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## Some Dangers of Taking Precautions Without Adopting the Precautionary Principle: A Critique of Food Safety Regulation in the United States

by Vern R. Walker<sup>1</sup>

**A** more substantive precautionary principle of international law is evolving as new treaties articulate new measures of precaution in different contexts.<sup>2</sup> Although there is considerable controversy over how to articulate or define a precautionary "principle" of law, the goal is to ensure that the mere lack of scientific knowledge about risks cannot justify a failure to take appropriate precautions. Where we have sufficient evidence of risk, we often take precautions, despite a lack of certainty about those risks. The question arises, however, what the difference is between adopting a precautionary principle and merely taking precautions. Put another way, what is to be gained by adopting a precautionary *principle* at all, as compared to merely taking precautions? This Article explores that question by using the example of food safety regulation in the United States.<sup>3</sup> My principal conclusion is that although precautionary measures for achieving food safety in the United States are some of the oldest and most successful in the world, even such measures fall short when they are evaluated from the unifying perspective of the precautionary principle.

Any articulation of the precautionary principle would apply at two distinct levels of decisionmaking: (1) decisions about the factual situations that trigger justifiable recourse to precautionary measures; and (2) the management decisions to select the desired level of protection and to establish measures to achieve that level of protection.<sup>4</sup> The first aspect involves primarily risk assessment, while

the second is part of risk management. This Article examines these levels of decisionmaking in the regulation of food safety in the United States. My objective is not, of course, to provide a comprehensive survey of that regulatory structure. Rather, the goal is to use food safety regulation to find concrete examples of the difference between merely taking precautions and adopting the precautionary principle. A by-product of this examination is a more detailed account of what it means to adopt the precautionary principle.

### Factual Triggers for Precautionary Measures in U.S. Food Safety Decisionmaking

A primary question is what findings of fact must be made in order to justify triggering any precautionary measures. This section outlines a variety of factual triggers in U.S. law and surveys the content of the legally required findings.

The Federal Food, Drug, and Cosmetic Act (FFDCA)<sup>5</sup> is the cornerstone statute, and it establishes a variety of factual triggers for precautionary governmental action. Many factual triggers depend on the kind of substance to be found in or on a food. Major categories and triggers are:

- A. Any marketed food is subject to enforcement or regulation if any substance that it bears or contains is "poisonous or deleterious" and that substance "may render" the food "injurious to health."<sup>6</sup>
- B. If the substance is a "pesticide chemical residue"<sup>7</sup> or a "color additive,"<sup>8</sup> then a use regulation

1. Vern Walker is a Professor of Law at Hofstra University School of Law. The research for this Article has been funded in part by the European Commission, but the views are expressed solely as those of the author.

2. See James E. Hickey Jr. & Vern R. Walker, *Refining the Precautionary Principle in International Environmental Law*, 14 VA. ENVTL. L.J. 423, 438-53 (1995). A typical articulation of the precautionary principle is:

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.

Rio Declaration on Environment and Development, June 14, 1992, 31 I.L.M. 874, 879.

3. An official description of U.S. decisionmaking on food safety can be found in Precaution in U.S. Food Safety Decisionmaking: Annex II to the U.S. National Food Safety System Paper, Final OECD-U.S. Summary Precaution Annex, March 2000 [hereinafter U.S. Document]. This document, an attachment to a summary of the U.S. national food safety system, is intended to show how precaution is embedded in that food safety system. *Id.* §A. The document can be found at <<http://www.foodsafety.gov/~fsg/fssyst4.html>>.

4. See Commission of the European Communities, Communication from the Commission on the precautionary principle, COM(00) 1, Feb. 2, 2000 [hereinafter Commission Communication].

5. 21 U.S.C.A. §§301-397 (2000).

6. *Id.* §342(a)(1). The word "marketed" is being used here to include any acts prohibited under *id.* §331.

7. *Id.* §§321(q), 342(a)(2)(B), 346a(a)(1). The statute deems adulterated any food that bears or contains a pesticide chemical residue that is "unsafe," *see id.* §342(a)(2)(B), but also deems any pesticide chemical residue in or on a food to be unsafe unless its use conforms with a regulatory tolerance or an exemption, *see id.* §346a(a). Thus, the trigger requiring pre-marketing approval is simply that the food bears or contains a pesticide chemical residue.

8. *Id.* §§321(t), 342(c), 379e(a). The statute deems adulterated any food that is, bears, or contains a color additive that is "unsafe," *see id.* §342(c), but also deems any color additive to be unsafe unless its use conforms with a use regulation or an exemption, *see id.* §379e(a). Thus, the trigger requiring pre-marketing approval is simply that the food is, bears, or contains a color additive.

or an exemption is required before the food can be marketed.

C. If the substance is a "food additive," a use regulation or an exemption is required before the food can be marketed.<sup>9</sup> However, if a substance is "generally recognized as safe" (GRAS)<sup>10</sup> or if it has been granted a prior sanction,<sup>11</sup> then it is not a food additive and does not trigger the pre-marketing approval required for food additives.<sup>12</sup>

D. If the substance is a "new animal drug" or a conversion product of one, then approval of a new animal drug application is required before the food can be marketed.<sup>13</sup> Excluded are drugs "generally recognized . . . as safe and effective" by qualified experts and other "grandfathered" drugs.<sup>14</sup>

E. If the substance is not a pesticide chemical residue, color additive, food additive, or new animal drug, but the substance is "added to" the food and is "poisonous or deleterious," then the food is subject to enforcement or regulation under certain conditions.<sup>15</sup>

Besides these factual triggers, the inspection-and-condemnation statutory provisions for meat and meat food products,<sup>16</sup> poultry products,<sup>17</sup> and egg products,<sup>18</sup> add a two-staged program of precautionary triggers and measures beyond those provided by the FFDCA.<sup>19</sup> For such products, inspection measures are triggered categorically for the relevant animals or products, or for establishments that process them.<sup>20</sup> Such inspections are generally required before the product can be lawfully distributed in commerce.<sup>21</sup> If the required inspection results in an administrative determination that a particular product is "adulterated," then that product can be condemned and destroyed.<sup>22</sup> The

relevant agency also has the authority to prosecute judicial proceedings directly under the statute, and the court is authorized to condemn and seize any covered product that is found to be adulterated and capable of being used as human food.<sup>23</sup> "Adulteration" is generally defined as bearing or containing any poisonous or deleterious substance that may render the product either injurious to health or unfit for human food.<sup>24</sup>

## Risk Management of Food Safety in the U.S. Regulatory Structure

Once risk has been identified, a management decision must be made about how to manage that risk. An appropriate level of protection can be selected and precautionary measures can be established to achieve that level of protection. The selection of a level of protection is a decision about the level of risk that is "acceptable" to the society on which the risk is imposed.<sup>25</sup> International agreements recognize such selections to be sovereign acts of government, at least as long as those selections are internally consistent and distinctions are justifiable.<sup>26</sup> The significant evidence for what level of protection has been selected is the standard actually employed when approval is given for the activity that poses the risk.<sup>27</sup> The following subsections discuss several of the risk management decision rules found in U.S. food safety law.

### *The Delaney Clause's Risk Management Decision Rule*

One of the clearest and most stringent levels of protection for carcinogens in U.S. food safety decisionmaking is that

9. *Id.* §§321(s), 342(a)(2)(C)(i), 348(a). The statute deems adulterated any food that is, bears, or contains a food additive that is "unsafe," *see id.* §342(a)(2)(C)(i), but it also deems any food additive (other than a food contact substance) to be unsafe unless its use conforms with an exemption or a use regulation, *see id.* §348(a). Thus, the trigger requiring pre-marketing approval is simply that the food is, bears, or contains a food additive. The primary condition for being a food additive is that the intended use of the substance "results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food." *Id.* §321(s).

10. A precondition for being a "food additive" is that the substance not be "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown . . . to be safe under the conditions of its intended use" (that is, that the substance not be GRAS). *Id.* §321(s). The basis for being GRAS is "scientific procedures"—unless the substance was used in food prior to 1958, in which case an alternative basis is "experience based on common use in food." *Id.* §321(s).

11. Excluded from the food additive category is any substance used in accordance with a sanction or approval granted prior to September 6, 1958 (having a "prior sanction"). *Id.* §321(s)(4).

12. 21 C.F.R. §170.30(g) (2000).

13. 21 U.S.C.A. §§321(v), 342(a)(2)(C)(ii), 360b(a) (2000). The statute deems adulterated any food that is, bears, or contains a new animal drug to be "unsafe," *see id.* §342(a)(2)(C)(ii), but it also deems any new animal drug to be unsafe unless its use conforms to an approved application, *see id.* §360b(a)(1).

14. *See id.* §321(v).

15. *Id.* §§342(a)(2)(A), 346.

16. Federal Meat Inspection Act, *id.* §601ff.

17. Poultry Products Inspection Act, *id.* §451ff.

18. Egg Products Inspection Act, *id.* §1031ff.

19. *See, e.g.*, U.S. Document, *supra* note 3, ¶¶ 20, 29-30, 35-60.

20. *See, e.g.*, 21 U.S.C.A. §§603, 604, 608 (2000) (meat and meat food products); *id.* §455 (poultry products); *id.* §1034 (egg products). To the extent that such inspection measures are triggered by risk, it is a generic risk associated with the possible adverse effects from ingesting such products. Such statutes typically establish triggers for any product of the relevant type that is "capable of use as human food," where there is a statutory presumption that the product is capable of such use. *See, e.g., id.* §§601(k), 604, 453(v), 455, 1033(b), 1034.

21. *Id.* §§610(c)(2), 458(a)(2)(B), 1037(b)(2).

22. *See, e.g., id.* §§604, 672, 673, 455(c), 467a, 467b, 1034(c), 1048, 1049.

23. *See, e.g., id.* §§610(c)(1), 673(a)(1)(B), 458(a)(2)(A), 467b(a)(1)(B).

24. *See, e.g., id.* §§601(m), 453(g), 1033(a).

25. Commission Communication, *supra* note 4, §5.2.1.

26. *See, e.g.*, Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, preamble, art. 5.5, Annex A.5; Vern R. Walker, *Keeping the WTO From Becoming the "World Trans-science Organization": Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute*, 31 CORNELL INT'L L.J. 251, 268-71 (1998).

27. However, the desired level of protection should be taken into account in setting a factual trigger. As the European Commission states: "Once the scientific evaluation has been performed as best as possible, it may provide a basis for triggering a decision to invoke the precautionary principle. The conclusions of this evaluation should show that the desired level of protection for the environment or a population group could be jeopardised." Commission Communication, *supra* note 4, §6.2.

provided by the three Delaney Clauses—for food additives,<sup>28</sup> color additives,<sup>29</sup> and new animal drugs.<sup>30</sup> The Delaney Clauses are “a *per se* risk management law” for carcinogenic substances in these three categories.<sup>31</sup> If a food additive, for example, is found to induce cancer when ingested by animals, then the Food and Drug Administration (FDA) has no discretion to approve that additive as safe.<sup>32</sup> During the 1980s, the FDA and the U.S. Environmental Protection Agency (EPA) tried to adopt more relaxed interpretations with respect to the Delaney Clauses. Congress can, of course, carve out exceptions from the Delaney Clause prohibitions whenever it wishes, as it has done in the case of saccharin.<sup>33</sup> But administrative efforts to relax or restrict the Delaney Clauses have met with limited success. The FDA’s policy is that a food or color additive that contains a carcinogenic chemical “constituent” does not necessarily trigger the Delaney Clause, and the safety of the additive as a whole is determined under the general safety clause.<sup>34</sup> But reviewing courts have generally found the language and intent of Congress in the Delaney Clauses to be clear, and have refused to allow re-interpretation in the principal applications of the clauses.<sup>35</sup>

### The “Safe” Level Management Decision Rule

The FDA has stated that the test for approving color additives as “safe” is “that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use.”<sup>36</sup> The administrative definition of

“safe” for food additives is similar: “safe . . . means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.”<sup>37</sup> In 1996, partly as a result of a judicial decision involving pesticide residues,<sup>38</sup> Congress changed the level of protection for carcinogenic pesticide residues from the zero tolerance of the Delaney Clauses to “a reasonable certainty that no harm will result.”<sup>39</sup> This recent statutory standard appears to track the FDA’s administrative definitions of “safe” for color additives and food additives.<sup>40</sup> The House Report accompanying this legislation makes it clear that Congress expected this level of protection to be, in the case of carcinogens, a lifetime risk no greater than one in one million, calculated using conservative assumptions.<sup>41</sup>

### Other Management Decision Rules

Other risk management rules can be found. For contaminants that are unavoidable by good manufacturing practices, the appropriate tolerance is one “necessary for the protection of public health.”<sup>42</sup> Moreover, if an ingredient occurs naturally in the food and is not “added” to it, then the food cannot be considered adulterated “if the quantity of such substance in such food does not ordinarily render it injurious to health.”<sup>43</sup>

### Critique Using the Precautionary Principle

Even this brief survey of factual triggers and management decision rules is sufficient to suggest the complicated poli-

28. 21 U.S.C.A. §348(c)(3)(A) (2000).

29. *Id.* §379e(b)(5)(B).

30. *Id.* §360b(d)(1)(I).

31. U.S. Document, *supra* note 3, ¶¶ 87-92. The management Delaney Clauses are not triggered unless the agency makes several determinations that normally involve science policies. *See, e.g.*, 21 C.F.R. §70.50 (2000) (color additives).

32. *See* U.S. Document, *supra* note 3, ¶¶ 87, 89. Because a food ingredient that is GRAS does not fall within the definition of “food additive,” it is not technically subject to the Delaney Clause. PETER BARTON HUTT & RICHARD A. MERRILL, *FOOD AND DRUG LAW, CASES AND MATERIALS* 338 (2d ed. 1991).

33. *See* HUTT & MERRILL, *supra* note 32, at 922-28.

34. *See* FDA, Advance Notice of Proposed Rulemaking, Policy for Regulating Carcinogenic Chemicals in Food and Color Additives, 47 Fed. Reg. 14464 (Apr. 2, 1982); *Scott v. Food & Drug Admin.*, 728 F.2d 322 (6th Cir. 1984) (upholding the FDA’s determination that the color additive as a whole did not cause cancer in test animals, although the p-toluidine present in minute quantities is carcinogenic when tested separately). Between the *Scott* decision and 1990, the FDA approved more than 30 color additives and indirect food additives containing a variety of trace carcinogenic constituents. HUTT & MERRILL, *supra* note 32, at 922.

35. *Public Citizen v. Young*, 831 F.2d 1108, 18 ELR 20173 (D.C. Cir. 1987), *cert. denied sub nom.* Cosmetic, Toiletry & Fragrance Ass’n v. Public Citizen, 485 U.S. 1006 (1988) (rejecting the FDA’s de minimis reinterpretation of the color additives Delaney Clause); *Les v. Reilly*, 968 F.2d 985, 22 ELR 21303 (9th Cir. 1992), *cert. denied sub nom.* National Agric. Chem. Ass’n v. Les, 507 U.S. 950 (1993) (rejecting EPA’s de minimis reinterpretation of the food additives Delaney Clause, in a case involving carcinogenic pesticides that concentrated during processing and therefore became food additives in processed food under the FFDCA as it was then written).

36. 21 C.F.R. §70.3(i) (2000).

37. *Id.* §170.3(i).

38. *See Les*, 968 F.2d at 985, 22 ELR at 21303. *See also* H.R. REP. NO. 104-669, pt. 2, at 32 (1996); Frank B. Cross, *The Consequences of Consensus: Dangerous Compromises of the Food Quality Protection Act*, 75 WASH. U. L.Q. 1155, 1160-62 (1997).

39. The Food Quality Protection Act of 1996, Pub. L. No. 104-170, 110 Stat. 1489, 1514-35, §405 (1996); 21 U.S.C.A. §346a(b)(2)(A)(ii) (2000). *See* H.R. REP. NO. 104-669, pt. 2, at 36 (1996). Under the prior law, pesticide residues that concentrated in food processing triggered the regulatory provisions for food additives, including the food additive Delaney Clause. *See Les*, 968 F.2d at 985, 22 ELR at 21303.

40. *See* Cross, *supra* note 38, at 1162-63.

41. H.R. REP. NO. 104-669, pt. 2, at 41 (1996), which states:

In the case of a nonthreshold effect which can be assessed through quantitative risk assessment, such as a cancer effect, the Committee expects, based on its understanding of current EPA practice, that a tolerance will be considered to provide a “reasonable certainty of no harm” if any increase in lifetime risk, based on quantitative risk assessment using conservative assumptions, will be no greater than “negligible.” It is the Committee’s understanding that, under current EPA practice, . . . EPA interprets a negligible risk to be a one-in-a-million lifetime risk. The Committee expects the Administrator to continue to follow this interpretation.

*See* Cross, *supra* note 38, at 1164-65. This quantitative level of protection of one in one million is precisely the risk that the FDA had announced to be negligible or de minimis. *E.g.*, HUTT & MERRILL, *supra* note 32, at 899-904; *Public Citizen v. Bowen*, 833 F.2d 364 (D.C. Cir. 1987).

42. 21 U.S.C.A. §346 (2000).

43. *Id.* §342(a)(1); 21 C.F.R. §109.3(c), (d) (2000). *Cf.* HUTT & MERRILL, *supra* note 32, at 948-50 (carcinogenic natural foods and ingredients).

tics behind food safety regulation. The constellation of interests focused on residues of carcinogenic pesticides is different, for example, than those focused on color additives or animal drugs. The trade offs among risks, benefits, and costs result in different factual triggers and different risk management rules. Adopting a precautionary principle would cut across these political lines and place a priority on consistent and transparent regulation in the face of scientific uncertainty.

### *Comments on Factual Triggers*

There are important inconsistencies in U.S. food safety law, and precautions are relaxed for some categories and not others. Adopting a precautionary principle would require assessing and justifying those inconsistencies.

First, the most precautionary factual trigger does not require that the substance be a known or suspected hazard, nor is any generic or substance-specific risk assessment required before precautions are triggered. For example, pre-marketing approval is required for all color and food additives. At the time that precautionary measures are triggered, there is a potential for human exposure to such additives through ingestion, but there may be no knowledge at all about the toxicity of those additives. This situation is unlike the situation with pesticides, where there may be reason to suspect toxicity of the entire class of substances,<sup>44</sup> and even unlike the situation with meat and poultry products, where a known and pervasive type of hazard (such as *E. Coli*) can justify precautionary measures.<sup>45</sup> But neither of these latter rationales applies in the case of food and color additives. With respect to such additives, exposure alone, together with unknown toxicity, provides sufficient risk to

trigger precautionary measures. This low factual trigger seems inconsistent with the position taken by the United States in the growth hormones trade dispute with the European Community. In that case, the United States persuaded the World Trade Organization Appellate Body that in the absence of any toxicity evidence on a synthetic hormone to be administered to animals raised for food, precautionary measures were inconsistent with the treaty.<sup>46</sup>

Second, the GRAS precondition for being a food additive means that a food manufacturer may market a substance that the manufacturer determines is GRAS without informing the FDA.<sup>47</sup> For example, in the case of genetically modified foods, the FDA encourages private parties to determine for themselves whether the substances in such foods are GRAS or whether they are food additives triggering precautionary review.<sup>48</sup> The FDA's policy has been to encourage but not require informal consultation with the agency on this issue.<sup>49</sup> The result has been that the vast majority of genetically modified foods have not triggered any required FDA review or regulation.<sup>50</sup> The FDA may have authority to regulate genetically modified foods as "adulterated" if a substance in the food is found to be either "poisonous or deleterious" or a food additive,<sup>51</sup> but the GRAS precondition provides an important avenue for marketing substances without undergoing pre-marketing review.

Third, there are significant differences between the triggers for the various categories, but the rationale for those differences is unclear. Color additives have an extremely protective trigger, with no exclusion from pre-marketing approval for substances that are GRAS or that were sanctioned prior to the passage of the law.<sup>52</sup> By contrast, the permissive trigger for genetically modified foods has the po-

44. See U.S. Document, *supra* note 3, §B.3. See 40 C.F.R. §180.2(a) (2000) (providing only a short list of pesticides generally recognized as safe).

45. See, e.g., *Texas Food Indus. Ass'n v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994).

46. Report of the Appellate Body, *EC Measures Concerning Meat and Meat Products (Hormones)*, Jan. 16, 1998, adopted Feb. 13, 1998, WT/DS26/AB/R & WT/DS48/AB/R, ¶ 201; Walker, *supra* note 26, at 298-300.

47. See FDA, Proposed Rule, *Substances Generally Recognized as Safe*, 62 Fed. Reg. 18937, 18941-42 (Apr. 17, 1997) (proposing a voluntary GRAS notification procedure to replace the voluntary GRAS petition process); see HUTT & MERRILL, *supra* note 32, at 332-34 (stating that "[u]nder this [traditional] system numerous food ingredients have come into common use based on the assumption by manufacturers, sometimes but by no means always endorsed by FDA, that they are GRAS," and that "FDA does not have a complete inventory of GRAS ingredients, and it lacks complete information about the extent and levels of their use"); Lars Noah, *Legal Aspects of the Food Additive Approval Process*, Appendix A in INSTITUTE OF MEDICINE, *ENHANCING THE REGULATORY DECISION-MAKING APPROVAL PROCESS FOR DIRECT FOOD INGREDIENT TECHNOLOGIES* 24 (1999); 21 C.F.R. §170.30(d) (2000).

48. FDA, Statement of Policy: *Foods Derived From New Plant Varieties*, 57 Fed. Reg. 22984, 22989 (May 29, 1992) [hereinafter FDA Statement of Policy].

49. *Id.* See FDA, Center for Food Safety and Applied Nutrition, *Guidance on Consultation Procedures, Foods Derived From New Plant Varieties* (Oct. 1997) (available at <<http://vm.cfsan.fda.gov/~lrd/consulpr.html>>); Statement of James H. Maryanski, Biotechnology Coordinator, CFSAN, FDA, Before the Senate Comm. on Agriculture, Nutrition, and Forestry (Oct. 7, 1999); FDA Consumer, "Are Bioengineered Foods Safe?"

(Jan./Feb. 2000) (available at <[http://www.fda.gov/fdac/features/2000/100\\_bio.html](http://www.fda.gov/fdac/features/2000/100_bio.html)>) (interview with Commissioner Jane E. Henney, M.D., in which she stated: "While consultation is voluntary, the legal requirements that the foods have to meet are not").

Recently, however, the U.S. Department of Health and Human Services announced that "FDA will publish a proposed rule mandating that developers of bioengineered foods and animal feeds notify the agency when they intend to market such products. FDA also will require that specific information be submitted to help determine whether the foods or animal feeds pose any potential safety, labeling or adulteration issues." Press Release, U.S. Department of Health and Human Services, *FDA to Strengthen Pre-Market Review of Bioengineered Foods* (May 3, 2000) (available at <<http://www.fda.gov/bbs/topics/NEWS/NEW00726.html>>).

50. NATIONAL RESEARCH COUNCIL, COMMITTEE ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, *GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION* 29 (2000), stating:

Guidelines for this voluntary consultation process were published by the FDA in October 1997. . . . Over 45 transgenic plants, including numerous transgenic pest-protected plants and all crop plants that have been marketed in the United States, have gone through the consultation process. FDA has not required that any of the proteins added to transgenic plants be reviewed as food additives.

See FDA, CFSAN, *FOODS DERIVED FROM NEW PLANT VARIETIES DERIVED THROUGH RECOMBINANT DNA TECHNOLOGY, FINAL CONSULTATIONS UNDER FDA'S 1992 POLICY* (Dec. 1999).

51. FDA Statement of Policy, *supra* note 48.

52. HUTT & MERRILL, *supra* note 32, at 360-76, 872-73 (also discussing the history of "provisionally listed" color additives).

tential to leave many such foods unreviewed by the FDA. The triggers for yet other substances, such as natural contaminants or contaminants not covered by more specific categories, involve specific findings of hazard or risk.<sup>53</sup>

Adopting the precautionary principle should lead to a review of the adequacy and consistency of these factual triggers. The precautionary principle would itself provide a justification for a conservative trigger, such as the trigger for color additives. Exposure through ingestion alone should justify requiring pre-marketing approval, even in the absence of evidence of toxicity. Moreover, the burden should be on government to justify any departures from this protective trigger in the case of food. The GRAS exclusion from the food additive trigger, including the absence of mandatory pre-marketing review for genetically modified foods, would have to be justified.

### *Comments on Risk Management Decision Rules*

Risk management decisions should take into consideration the level of protection deemed appropriate, the scientific uncertainty associated with the available risk information, and public concerns about the risks and uncertainties involved.<sup>54</sup> Decisions to take less than full precautions might be justified by considering the potential benefits and costs, but when circumstances trigger the need for precautions, concern about benefits or costs must be sufficient to outweigh the known risks and the uncertainties. The burden of proof should always be on those who would relax precautions in order to obtain benefits. Moreover, lawmaking procedures affecting safety should place a high priority on transparency and public participation, especially when members of the public have voiced concerns. Decisionmaking about food safety necessarily balances competing values and interests.<sup>55</sup>

### *Consistency and Transparency of Decisions Made*

When there is scientific uncertainty, there are alternative but scientifically plausible accounts of the risk posed.<sup>56</sup> To the

extent that there is scientific uncertainty about the risk posed, decisions about what constitutes "safety" cannot be purely scientific. At a minimum, the lack of certainty on the part of experts makes public concerns about safety all the more reasonable. It might be a natural tendency on the part of regulators to reassure the public about safety and to obtain the public's trust, but the precautionary principle emphasizes the need to identify scientific uncertainty and to take it fully into account. And undoubtedly, adopting the precautionary principle means that acknowledgment of uncertainty must be a higher priority than political expediency.

Governmental risk managers should select a level of protection and characterize for the public the level of safety associated with it. Traditionally, when scientific evidence from animal studies indicates that a threshold exists for adverse effects, risk managers have adopted policies about what margins of safety to create.<sup>57</sup> For example, Congress requires EPA to assess the risk of pesticide residues specifically to infants and children, and requires EPA to adopt "an additional tenfold margin of safety" for them.<sup>58</sup> This is certainly an act of risk management and not a conclusion of pure science. As a result, the margins of safety normally applied to noncarcinogenic effects studied with animal data may be different for food or color additives (1/100) than they are for pesticide residues (1/1000), at least when infants and children might be exposed.<sup>59</sup> The precautionary principle would require a justification for having a more relaxed management rule for color and food additives than for pesticide residues.

Suspected carcinogens are treated differently than noncarcinogens because there is normally insufficient evidence to establish a safe threshold. Risk managers must decide about safety by establishing management cancer policies. The Delaney Clauses, for example, reflect a very protective management decision by Congress in the face of sci-

53. See *supra* categories A and E in section, *Factual Triggers for Precautionary Measures in U.S. Food Safety Decisionmaking*. Indeed, some regulatory precautions are triggered not because of any substance in or on the food, but simply because the food has been produced or distributed under "unsanitary conditions" that might lead to contamination or becoming injurious to health. See, e.g., 21 U.S.C.A. §342(a)(4) (2000).

54. As the U.S. Document, *supra* note 3, states at ¶ 181 (discussing the roles of risk assessment and risk management at the U.S. Animal and Plant Health Inspection Service): "Decision-makers, taking account of risk assessment findings, the degree of uncertainty, and public attitudes toward risk, may reasonably use precaution while in the process of determining an acceptable level of risk." See Commission Communication, *supra* note 4, Summary at 5, §§5.2, 6.1.

55. See Commission Communication, *supra* note 4, Summary at 5, §5.2.1 (such decisions are "eminently political"). Any actions taken should also adhere to the general legal requirements of proportionality, nondiscrimination, and consistency. *Id.* §6.3. Predictability, accountability, and administrative efficiency are also general requirements of the rule of law and are not peculiar to legal action to secure food safety.

56. Walker, *supra* note 26, at 255-72 (discussing risk assessment, scientific uncertainty, and risk management within the context of the

World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures, and concluding that it is characteristic of scientific uncertainty that, even after all available scientific data have been taken into account, there remain two or more alternative accounts of risk that are within the realm of scientific plausibility).

57. See U.S. Document, *supra* note 3, §§B.1, B.3, ¶ 82. The normally applied safety factor for a color additive is "1/100th of the maximum no-effect level for the most susceptible experimental animals tested." 21 C.F.R. §70.40 (2000). The tolerance for a food additive normally will not exceed "1/100th of the maximum amount demonstrated to be without harm to experimental animals." *Id.* §170.22. The requirement to consider "safety factors" for food and color additives is statutory. 21 U.S.C.A. §§348(c)(5)(C), 379e(b)(5)(A)(iii) (2000). For similar use of a 100-fold safety factor by EPA in setting tolerance levels for pesticide residues, see H.R. REP. NO. 104-669, pt. 2, at 41 (1996).

58. 21 U.S.C.A. §346a(b)(2)(C) (2000). EPA is authorized to "use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children," *id.*

59. Compare *supra* note 57 with 21 U.S.C.A. §346a(b)(2)(C) (2000); see H.R. REP. NO. 104-669, pt. 2, at 41, 43 (1996); Cross, *supra* note 38, at 1166-67.

entific uncertainty.<sup>60</sup> Because the Delaney zero tolerance remains in place for carcinogenic food additives, color additives, and new animal drugs, there are now at least two different statutory levels of protection for carcinogenic food ingredients.<sup>61</sup> The less protective management rule for carcinogenic pesticide residues should be justified, and is perhaps justifiable on a case-by-case or category-of-pesticide basis due to the benefits of particular pesticides. But without the adoption of the precautionary principle, there may be no expectation that such differences in level of protection need to be justified.

With regard to cost-benefit balancing in food regulation, the government plays down the role of such balancing in setting levels of protection.<sup>62</sup> But cost-benefit balancing plays a significant role. The congressional decision to establish a different level of protection for carcinogenic pesticides was clearly influenced by weighing the generic benefits of pesticides against the potential risks.<sup>63</sup> Furthermore, Congress authorizes EPA to relax the quantitative level of protection for carcinogenic pesticides even further in certain cases where the pesticide is needed "to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply."<sup>64</sup> Benefits as well as risks are also taken into account in the level of protection for "poisonous or deleterious" substances "added to" food that are not pesticide chemical residues, food additives, color additives, and new animal drugs.<sup>65</sup> Such contaminants are generally deemed unsafe and the food containing them adulterated, but this level of protection is relaxed "where such substance is required in the production" of the food or "cannot be avoided by good manufacturing practice."<sup>66</sup> Under this provision, the FDA considered benefits as well as risks in setting a tolerance for polychlorinated biphenyls (PCBs) in fish and shellfish.<sup>67</sup> The FDA has also weighed economic benefits in its various decisions to allow blending of corn contaminated with the carcinogen aflatoxin.<sup>68</sup> Perhaps law-

makers think that it is more reassuring to the public if they pretend that determining acceptable levels of food risk is always a purely scientific matter, instead of a management decision involving costs and benefits. But adopting the precautionary principle would mean placing a higher value on acknowledging scientific uncertainty and on transparency, and placing the burden of proof on those who would trade off protection against benefits. At a minimum, an adequate discussion of risk management principles in both Congress and the agencies would produce a more complete picture of cost-benefit analysis in U.S. decisionmaking.

#### Transparency and Adequacy of the Decisionmaking Process

Adopting the precautionary principle should prompt a review of the transparency and adequacy of administrative procedures—from priority setting and decisions whether to regulate, to data requirements and review of available data, to choice of mode of regulation and decisions about enforcement. Current judicial review of such procedures is limited.

First, decisions whether to regulate or not can be shielded from effective public scrutiny. Executive Order No. 12866 directs federal agencies to consider costs and benefits in regulating, whenever the agencies are not prohibited by law from doing so.<sup>69</sup> It is not clear whether the regulatory philosophy and principles in the Executive Order can legitimately influence an agency's decisions in setting priorities for regulation, decisions not to issue regulations, decisions about the mode of regulation or enforcement, and decisions about whether or not to enforce. Nor is it clear how adequacy, consistency, and transparency can be assured in decisions about priority setting for regulation or decisions not to regulate at all. For example, any private petitioner seeking to force an agency to initiate a rulemaking has a very high burden in judicial review, and courts are very reluctant to require an agency to initiate rulemaking.<sup>70</sup>

60. U.S. Document, *supra* note 3, ¶¶ 87, 89-92. For a candid discussion of management of risks and benefits under 21 U.S.C. § 346 when there are carcinogenicity data, see FDA, Final Decision, Polychlorinated Biphenyls (PCBs) in Fish and Shellfish; Reduction of Tolerances, 49 Fed. Reg. 21514 (May 22, 1984) [hereinafter FDA, Reduction of Tolerances].

61. This is without taking into account carcinogenic natural foods. See HUTT & MERRILL, *supra* note 32, at 948-50.

62. See U.S. Document, *supra* note 3, §E, ¶¶ 209-13. For a general discussion of the role of cost-benefit considerations in precautionary risk management, see the Commission Communication, *supra* note 4, §6.3.4.

63. See, e.g., H.R. REP. NO. 104-669, pt. 2, at 29-30, 32 (1996); Cross, *supra* note 38, at 1157-61.

64. See 21 U.S.C.A. § 346a(b)(2)(B) (2000); H.R. REP. NO. 104-669, pt. 2, at 41-43 (1996). The statute places a relative quantitative limit on the amount of relaxation authorized, 21 U.S.C.A. § 346a(b)(2)(B)(ii), (iv) (2000).

65. *Id.* § 342(a)(2)(A). For a discussion of the relevance of balancing benefits and costs in a decision whether to allow sale of a new animal drug, see Hess & Clark, Inc. v. Food & Drug Admin., 495 F.2d 975, 993-94, 4 ELR 20147, 20156-57 (D.C. Cir. 1974); Rhone-Poulenc, Inc. v. Food & Drug Admin., 636 F.2d 750, 754, 11 ELR 20457, 20458 (D.C. Cir. 1980).

66. 21 U.S.C.A. § 346 (2000).

67. FDA, Reduction of Tolerances, *supra* note 60; U.S. Document, *supra* note 3, ¶ 213.

68. See HUTT & MERRILL, *supra* note 32, at 256-59, 904-08.

69. Exec. Order No. 12866, Regulatory Planning and Review (Sept. 30, 1993), ELR ADMIN. MAT. 45070; U.S. Document, *supra* note 3, §E, ¶ 209.

70. See generally ALFRED C. AMAN JR. & WILLIAM T. MAYTON, ADMINISTRATIVE LAW 47-49 (1993); PETER L. STRAUSS ET AL., GELLHORN AND BYSE'S ADMINISTRATIVE LAW, CASES AND COMMENTS 488-509 (9th ed. 1995). See, e.g., Nader v. EPA, 859 F.2d 747, 19 ELR 20246 (9th Cir. 1988), cert. denied, 490 U.S. 1034 (1989) (involving EPA denial of citizen petition for rulemaking to revoke pesticide tolerance for daminozide).

An interesting example is Public Citizen v. Bowen, 833 F.2d 364, 18 ELR 20478 (D.C. Cir. 1987), which held that the court had no jurisdiction to review a failure of the FDA to ban methylene chloride as a food additive used in decaffeinating coffee, despite an FDA proposed ban on the use of methylene chloride in cosmetic uses due to its carcinogenicity. The food additive approval for methylene chloride in decaffeinated coffee remained in effect. 21 C.F.R. § 173.255(c) (2000). Also see Consumer Fed'n of Am. v. U.S. Consumer Prod. Safety Comm'n, 883 F.2d 1073 (D.C. Cir. 1989) (upholding the Consumer Product Safety Commission's denial of a consumer group's petition to ban methylene chloride as a hazardous substance, under statutory provisions and regulations requiring the petition to present "reasonable grounds," where the petition requirements track those required for certain petitions to the FDA).

In some situations, administrative action is forced by the need for private parties to obtain pre-marketing approval. When such regulatory schemes require the interested private party to produce the data concerning safety, any safety determination made on the basis of the data can only be as warranted as those data allow. Therefore, the data requirements should be adequate. On the other hand, compliance with such data requirements can be costly,<sup>71</sup> so such requirements should also be necessary and reasonably efficient. There are many, diverse data requirements for approvals of food ingredients under U.S. law. For example, one can contrast the extensive data requirements for EPA approval of pesticides for use on agricultural crops,<sup>72</sup> and the data requirements for new animal drugs for use in food-producing animals,<sup>73</sup> with the summary information "recommended" by the FDA for the voluntary consultation process for genetically modified foods.<sup>74</sup> If the precautionary principle were adopted, it would become necessary to justify the data requirements, as well as any differences between the various sets of requirements.

Once studies have been produced, risk assessors should apply consistent criteria in evaluating those studies and in arriving at inferences based on them. For example, the FDA's Center for Food Safety and Applied Nutrition has stated that during the voluntary consultation process on genetically modified foods, "the FDA does not conduct a comprehensive scientific review of data generated by the developer."<sup>75</sup> While agencies often use conservative assumptions when performing risk assessments,<sup>76</sup> this is not the same as applying explicit and public science policies in conducting risk assessments under the various regulatory programs. As EPA recognizes, explicit science policies would allow risk assessments to achieve consistency and transparency in the

face of scientific uncertainty.<sup>77</sup> Without a precautionary principle to apply, reviewing courts cannot require consistency of science policies, for agencies generally receive judicial deference in their interpretations of their own statutory triggers and standards of protection.<sup>78</sup>

In U.S. food safety decisionmaking, agencies often have considerable discretion to manage risks through different administrative procedures. In the case of unavoidable contaminants in food, for example, the FDA can choose to proceed by formal rulemaking procedures in setting tolerances,<sup>79</sup> by informal rulemaking,<sup>80</sup> or merely by prosecutorial action in court to enforce the statutory prohibition without administrative rulemaking.<sup>81</sup> Furthermore, the use of "action levels" by the FDA can eliminate the need even for enforcement proceedings. Action levels state the conditions under which the FDA might seek to have a court find a food to be adulterated. Although action levels, as public statements of policy, are freed from the notice-and-comment procedures of informal rulemaking required by the Administrative Procedure Act,<sup>82</sup> they can announce the sort of usage conditions usually associated with a substantive regulation.<sup>83</sup> By publicly announcing its enforcement policies, an agency can often achieve voluntary harmonization without the need for resource-consuming rulemaking.<sup>84</sup> Different administrative procedures can have different requirements for transparency, and agency discretion to choose the mode of regulation does not ensure adequate transparency.

When the FDA seeks to enforce the FFDCA's statutory prohibitions directly through a civil seizure action, the government must prove its case by a preponderance of the evidence.<sup>85</sup> Pre-marketing approval requirements and presumptions of lack of safety, however, effectively shift the burden of proof to industry.<sup>86</sup> Under particular statutes pro-

71. See, e.g., H.R. REP. NO. 104-669, pt. 2, at 30-31 (1996) (costs of generating data for pesticide registration).

72. See 40 C.F.R. pt. 158 (2000).

73. FDA, CVM, GENERAL PRINCIPLES FOR EVALUATING THE SAFETY OF COMPOUNDS USED IN FOOD-PRODUCING ANIMALS (Revised July 1994).

74. FDA, CFSAN, GUIDANCE ON CONSULTATION PROCEDURES, FOODS DERIVED FROM NEW PLANT VARIETIES (Oct. 1997).

75. *Id.*

76. U.S. Document, *supra* note 3, §A.4, ¶ 110.

77. See EPA, Memorandum From the Administrator: EPA Risk Characterization Program, at 2 (Mar. 21, 1995) (available at <<http://www.epa.gov/ordntmt/ORD/spc/rccover.htm>>); Walker, *supra* note 26, at 259-62.

78. See *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 14 ELR 20507 (1984).

79. 21 U.S.C.A. §§342(a)(2)(A), 346, 371(e) (2000).

80. *Id.* §§342(a)(1), 371(a); *Young v. Community Nutrition Inst.*, 476 U.S. 974 (1986); *Community Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1987); FDA, Final Rule, Action Levels for Added Poisonous or Deleterious Substances in Food, 55 Fed. Reg. 20782 (May 21, 1990); U.S. Document, *supra* note 3, ¶¶ 17-18, 205-06.

81. See, e.g., 21 U.S.C.A. §§331, 332, 342(a)(1) (2000); 21 C.F.R. §109.4, 109.6 (2000); *HUTT & MERRILL, supra* note 32, at 295-306. *Cf., e.g., Consumer Fed'n of Am. v. U.S. Consumer Prod. Safety Comm'n*, 883 F.2d 1073 (D.C. Cir. 1989) (discussing the Consumer Product Safety

Commission's regulation of methylene chloride through a "Statement of Interpretation and Enforcement Policy").

82. See *Community Nutrition Inst.*, 818 F.2d at 943 (distinguishing procedures for general statements of policy from those for substantive rules). For a parallel example of a U.S. Department of Agriculture (USDA) interpretive rule, see *Texas Food Indus. Ass'n v. Espy*, 870 F. Supp. 143 (W.D. Tex. 1994) (holding that the USDA's decision to consider *E. Coli* an "adulterant" of raw ground beef was an interpretive rule and therefore exempted from notice-and-comment procedures). In the case of the FDA action levels under the FFDCA, it is unclear how they would be governed by procedures for "guidance documents" under 21 U.S.C.A. §371(h) (2000). See FDA, Proposed Rule, Good Guidance Practices, 65 Fed. Reg. 7321 (Feb. 14, 2000).

83. See *HUTT & MERRILL, supra* note 32, at 256-59, 292-306.

84. See, e.g., *Texas Food Indus. Ass'n*, 870 F. Supp. at 143 (stating that the USDA argued that its beef testing program and interpretive rule, which required no notice-and-comment procedures, had "already begun to achieve its intended purpose of spurring industry to use preventive measures"); *Consumer Fed'n of Am.*, 883 F.2d at 1073 (in a non-food case involving methylene chloride, the Consumer Product Safety Commission had announced both a proposed rule and an enforcement policy, and indicated it could proceed with the rulemaking if voluntary compliance under the enforcement policy proved inadequate).

85. See generally *HUTT & MERRILL, supra* note 32, at 1121-25, 1130-32; Noah, *supra* note 47, at 16. See 21 U.S.C.A. §334 (2000).

86. U.S. Document, *supra* note 3, ¶¶ 81, 91, 104, 198; Noah, *supra* note 47, at 16-18, 32-33.

tecting public health, there can also be complicated shifting of burdens of proof.<sup>87</sup> A precautionary principle adopted into law would require a justification for which parties should bear what burdens of evidence production and proof.

Finally, U.S. courts have a very limited role to play in ensuring the adequacy and consistency of administrative actions. Measures that are egregiously disproportionate or inconsistent within a narrow confine might be held unlawful and set aside on judicial review as being "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."<sup>88</sup> In the area of administrative fact-finding, courts show great deference to administrative findings of fact concerning risk, especially when those findings are within the agency's expertise and are made on "the frontiers of scientific knowledge."<sup>89</sup> This substantive deference can be greatly reinforced in particular cases by judicial deference to the agency's own interpretation of statutory language,<sup>90</sup> by rules on burdens of proof,<sup>91</sup> and by the possibility of administrative summary judgment to obviate public hearings.<sup>92</sup> Moreover, there is limited judicial authority to review agency decisions not to regulate or not to enforce.<sup>93</sup> Under U.S. administrative law, the decision whether or not to bring an enforcement action is generally committed to an agency's absolute discretion, and such a decision is pre-

sumed to be judicially unreviewable.<sup>94</sup> As noted above, there is often discretion to rely on prosecutorial enforcement of the statute directly, or on the mere threat of such enforcement, instead of engaging in rulemaking. This combination of features can allow agencies to shield some of their measures from effective judicial scrutiny. The net result is that the courts currently cannot ensure that the evidence adequately supports an agency's findings or decisions about risk. Adopting the precautionary principle might lead to statutes that are better designed to allow effective judicial review of agency procedures and substantive determinations concerning safety.

## Conclusion

Many precautions are taken in decisionmaking about food safety in the United States. However, even this brief review of those many and diverse precautions provides convincing evidence that U.S. decisionmaking could benefit greatly by adopting a precautionary principle and using that principle to evaluate those precautions. A structured evaluation of the complicated array of decisionmaking programs would reveal considerable room for improving the adequacy, consistency, and transparency of the current system.

87. See, e.g., *Environmental Def. Fund v. EPA*, 548 F.2d 998, 7 ELR 20114 (D.C. Cir. 1977), *cert. denied sub nom. Velsicol Chem. Corp. v. EPA*, 431 U.S. 925 (1977) (discussing burdens in proceeding to suspend the registration of a pesticide); *Hess & Clark, Inc. v. Food & Drug Admin.*, 495 F.2d 975, 4 ELR 20147 (D.C. Cir. 1974) (discussing burdens in proceeding to withdraw approval of a new animal drug application); *Rhone-Poulenc, Inc. v. Food & Drug Admin.*, 636 F.2d 750, 11 ELR 20457 (D.C. Cir. 1980) (same).

88. Administrative Procedure Act, 5 U.S.C. §706(2)(A), available in ELR STAT. ADMIN. PROC..

89. See U.S. Document, *supra* note 3, ¶¶ 196-199; e.g., *Environmental Def. Fund*, 548 F.2d at 998, 7 ELR at 20114.

90. See *supra* note 78 and accompanying text.

91. See *supra* notes 85-87 and accompanying text.

92. E.g., *Community Nutrition Inst. v. Young*, 773 F.2d 1356 (D.C. Cir. 1985), *cert. denied*, 475 U.S. 1123 (1986).

93. See *supra* notes 69-70 and accompanying text.

94. *Heckler v. Chaney*, 470 U.S. 821 (1985); *Community Nutrition Inst. v. Young*, 818 F.2d 943, 950 (D.C. Cir. 1987) ("... FDA enjoys complete discretion not to employ the enforcement provisions of the FDC Act, and those decisions are not subject to judicial review").