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EU VIEW OF PRECAUTIONARY PRINCIPLE IN FOOD SAFETY

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1. Introduction

I would like to thank the organizers for their kind invitation to address you on the precaution approach, or as we in Europe call it, the precautionary principle.

This topic is of major importance to the EU and to our trading partners and therefore it is in the interests of all to foster a general understanding of the use of precaution in Food Safety decision making both within the European Community and internationally.

My task here today is to outline the European Union's approach to the use of precaution, its initiatives relating to precaution and how the Commission views the activities on this matter in the international arena.

In many ways, the precautionary principle I am talking about, that is the PP applied to human and animal health, is a principle of common sense. It is a legitimate tool available to decision-makers in those circumstances when we are faced with potentially harmful effects on health, but there is scientific uncertainty concerning the nature or extent of the risk. When faced with these circumstances, decision-makers must consider taking action, whether this is adopting legal measures or other appropriate actions. Those in public office entrusted with the protection of health have a duty to respond and not wait until their worst fears are realized. Precaution requires them to err on the side of safety when there is scientific uncertainty in order to achieve the necessary level of health protection. In the European Union, precaution is now part of primary and secondary European legislation (e.g., Article 174 of EC Treaty says action in the environmental field "shall be based on the precautionary principle" and Regulation on General Food Law).

As regards more specifically human and animal health, the European Commission adopted its Communication on the Precautionary Principle in the year 2000. The Council of Ministers and the European Parliament supported fully the Commission's Communication.

4. Precaution at the International Level

We welcome the declaration from the November WTO meeting in Doha, which provides for further consideration of precaution in relation to trade matters by reaffirming the right of governments to set the level of protection that they deem necessary to protect health and the environment. We believe that clarification on the application of the precautionary principle in the WTO framework is an important issue and we will continue to press for work to be taken forward in this context.

The Commission has also promoted risk analysis principles in other international discussions, for example: in the context of Codex, the SPS (Sanitary and Phytosanitary) and TBT (Technical Barriers to Trade) Agreements of the World Trade Organization and the WHO.

Article 5(7) SPS - Guidelines. SPS was annexed in 1994 to the WTO agreement. What does it say? Article 5(7) stipulates that: "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 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." (See the General Food Law.)

5. Conclusions

We are not married to the expression "Precautionary Principle." Recent debate on this subject has often been marked by emphasis on the differences between the EU and the US—some real, others borne of misunderstanding.

A couple of weeks ago I had the opportunity to see a draft of the US paper on Precaution. A few months ago, Health Canada published their version. In all honesty, if you compare the three versions, the US, the Canadian and the Communication of the Commission of 2000, all three are very similar and are based exactly on the same principles. Obviously, the precautionary approach or principle is a sensible concept. It needs to be applied wisely and on a case-by-case basis. And given that the dynamics of science are not predictable, it is important to consider the dangers of excessive precaution.

[Quote: J.G.: *Take the response of Brussels to "mad cow's disease." Once the British government and industry had taken all reasonable steps to address this problem, Brussels instructed member states of the EU to lift their bans on beef imports from the UK. All member states complied except France, who argued that French beef might still be safer than British beef and that France has the right to invoke the precautionary principle. Brussels took France to the European Court of Justice, where the Court ruled against France, indicating that speculative appeals to the precautionary principle must have some grounding in science.*

Much more recently, the EC has rejected an unauthorized use of the precautionary principle by the provincial government of Upper Austria. In March of this year, Austria notified Brussels of its proposed ban of genetically modified seeds that the EC had approved for cultivation under the EC Directive 90/220. Upper Austria appealed to the precautionary principle but Brussels overruled them. "Recourse to the precautionary principle presupposes that potentially dangerous effects…have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty." The EC noted that Upper Austria had not made this case and there was certainly nothing unique about the safety of GM seeds in Upper Austria. Unquote]

Italy and others (France, Germany, Luxemburg, Greece and UK) banned GMOs on their territory, even if they had been approved at the EU level. The Commission took the scientific evidence provided by these member states as justification for the bans and submitted it to the European Scientific Committee for opinion. In all the cases, the Scientific Committee deemed that there was no new evidence which would justify overturning the original authorization decision.

But to suggest, as the National Foreign Trade Council does, that the EU uses the PP to create obstacles to trade continuously is, excuse my French, utter rubbish. The NFTC is clearly biased against everything the EU does, and what it does is promote its own self-interest. The authors of NFTC papers on the subject like to imagine European officials working whole days and sometimes nights on Machiavellian schemes to make life difficult for US industry. But that is totally cock-eyed. As the second largest exporter in the world, the EU has more to lose than any other trading partner if the PP were abused.

The NFTC and the dozen or so US-based industry associations that form the core of the new coalition behave like a kind of Don Quixote fighting windmills that do not exist. But my comparison is perhaps not quite sound—at least Don Quixote's heart was in the right place.

Hormones

Gauging US reaction to the new Hormones Directive 2003/74, published in the *Official Journal* on 14 October, based on Scientific Opinions of Scientific Committee on Veterinary Measures relating to Public Health of 1999, 2000 and 2002, which concluded that:

- risk to the consumer has been identified with different levels of conclusive evidence for the six growth hormones [endocrine, developmental, immunotoxic, genotoxic and carcinogenic effects could be envisaged (prepubertal children among most vulnerable)];
- oestradiol 17 beta has to be considered a complete carcinogen;
- for the other five, risk has been identified, but no acceptable daily intake can be established. The new Directive keeps a permanent ban on oestradiol 17 beta and places a provisional ban on the other five, pending further scientific information. Three therapeutic uses of oestradiol will still be allowed under tight conditions—these are to be phased out in the future.

The EU is now in compliance with its WTO obligations and will request that US and Canada lift the trade sanctions. There is a high possibility that the US will want the DSB to examine the WTO compatibility of the new Directive.

If NFTC had personal responsibility for millions of people's lives, they might sing a different tune. The PP is a legitimate tool available to risk managers who have a tremendous responsibility—when, on the basis of scientific indications, a situation exists that is potentially harmful to human health. They might go to court or to jail if they do not take the appropriate measures in time.

To suggest that the EU now uses the PP to undermine rather than safeguard is unmitigated rubbish.

The truth is that the US industry is not getting used to the fact that the 15-nation EU (and soon 25-nation EU) increasingly assets regulatory powers in the marketplace and, in so doing, threatens the US role as the world's standard setter for manufacturing and safety…