exist a number of cases in which the ECJ dealt with the consistency of national measures that hindered the free movement of goods. The authorities of the Member States claimed to be protecting human health or the environment. A well-known example is the Cassis de Dijon case 120/78, where Germany tried to convince the ECJ that prescribing minimum levels of alcohol content for fruit liqueurs was necessary to protect public health and consumers. The reason for the rule was avoiding the proliferation of alcoholic beverages with a low alcohol content on the national market, as these products may more easily induce a tolerance towards alcohol than more highly alcoholic beverages (para 10). The Court was not convinced by this line of argumentation, noting that there was a wide range of weakly or moderately alcoholic products being sold in Germany, as well as a large amount of alcoholic beverages with a high alcohol content that were frequently consumed in a diluted form (para 11). The inconsistency of the German rule was exposed in this way, and as a result it was declared in violation of European law. Another famous case involving German beverages is the Reinheitsgebot case 178/84 on the ancient beer purity rules, banning the marketing of beer with additives. The public health justification brought forward by Germany (minimising the quantity of additives ingested by banning them in beer, "a foodstuff consumed in considerable quantities by the German population" (para 48), did not stand the Court's scrutiny. The reason was that Germany did allow the same additives banned in beer in virtually all other beverages. This inconsistent approach contributed to the conclusion that again, German law was not in conformity with European law.

The WTO judiciary has also discussed the element of consistency, notably in the EC-Beef hormones dispute. Here it was noted that the arbitrary or unjustifiable character of differences in the level of protection chosen by a party may operate as a "warning" signal that the measure in its application might be a discriminatory measure or might be a restriction on international trade disguised as a measure for the protection of human life or health (para 215 AB report). It follows from these cases that the regulatory responses to comparable risks (like additives in beer and the same additives in other beverages) should be consistent with each other.

Furthermore, it can be added that the Smart regulation policy attaches greater importance than before to evaluating the functioning and effectiveness of existing legislation (p. 3) in order to ensure that individual pieces of legislation and legal regimes on specific areas (the “fitness checks”) are as smart as possible (p. 4). Specifically the latter effort is intended “to identify excessive burdens, *inconsistencies* and obsolete or ineffective measures and to help to identify the cumulative impact of legislation” (p. 4, emphasis added). Where new legislation is concerned the Smart regulation policy aims at ensuring that this is necessary, cost-effective and of high quality (p. 6), clearer and more accessible than in the past (p. 8). Thus, the Smart regulation policy is aimed at ensuring consistency of EU measures and developments in this regard need to be taken into account when designing precautionary measures. Hopefully, these developments will be paying more attention than has been the case so far to the special issue of potential risks that cannot be tackled the same way as other policy issues.

Consistency of precautionary measures
In cases where precautionary measures are contemplated, the absence of full scientific certainty makes it all the more important to ensure that the measure is consistent with the reaction to similar risks. As it can be hard or impossible to provide definitive answers to the question how strict a precautionary measure should be due to the limited findings in the risk assessment phase, it will be all the more useful to ensure that the envisaged precautionary measure is comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available, i.e. prevention measures.

The fact that consistency of precautionary measures forms a legal norm was confirmed by the EFTA Court. This Court dealt with precautionary measures at several occasions. An early example is the case against Norway about fortified corn flakes (Case E-3/00), lawfully produced and marketed in other EEA States but banned in Norway. The EFTA Court explained that "measures taken (...) must be based on scientific evidence; they must be proportionate; non-discriminatory, transparent[47] and consistent with similar measures already taken" (p. 26).

Consistency of chemicals regulation
For decisions on chemicals, the consistency norm looks primarily at decisions taken in the risk management phase. It could be that consistency can also have implications in the risk assessment phase, for instance where the way in which prudency is applied in designing and applying safety margins, or where it concerns using the results of tests already carried out for similar substances.

4. Costs/benefits

Communication (2000)1 on costs/benefits
According to the Communication, this element needs to encompass a comparison between "the most likely positive or negative consequences of the envisaged action and those of inaction in terms of overall costs to the Community, both in the long- and short-term." The measures envisaged "must produce an overall advantage as regards reducing risks to an acceptable level." It is stressed that only performing an economic cost-benefit analysis does not suffice, although such an analysis is to be performed "where this is appropriate and possible" / "feasible". Rather, a wider scope is to be applied including non-economic considerations. Other issues that can be taken into account, according to the Communication, are the analysis of the efficacy of possible options, and their acceptability to the public. On the latter point it is explained that society may be willing to pay a higher cost to protect an interest such as the environment or health, to which it attached priority. Finally, the Commission stipulated that "requirements linked to the protection of public health should undoubtedly be given greater weight than economic considerations."

General remarks on costs/benefits
Resources being finite in societies, choices need to be made on questions of allocation. Hence, the costs and benefits of measures need to be considered. Where EU environmental policy is concerned, this is even laid down in primary law. Article 191(3) TFEU expresses the duty to take account of the "potential benefits and costs of action or lack of action", a general duty applicable to environmental measures, whether preventative or precautionary. The need to take only cost-effective precautionary measures featured in Principle 15 of the Rio Declaration.

Within the WTO, costs and benefits regularly feature as an element to be taken into account. For instance, Article 5(3) SPS Agreement stipulates that where protection measures against sanitary or phytosanitary risks from parties are concerned, the "Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry,

[47] The issue of transparency raised by the EFTA Court seems like an additional element compared to Communication (2000)1. From the Report for the hearing in this case it follows that "the government has aimed at limiting fortification and ensuring that the system is transparent, so as to minimise the risks of adverse effects from excessive intake of vitamins and minerals" but no further indications were found on what is meant by this transparency, or why the EFTA Court mentioned this issue here.

establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks."

In Case T-13/99 *Pfizer Animal Health*, the ECJ stipulated that "a cost/benefit analysis is a particular expression of the principle of proportionality in cases involving risk management" (para 410) and investigated whether the disadvantages caused by the contested regulation were disproportionate to the objective pursued, and whether, in the framework of a cost/benefit analysis, those disadvantages are disproportionate by comparison with the advantages which would ensue if no action were taken.

A clear example of this kind of choices can be taken from human health care, namely the use of screening operations in order to detect a limited number of cases at an early stage. The costs of such operations are usually measured against the benefits for a group of persons. The fact that the ECJ and the Commission rank the protection of human health very high does not alter the need to carry out a cost benefit analysis. Opinions differ greatly on the best way in which this needs to be done in practice. Some developments can be of help to describe (where monetary calculations are difficult or impossible) and, where possible, calculate the potential benefits and costs of action or lack of action.

In practice, gathering the information from industry on costs can turn out to be difficult, as was put forward at the consultative workshop. Within the EU, greater emphasis has been placed on performing assessments of the costs and benefits of regulatory measures after the adoption of the Communication. In 2002, Communication (2001)726 was adopted setting out the need for and way to perform impact assessments on draft proposals for regulatory measures. Since then, these assessments were embraced by the broader policy aimed at better regulation, an issue dealt with in Communication (2005)97.

In the same year, the Commission adopted Guidelines for the Performance of Impact Assessments (SEC (2005)791). In the latter document, the Commission proposed that all items on the Commission's Work Programme would need to be preceded by impact assessments. That meant that from that moment on, regulatory proposals (but also White Papers) were made subject to a description of their impact. The Guidelines explained in some detail how a quantitative economic analysis is to be carried out and even include indications on the value of a statistical life. Also, the issues of how to analyse costs and benefits, and cost-effectiveness of proposed measures are defined and briefly touched upon in the annexes to the Guidelines (p. 42). Interestingly enough, cost-benefit and cost-effectiveness analyses were presented as 'alternative approaches' (p. 39 and footnote 45).

The EU system of impact assessments received a large amount of criticism. The Commission was accused, for instance, of not taking adequate account of the costs and benefits of proposed measures. Assessments were judged to be not informative enough, notably due to inadequate quantification of benefits (Zander, p. 141 with further references). The Commission did endeavour to introduce improvements to the system, notably by introducing an Impact Assessment Board that checks the quality of the assessments in 2006, by switching to an integrated approach (by which it is meant that the potential impacts of new legislation or policy proposals in economic (including competitiveness), social, and environmental fields is assessed), and by revising the Guidelines in 2009 (based on an external evaluation of the Commission's impact assessment system in 2006/2007, the experience of the independent Impact Assessment Board and the experiences of the Commission services in preparing impact assessments).[48] Nevertheless, the system is still criticised frequently. The present system enables the Commission to ask Directorates General to adapt proposals where these are judged to contain undesirable elements. In principle, this will be improving the quality of the proposals, but it might also stand in the way of proposals that are considered 'too green', or, to focus on the topic of this report, 'too precautionary'.

Where the PP is concerned, the new Guidelines also can be criticised as the system is not adequately tailored to the special issue of potential risk situations. For instance, in the part dealing with risk assessments, the following is stated: "As a working definition you can equate the value of a given risk

[48] See http://ec.europa.eu/governance/impact/commission_guidelines/commission_guidelines_en.htm.

with the magnitude of the hazard, multiplied by the probability that it will occur. When the hazard under consideration may have consequences that are not yet fully scientifically established, and that may be irreversible, a full risk assessment by a scientific committee is necessary." A first comment to this statement would need to be that if science is still unable to establish the consequences, the PP would apply meaning that a full risk assessment is impossible to conduct. It would have been better if the Guidelines had demanded that in such circumstances 'a risk assessment as far as possible' would be carried out. Furthermore, it seems like the element of irreversibility is introduced here as should not be interpreted as a condition for applying the PP. As discussed above, the Communication did not introduce specific conditions of seriousness[49] or irreversibility, offering a somewhat greater flexibility to the regulator.

The Guidelines continue by claiming: "In such cases, particularly when risks to the environment and human, animal and plant health are involved, the 'precautionary principle' may be applied as a first step towards the management of risk. This means that temporary decisions may need to be taken on the basis of limited or inconclusive evidence, and that more permanent arrangements are postponed until the necessary scientific assessment is available. In the light of the risk assessment, you will have to prepare further measures to manage the risk." Here, the new Guidelines seem to suggest that only temporary decisions can be adopted while uncertainty prevails, and permanent arrangements can only be adopted once scientific assessments are complete. Annex 12 even goes a step further by demanding that the PP can only be invoked "if consequences are likely to be substantial and irreversible and the likelihood of the occurrence of a negative consequence cannot be assessed". Compared to the Communication, for the reasons set out above, the new Guidelines form a step backwards where possibilities and conditions to apply the PP are concerned.

As for the European judiciary, in the *Pfizer Animal Health* case T-13/99 already mentioned in the introduction to this part on the cost/benefits element, the CFI contemplated that contested regulation banning a antibiotic (marketed for 30 years already) is "founded on a political choice, in respect of which the Community institutions were required to weigh up, on the one hand, maintaining, while awaiting further scientific studies, the authorisation of a product which primarily enables the agricultural sector to be more profitable and, on the other, banning the product for public health reasons" (para 468). The CFI continued by examining Pfizer's complaint that the institutions, when making their policy choice, did not carry out a cost/benefit analysis, stating that "it is apparent from the documents before the Court that an assessment of that kind was made in several of the reports by international bodies which had been submitted to the institutions during the procedure culminating in adoption of the contested regulation and which were examined" and that the implications of a ban "were extensively discussed by specialists from all the Member States, the Commission and the industry" (para 469).

As to the claim that the institutions made errors when weighing up the various options, the Court observed that "the legality of the contested regulation could be called in question only if the institutions had made a manifest error of assessment in deciding upon their policy." the Court had emphasised that the use of antibiotics is not strictly necessary in animal husbandry, and that alternative methods of husbandry are available that could lead to higher costs for farmers and consumers. In addition, it was stressed that the withdrawal of the authorisation of virginiamycin formed a provisional measure subject to the duty of re-examination.

It shows that, as was the case with the testing by the judiciary of the proportionality of precautionary measures, the scrutiny of the way in which regulators measure costs and benefits is again marginal, leaving the regulator of chemicals with a wide degree of discretion. Still, for the same reasons as set out above (notably transparency and increased acceptability), it is necessary to be as thorough as possible in describing and, where possible, calculating the costs and benefits of action or lack of action.

[49] Although 'seriousness' was mentioned once at p. 16 of Communication 2000(1).

Costs and benefits of chemicals regulation

Within chemicals regulation, like in other areas of EU action, the costs and benefits of action or lack of action need to be weighed. This weighing process should in principle be in line with the Guidelines on the performance of Impact Assessments where these apply and other indications set out in Commission communications on better / smart regulation and follow up initiatives. Where regular preventive measures are concerned, it is not an easy task to come up with an accurate description of these costs and benefits, notably because it might be possible to calculate the costs of a measure where this would affect a producer, but it is much harder to calculate in monetary terms the benefits, as this involves incorporating the costs of human health and human lives, of the environment, clean water etc. In situations of uncertainty where the PP applies, the challenge becomes even greater because of the uncertainties involved. The suggestions set out in the new Guidelines for the Performance of Impact Assessments do not contribute much to clarification of the way to perform a cost benefit analysis regarding precautionary measures. Fortunately for the European regulator, the judiciary grants a large deal of discretion in complex situations like these, and attaches most value to the protection of human health. In practice, the European regulator that needs to assess the costs and benefits of precautionary measures can balance the indications from Communication (2000)1 and the newer indications like those from the IA Guidelines discussed and commented upon here in order to arrive at an optimal result that takes economic, social and environmental concerns (in line with the Smart Regulation policy) into account.

What is also clear is that in carrying out an analysis, those factors on which certainty exists are to be calculated as far as possible (an economic cost-benefit analysis is to be performed “where this is appropriate and possible” / “feasible" according to the Communication), while keeping in mind that only performing such an economic cost-benefit analysis does not suffice.

The Communication suggests examining the most likely positive or negative consequences of the envisaged action and those of inaction in terms of overall costs to the Community, both in the long- and short-term. Indeed, especially in situations where potential risks are expected to occur only in the long run, it is of importance to consider long-term consequences. The BSE induced export ban for British beef forms a case in point here. With the potential serious and irreversible risk of people falling ill years after having consumed beef from 'mad cows' the long-term damage justifies adopting precautionary measures, in spite of the considerable damage to British agriculture (as confirmed by the ECJ in the cases C-180/96 UK and Northern Ireland v Comm. and C-157/96 The Queen v Ministry of Agriculture.

5. Examination of scientific developments

Communication (2000)1 on examination of scientific developments

Precautionary decisions shall be maintained as long as the scientific data remain inadequate, incomplete, imprecise or inconclusive and as long as the risk is considered to be too high to be imposed on society. Deadlines can be imposed in measures, stipulating that the measure in question may have to be modified or abolished by a particular moment, in the light of new scientific findings. The Communication stresses that modification or abolishing is not always linked to a specific time factor, but to the development of scientific knowledge. Arguably, this implies that it is not necessary to always include a specific provision in a precautionary measure on re-examinations.

The Communication does stipulate that scientific research should be carried out with a view to obtaining a more advanced or more complete risk assessment. In this context, the precautionary measures that were adopted should be subjected to " regular scientific monitoring, so that they can be re-evaluated in the light of new scientific information." Gathering more data thus may lead to modification or abolishing of the precautionary decisions.

The Communication looks at the conditions expressed in the WTO's SPS Agreement and explains that these apply only to sectors covered by this agreement, and that this may mean that in other sectors

such as the environment "somewhat different principles have to be applied". SPS precautionary measures, based on Article 5(7), must be of a provisional nature "pending the availability of more reliable scientific data". Note that the provision actually tells that "additional information for a more objective assessment of risk" is to be collected. Both the wording of the Communication's summary and the original text of the SPS Agreement have their shortcomings, as absence of scientific certainty does not equal unreliable data or subjectivity.

General comments on the need to (re-)examine scientific developments

Any decision on EU environmental policy needs to take account of available scientific and technical data, Article 191(3) TFEU stipulates. The same holds true for decisions in a wider area of topics like human health protection, food law etc.

If the available scientific and technical data at the time when the precautionary measure was adopted did not allow for a full risk assessment, it is necessary to investigate whether science progressed after a reasonable period of time, and re-examine whether the precautionary measure is still warranted or needs to be modified or abolished. This is confirmed in the case law of the European judiciary, usually when the proportionality of a contested precautionary measure was at stake. The ECJ has considered the temporary nature of precautionary measures restricting the use of substances in its case law, for instance in the *Afton* case C-343/09, para 53. The fact that the measure was of a temporary nature, combined with the absence of testing methods, brought the Court to conclude that the measure was not violating proportionality principle / necessity test. The duty to review was expressed even stronger in two other cases. In the *Mirepoix* case 54/85 the Court explained that "[t]he authorities of the importing member state are obliged to review the prohibition on the use of a pesticide or a prescribed maximum level if it appears to them that reasons which led to the adoption of such measure changes (...) as a result of the discovery of a new use of a particular pesticide or as a result of further information becoming available through scientific research" (para 16). In the *Agrarproduktion Staebelow* case C-504/04, the Court held that "[w]hen new elements change the perception of a risk or show that that risk can be contained by less restrictive measures than the existing measures, it is for the institutions and in particular the Commission, which has the power of legislative initiative, to bring about an amendment to the rules in the light of the new information" (para 40).

Having thus established that case law demands that precautionary measures are re-examined, another issue to look at is whether such measures should always be of a temporary nature or not. Regulatory decisions can be regular (valid for an undetermined period of time) or temporary (like in the example of the phthalates case). Note that if the form of a regular decision is chosen, a period within which the decision is to be updated where necessary on the basis of new scientific evidence / data might be included.

The Communication examined the strict rules applied under WTO law for sanitary and phytosanitary measures. Precautionary SPS measures can only be of a provisional nature. The Communication correctly explained that these particular conditions only concern the scope of the SPS Agreement and that in other sectors such as the environment, different principles can apply. The idea that all precautionary measures should, as a principle, only be of a provisional nature, as advanced by DG XXIV, was not followed in the Communication. Even considering the case law of the EU judiciary, this choice can be held on to in order to maintain flexibility where necessary.

Recommendations on examination of scientific developments

Where precautionary measures are adopted with regard to chemicals, these measures can take the form of regular measures, or measures of a provisional nature. If the form of a regular measure is opted for, depending on the circumstances of the case, a provision calling for an evaluation or re-examination can be opted for. Indications that could influence the need for doing so could be found in the absence of test methods that are however being developed. Once these methods are available, a re-examination is called for.

Where the measures would fall within the scope of the WTO's SPS Agreement, it would need to be ensured that the measure meets the Article 5(7) requirement by being of provisional nature.
Whatever manner the re-examination is taken care of, it will need to be clear how the responsibility is assigned for producing the scientific evidence necessary for a more comprehensive risk assessment.

Finally, it can be pointed out that the Communication (2010)543 on Smart Regulation stresses the need to evaluate existing legislation and to adapt it where necessary.

f. Process for reaching decisions

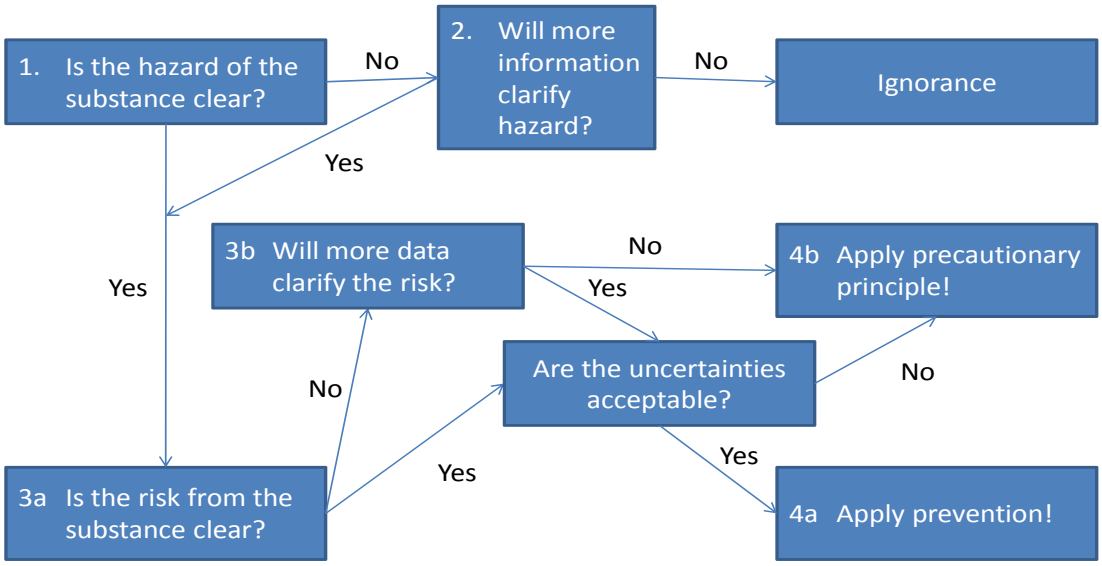
> *The absence of scientific proof of the existence of a cause-effect relationship, a quantifiable dose/response relationship or a quantitative evaluation of the probability of the emergence of adverse effects following exposure should not be used to justify inaction.*
>
> *--2000 Communication, p. 16*

When a substance is subjected to risk assessment, it normally undergoes a number of iterations to refine all the elements before a conclusion is reached. However, it is rare that there is a perfect set of data. Normally it is always possible to gather more information (hazard or exposure) to improve the reliability of the conclusion. This can, however, extend the time taken to carry out the risk assessment for many years. For example, the risk assessment of DecaBDE took 10 years and reviewed 234 studies with an additional 354 additional reports after the risk assessment was closed[50]. The risk assessment of Bisphenol A as a food contact material has been equally extended. This does not always mean that consensus is reached; there are still doubts over the conclusions of the assessment in some quarters with a call for precautionary actions as "in the absence of adequate scientific knowledge, coupled with the time it would take to gather the information needed to enable an adequate scientific evaluation, the risk should be considered unacceptable"[51].

To ensure that precautionary action can be taken in a reasonable time-scale there is a need to ensure that a decision is taken using the information that is to hand. The framework to make these decisions is described below and illustrated in the following flow chart:

[50] Q&A on the European Commission Decision to Exempt Deca-BDE from RoHS
[51] WWF's submission on deca-BDE (2004) available at http://www.wwf.eu/news.cfm?15150/WWFs-submission-on-deca-BDE.

Figure D: Describing the decision framework for application of the PP



1. Is the hazard of the substance clear?

The first question to be asked is whether or not the hazard of the substance is well described, i.e., is the effect that is causing concern clear enough to make a decision that action should or should not be taken. Or is there enough uncertainty about the effect and its relevance for humans and/or the environment that a clear decision on the hazard cannot be made?

- If the hazard/effect is well described and deemed to be relevant for humans and/or the environment then the issue can be moved onto the risk assessment stage.

- If the hazard/effect cannot be well described, this could be because either the identification methodology (e.g. animal tests or (Q)SAR modelling) used in the assessment is of low quality/accuracy, or that new methods are required to characterise the hazard/effect which may take many years to develop, or that even though the information is of high quality, the characterisation of the effect and/or its relevance for man and/or the environment is unclear.

In the former case, it is likely that more hazard information would assist with further clarification. In the latter case it would be questionable if more information would help; it may mean precaution would be justified if the effect was serious (see section 5a) and the consequences were likewise serious. If the difficulties in characterising the hazard are due to uncertainties in the data and further information gathering is unlikely to clarify the situation, the seriousness of the effect may indicate precaution is justified.

Box: The Low Dose Conundrum

Studies conducted using low doses (in the µg/kg range) have shown variable and conflicting effects of BPA on endpoints relevant to development and endocrine function, although good quality information was available indicating overall an absence of effects on classical markers of reproductive function. Despite the inherent conflicts in the data, a decision was taken to invoke the precautionary principle instead of waiting for more information because of the uncertainties in fully characterising the risk.

Box: The 'unusual' endpoint

Certain endpoints are difficult to characterise, especially endocrine disruption where a definitive test method does not exist. The discussion on Fenarimol revolved around identification of if a hazard actually existed. There was no consensus between MS on the hazards of the substance but the Scientific Committee on Plants concluded that the effects of Fenarimol on male fertility seen in rats were relevant for human risk assessment although humans are less sensitive than rats.

2. Will more information clarify the hazard?

If further information gathering is indicated and this is likely to clarify the hazard or lack of hazard, a clear timetable is required that is reasonable to both the manufacturer/importer/user of the substance and the population being exposed (the more serious the consequences the less time that should be allowed). Conversely if the hazard of the substance is not clear and more information will not clarify the situation then the regulator has the choice of either invoking the precautionary principle or deciding that there is not enough information and clarity to justify any decision.

Box: The cases of the phthalates and Bisphenol A

One of the initial uncertainties in the risk assessments of the phthalates related to the characterisation of the exposure of children, a vulnerable population. There was a lack of acceptable scientific methods for testing the migration of phthalates from toys to the mouth. Industry were given a defined time to develop such methods, and these methods provided the basis for an exposure assessment that ultimately led to the conclusion that small children were at risk.

In the case of Bisphenol A, the original EU RAR concluded that there was a need for a comprehensive three-generation study on BPA in the rat, in order to prove or disprove the reported low-dose effects of BPA in a number of different animal systems. This study was undertaken by industry over a period of several years and the results provided to the relevant regulatory authorities. Subsequently a similar study has been carried out in the mouse, followed by a neurodevelopmental study in the rat. Despite these studies, the hazards of BPA are still not clarified but in the meantime the PP has been invoked.

3a. Is the risk from the substance clear?

The next question is whether the risk from the substance is solid enough, accounting for all the relevant uncertainties. This involves a clear risk characterization involving hazard characterization (dose response relationship, as appropriate) and a valid exposure estimate for potentially affected populations(s).

The hazard from the substance may be clear at this point and a no-observed effect level (NOEL) may have been derived (hazard characterization). A valid exposure estimate for the substance should be (or have been) derived, based on either measured or modelled data. This will be compared to the derived NOEL and the risk characterised via a Margin of Safety[52] (MoS) or a Risk Characterisation Ratio[53] (RCR).

Box: The case of phthalates

In the phthalates case study, the hazard of the substances was relatively well described with derived no observed adverse effect levels (NOAEL) available. For 3 substances under consideration it was assessed that the levels of migration of phthalates into a model saliva solution (the exposure) compared with the NOAEL led to a very low margin of safety and was a "cause for concern".

3b. Will more date clarify the risk?

Some of the uncertainties (e.g. use of animal models) can be accounted for with assessment factors at this stage. However, uncertainties are still likely to remain and it needs to be assessed if more information on exposure, for example, will reduce those uncertainties or not. If there are no or few uncertainties it is likely there is no need to apply the precautionary principle as the prevention principle can be utilised and adequate risk management implemented. On the other hand, high uncertainties are more likely to shift the balance towards invoking the precautionary principle if it remains a possibility that a risk could occur with a certain seriousness of consequences. In this case, it should also be considered what are the populations affected by the hazard and the consequences of not taking action assessed. The balance again would be tipped if the population affected is a vulnerable one e.g. children, as the consequences are likely to be magnified in such populations and/or political pressure may be brought to bear to invoke the precautionary principle, as in the case of BPA.

4a. Apply prevention

The prevention principle can be applied when the hazard from and the risk of the substance is clear and quantifiable and the uncertainties are manageable. In this case, the risk assessor user of the chemicals can be reasonably sure that risk management measures will control the substance to the extent necessary. The regulator will need to consider the chances that the risk will materialise, the seriousness of the damage etc. and decide on what action to take.

4b. Apply the precautionary principle

If the risk is not clear, and it is unlikely that further information will improve the situation, then it should be considered to apply the precautionary principle as there is an identified (serious) hazard but an unquantifiable risk.

[52] Pesticides/biocides: MoS = Exposure/NOEL. A MoS of 100 is often taken as being acceptable.
[53] REACH: RCR = Exposure/ NOEL (adjusted for assessment factors)/. If the RCR is >1 then there is a risk.

g. Is there a plan for reviewing the actions taken if new scientific knowledge emerges?

> *Subject to review in the light of new scientific data, means measures based on the precautionary principle should be maintained so long as scientific information is incomplete or inconclusive, and the risk is still considered too high to be imposed on society, in view of chosen level of protection. Measures should be periodically reviewed in the light of scientific progress, and amended as necessary.*
>
> *--2000 Communication, p. 5*

It is useful to set in place mechanisms for reviewing the situation at specific dates in the future, in order to consider new information that may have become available in the interim. This can enable decisions to be reassessed in light of new understanding. This is supported by the general requirements of Communication (2010)543 on Smart Regulation, which requires ex-post evaluation of legislation.

Precautionary measures may also be time-limited, with a cut-off date for reviewing if new information is available about the possible risk. This was an option used with respect to phthalates in toys and childcare articles; with the temporary restriction extended several times until finally a "regular" restriction was established.[54] This can be useful for helping to respond to stakeholders who do not agree with the need to take a precautionary measure.

It can also be important to build in feed-back loops and back-up plans. For example, if only limited alternatives are available to replace a substance of concern and those alternative substances have also not been fully assessed, it may be critical to carry out additional research on the alternatives and to set in place monitoring systems to make sure the alternatives are not worse than the substance now restricted. This may be a trade-off needed to take a timely decision on the initial substance of concern.

[54] Entries 51 and 52 of Annex XVII to REACH contain an obligation for the Commission to re-evaluate the measures provided for in the light of new scientific information on such substances and their substitutes.

6. Other considerations

a. Documenting the scientific evaluation

The more discretion that a regulatory decision maker has, the more extensive the argumentation and reasoning is required for the decisions he/she makes. All stages of the procedure need to be documented, with extensive reasoning and the scientific background given for those reasons, including remaining uncertainties.

It is suggested that the elements to be included in such documentation are adequately covered by the elements required in an Annex XV dossier for a restrictions proposal under REACH. Therefore, it is proposed that the following information shall be documented when the precautionary principle has been implemented for a substance:

1. ***Summary of reasoning***
   The summary shall include the identity of the substance and the measure(s) proposed for the manufacture, placing on the market or use(s) of the substance and a summary of the justification.

2. ***Information on the substance and its uses***
   The substance to which the precautionary principle has been addressed shall be clearly identified and its manufacture and uses summarised.

3. ***Information on hazard and risk***

   The risks to be addressed shall be described based on an assessment of the hazard and risks according to the relevant parts of Annex I of REACH and shall be documented in the format set out in Part B of that Annex for the Chemical Safety Report. In addition, it is important to communicate the uncertainties under this section:

   - Set-up, limitations of approach
   - Presentation of methods
   - Communicating the results of the assessment

4. ***Information on alternatives***
   Available information on alternative substances and techniques shall be provided, including:

   - information on the risks to human health and the environment related to the manufacture or use of the alternatives,
   - availability, including the time scale,
   - technical and economical feasibility.

5. ***Justification for Precautionary action***

   Justification shall be provided that:

   - action is required on a Community-wide basis under the Precautionary Principle,
   - an assessment of the measure proposed under the following criteria:
     - proportionality,
     - non-discrimination,
     - consistency,
     - examination of the benefits and costs of action or lack of action
     - examination of scientific developments."

6. ***Socio-economic assessment***
   The socio-economic impacts of the proposed measure may be analysed with reference to Annex XVI of REACH. To this end, the net benefits to human health and the environment of the proposed restriction may be compared to its net costs to manufacturers, importers, downstream users, distributors, consumers and society as a whole.

7. ***Information on stakeholder consultation***
   Information on any consultation of stakeholders and how their views have been taken into account shall be included in the dossier.

b. Public consultation & stakeholder involvement

> *All interested parties should be involved to the fullest extent possible in the study of various risk management options that may be envisaged once the results of the scientific evaluation and/or risk assessment are available and the procedure be as transparent as possible.*
>
> *--2000 Communication, p. 16*

Although the 2000 Communication does not elaborate on the topic, it sets out that the process of deciding whether precautionary actions are to be taken should also involve interested parties. The Communication reflects the Commission's desire for transparency and dialogue with all stakeholders. It mentions several recent events as having shown that the public is increasingly aware of potential risks to which they and their environment are potentially exposed.

Further guidance can be found in the Commission Communication *elaborating on general principles and minimum standards for consultation of interested parties by the Commission*.[55] While the benefits of consultation of interested parties are recognised, no common approach was identified on how to undertake such consultation. The Communication aims at identifying general principles that should govern the relation between the Commission and the interested parties as well as a set of minimum standards for the Commission's consultation processes.

Guidance on public consultation and stakeholder involvement depends on the definition of 'the public'. The 2000 Communication refers to the involvement of 'interested parties'. Here, it is important to distinguish between *'interested parties'* and *'the public*'. In general, the term 'interested parties' include the industry concerned, civil society organisations or other interest groups. The Commission regularly consults so-called **'**interested parties', which can be any group who wishes to participate in consultations initiated by the Commission.

The term 'the public' covers a much broader group: the public at large or the consumers. An important characteristic is that this is not an organised group in a manner that can be seen with the interested parties. Another factor that distinguishes these groups is that interested parties already be actively involved in the decision making process (such as providing comments on draft regulations), whereas the public, would have a more passive involvement.

In the process of deciding whether or not to apply the precautionary principle, the focus is on the involvement and consultation of interested parties (stakeholders). The Commission states that the process should be "transparent and should involve as early as possible and to the extent reasonably possible all interested parties".[56] This will assist decision makers in taking legitimate measures which are likely to achieve the society's chosen level of health or environmental protection.[57]

[55] Communication (2002)704.
[56] Communication 2000(1), p. 4.
[57] Communication 2000(1), p. 17.

Existing legislation in the field of chemicals provides examples of how to integrate consultation of interested parties into the decision making process. The preamble to REACH Regulation includes several references to the need to involve the option of interested parties. In general, it is laid down that the 'participation of stakeholders and initiatives involving all interested parties should be sought' (recital 40). The actual implementation of the involvement of 'interested parties' in REACH can be found in the following articles:

- *Article 58 on the inclusion of substances in Annex XIV*. According to Article 58(4) of Regulation 1907/2006, the Agency, before sending its recommendation to the Commission, shall make it publicly available on its website, clearly indicating the date of publication, taking into account Articles 118 and 119 on access to information. The Agency shall invite all *interested parties* to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement.

- *Article 59 on the identification of substances referred to in Article 57.* In paragraph 4, this Article establishes that the Agency shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. Following, the Agency shall invite all *interested parties* to submit comments within a specified deadline to the Agency.

- *Article 69 on the preparation of a proposal.* As part of the restriction process, Art. 69(6) lays down that the Agency shall make all dossiers conforming with Annex XV including the restrictions suggested publicly available on its website. It invites all interested parties to submit (individually or jointly) (a) comments on dossiers and the suggested restrictions and/or (b) a socio-economic analysis, or information which can contribute to one, of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions. These comments are to be received by the Agency within 6 months of the date of publication.

Other examples of institutionalised stakeholder consultation can be found in the CLP Regulation. For example, invites concerned parties to comment on proposals for harmonised classification and labelling submitted by MSCA; proposals for harmonised classification & labelling submitted by manufacturers, importers or downstream users; and other aspects relevant to the harmonisation of the classification and labelling.

Ensuring the involvement of interested parties can include such measures as:

- *Access to information and transparency*

Non-confidential information on chemicals can be made available in a manner that the interests of the stakeholders is balanced with the need to keep certain information confidential. Some information can be published on the Commission's web site, whereas other information can be kept confidential.[58]

- *Institutionalised stakeholder consultation in chemicals regulation*

The examples from REACH and CLP show that the consultation of stakeholders or 'interested parties' can be established as part of the procedures and the decision making processes in the chemicals regulation. Stakeholders should be provided with ample opportunities to comment on the draft decisions.

- *Web-based consultation*

The Commission can publish consultations widely on the internet to meet all target audiences.

[58] DG ENV, REACH in brief, p.15.

- *Organisation of stakeholder groups*

  Stakeholder groups can be formed to organise monitoring and/or discussion of options or follow up on a structural basis (depending on the stage of identification of risks). In addition, informal contacts can be promoted for information sharing.

- *Consultative workshops*

  The Commission can organise consultative workshop on an ad hoc basis to share knowledge with relevant stakeholders. These workshops can cover issues where needed in the process, such as whether a potential negative effect can be identified, ort discuss the options that are available for controlling the risk of possible harm.

As discussed, involvement of the 'public' is not covered by the Communication. In promoting involvement of the public, the level of knowledge should be taken into account. Moreover, a distinction should be made between involving the public and asking their opinion. In general, the broader public will be informed rather than asked about its opinion. The realisation of involvement of the boarder public in applying the precautionary principle in chemicals regulation requires further discussion and debate.