




"Representing consumers' real interests"

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Food Safety and Inspection Service

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**Comments of Consumer Alert
on the Proposed Draft Principles and Guidelines
for the Conduct of Microbiological Risk Management
by the Codex Committee on Food Hygiene
CX/FH 00/6**

Consumer Alert would like to express its views on several issues presented in the Codex Committee on Food Hygiene's "Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management."

Precautionary Principle

The primary focus will be on the proposed inclusion of the "precautionary principle" and the definition of the "precautionary principle" in 5.2.1.2:

"[Precautionary Principle - A decision-making approach which may be applicable when there is a suspicion of adverse effects but where there is no evidence as to the existence or extent of risks to human health, leading to protective measures without having to wait until the reality and seriousness of risks to human health become apparent.]"

(1) **Principles Before Application:** The effort to insert a decision rule that may well distort safety choices into the specific committee deliberations of the Codex before that principle (the "precautionary principle") has been evaluated by the Committee on General Principles is dangerous. It would violate the precautionary principle itself -- leaping before we look.

The inclusion of a precautionary principle section itself in this document is premature and should be deleted. That issue is being considered in the Committee on General Principles, where Consumer Alert would urge the U.S. delegation to expend a major effort to challenge the so-called principle. If it is decided in that committee that the precautionary principle will be included, with specific wording, that would then be applicable to all committees. If it is decided

that the precautionary principle is not appropriate in the General Principles, and thus no language is included, then it should be expected that it would not be reflected in other committees' work.

The precautionary principle itself should be challenged in all Codex fora. It does not have any place in decision-making under uncertainty. It is a vague and arbitrary concept, represents a biased approach to decision-making, ignores the risk that its application could create, raises the "moral hazard" problem, and readily leads to a disguised form of protectionism in trade.

The principle itself can be challenged using the precautionary principle. Using this concept, one can envision adverse effects on human health and the environment from restricting technology, for example, food irradiation. The PP thus can be turned against itself, which illustrates its inapplicability to rational decision-making.

The debate in Codex on the precautionary principle seems to be moving quickly into a legalistic rather than a substantive debate. It revolves around how to use it and how to apply it, before some fundamental questions are resolved . . . or even asked. The first step is to rethink this debate. The goal should be not to clarify the PP but to replace it with a decision-making approach that more rationally and more equitably deals with uncertainty.

The debate currently is an impoverished one by ignoring a critical element -- whether other approaches to risk assessment and risk management can better handle decision making under uncertainty.

(2) The Risks of Biased Risk Management Rules: The PP is best seen as a biased, truncated risk management rule -- applicable only when the status quo is risk free. This case is rare to non-existent. To adopt the PP in the real world would be to place greater emphasis on the risks of the novel, the innovation, the change -- than on the risks of the old, the traditional, the status quo. All food safety technologies have introduced new risks into society --while lowering older risks -- fire, for example, is an extremely dangerous technology yet it vastly reduced other risks that had faced mankind -- exposure to the elements, risk of wild animal attacks, inability to store or prepare food safely.

The PP must be balanced with an equally close scrutiny of the risks to which people are now being exposed. We should not allow people that might be saved by safety-enhancing technologies to continue "dying in the streets." All risk management rules must consider the reality of the Risk/Risk tradeoff.

Proponents of the precautionary principle want to err on the side of "caution," but that bias ignores the fact that caution may instead mandate innovation. Focusing on the risks of the new, they ignore the off-setting risks that food shortages might become severe, that existing vaccines might become ineffective, even when the evidence on these risks is not conclusive.

Attempting to prevent harms by limiting the use of technologies or by insisting on standards for food hygiene that do not recognize risk trade-offs may be counterproductive. Specifically, it may result in the failure to adopt new technologies that significantly reduce actual and potential risks faced by humans and the environment. In addition, insisting on a level of safety that approaches

zero risk can actually harm consumers by causing increases in food costs that, because they spend a larger proportion of their income on food, would significantly impact the poor.

- (3) **Moral Hazard:** The PP when applied could also raise the "moral hazard" problem -- that is, consumers may not themselves take proper precautions in food hygiene and preparation because they may be misled into thinking that there is "zero risk" in the food supply -- an unattainable goal.

The PP would create a serious health risk for consumers by presuming that all safety rules are pre-cautionary while, of course, much safety is post-cautionary. It is critical that we do nothing that might encourage careless attitudes among consumers in the storage, handling and preparation of food. A safer society can only be achieved if each party plays their role -- yet, the emphasis on the "pre" in this debate suggests that the "post" can be ignored. This moral hazard problem creates difficulties for all insurance schemes and deserves far more attention by the Codex participants than it has received to date.

- (4) **The Risks of Politicizing Safety Policy:** Codex has long been the major bulwark against protectionist pressures that threaten to undermine the open trading rules that have done so much to advance human welfare over the last half century.

All nations have powerful groups who seek protection from open world trade. Article XX, the SPS Article, is essential but has always entailed the risk that special interests in the various nation states would advance their protectionist agenda under a "safety" guise. Codex has resisted that temptation -- standing firm -- insisting that only sound factual grounds for open trade exemptions would be entertained. Fears, suspicions, worries, potentials, possibilities -- all would be considered and evaluated on a factual basis; we would not sacrifice the welfare of the peoples of the world on vague fears of possible future risks to some unspecified and small populations. The PP would undermine that position -- massively expanding the SPS exemption - and encouraging trade wars around the world. Again, to leap ahead with such vague and dangerous policy innovations that might well threaten the health and safety of the world's population would be a massive violation of the PP itself.

- (5) **Problems with the CCFH Draft's "New" Definition of the PP.** The definition itself, the clause "when there is a suspicion of adverse effects but where there is no evidence as to the existence or extent of risks to human health . . ." is completely unacceptable for inclusion in any document that purports to deal with science.

In addition this clause is not a decision-making approach at all. It is rather a means of enabling decisions to be made for reasons other than science. Consumer Alert would suggest that the inclusion of this section and this language absolutely must be challenged.

It creates "suspicion," defined in Webster's as "a state of mental uneasiness," that this language was included in response to lobbying by powerful interests, perhaps to be able to use this definition to disguise protectionist trade practices.

The use of the word "suspicion" is a document that purports to be based on scientific principles is startling. It lends itself to the use of vague, uninformed, and unsupported guesses that could wreak havoc on the exchange of healthy and nutritious food made possible by open trade.

The combination of the "suspicion" with "no evidence" would lead to a retreat from reason and science to one of fear and superstition. Witches' cauldrons could replace scientific tests under this definition.

(6) Unintended Consequences Arising from the PP. Consumer Alert would offer that the inclusion of the PP in the food hygiene guidelines can lead to some unintended consequences relating to certain foods that many consumers desire even when they are aware of small risks associated with their consumption. The PP approach could have serious ramifications, especially for some countries advocating its inclusion.

For example, the PP can readily be applied to unpasteurized cheeses -- cheeses made from raw milk, including some of the most celebrated cheeses in the world. Products made from raw milk, however, can be contaminated with bacteria, such as *Listeria monocytogenes*. According to public health officials and government agencies, illness from eating such foods can be serious for some people. Recently, in a sausage recall, the USDA's Food Safety and Inspection Service provided the following information about the disease, and noted that precautions people at risk should take include not eating unpasteurized cheeses: "Consumption of food contaminated with *Listeria monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease. Healthy people rarely contract listeriosis. Listeriosis can cause high fever, severe headache, neck stiffness, and nausea. Listeriosis can also cause miscarriages and stillbirths, as well as serious and sometimes fatal infections in those with weak immune systems . . ." (USDA FSIS Recall Release 00-066, October 4, 2000)

Consumer Alert is not suggesting that unpasteurized cheeses should be recalled -- only that desirable foods, because they may present a risk for some, could be banned under the precautionary principle. Consumer Alert would urge the U.S. Delegation to stress this point, particularly with the Committee.

Summary. The precautionary principle is seriously and irremediably flawed, and the U.S. Delegation to the Committee on Food Hygiene should reject its inclusion in the guidelines. Consumer Alert would urge the U.S. Delegations to other Codex committees, especially the Committee on General Principles, to challenge any inclusion of the precautionary principle in Codex documents, for the following reasons. The PP --

- Is a vague and nebulous concept
- Biases decision-making against innovation
- Does not recognize that there are risk trade-offs
- Its application paradoxically can create risks
- Can create a "moral hazard" problem
- Formal use of the PP threatens developing countries' progress made under a more open trading system

- Ignores the fact that there are more effective approaches to decision-making under uncertainty and better approaches to evaluating and managing risk that recognize risk/risk trade-offs.

Submitted by Frances B. Smith, Executive Director, Consumer Alert

Frances B. Smith 10/6/08