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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COORDINATING COMMITTEE FOR EUROPE

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### THE PRINCIPLE OF PRECAUTION: CONSIDERATIONS FOR ITS UNIFORM INTERPRETATION AND APPLICATION IN THE EUROPEAN REGION

(Prepared by Spain)

#### 1. MOTIVATION

Resorting to the Principle of Precaution is not a novelty in the management of food risks, despite the fact that only recently has the concept started to be employed in the field of food safety, with concept and application becoming the subject of specific documents and an element of debate in international forums.

Such debates, which reflect the eternal conflict of the search for equilibrium between the efficacy and proportionality of risk management measures, together with the well-founded fear concerning the potential erection of barriers supposedly based on reasons of a health nature, i.e., on the Principle of Precaution, ought to contribute to a uniform understanding of the concept and scope of its application. Nevertheless, it cannot be denied that the proliferation of forums all aimed in the same direction though not necessarily agreeing with each other, and which are promoting a discussion based around these questions, runs the risk of diminishing the concept for the sake of achieving a consensus of “minima”.

If the Principle of Precaution has been able to be applied “de facto” in policies concerning the harmlessness of food, even though the principle was not known by that name, now is the moment when, owing to the growing awareness in the face of so-called food crises, there is an increasing need to establish general rules of reference making it possible for there to be a homogenous understanding – the basis of mutual confidence – in the application of this Principle.

It therefore seems appropriate to base oneself on the works of the Codex Alimentarius as the primary reference at the world level for all aspects related to the application of the Principle of Precaution in risks analysis. At the European level, it is in any case desirable to promote a clear agreement between the European Union and the Codex Alimentarius, identifying and acknowledging the undoubted points of agreement between the Communication on the Principle of Precaution of the European Commission and the works of the Codex Committee on General Principles. Although just the application of the Principle of Precaution will, with the passage of time, be able to generate a definite doctrine in this field, it is essential to promote this starting from premises that are free of any controversy. And above all, considering a prior management of food risks at the service of the protection of public health as an overriding interest, though in equilibrium with other legitimate interests, it is necessary to descend to the level of the specific regarding questions such as the suppositions in which the Principle of Precaution can be evoked. At the same time, it is of supreme importance to prevent the improper use of the term leading to the concept becoming tarnished and, with that, the adulterating of basic directives on which the legitimacy of its application could be founded.

## **2. EXISTING REFERENCES**

The works of the Codex Committee on General Principles (Doc. CX/GP 00/3), together with the Communication of the European Union relating to the Principle of Precaution COM (2000) 1 (Doc. CX/GP 00/3-Add 2) provide clear references in terms of the conceptual and operational consideration of the Principle of Precaution, though the first of these is in progress and the Communication is kept within the scope of the European Commission.

The question has also been tackled in works carried out by the Ad Hoc Group “Food Safety” within the OECD (Paris, January-May 98) without it being possible for it to be unaware that the actual Agreement on Health and Phytosanitary Measures (WHO) incorporates this philosophy, though more closely tied to safeguard measures.

## **3. THE PRINCIPLE OF PRECAUTION IN THE RISKS ANALYSIS OF THE CODEX ALIMENTARIUS**

The consideration of Risk Analysis, necessarily made up of the evaluation, management and communication of those risks, is essential as a preliminary framework for demarcating the concept, the Principle of Precaution.

The “Precaution” has, to a greater or lesser degree, been inspired by a great many provisions contained in the legal framework on food. This assessment takes on particular importance if we assume that the production of regulations is none other than a component of risk management. Nevertheless, it is vital to avoid any conceptual and terminological ambiguity, on the assumption that the Principle of Precaution deals with something more concrete, which must necessarily be linked exclusively to Risk Management as a political decision and therefore equally directly related to the political decision related to the choice of the level of protection that it is intended to offer a population.

It can now be concluded, therefore:

- That the Principle of Precaution DOES NOT lie in the evaluation of the risk since this does not entail the adoption of management measures but instead, in the best of cases, it promotes and sustains them, even by means of the absence or insufficiency of that evaluation.
- That the uncertainty in the scientific method is NOT equivalent to the Principle of Precaution. This will be able to be invoked a posteriori by the Manager once the existence of uncertainty or controversy in the result of an evaluation that was carried out has been passed on to him by the evaluator.
- That the resorting to the Principle of Precaution is only legitimate following due consideration of the evaluation of the risk, even when from that consideration it can only be concluded that the evaluation of risks has not been carried out – this would be the case with dangers appearing for the first time, without any precedent. However, in the face of such a pre-existing risk that is catalogued as insufficient, it is important to try to identify what are the element or elements of that evaluation that prevent conventional risk management from being carried out without resorting to the Principle of Precaution.

In other words, the application of the Principle of Precaution will be better matched, more proportional and better directed if it can be identified which elements of the evaluation are insufficient:

- Non-definition in the IDENTIFICATION OF THE DANGER (noxious effects in consumers or in the environment, noted before having identified the danger) (toxic oil syndrome);
- Inadequate or insufficient CHARACTERISATION OF THE DANGER (dose-effect controversy) (Infecting dose of L. Monocytogenes in risk groups);
- Shortcomings in the EVALUATION OF THE EXPOSURE (1999 dioxins crisis);

- Incorrect CHARACTERISATION OF THE RISK, per se or due to an insufficiency of the preceding elements.

The consideration of these aspects can contribute to providing objectivity, foundation and proportionality to the application of the Principle of Precaution and, as a consequence, it should likewise contribute to dispelling the reservations of those who identify the Principle of Precaution exclusively as an instrument at the service of arbitrariness and of the generation of covert restrictions.

There can certainly exist an undesirable facet in this process of analysis linked to the adoption of the Principle: insufficiency in the evaluation elements can bring with it a deformation of the real risk due to overdimensioning. In any case, this is always preferable to underestimation, which would endanger the health of citizens.

In any case, the positioning of the Principle of Precaution as a political decision taken by the political manager within the framework of Risk Analysis, with the inevitable analysis of the four elements making up the insufficiency of the evaluation that advise resorting to that Principle, establishes certain coordinates of uniformity around the concept and its application. This is an aspect that is in any case necessary in order not to detract from an instrument which, if it does not exist “de jure” under certain commonly accepted basic premises, will be given “de facto” without any systematic guarantees in terms of the foundations of its application.

Likewise, the political manager must inform and, as appropriate, involve all operators affected by the application of the Principle of Precaution in a search for the transparency that is needed in this type of decision.

#### **4. GENERAL SUPPOSITIONS IN THE APPLICATION OF THE PRINCIPLE OF PRECAUTION**

In line with the points discussed in the above section, it can be concluded that, without losing sight of the inappropriateness of trying to restriction as far as possible the conditions of application – this would be contradictory to the very essence of the Principle – it is indeed possible to establish certain common basic directives in terms of the application of the Principle of Precaution.

The Communication relating to the Principle of Precaution drawn up by the European Commission has meant an important step in this regard. The necessary efforts in any case need to be devoted to identifying the equilibrium between the generic nature of directives and the possibility of identifying them with concrete problems to be solved in risk management. In the majority of cases, it should not be overly complicated to establish a parallel between the insufficiency noted in the elements of the evaluation and the general problems that are identified in the management of incidences or crises concerning food safety.

For the sake of a suitable risk management it is necessary to go beyond the generic justification “Insufficient Evaluation / Application of the Principle of Precaution”. Otherwise, the reductionist situation could occur of limiting the legitimate application of the Principle of Precaution solely to suppositions suffering from an insufficient identification and characterisation of the danger, forgetting the fact that the deficiencies in the evaluation of the exposure or in the characterisation of the risk would convert this into something unmanageable in food safety terms, without resorting to that Principle.

So, various suppositions – equivalent to directives – could be listed in which the resorting to the Principle of Precaution becomes unavoidable:

- Risk Evaluation absent, insufficient, not updated or subject to controversy.
- Insufficiency in the information in terms of the real or potential exposure to a risk, even if it has been sufficiently evaluated.
- Non-viability, either materially or time-wise, for analytical accrediting the absence of risk in products or processes linked to others in which the existence has been noted of a risk that has been sufficiently evaluated.

- Impossibility of achieving the same level of protection by resorting to alternatives other than the Principle of Precaution.
- Valuation of the Cost/Efficacy ratio.

At the level of risk management, the resorting to the Principle of Precaution leads to the adoption of measures, be they standards, instrumental or both.

In adopting those measures, consideration is in all cases given to the principles of proportionality – though the difficulty in making proportionality compatible with insufficient information must be assumed a priori – arbitrary non-discrimination, the maximum possible restriction in the concordant time and space, when this is the case, with the cautionary nature of those measures. Such considerations remain subordinate to the objective of protecting health in objective terms (impossibility of managing “zero risk”).

It is imperative to identify and maintain an equilibrium between the concepts “Evidence” and “Principle of Precaution”. Faced with a risk that has been sufficiently and unfavourably evaluated, the manager cannot be required to take on absolutely the entire burden of proof as a prior justification to the adoption of any cautionary measure, with the conclusion being drawn that the opposite is only justified in the Principle of Precaution. The adoption of such cautionary measures based, for example, on exclusively epidemiological evidence can be justified without turning to that Principle.

## **5. PRINCIPLE OF PRECAUTION, PRE-EXISTING REGULATION, SAFEGUARD CLAUSES AND FUTURE REGULATIONS**

From the viewpoint of legal security, it is desirable to have references – if not binding certificates – that set down conceptual and operational directives in relation to the Principle of Precaution.

Nevertheless, the limiting of the application of the Principle to our prior instrumentation in pre-designed safeguard measures must be avoided, even if such measures are based on the consideration of a philosophy of Precaution. In the same way, it is possible that if some of the cautionary measures that might be adopted by virtue of the Principle of Precaution and as a result of its application were later on to be set down a posteriori in a legal text, then such a text would become comparable to a safeguard clause.

It is important to use the Principle on certain directives or conditions, but its application cannot be invalidated a priori if this application previously fails to find a legal base expressed in a safeguard clause. Such a procedure would lead to the Principle of Precaution becoming devoid of content at the same time as implying the paradox of necessarily having forecasted that which, since its forecasting is impossible, requires turning to the Principle of Precaution.

On the other hand, the assumption of the possibility of resorting to the Principle of Precaution must entail certain considerations with a view to food legislation at the international scope or rank that might be passed in the future.

If it is intended, as is desirable, to create a doctrine of the right application of the Principle of Precaution, it is, whenever possible, necessary that the provisions of the legal framework on food, even those that are most horizontal or deregulating in spirit, should truly respond to health protection needs that consumers are rightly demanding.

It is certainly not a matter of promoting “zero risk” legislation, which is incompatible with reality and absolutely outside the equilibrium that must exist between the protection of health – though a priority – and other legitimate interests of citizens and economic and social agents. In theory, legislation of such a nature would reduce the need to resort to the Principle of Precaution to minimal levels. Or it would at least limit the need to invoke it to those fields that are unregulated. Nevertheless, the potential suggestion of invoking the Principle in fields that are already wholly or partially regulated cannot be denied.

It is necessary to legislate finding the equilibrium between the protection of health and the protection of markets. Nevertheless, it needs to be recalled that the establishing of the level of protection that it is sought to provide for the population is a political decision. Along the same lines, the political manager will adopt the political decision of invoking the Principle of Precaution in order to be able to assure the level of protection committed to being offered to citizens when legislation, due to having become slack for the sake of consensus and partial solutions, is insufficient for obtaining and maintaining the established level of protection.

To conclude, the legislative bodies can make a very favourable contribution towards a use of the Principle of Precaution that is well-founded, committed and neither arbitrary nor systematised.