

The Precautionary Principle in Switzerland and Internationally

Synthesis Paper by the Interdepartmental Working Group on the Precautionary Principle, August 2003

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1. Preface

The precautionary principle is defined differently in different specialised fields, and also understood differently at the national and international levels. This Synthesis Paper, which was commissioned by the directorates of the Swiss Federal Office of Public Health (SFOPH) and of the Swiss Agency for the Environment, Forests and Landscape (SAEFL), has been drawn up by an interdepartmental working group to examine those provisions of Swiss law which might be understood as encapsulating the precautionary principle and how each of them are defined.

The paper's threefold aim is as follows:

- Firstly to provide a catalogue of criteria for the implementation of the precautionary principle based on prevailing law.
- Secondly to enable the federal administration to communicate the various interpretations of the precautionary principle in an informed manner.
- Thirdly to provide a guideline for Swiss delegations when conducting negotiations on international agreements.

2. Introduction

2.1 The precautionary principle and its standardisation

The concept of precautionary principle is rooted in the environmental discussions of the 1970s. Before that, generally trade-restrictive measures could only be taken on the basis of clear scientific evidence. Once the notion of precautionary principle had been introduced it became possible to issue measures even in cases of scientific uncertainty. The principle is based on the realisation that increasingly complex interactions between natural phenomena, which often are not fully understood, do not always make it possible to adopt early on and with certainty the appropriate measures for preventing an environmental threat, and yet the failure to adopt precautionary measures might result in irreversible environmental damage.¹ Over the years and decades that followed, the principle was embodied in Switzerland's environmental law. Thereafter it became an increasingly important element of international (environmental) treaties and thus part of international law. Principle 15 of the Rio Declaration adopted at the World Summit in Rio de Janeiro in 1992 is generally regarded as the point of reference for the precautionary principle in the area of sustainable development (viz. Clauses 2.2 and 5.1). Over the past few years the Principle itself has become more specified and been developed further in different ways and in different fields.²

¹ Perrez, Franz Xaver, *The World Summit on Sustainable Development: Environment, Precaution and Trade – A Potential for Success and/or Failure*, 12/I RECIEL (2003), page 15

² viz. Perrez, as in footnote 1, pages 15-16

2.2 Frequently cited definitions at the international level

Although the precautionary principle is formulated differently in different publications, the individual definitions are not essentially conflicting.³ Each formulation of the principle rests on the basic notion that it may be possible to adopt a measure to avert damage to the environment or human health even if there is no conclusive scientific evidence of such damage. A comprehensive and often cited definition can be found in the 1998 Wingspread Statement:

“When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”⁴

Principle 15 of Rio mentioned under 2.1 still referred solely to the environment:

“In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. 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.”⁵

In 2000 the Commission of the European Communities also expressed its view on the precautionary principle and the general principles for its application. These observations are now frequently alluded to in the debate (viz. item 5.2.1), and show the way particularly in the area of food safety.

“Whether or not to invoke the Precautionary Principle is a decision exercised where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection.”⁶

While the different definitions may differ in their wording and scope, common key elements have emerged in the course of recent years. These elements can be described as follows:

1. The precautionary principle is relevant in situations where scientific certainty is lacking or insufficient with regard to the possible cause and effect relationships, and where there are strong indications of a serious threat to the environment or to human and animal health.
2. Where there is scientific uncertainty there is also a right or obligation to adopt precautionary measures. The principle should be elaborated and

³ Silberschmidt, Gaudenz, The Implementation of the Precautionary Principle as a Topic of the European Environment and Health Process, proposal submitted by Gaudenz Silberschmidt, International Society of Doctors for the Environment ISDE, environment NGO representative to the 3rd session of the EEHC in Dublin 29.11.-1.12.2000

⁴ Drawn up by a conference of experts in Wingspread, Wisconsin, USA, in January 1998; viz. <http://www.sehn.org/wing.html>

⁵ Rio Declaration on Environment and Development (1992); <http://www.un.org/esa/sustdev/documents/agenda21/index.htm>

⁶ Communication from the Commission of the European Communities on the Precautionary Principle, 2.2.2000; <http://europa.eu.int/scadplus/leg/en/lvb/l32042.htm>

implemented using transparent processes that accord with the rule of law.⁷

3. Further research, also for alternatives, should be conducted in an attempt to eliminate the element of scientific uncertainty.

There is also the view that a reversal of the burden of proof can be demanded, in which case the burden of proof of safety is the responsibility of the originator of a potentially dangerous activity rather than of its potential victims (reversal of the burden of proof).⁸

3. Terminology

3.1 Risk analysis: risk assessment, risk management and risk communication

It is generally acknowledged that risk analysis is the process best suited to assess, manage and communicate a potentially dangerous situation in a structured and comprehensive manner. It is founded on the principles of scientific character and transparency. A comprehensive risk analysis comprises recognising the hazard, assessing according to scientific principles the risk of the threat to the environment and to human and animal health, and possible strategies and courses of action for reducing that risk. The results of the risk analysis and the derived measures are communicated to those concerned and where necessary to the general public in a way that is both understandable and transparent. As a rule the precautionary principle is the result of an ordinary risk analysis, which is to be described below for the sake of a better understanding of its function.

Risk analysis is usually subdivided into the three elements of risk assessment, risk management and risk communication. While risk assessment is the domain of science, risk management, which also incorporates non-scientific elements in its considerations, is to be seen as a political process. Whenever risk management comes up against scientific uncertainty, the precautionary principle can take effect so that the appropriate measures can be adopted to achieve the socially accepted level of protection; in other words the precautionary principle is an instrument of risk management used to contain risks with the help of risk assessment. While those in charge of risk assessment and risk management should seek permanent dialogue, the two functions should be kept as autonomous as possible. The task of risk communication, for its part, is to communicate in the appropriate form the measures adopted and their context not only to those concerned but also where necessary to the public at large.

The three elements of risk analysis might be defined more precisely in the following way:⁹

⁷ Silberschmidt, as in footnote 3

⁸ Silberschmidt, as in footnote 3

⁹ Based on "Principles for Risk Analyses at the FVO", published by the Swiss Federal Veterinary Office, 2001, page 4f

Risk assessment: Up-to-date information is systematically collated, documented and evaluated by means of analytical methods, literature searches and surveys among experts using scientific criteria. Existing gaps, restrictions and uncertainties are documented transparently. Risk analysts then use the structured data to estimate the risk, which consists of the likelihood of the undesirable event occurring and the extent of the potential damage. In a qualitative risk assessment the result is described in word form. If necessary and if the data available is sufficient, the risk can also be expressed in quantitative terms, i.e. as a numerical value based on mathematical models.

Risk management: With the co-operation of those in charge of risk assessment the necessary measures are drawn up and initiated, taking into account scientific and other legitimate factors. The aim of the measures is to reduce the risk to a level more or less acceptable to all those affected by the risk (those likely to suffer in the event of an undesirable incident). The repercussions of the measures adopted are monitored. Should the findings change, the strategies aimed at reducing the risk or at least the risk assessment are to be revised.

Risk communication: Subjective perceptions of risks are the rule in today's environment of globalised markets and the rapid spread of information through the media and the Internet. If all those concerned by and participating in the process of risk analysis are involved early on, the various concerns and fears can be recognised in good time and the appropriate response adopted. The aim in principle is to achieve the greatest possible level of transparency. The fears and anxieties of the population should also be taken into account. This strengthens the confidence of those concerned in the decisions of the authorities, and bolsters their understanding of the measures to be adopted. Conversely a lack of, or inadequate, risk communication can result in a potential risk being perceived as disproportionately large by the public. Risk communication is a mainstay of any successful risk analysis.

3.2 Prevention and precaution

The two terms prevention and precaution are not just closely related, they often overlap and are used interchangeably, which is why it is important for the debate to draw a clear line separating their respective meanings. Etymology provides a good starting point. *Prevention* comes from the Latin and literally means “to come before”; it is a term widely used in health and in law in the sense of *pre-empting* (an illness, a crime). By contrast *precaution* is defined as *provident care* and therefore slightly differs in meaning inasmuch as its aim is not so much to prevent a specific event but to preserve an asset (such as human health or intact environment).

The way the term precaution has evolved mainly in environmental law refers exclusively to provident measures that are taken whenever there is scientific uncertainty with regard to the existing of a hazard or risk. This is the *narrower interpretation* of the term. The key characteristic of precaution in its narrower sense is the fact that no statement can be said with the requisite certainty about the potential harmful effect of a substance or activity or about the likelihood or extent of a potential damage. The aim of precaution is therefore to provide a

guideline on how to deal with scientific uncertainty; it orients itself according to the scientific knowledge available, the level of ignorance and non-scientific values. It is generally accepted however that there have to be at least credible indicators of the possibility of a threat before precaution comes into play. The Commission of the European Communities defines scientific uncertainty as follows:

“Scientific uncertainty results usually from five characteristics of the scientific method: the variable chosen, the measurements made, the samples drawn, the models used and the causal relationship employed. Scientific uncertainty may also arise from a controversy on existing data or lack of some relevant data .Uncertainty may relate to qualitative or quantitative elements of the analysis.”¹⁰

If a threat is well known, any relevant regulation can be a preventive measure, in which case we do not talk of precaution since any scientific uncertainty has been dispelled.¹¹

4. Application of the precautionary principle in Switzerland

4.1 How Swiss federal agencies invoke the precautionary principle

4.1.1 SAEFL: Legal principle of the EPA [USG] and other laws

The precautionary principle is of major significance to environmental protection as a whole. It was explicitly confirmed in Section 74 Paragraph 2 of the Federal Constitution [BV] in its complete review of 1998, specifically, in the form in which it had been valid thus far in environmental law (updating of constitutional law).¹² In principle all the formulations of the concept of precaution in environmental protection are based on the notion that indeterminable risks are to be avoided; any effect likely to be harmful or noxious is to be limited as far as possible.

Accordingly all environmental orders also comprise precautionary regulations tailored to the individual environmental sectors. Environmental protection law does not make the clear separation between prevention (in the case of known effects and known causal relationships) and precaution (in the case of unknown effects or a lack of knowledge of their causal relationships) as described above. Precaution as it is understood in environmental protection law covers both prevention and precaution simultaneously. There is no need subsequently to break down environmental protection law into the various precautionary approaches for reasons of constitutional law or due to statutory requirements.

The precautionary principle is the third mainstay within the scope of the Environmental Protection Act (EPA) [*Umweltschutzgesetz, USG*], after the duty to prevent or eliminate harmful or noxious effects and the polluter-pays principle. The special-purpose Section already specifies: “Precaution as defined implies that any effects likely to be harmful or noxious are to be limited early on.” (EPA

¹⁰ see footnote 6

¹¹ Silberschmidt, as in footnote 3, page 3

¹² Section 74 Federal Constitution, Anne Petitpierre-Sauvain, *Verfassungsrecht der Schweiz*, § 36 N. 18/19, specifically footnote 46

Section 1 Para. 2, SR 814.01). This formulation comprises the obligation to limit effects that are below the threshold of harmfulness and the obligation to limit effects for which no threshold of harmfulness can be ascertained by scientific means.

Two examples taken from the law on protection against harmful effects on the environment are to illustrate how the precautionary principle in environmental law has been formulated based on identical statutory provisions (Section 1 Para. 2 and Section 11 EPA):

- *Noise abatement* specifies immission standards which express the level as of which noise is considered in law as harmful to or as a nuisance for human health. It is uncontested scientifically that some people may perceive noise values below that standard as harmful or as a nuisance. However the standard reflects the threshold as of which noise is harmful to a certain percentage of the population. There is therefore sufficient scientific clarity about the harmfulness of noise immissions. To protect people from the harm or nuisance caused by noise the necessary measures are then taken. The EPA provides two levels for specifying measures. Firstly more stringent measures are stipulated for the observance of the immission limits (Section 11 Para. 3 EPA). Secondly precautionary measures (Section 11 Para. 2 EPA) are called for in order to limit noise further even below the immission limits. Under the terminology used in international law both these levels of measures would be referred to as preventive since they are used to prevent noise, the harmfulness of which to individual human beings is scientifically uncontested. However the Environmental Protection Act provides different criteria for “more stringent” and “precautionary” measures: Unlike more stringent measures precautionary measures must always be economically viable.
- Immission standards have also been specified for *non-ionising radiation*. These standards describe the short-term radiation levels as of which acute harmful effects occur in human beings. It is presumed however that lesser radiation levels and longer exposure times also have a harmful effect on people (non-thermal biological effects), even though conclusive scientific evidence pro or contra has yet to be established. To protect people against harmful radiation, the necessary measures are again adopted at two levels based on the EPA. More stringent measures up to and including the observance of the immission standards are stipulated, and precautionary measures are also required (precautionary standards in locations with sensitive use). Under the terminology used in international law the more stringent measures would again be referred to as preventive. The precautionary level of measures would be deemed as a precaution. In terms of environmental law the two levels differ once again insofar as unlike precautionary measures the more stringent measures are not limited to their economic viability.

In conclusion we can therefore say that in the environmental sector the term “precautionary measure” is used differently at the national level as opposed to the international level, specifically in a broader sense. It does not continue on from the existence of scientific uncertainty but from a threshold of harmfulness determined on the basis of various scientific criteria. In national law measures

below that threshold are deemed as precautionary and may only be demanded insofar as they are viable economically and operationally.

4.1.2 FOAG: Definition as part of the 2007 Agricultural Policy

The Agricultural Act [*Landwirtschaftsgesetz*] revised as part of the 2007 Agricultural Policy defines the precautionary principle in a new Section. In terms of content the application criteria accord with those of the EU.

Section 148a (new)

1 Precautionary measures may be adopted if it appears plausible that a farming product or plant material, which can be a carrier of particularly dangerous pests, can have an unacceptable side-effect for human, animal or plant health or the environment, and the likelihood of occurrence is assessed as considerable or the corresponding consequences are far-reaching yet the scientific information for a comprehensive risk assessment of the agricultural product or plant material is insufficient.¹³

The Bill was passed by Parliament in June 2003. In its message to Parliament the Swiss Federal Council [*Bundesrat*] argued the interpretation of the precautionary principle as follows:

“Risk management is founded essentially on the results of risk assessment, which is in turn based on scientific data. In certain cases the scientific findings are insufficient for an assessment. It is possible therefore that an event is presumed to have detrimental repercussions even though there is still no scientific evidence to substantiate such an assumption. In such cases measures are to be stipulated in accordance with the precautionary principle. Precautionary measures are provisional in nature. To avoid abuse precautionary measures are to be adopted only in cases where such a procedure is warranted. Precautionary measures may be adopted if there is a strong likelihood of an event having detrimental repercussions. Precautionary measures are also possible in cases of increased threat to the environment or to human, animal and plant health. Precautionary measures may only be ordered if the risk hypotheses are scientifically plausible.”¹⁴

and further:

“Precautionary measures to restrict the marketing or use of individual products or procedures may also be appropriate if such side-effects are to be feared due to a plausible but as yet unproven scientific hypothesis. For this reason the possibility of adopting precautionary measures should be embodied in the Agricultural Act [LwG] and the framework defined in which such measures may be adopted. The enforcement of precautionary measures is to take account of international developments in this field, in particular the work of the Codex Alimentarius and the EC. Elements such as proportionality, the prohibition of discriminatory practices or the requirement of coherence must be observed whenever precautionary measures are applied.”

¹³ BBL No. 29 of 23.7.2002, page 4870 ff. Available under <http://www.bk.admin.ch/ch/d/ff/2002/4870.pdf> (in German)

¹⁴ BBL No. 29 of 23.7.2002, page 4727 ff. Available under <http://www.bk.admin.ch/ch/d/ff/2002/4727.pdf> (in German)

4.1.3 SFVO: Precautionary principle as an implicit part of the legislation

The precautionary principle is not explicitly mentioned in the field of operations of the Swiss Federal Veterinary Office (SFVO). However the duty to invoke the precautionary principle can be clearly deduced from Section 9 Epizootic Diseases Act [TSG] (SR 916.40) and Sections 9 and 10 Foodstuffs Act [LMG] (SR 817.0). Section 9 TSG reads:

“The federal government and the cantons shall take all measures deemed appropriate in the light of the latest scientific findings and of experience to prevent the occurrence and spread of epizootic disease.”

In 2001 the executive management of the SFVO also adopted a document on the principles of risk analysis.¹⁵ While the precautionary principle is explicitly mentioned in the definition of the outline conditions, it is not specified elsewhere:

“The precautionary principle may be applied in situations where there are indications of a potential risk but where a scientific basis for a decision cannot be established within a useful period of time or where the findings of a scientific assessment prove inconsistent.”¹⁶

The precautionary principle is therefore a legitimate procedure within the framework of SFVO risk analyses, one which allows risk management to adopt measures even if the scientific basis is uncertain or inconsistent. If during risk analysis it emerges that measures to prevent or reduce a risk are indispensable despite the lack of scientific certainty and therefore despite the lack of a risk assessment, the precautionary principle may be applied providing the following aspects are taken into account:

- Aspects such as human and animal health and safety are given priority. The decision whether or not to invoke the precautionary principle depends on the existence of facts indicating a strong likelihood of harm being caused.

If the precautionary principle is invoked, the following points need to be taken into account:

- The measures adopted must be proportionate;
- Any decisions taken must be well founded and intelligible, and be communicated in a way that can be understood by those concerned and, where necessary, by the public;
- The measures adopted are of a provisional nature; their consequences are continually monitored and regularly analysed. Should the measures adopted prove unsuitable in the light of new scientific findings or risk assessments, the precautionary measures are to be adapted to the new situation.

¹⁵ See footnote 9

¹⁶ See footnote 9, page 2

4.1.4 SFOPH: Inherent embodiment and recommendations

Foodstuffs: The precautionary principle is not explicitly mentioned in the Foodstuffs Act [*Lebensmittelgesetz, LMG*]; however approaches can be found in several provisions. The principle is embodied inherently insofar as under the Foodstuffs Act foods when used as prescribed must not put the health of consumers at risk. In principle the person who brings any product or goods into circulation is responsible for satisfying the terms of this provision through self-regulation. Since the Foodstuffs Act is drawn up in accordance with the positive principle, that person may only bring into circulation that which is explicitly defined in the ordinance or approved by the Swiss Federal Office. Any substance contained in foodstuffs that is potentially hazardous to human health may only occur in quantities that are harmless from a health point of view and technically unavoidable. If there is a justifiable suspicion that legal provisions are not satisfied, the controlling bodies have the jurisdiction to seize goods even in cases where the necessary basis to establish a risk assessment with sufficient certainty is lacking. Restrictions are also conceivable in addition to bans, for instance a limited licence, the commitment to a monitoring process, a licence limited in time or quantity, or special declaration provisions. The measures must be proportionate, i.e. the means of enforcement applied must not be more stringent than warranted by the circumstances. The precautionary principle is also invoked in cases of potential infringements of protection against deception in connection with the protection of public health.

Radiation protection: Radiation is characterised by the fact that generally speaking it is or can be a health risk due to its physical and biological interactions: It is solely a question of dosage. Therefore the primary principle of radiation protection is to minimise the dosage or the exposure to radiation. Minimising the dosage or exposure in this way may also be regarded as a precaution. Its effect is not only preventive with regard to known risks but also precautionary with regard to as yet unknown low-dosage effects; at the same time it also creates a margin of choice for future developments by not utilising to the limit the exposure potential.

The risks of *ionising radiation* are well known. These are stochastic risks; a zero risk does not exist. Accordingly the principles of radiation protection are defined by *justification*, *optimisation* and *limitation*. The statutory basis is the Radiation Protection Act [*Strahlenschutzgesetz, StSG*] and the Radiation Protection Ordinance [*Strahlenschutzverordnung, StSV*]. A radiation application must first of all be justified. Its risk should be outweighed by its benefit. Limitation means that the risk is no longer acceptable. Optimisation is the range defined by justification and limitation: Minimising the radiation dosage in relation to the optimum benefit achieved through radiation. Optimisation is based on the ALARA principle (i.e. as low as reasonably achievable), and is effected through recommendations, directives, etc.

Non-ionising radiation (NIR) covers the areas of electromagnetic fields (EMF) and optical radiation. In optical radiation the emphasis of radiation protection is on cancer prevention during UV radiation. The precautionary principle is invoked in the EMF sector with regard to environmental exposure to stationary installations

(antennas, high-voltage lines) (see Item 4.1.1, second case study). There is no clear standardised statutory regulation with regard to radiation and health protection for exposures to equipment and apparatus and for occupational or medical exposure. Within the framework of “soft law” recommendations and directives are used to draw attention to a precautionary approach to EMF. Two motions currently call for a review of the precautionary principle in this field.

In other areas of **public health** dealing with scientific uncertainty has not been – and still is not usually – referred to as precautionary principle, even if de facto the same considerations are used in the decision-making process. A classic example of this are new incidences of disease such as SARS. The fact alone that the Severe Acute Respiratory Syndrome is referred to as a syndrome shows that primarily only a group of symptoms was known and not the cause. Once the disease was presumed to be infectious in origin, the general rules for the control of epidemics were adopted initially before moving on to more specific measures once scientifically founded hypotheses began to emerge with regard to the causative agent, mode of transmission, incubation time and course of the disease.

Chemicals: Neither the applicable Poisons Act 1969 [*Giftgesetz*] nor the relevant implementing ordinance (Poisons Ordinance 1983, [*Giftverordnung, GV*]) mention the precautionary principle explicitly. Likewise the precautionary principle is not mentioned explicitly in the new Toxic Substances Control Act [*Chemikaliengesetz*], which is to come into force in 2005. In its message to Parliament the Swiss Federal Council [*Bundesrat*] justified the exclusion of the precautionary principle from the special-purpose Section of the Toxic Substances Control Act by arguing that by their very nature the provisions were inherently preventive. Indeed the precautionary character can be deduced from several provisions from both the current and future legislation. The protective aim of such legislation, namely to protect people against the harmful effects of chemicals (Section 1 GV; Section 1 ChemG), can require precautionary measures.

Chemicals may only be brought into circulation subject to an assessment of their hazardous nature. Such an assessment is based on scientific data, primarily toxicological studies, and leads to the classification, packaging and labelling of the chemicals in accordance with the hazards they pose, and where appropriate to conditions for contact and transaction with such chemicals (e.g. application restrictions or bans). The precautionary principle is to apply whenever there is scientific uncertainty that cannot be dispelled about the hazardous nature of a particular chemical. In such cases exposure to the chemical plays a key role. Scientific uncertainties with regard to toxicological properties that do not take effect due to lack of exposure are unlikely to give rise to serious precautionary measures (e.g. a ban on the chemical’s circulation). Elsewhere the precautionary principle takes effect especially in cases where new scientific findings point to hazards hitherto unknown. The promotion of toxicological research by the federal government is called for explicitly in both the current Poisons Act (Section 20) and the future Toxic Substances Control Act (Section 37). The conditions and prerequisites under which the precautionary principle is invoked correspond largely to those of the EC Commission (see 5.2.1.).

4.1.5 *seco*: trade law barriers

The decision whether or not to adopt measures under the precautionary principle rests in each case within the competence of the specialist agency. *seco* plays an attendant role. The main focus of interest here is on analysing a measure's economic repercussions and assessing it with regard to its compatibility with international trade commitments. Authoritative here are the federal law on technical trade barriers (THG, SR 946.51), the WTO Agreement¹⁷ (in particular TBT and SPS¹⁸) and other international standards such as trade commitments in MEAs (Multilateral Environment Agreements) that refer to the precautionary principle. The assessment of a measure is based on the agreement applicable in each case.

seco applies the following principles as criteria used for the assessment of measures based on the precautionary principle: Measures adopted based on the precautionary principle are to be in the public interest, proportionate (necessity, suitability and proportionality in the narrower sense, in particular cost-benefit ratio) and satisfy the requirement of non-discrimination (national treatment, most-favoured nation treatment). Moreover precautionary measures should be drawn up in such a way that they must be revised in the light of new scientific findings (provisional character). On no account is the precautionary principle to be used to disguise protectionist interests.

¹⁷ Agreement on the founding of the World Trade Organisation, SR 0.632.20;
http://www.wto.org/english/docs_e/legal_e/legal_e.htm

¹⁸ www.wto.org/english/docs_e/legal_e/17-tbt.pdf;
http://www.wto.org/english/docs_e/legal_e/15-sps.pdf

4.2 Common aspects and differences in the application of the precautionary principle

4.2.1 Overview in table form

	PP defined explicitly	Legal status	Criteria for invoking the PP (<i>If and How</i> criteria)	Possible measures
SAEFL	Yes	Art.74 Section 2 BV; Section 1 Para. 2 EPA; however definition in the EPA is broader than the internat. terminology	<i>if:</i> if effects could become harmful or noxious <i>how:</i> technical and operationally feasible, economically viable	Regulations, bans, limit values; establishment of protection zones
SFVO	No	Section 9 TSG and Sections 9 and 10 LMG	<i>if:</i> threat to human or animal health; strong indications of potential harm; <i>how:</i> measures well-founded and intelligible; communicated transparently, regularly reviewed and adapted	Bans, regulations, conditions
FOAG	Yes	LwG Section 148a	<i>if:</i> strong likelihood of an event having detrimental repercussions; plausible risk hypothesis <i>how:</i> proportionality, non-discriminating, requirement of coherence	Ban/conditions regarding import, putting into circulation and use of a farming product
SFOPH Food	No	Precautionary principle as inherent part of food legislation; Art. 1, 3 & 6 LMG	<i>if:</i> justifiable suspicion of harm to human health; plausible risk hypothesis <i>how:</i> criteria of the EC Commission of 2.2.2000	Precautionary seizure, import ban, conditions for bringing foodstuffs into circulation
SFOPH Radiation	No	Recommendations	<i>if:</i> Scientific indications of a hazard to health, sustainability	Recommendations, directives, training on how to handle radiation, information, promotion of research
SFOPH Chemicals	No	Inherent part of the Toxic Substances Act	<i>if:</i> Suspected hazard to health based on scientific uncertainties (not unequivocal or incomplete) <i>how:</i> criteria of the EC Commission of 2.2.2000	Labelling, warnings, restrictions on putting into circulation, including bans
seco	No	THG WTO MEAs Intern. standards	<i>if:</i> overriding public interest at stake (to be considered by specialist agencies) <i>how:</i> measures proportionate and non-discriminating, provisional in character, reviewed and adapted where necessary; disguised trade restrictions not permitted	none

4.2.2 Common traits and differences

The Agencies are agreed as to the importance of the precautionary principle. They are aware that there are terminological differences between national and international usage (due mainly to the way in which national legislation has evolved in the environmental sector); however these differences do not constitute any discrepancies in the understanding of the precautionary principle. In the Working Group a distinction was made in terms of the differences in application between the precautionary principle in the narrower sense (SFOPH, FOAG, SFVO, SAEFL and more generally at the international level) and the precautionary principle in the broader sense (SAEFL, SFOPH in the area of protection against deception).

The precautionary principle in the narrower sense: All the Agencies employ the term precaution— explicitly or implicitly – in the narrower sense and are agreed that its potential application has to be subject at least to initial scientific indications of a potential threat, a plausible risk hypothesis or justifiable suspicion. If the precautionary principle is invoked, an assessment of relative merits may be carried out in different ways; especially also in view of the different scopes and weighting of the interests represented by the Agencies. They are in agreement that certain application criteria (*How* criteria) must be observed (see 4.2.3).

The precautionary principle in the broader sense: The concept of precaution is applied in the broader sense in the environmental and health sectors, i.e. it covers both precautionary and preventive acts simultaneously; as a result considerations are governed by other principles (technical and operational feasibility, economic viability). The use of safety margins and other concerns such as for example protection against deception are often referred to as precautionary measures, and are to be seen as measures in the broader sense of the precautionary principle.

4.2.3 Criteria (*If and How* criteria)

Significantly the criteria governing the potential application of the precautionary principle are divided into *If* criteria (in what cases is the principle to be applied?) and *How* criteria (how is the principle to be applied?).

If criteria:

The table in 4.2.1 provides an overview which shows that the *If* criteria in the use of the precautionary principle in the narrower sense accord well, even the wording chosen differs slightly: The precautionary principle can be invoked at these three Agencies if

- there is a **plausible risk hypothesis** (e.g. in connection with persistencies and irreversibilities);
- there is **justifiable suspicion** or
- **strong indications** of potential harm to the asset to be protected, and
- if there is a **strong likelihood** that an event has harmful consequences.

The likelihood of a presumed cause and effect relationship that is not however sufficiently proven scientifically must therefore clearly be > 0%; the consequences for the environment or for human, animal and plant health must be potentially harmful or dangerous and incompatible with the chosen level of protection.

The situation is different with the SAEFL, which invokes the precautionary principle in the broader sense. The special-purpose article of the EPA obliges precautionary-preventive action to be taken **as soon as an effect could become harmful or noxious**. This means that the (political) decision for or against precautionary action does not depend on a risk analysis following a lack of scientific certainty; instead the Agency must take precautionary action in the broader sense in the case of any effect that falls within its sphere of responsibility, for instance when specifying emission limits. There is an overlap here between precaution and prevention.

How criteria:

With *How* criteria the Agencies agree that the precautionary principle is applied as part of an ordinary risk analysis and represents an instrument of risk management. They believe that the application of the precautionary principle should result in concrete action with regard to the chosen level of protection and is therefore to be seen as a political act. The agencies are also agreed that certain principles should be applied whenever it is invoked, principles such as they are formulated by the EC Commission or the Codex Alimentarius:

1. Principle of proportionality (the measures are proportional to the chosen level of protection);
2. Requirement of coherence (in comparable situations the same yardsticks are to be used in the assessment);
3. Prohibition of discriminatory practices (measures are not to be applied differently to domestic and foreign products without factual reasons);
4. The measures are not to aid and abet any disguised trade interests;
5. The application of measures is to be based on the most comprehensive scientific assessment possible;
6. The measures are well-founded and intelligible; they are provisional in character insofar as they are regularly reviewed in the light of new scientific findings and adapted where necessary;
7. The role of risk management (recourse to the precautionary principle leads to a decision pro or contra taking action); This involves a political decision which is to be taken by the risk manager and depends on the level of risk which society regards as "acceptable".
8. Transparency (the process is to be transparently structured and the measures transparently communicated).

5. The precautionary principle internationally

5.1 The precautionary principle as a rule of customary international law

Practically every state applies the precautionary principle at the national level. At the international level the reformulation of the precautionary principle in accordance with Principle 15 of the Rio Declaration is generally uncontested. The

importance of the precautionary principle as an environmental principle has repeatedly been recognised at the international level and explicitly acknowledged once again at the World Summit on Sustainable Development in September 2002 in Johannesburg. To this extent the validity and applicability of the principle, particularly in the environmental sector, are uncontested in principle.

The question of whether the precautionary principle is already a rule of (environmental) customary international law that would have effect even in the absence of interstate agreements is contested, and has yet to be clarified by international case law. To apply as a rule under customary law, two conditions would have to be complied with in principle.¹⁹ Firstly the principle would have to have been applied internationally in consistent and lasting practice;²⁰ secondly the practice would have to be based on the conviction that the legally binding effect of the principle is an inalienable part of the legal order.²¹ More recently the opinion has also been expressed that customary international law can also occur spontaneously based on general legal conviction. The academic debate is inconclusive as to whether the precautionary principle has already attained the status of a rule under customary law. Generally however it is at least recognised that it is in the process of “settling” into customary law or of “crystallising” into a rule under customary law. The EU for example has recognised the precautionary principle as a rule of customary international law. Switzerland has in the past always pleaded in favour of a further consolidation and definition of the precautionary principle. In doing so it has stated that it regards the principle as an important element of international law and invokes it both nationally and internationally. However it has not so far explicitly expressed itself regarding the status of the precautionary principle under customary international law.

5.2 How international organisations and bodies invoke the precautionary principle

5.2.1 European Union

The Communication from the Commission of the European Communities of 2 February 2000 on the precautionary principle reads as follows:

„Whether or not to invoke the Precautionary Principle is a decision exercised where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection.“²²

¹⁹ Statute of the International Court of Justice (ICJ): Article 38.1 lit b: 1. The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply: (b.) international custom, as evidence of a general practice accepted as law;

²⁰ General practice as an objective element: Covers the partial aspects of duration, uniformity and dissemination.

²¹ “Recognised as law” as a subjective element: What is decisive is the conviction in the sense of a secured position that a certain practice is called for because it corresponds to that which the subjects of international law see as in accordance with the law.

²² See footnote 6

In its communication on the applicability of the precautionary principle the Commission emphasises a number of essential conditions:²³

- The precautionary principle is invoked as part of a general risk analysis. The precautionary principle is an instrument of risk management. It involves a political decision that depends on the level of risk which society considers as “acceptable”.
- The precautionary principle can only be invoked if there is a potential risk. Under no circumstances is the precautionary principle to justify an arbitrary decision. The precautionary principle must lead to a decision pro or contra taking action.

The Commission defines the following precondition for invoking the precautionary principle, i.e. for adopting measures (*How* criteria):

1. Proportionality

The measures must comply with the chosen level of protection. It is rare that a risk can be reduced to zero, and for this reason a ban cannot be the only possible response to a danger.

2. Non-discrimination

Comparable facts must not be dealt with differently, unless justified by objective reasons.

3. Consistency/co-ordination

New measures must be co-ordinated with measures adopted in the past. They must comply in terms of scope and content with measures adopted in similar areas for which complete scientific data is already available.

4. Cost-benefit analysis (not just monetary consideration)

The overall costs incurred in the short and long terms depending on whether or not the Community takes action are to be compared. It is not a matter of a purely economic cost-benefit analysis but also of a more general consideration of interests, e.g. the public’s acceptance of the measures.

5. Review of the measures in the light of new scientific findings

As soon as new scientific data is available the measures adopted must be reviewed in the light of scientific progress and modified where appropriate.

6. Responsibilities for producing new scientific evidence

Responsibilities are defined whenever such measures are issued. A reversal of the burden of proof is also possible with regard to the production of new scientific fundamentals.

These guidelines have also been adopted in the food sector. With the new outline regulation on food safety the European Union has explicitly raised the precautionary principle to a general principle of the law relating to food production and distribution:

“Article 7 Precautionary principle: (1) In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to

²³ See footnote 6

ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

(2) Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.”²⁴

Since spring 2002 it has therefore been clearly regulated by law for the food safety sector that in cases where there is a risk to life or health but scientific uncertainty persists the precautionary principle has to be invoked as a mechanism in order to define and implement measures within the framework of risk management.

5.2.2 Codex Alimentarius

The Codex Committee on General Principles discussed the precautionary principle at its 18th meeting in Paris on 7 to 11 April 2003 as part of risk analysis²⁵. The draft of these working principles – intended only for internal Codex use – was adopted by the Codex Alimentarius Commission at its 26th meeting held in Rome on 30.6. - 7.7. 2003. Within the Codex too, the process of risk analysis is subdivided into risk assessment, risk management and risk communication. Precaution is perceived as an inherent part of risk analysis. As there are many uncertainties in the process of risk assessment and risk management of food-related risks, the level of uncertainty and the variability of the scientific information available must – according to the Codex – be incorporated in the risk analysis.²⁶ Restrictions, uncertainties and assumptions that affect risk assessment should be taken into account during each phase of the process and documented in a transparent way.²⁷ Minority views should also be incorporated. It is felt that the responsibility for the influence of scientific imponderables on the decisions of risk management rests with risk management and not risk assessment. The actual definition of the precautionary principle is as follows:

“When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence from a preliminary risk assessment to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for risk managers to apply precaution through interim measures, in order to protect the health of consumers without awaiting additional scientific data and full risk assessment. However, additional information should be sought, a more complete risk assessment should be performed, and the*

²⁴ Regulation specifying the general principles and requirements of the law relating to food production and distribution for the establishment of the European Agency for food safety and for specifying procedures for food safety 178/2002 of 28 January 2002, Sections 6 + 7

²⁵ Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, ALINORM 03/33A, Appendix IV, page 38 ff; www.codexalimentarius.net/reports.asp

²⁶ *ibidem* Para. 11

²⁷ *ibidem* Para. 23

measures taken reviewed, all in a reasonable time frame."²⁸

**Some Members refer to this concept as the "precautionary principle"*

If the precautionary principle is invoked, the Commission recommends that the following elements be taken into account:²⁹

- All the management options should be reviewed with the persons concerned;
- The necessity of measures should be communicated transparently;
- The measures adopted should be proportionate;
- The measures adopted should be consistent with measures adopted in comparable situations and incorporate all the conclusive information;
- The measures adopted to protect the health of consumers should have as little effect on trade as possible;
- The decisions/measures should be continually reviewed;
- To improve the level of knowledge further findings are to be collated and the measures adopted reviewed in the light of new information acquired.

5.2.3 *Multilateral environmental agreements*

Principle 15 of the Rio Declaration provides the starting point for invoking the precautionary principle in the environmental sector (see 2.2). It defines four elements which have since been developed further in various treaties and agreements:

- The threat of serious or irreversible harm;
- The lack of complete scientific certainty;
- Cost-effective measures;
- The prevention of environmental damage.

This formulation of the precautionary principle is relatively open and allows various interpretations. Since then the main points of discussion have been:

- Precaution as a right or obligation;
- General obligation to avoid risks;
- Errors better "in favour of" than to the detriment of the environment;
- Reversal of the burden of proof (what has to be proven is not the necessity of a measure to protect the environment but the safety of an activity or product);
- Co-operation principle to reduce scientific uncertainty.

Principle 15 of the Rio Declaration has evolved differently in different areas. The **Bio-diversity Convention** (1992) for instance defines a lower threshold for precautionary measures: the trigger is the threat of a significant loss of biological

²⁸ CX 4/10 CL 2002/39-GP July 2002, Annex 2, para 32

²⁹ The application is limited to the Codex and is not applicable to the governments of the member states.

diversity (rather than serious or irreversible damage), and there is no mention of the fact that precautionary measures have to be cost-effective:

“Where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as reason for postponing measures to avoid or minimise such a threat.”³⁰

The **Cartagena Biosafety Protocol** (2000) talks of “adverse effects” and includes human health; again there is no mention of cost-effectiveness:

“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 the Party from taking a decision, as appropriate, (...)”³¹

The **Stockholm Convention on Persistent Organic Pollutants (POPs)** (2001) refers to human health as an object of protection besides the protection of the environment; here too there is no mention of cost-effectiveness. Concerning the inclusion of new substances it specifies generally that a *“lack of full scientific certainty shall not prevent the proposal from proceeding”*.³²

So generally speaking it may be said that since the adoption of the Rio Declaration the precautionary principle has evolved differently in the various environmental sectors. It is in part extended to measures aimed at the protection of health; the criterion of cost-effectiveness is mentioned increasingly rarely; and the trigger threshold for the risk of serious or irreversible damage has in part been lowered. In other words there is still no horizontally consistent further development and interpretation of the precautionary principle in the environmental sector. Efforts by Switzerland in this direction were rejected at the 2002 World Summit on Sustainable Development (WSSD). However there is agreement that Principle 15 of the Rio Declaration can be used in all areas as a basis for invoking the precautionary principle. What all the developments have in common is that the precautionary principle is invoked in situations in which the effective threat potential cannot be proven with scientific certainty. Precautionary measures are to be possible in such situations. This shatters the principle of international commercial law that the need for environmental protection measures has to be demonstrated scientifically. It is generally recognised however that there have to be serious indications of the possibility of a threat in order to invoke a precautionary measure. Finally there is also agreement that this foundation relating to Principle 15 of the Rio Declaration applies in all areas in principle and that in specific areas such as chemicals or biological diversity the precautionary principle has evolved further.

³⁰ Preamble to the Bio-diversity Convention

³¹ Article 10(6) Cartagena Protocol on Biological Safety

³² Article 8.7(a) POP Convention

5.2.4 WTO: SPS, TBT and GATT 1994

Trade agreements within the WTO regulate the rights and obligations of member states in connection with international trade. In particular the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the Agreement on Technical Barriers to Trade (TBT Agreement) and the General Agreement on Tariffs and Trade (GATT 1994) are applicable to precautionary measures that can have repercussions on cross-border trade. Generally speaking it may be said that the free movement of goods may only be restricted with regard to legitimate (overriding) public interests; that any such restriction must be applied without discrimination, and whenever possible be established scientifically.

The precautionary principle is not explicitly cited in WTO law. The **SPS Agreement** is the only one of the three Agreements to contain a reference in Article 5.7 to the rights and obligations of WTO members in cases where there is insufficient scientific evidence:

“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 organisations as well as from sanitary or phytosanitary measures applied by 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.”³³

Article 5.7 of the SPS Agreement has already been the object of several dispute settlement cases in the WTO. Several rulings have served to spell out the corresponding provision³⁴: In the *EC Hormones* dispute the WTO’s Appellate Body has expressed its view concerning the relation between precautionary principle and SPS Agreement. It was confirmed that the precautionary principle is in fact reflected in Article 5.7 of the Agreement. It was also considered that other sections of the Agreement had a bearing on the precautionary principle, specifically the sixth paragraph of the Preamble and the provisions pertaining to the “appropriate level of sanitary protection” in Article 3.3 of the Agreement. In the case *Japan – Agricultural Products II* the Appellate Body ruled in favour of a strict interpretation of Article 5.7 of the SPS Agreement, and highlighted the following four requirements from Article 5.7 to be met cumulatively:

“Article 5.7 of the SPS Agreement sets out four requirements which must be met in order to adopt and maintain a provisional SPS measure. Pursuant to the first sentence of Article 5.7, a member may provisionally adopt an SPS measure if this measure is:

- (1) imposed in respect of a situation where ‘relevant scientific information is insufficient’;*
- and*
- (2) adopted ‘on the basis of available pertinent information’*

Pursuant to the second sentence of Article 5.7, such a provisional measure may not be maintained, unless the Member which adopted the measure:

³³ Viz. SPS Agreement (as in Footnote 18), Article 5.7

³⁴ WTO: WTO Analytical Index [1st edition (2003)]: Guide to WTO Law and Practice, Vol. 1, page 516 ff.

- (1) 'seek[s] to obtain the additional information necessary for a more objective assessment of risk'; and
- (2) 'review[s] the ... measure accordingly within a reasonable period of time.

These four requirements are clearly cumulative in nature and are equally important for the purpose of determining consistency with this provision. Whenever one of these four requirements is not met, the measure at issue is inconsistent with Article 5.7.³⁵

In its scope the Agreement on Technical Barriers to Trade (**TBT Agreement**) is complementary to the SPS Agreement. This means that a measure that does not fall within the limited scope of the SPS Agreement is to be judged under the TBT Agreement.³⁶ The points of reference are known as the Technical Regulations.³⁷ Unlike the SPS Agreement the TBT Agreement does not contain any provision governing the case of a lack of scientific data. To be compatible with the provisions of the TBT Agreement a measure must not be discriminatory. In addition the measure must pursue a legitimate public interest,³⁸ and be defined in such a way that it is not more trade-restrictive than necessary to achieve the legitimate interest (proportionality).³⁹ A further requirement is that the measure be based on an evaluation of the risk, with the evaluation incorporating existing scientific and technical data, applicable production and processing methods, and the intended end use of the product.

In accordance with the TBT Agreement there is also the obligation to base any measures on international standards, where such standards exist. Further measures to achieve a higher level of protection are permissible if the international standards are insufficient for the purpose. The Agreement also contains a revision clause⁴⁰ which states that a measure must be lifted or modified as soon as the circumstances or objectives for which the measure was initially adopted change or the concerns can be resolved in a way that is less trade restrictive.

Both the SPS and TBT Agreements contain provisions regarding transparency. At the draft stage of a regulation (or, in urgent cases, once it has come into force) the measures must be brought to the knowledge of the other member states by means of a notification. This gives the WTO member states the opportunity to comment on the measure and to demand justification with regard to its WTO compatibility.

In general it is presumed that both the SPS and TBT Agreements represent a more precise rendering of Article XX (and in particular lit. b and g)⁴¹ of the General Agreement on Tariffs and Trade (**GATT 1994**). Based on this fact the

³⁵ Appellate Body Report on Japan – Agricultural Products II, paragraph 89

³⁶ Viz. TBT Agreement (see footnote 18), Article 1.5

³⁷ Technical Regulation: Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

³⁸ Article 2.2 of the TBT Agreement contains an indicative list of such legitimate public interests: national security interests, prevention of unfair / misleading business practices, protection of (human, animal and plant) health, and environmental protection.

³⁹ what is known as "least trade-restrictiveness"

⁴⁰ Viz. TBT Agreement (see footnote 18), Article 2.3

⁴¹ Specifically the Article that lays down the exceptions to the general GATT obligations.

Appellate Body has in previous disputes first examined the compatibility with the *lex specialis* and ruled that it was possible to invoke TBT and SPS provisions independently of any infringement of GATT obligations. For the SPS Agreement it is presumed that any measure compatible with the SPS Agreement also complies with GATT.⁴² The TBT Agreement does not contain any corresponding provision. Therefore it is to be assumed that compatibility with the TBT and GATT Agreements will be verified for any environmental measures adopted on the basis of the precautionary principle.

5.2.5 WHO

As a key international health organisation the WHO usually formulates its recommendations on health and safety on the basis of conclusive scientific evidence. However at the Third European Ministerial Conference on Environment and Health 1999 it was called upon to take greater consideration of the precautionary principle when assessing risks, and to adopt a more preventive, more proactive attitude towards potential risks. To clarify the theoretical principles and develop the concept further and also to discuss case studies the WHO subsequently organised several events on the theme of the precautionary principle: The workshop "Precautionary Policies and Health Protection: Principles and Applications" (Rome, May 2001); the symposium "Environmental Exposures, Public Health, and the Precautionary Principle" (Vancouver, August 2002); and jointly with the European Commission the international workshop "Application of the Precautionary Principle to Electromagnetic Fields" in Luxembourg (February 2003).⁴³

The aim of the works of the WHO is to launch a comprehensive, open and transparent process to create a general framework for the application of the precautionary principle for all topics relating to public health. The precautionary principle is to occupy a prominent place on the agenda of the Fourth Conference on Health and the Environment in Budapest in 2004. WHO is in the process of drawing up a corresponding position paper at several preparatory meetings: "Dealing with uncertainty: how can the Precautionary Principle help protect the future of our children?"⁴⁴ The work on the precautionary principle received the broad support of member states of WHO Europe at the Second Intergovernmental Preparatory Meeting of Environmental and Health Minister in Stockholm on 27-28 June 2003. It was emphasised that the findings should concentrate on practical application, terminology definition and scope clarification. According to the paper tabled at Stockholm the precautionary principle should be construed as an overlapping principle to be applied to the entire process, from problem definition to risk assessment, evaluation and application of potential fundamental options, up to and including the monitoring and processing of its implementation, and the specification of research projects. Precautionary measures should for a continuous, iterative process to search lastingly for possibilities to reduce effects that are a hazard to human health. It is felt that a proactive approach to precaution with the aim of creating the conditions

⁴² Viz. SPS Agreement (as in Footnote 18), Article 2.4

⁴³ <http://www.who.int/emf>

⁴⁴ Background paper for the Second Intergovernmental Preparatory Meeting, Stockholm, 26-27 June 2003; http://www.euro.who.int/budapest2004/Topics/20030325_2

for sustainability and health instead of simply reacting subsequently to problems is of inestimable value for the well-being of children and future generations.⁴⁵ Accordingly two main points are to be addressed during discussions in Budapest: Firstly the role of the precautionary principle as an instrument for supporting sustainable development and as a means for improving the health protection of future generations, and secondly the role of scientific findings with regard to the precautionary principle.⁴⁶

6. Synthesis

National and international level

The findings at national and international level did not differ fundamentally from one another as developments at national and international level have fostered one another. The precautionary principle is already well established at the international level. Regulations are to be found in multilateral environmental agreements, in the Codex Alimentarius, in the WTO (SPS) and in the EU. WHO alone took up the discussion only recently and intends to treat the principle of the precautionary principle at the next conference of health and environmental ministers in Budapest in June 2004.

Common traits

With regard to the understanding of the precautionary principle there are essentially no fundamentally different viewpoints between the Federal Offices. There are in part different conceptual perceptions in the different fields of work and areas of application, which should be respected; these do not in fact pose a problem. Moreover agreement on the fundamental principles does not preclude a different use of the terminology in actual application.

The precautionary principle is an instrument with which the Agencies involved are familiar and that is applied by them. All the Agencies involved consider the precautionary principle in the narrower sense basically as an instrument of risk analysis (risk assessment, risk management, risk communication), and more specifically of risk management. In cases where there is a lack of or insufficient scientific information the risk manager decides pro or contra taking action.

Differences

Risk assessment is oriented according to the scope of the agency concerned, and for this reason it makes little sense to draw up a harmonised catalogue of criteria with regard to the assessment of the certainty or uncertainty of the scientific foundations.

The precautionary principle is regulated differently in law. The forms range from regulation in the Federal Constitution (environmental sector) to explicit legislation (environment, agriculture) and inherent part of statutory regulations (health, veterinary office). In the veterinary sector there are also binding quality management guidelines for the precautionary principle.

⁴⁵ ibidem page 4

⁴⁶ ibidem page 2

Although all the agencies know and invoke the precautionary principle, there are certain differences in the definition, as mentioned earlier, which are due to the different ways in which legislation has evolved in the relevant areas of application. In the discussions of the Working Group a distinction emerged with regard to the precautionary principle in the narrower sense and in the broader sense. The precautionary principle in the narrower sense refers to the adoption and implementation of measures in the case of scientific uncertainty as to the cause and effect relationship of potential harm while the precautionary principle in the broader sense is considered as generally precautionary action. The precautionary principle in the broader sense covers precautionary *and* preventive measures and at the national level concerns the environmental sector in particular. Here the precautionary principle continues on not just from the existence of scientific uncertainty but also from a threshold of harmfulness determined on the basis of various scientific criteria. Measures below that threshold are deemed in national environmental law as precautionary and may only be invoked insofar as they are viable economically and operationally.

Application criteria (If and How criteria)

Switzerland's understanding of the **precautionary principle in the narrower sense** is similar to the EU's, as explained in the Communication from the Commission of 2 February 2000, and may be described as follows:

In the event of an imminent threat of irreversible and serious damage to human, animal or plant health and to the environment a lack of scientific certainty as to the cause and effect relationship of a product or process should not constitute a reason for delaying measures to protect health and the environment. For the precautionary principle to be invoked, the following *If* criteria (in what cases is the principle to be applied?) must be satisfied:

1. Overriding public interest is at stake;
2. There must be initial scientific indications of serious or irreversible harm or at least a scientifically plausible risk hypothesis.

When the precautionary principle is applied, the measures adopted must satisfy the following *How* criteria (how is the principle to be applied?):

1. **Proportionality**

The measures are proportional to the chosen level of protection. Before any decision pro or contra taking action the risks and consequences should be assessed with regard to expenditure, effectiveness and duration.

2. **Requirement of coherence**

In comparable situations the same yardsticks are to be applied for the assessment; the measures are co-ordinated with measures adopted in similar cases or based on similar approaches. Where possible, consistency should be aimed at with regard to the chosen level of

protection so that action by the state can be made as calculable as possible.

3. Prohibition of discriminatory practices

The measures are not to be applied differently to domestic and foreign products without factual reasons (national treatment) nor must a distinction be made between products of foreign origin (most-favoured nation treatment) without factual reasons.

4. Prohibition of disguised trade restrictions

The measures are not to aid and abet any disguised trade interests.

5. Scientific assessment

The application is to be based on the most comprehensive scientific assessment possible. The extent of the scientific uncertainty should be determined as far as possible.

6. Intelligibility, review

Measures are well-founded and intelligible; they are provisional in character insofar as they are regularly reviewed in the light of new scientific findings and adapted where necessary.

7. Risk management

Recourse to the precautionary principle must lead to a decision pro or contra taking action. This involves a political decision which is to be taken by the risk manager and depends on the level of risk which society regards as "acceptable".

8. Transparency

The process and the responsibilities are structured transparently and the measures openly communicated.

7. Conclusions

1. Switzerland is willing to pursue its commitment to the precautionary principle at the international level, and accordingly is advocating the strengthening, clarification and operationalisation of the precautionary principle in the sense described above.
2. Switzerland supports the further consolidation of the precautionary principle into a rule of customary international law and where possible also into a contractual rule.
3. The document is to be incorporated in the preparations for international negotiations.
4. When invoking and applying measures adopted on the basis of the precautionary principle, the Swiss authorities observe not only the legal foundations but also the criteria that have been identified as part of the interdepartmental process.
5. The document is to be disseminated at all the participating Agencies.

Berne, August 2003

Glossary

Term	Description	Examples
Harm	Undesirable event with negative consequences for human, animal and plant health and/or the environment.	
Hazard	Biological, chemical or physical agent (organism, substance, particle, product) or activity that can have negative repercussions (harm).	Aflatoxin in nuts
Ignorance	“Unknown” effect and therefore “unknown” likelihood.	Surprise about the damaging effect of CFCs on the ozone layer before 1974; asbestos as a cause of Mesotheliom cancer before 1959
Magnitude of consequences	Negatively valued consequence of an unwanted event that pertains to a specific duration and a specific area.	
Precaution	Measures adopted in the event of uncertainty with the aim of precluding, detecting and reducing a harmful effect or magnitude of consequences.	In the case of chemicals inclusion of properties such as persistence or bio-accumulation as predictors of potential harm
Precautionary prevention	Measures used to reduce potential risks	e.g. reduction/elimination of human exposure to antibiotic-resistant animal germs
Prevention	Measures used to reduce known risks	Preventing exposure to asbestos dust
Risk	Function of the likelihood of the occurrence of the unwanted event and the potential damage resulting therefrom. “Known” effect and “known” likelihood.	Asbestos as the cause of lung disease, lung and Mesotheliom cancer after 1965
Uncertainty	Consequence of incomplete knowledge of a presumed causal relationship; can be reduced through specific research. “Known” effect of “unknown” likelihood and/or “unknown” magnitude of consequences.	Antibiotics in animal feed in connection with human resistance to antibiotic-resistant animal bacteria, 1969 to present; low-dosage effects of radioactive and electromagnetic radiation

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