

Science in Sanitary and Phytosanitary Dispute Resolution

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Abstract

The World Trade Organization Sanitary and Phytosanitary Agreement (SPS Agreement) relies heavily on science and expert organizations to avoid and resolve trade disputes over measures enacted under the rationale of food safety or plant and animal health protection. However, the state of science for sanitary and phytosanitary risk analysis is highly uncertain, and the SPS Agreement leaves many science policy issues unsettled. The international agencies charged under the SPS Agreement with harmonizing standards and forging international scientific consensus face a daunting and politically-charged task.

Two case studies are briefly developed. In the first case, the international scientific consensus strongly supports the U.S. challenge of the European Union's ban on cattle growth hormones, but the root causes of the dispute go much deeper. The case suggests that establishing a precedent for SPS measures based solely on "sound science" may be a slippery objective. In the second case, domestic avocado producers challenged a U.S. Department of Agriculture assessment which concluded that a partial lifting of the ban on Mexican avocado imports posed a negligible plant pest risk. Although the Department's phytosanitary risk assessment gained endorsement by independent scientists, a contributing factor to resolving this dispute was the threat of retaliation against U.S. agricultural exports to Mexico.

A recent survey of current and proposed technical barriers to U.S. agricultural exports suggests that the trade impacts could approach \$5 billion a year and that the most common SPS disputes in the future will be over biological hazards--particularly plant pests and food-borne microbial pathogens. This poses a tremendous challenge, however, because the practice of risk assessment for biological stressors is much less developed than that for chemical substances. The paper concludes with some proposed criteria for evaluating the weight of scientific evidence in SPS risk assessment.

Key Words: food, agriculture, world trade organization, sanitary and phytosanitary risk

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A. BACKGROUND

In the vernacular of international trade, sanitary and phytosanitary measures (SPS measures) are laws, regulations, and procedures instituted by countries to protect human, animal or plant life or health.¹ (Sanitary refers to human and animal health, phytosanitary to plant health.) The World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Measures (the “SPS Agreement”) seeks to ensure that SPS measures do not result in unnecessary barriers to international trade by requiring that countries establish or maintain SPS measures on the basis of scientific risk assessment.² Given the downward pressure on international trade tariffs and agricultural subsidies resulting from the 1994 conclusion of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), many observers expect SPS measures to be a growing area of trade disputes as countries seek to protect their agricultural producers from international competition. An SPS restriction can be a very effective protectionist device, and because of its technical complexity, a particularly deceptive and difficult barrier to challenge. The American Farm Bureau Federation estimates that the cost of SPS barriers to trade is in the hundreds of millions of dollars annually in U.S. commodity exports (Schaffer 1996). The USDA estimates that if proposed foreign barriers are

SPS Measures

Plant and Animal Health Measures: protect plants and animals from risks arising from pests, diseases, disease-causing organisms, feed additives, toxins, and pesticides. Examples would include seasonal and regional restrictions on the import of Mexican avocados.

Food Safety Measures: protect human life and health from risks arising from food-borne pathogens/contaminants, pesticide residues, additives, veterinary residues, naturally occurring toxins, and transgenic diseases. Examples would include Maximum Residue Limits for pesticides on produce or veterinary drugs in meat products.

Multi-purpose/Cross-boundary Measures: Some SPS Measures are multi-purpose, while others cross food-plant-animal boundaries. For example, food-borne pathogens can affect human, animal, or plant life. Foot-and-mouth disease (FMD) is an example of a food-borne pathogen that affects animal health. Therefore, cooking requirements for beef exported from a country with FMD could prevent introduction of the disease into a country without the disease.

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² The SPS Agreement was negotiated under the auspices of the GATT. The WTO has superseded the GATT as the international organization governing global trade. See the WTO webpage (<http://www.wto.org>) for a copy of the SPS Agreement, the status of SPS disputes, and other relevant information.

also considered, the annual trade impact could approach \$5 billion (Roberts and DeRemer 1997).

At the same time, the WTO Sanitary and Phytosanitary Agreement acknowledges the legitimate use of SPS measures to restrict trade to protect against *bona fide* risks to human, animal, and plant health. In addition to concerns over human health risks from imported foods (e.g., the recent outbreak of *Cyclospora* gastroenteritis that was traced to raspberries imported from Guatemala and the British “mad cow disease” (bovine spongiform encephalopathy) episode), there are growing concerns over the global spread of harmful non-indigenous species (NIS). Examples of the damages from NIS include fouling of water pipes by the zebra mussel (*Dreissena polymorpha*), which entered the Great Lakes via ballast water discharged from ships in the 1980s, has imposed large expenses on electric and water utilities and their customers. An estimated \$100 million is spent annually in the Southeast US to control non-indigenous hydrilla (*Hydrilla verticillata*), which clogs irrigation and drainage canals, increases sedimentation in flood control reservoirs, interferes with public water supplies, and impedes navigation. The total cost of harmful NIS to the U.S. economy is perhaps billions of dollars annually (OTA 1993). The recent Norway/U.N. Conference on Alien Species calls for global action to stem the rising tide of pest species (Baskin 1996). Although the SPS Agreement recognizes measures to protect native species of flora and fauna as legitimate, existing SPS measures and institutions focus primarily on protecting commercial plant varieties and animal breeds.

The SPS Agreement relies heavily on science and expert organizations to avoid and resolve trade disputes, but it also raises a number of unsettled science policy issues. Many of these issues were discussed in great detail during the Uruguay Round of trade talks, and the debate was not limited to the SPS arena. Language contained in the “Dunkel Draft” of the Uruguay Round Agreements also contained so-called “sound science” provisions for environmental protection measures that could restrict free trade. Discussions continue about the potential of international harmonization of environmental standards to reduce unnecessary or disguised trade barriers, and the 1994 Marrakech Ministerial Meeting which culminated the Uruguay Round of trade talks established a WTO Committee on Trade and Environment. The final WTO Trade Agreements, however, do not directly call for scientific criteria to be used in evaluating the trade measures most closely associated with pollution control standards. (Although Technical Barriers to Trade must be the “least trade restrictive” approach to achieve a country’s chosen level of protection.) The SPS Agreement will be implemented and evaluated, therefore, with an eye toward the potential use of science and expert bodies in resolving trade disputes regarding all measures designed to protect human health, safety, and the environment.

B. SCIENCE IN THE SPS AGREEMENT

Science and expert agencies occupy prominent positions in the SPS Agreement. So too does “risk assessment,” the vehicle for interpreting and characterizing scientific

evidence.³ As might be expected of any highly brokered document, however, the SPS Agreement raises as many questions as it answers regarding the use of science for evaluating SPS measures which may affect international trade. Article 2 requires Members (signatory countries) to ensure that any SPS measure be based on scientific principles and not be maintained without sufficient scientific evidence, unless the relevant scientific evidence is insufficient, in which case Members may adopt provisional SPS measures. However, the SPS Agreement offers no guiding principles for determining what constitutes sufficient scientific evidence, nor does the agreement identify who bears the responsibility of demonstrating to whom that sufficient or insufficient scientific evidence exists in any particular case.

Article 3 calls for the widest possible international harmonization of SPS measures, and identifies three international organizations to promote this objective: the Codex Alimentarius Commission (Codex, for food safety measures); the International Office of Epizootics (OIE, also known as the World Animal Health Organization); and the Secretariat and other organizations operating under the International Plant Protection Convention (IPCC, for plant pest measures). These organizations are members of the SPS Committee established by the SPS Agreement to provide a forum for consultations about SPS measures short of the formal WTO dispute settlement procedures (enacted under the separate Dispute Settlement Understanding). The international standards set by these organizations, as well as their negotiations concerning the interpretation of scientific evidence and the development of analytic methods, should prove to be important processes in efforts to avoid and settle disputes over SPS measures. (Codex, for example, recently initiated the process of negotiating harmonized human health risk assessment guidelines for chemical additives, pesticide residues, and microbial pathogens in food products.) Article 3 also permits a Member to introduce or maintain SPS measures which result in a higher level of protection than would be achieved by relevant international standards, if the Member determines on the basis of a risk assessment (see discussion of Article 5 immediately below) that the international standards are insufficient to achieve the level of protection a Member determines to be appropriate.

Article 5 contains the provisions concerning the assessment of risk and the determination of the appropriate level of SPS protection. Members are required to base SPS measures on an assessment of risks, taking into account: risk assessment techniques developed by the relevant international organizations; available scientific evidence; the prevalence of specific diseases or pests; the existence of pest- or disease-free areas within countries; potential damages in the event of entry, establishment, or spread of a disease or pest; control costs; and the relative cost-effectiveness of alternative risk management approaches. Thus, Article 5 requires that SPS risk assessments surpass hazard identification (a “qualitative” risk assessment, e.g., a determination that a suitable host species occurs for a pathogen) to consider an assessment of the magnitude of potential damages. With the exception of some carcinogenic chemical additives or contaminants

³ Although it often falls short of the mark, it is useful to consider risk assessment as a means of evaluating the nature, likelihood, magnitude, and distribution of possible damages resulting from exposures to potential hazards.

in food, SPS risk assessments traditionally have emphasized qualitative hazard identification (i.e., something is or is not likely to be a hazard) or have sought to determine levels of hazards that are either “safe” or “as low as reasonably achievable.” Only recently have there been any attempts to provide ordinal estimates (high, medium, low) of expected damages to plant or animal health (e.g., USDAFS 1993).

Because Article 5 requires the consideration of “available” scientific evidence (as opposed to a less inclusive set of data), the SPS Agreement is viewed as being tougher on countries seeking to defend SPS measures than previous trade agreements (e.g., the North American Free Trade Agreement). The SPS Agreement also contains various provisions (i.e., Articles 5, 7, and 9) to encourage full disclosure of scientific information and to promote symmetry of information among Members. It remains unclear, however, how scientific information to be used in assessing SPS risks is to be generated by the scientific community and acquired by the Members, who creates the demand for the information, and how critical scientific uncertainties are identified to inform the research agenda-setting process.

Article 5 also requires a Member to avoid arbitrary or unjustifiable distinctions in the levels of protection it deems appropriate if such distinctions discriminate between imported and domestic products or create a disguised trade barrier. It remains unclear, however, what constitutes an unjustifiable distinction in levels of protection. It may be consistent with public preferences to tolerate different levels of protection against different health risks because some health outcomes are more dread than others (e.g., childhood diseases are particularly dread). Appropriate levels of protection may also vary due to the feasibility of mitigation measures or the magnitude of the societal benefits balanced against the risks.

There is a built-in tension between Articles 4 and 5 of the SPS Agreement regarding the choice among alternative SPS measures that seems guaranteed to become a principal focus of future disputes. Essentially, the tension is over who bears the burden of proof. Article 5 requires Members to ensure that their SPS measures are not more trade-restrictive than required to achieve the desired level of SPS protection. Article 4, however, places on the exporting country the burden of demonstrating to the importing country the equivalence of different SPS measures. Whereas Article 5 presumes that the available scientific information is sufficient to distinguish the least trade-restrictive measure that achieves a given level of protection with a given degree of certainty, Article 4 recognizes that the weight of scientific evidence required to satisfy the demonstration of equivalence can vary considerably, depending on the possible consequences of the decision and the degree of risk aversity. Even if the exporting country can demonstrate that the expected, or average, level of protection supplied by alternative measures is identical, the alternatives may differ in terms of the tails of the risk distributions. (This difference may be consequential in the case of low probability, high consequence risks.)

Just as Article 4 requires exporting Members to demonstrate the equivalence of alternative SPS measures to the satisfaction of importing Members, Article 6 requires exporting Members to demonstrate that areas within their territories are pest- or disease-free areas. This provision suggests the likelihood of disputes that boil down to differing judgments about the

acceptable rate of false negatives arising from pest or disease prevalence surveys. Although the statistical conventions regarding acceptable rates of false positives and false negatives are frequently mischaracterized as “scientific” decision rules, these conventions are nonetheless arbitrary, and acceptable error rates are correctly understood as context-dependent. The statistical conventions, therefore, may prove to be unreliable means of resolving SPS disputes.

C. THE UNCERTAIN STATE OF SPS SCIENCE

The reduction of protectionist trade barriers can lead to increased international trade, which offers the promise of economic growth and socioeconomic development. However, SPS risk analysis typically entails high levels of scientific uncertainty. Regarding food safety risk assessment, FAO (1997) notes “that in many cases, there is insufficient quantitative information to translate requirements for ‘safety and wholesomeness’ into a definitive quantitative assessment of the risks to human health.” The same is doubly true for animal and plant health risks and for biological stressors such as food-borne microbial pathogens and plant and animal health pests and diseases in general. Some SPS hazards combine the uncertainties of both biological and chemical risks. Staphylococcal food poisoning, for example, is not an infection but results from the production of a heat-stable chemical toxin by *Staphylococcus aureus*. The quantity of the toxin present in food, however, is a function of staphylococcal growth.

By default, most SPS risk assessments are not quantitative predictions of the expected level of damaging effects but rather binary assessments of whether a particular level of a stressor is safe or unsafe. Although the bounds of uncertainty for risk assessments of chemical food additives and contaminants may span multiple orders of magnitude (i.e., factors of 10), principles, methods, data, and conventions for chemical risk assessment are far more developed than are those for the analysis of risks due to biological stressors. In addition, it is expected that most SPS trade issues will involve concerns about biological stressors.⁴ Therefore, the discussion below focuses primarily on the state of the science for predicting the effects of biological stressors. (WHO (1990) explains the principles, concepts, and definitions used by the United Nation’s Food and Agricultural Organization and World Health Organization when assessing toxicological data on pesticide residues in food and establishing acceptable daily intakes. WHO (1987) explains the principles used in assessing the safety of food additives and contaminants. Several recent reports by the National Research Council (NRC 1989a, NRC 1989b, NRC 1992a, NRC 1992b, NRC 1993a, NRC 1993b, NRC 1994, and NRC 1995) provide comprehensive discussions on the state of the science for chemical risk assessment.)

In many cases, there may be large, irreducible uncertainties in predicting the effects of biological stressors. The main difference between chemical and biological stressors are that biological organisms: (a) grow, reproduce, and may multiply; (b) disperse both actively and passively, often in “jumps” that are hard to predict; (c) interact with ecosystems in ways that

⁴ See the discussion below of the survey by Roberts and DeRemer (1997) concerning foreign technical barriers to U.S. agricultural exports.

can be complex and are hard, if not impossible, to predict; and (d) evolve, and this evolution is largely random (Simberloff and Alexander 1994). To appreciate the novel risk assessment challenges posed by biological stressors, consider that chemical contaminants present below analytical detection limits typically pose negligible risks. Undetectably low biological population levels, however, may increase exponentially without warning. Additionally, once benign microorganisms may evolve to become virulent. For example, during the 1980s, a form of *Escherichia coli* (serotype O157:H7) detected in ground beef and unpasteurized milk and apple juice appears to have mutated from an innocuous bacterium to one causing hemolytic uremic syndrome (a potentially fatal kidney disease in children).

Environmental risk assessments for biological stressors need to consider four biological factors: survival, proliferation, dispersal, and effects.⁵

Survival

Considerable uncertainty exists in predicting the probability of survival of biological stressors in environments to which they are introduced. Determining what constitutes adequate habitat for a species and predicting the viable population size can require detailed understanding of the organism's natural history in combination with experimental research. Survival and viability are functions of abiotic (e.g., temperature and humidity) and biotic environmental conditions. An example of the influence of abiotic conditions on survival is the observation that stomach acids provide some protection against *Vibrio cholerae* infection. Infection occurs more easily in children than in adults because a child's stomach is generally a less acidic environment. Survival may also depend on competitive, predatory, and parasitic interactions among species.⁶ For example, certain bacteria normally found in the human gut are antagonistic to virulent microorganisms. This is due in some cases to competition for nutrients and in others to the production of substances that suppress microbial competitors. (The health significance of microbial antagonism is forcefully illustrated by infections which sometimes occur during treatment with broad-spectrum antibiotics.)

With respect to potentially harmful non-indigenous species, Simberloff (1986) hypothesized that survival may be less likely in more diverse, complex ecological communities due to the increased "biotic resistance" from resident species. However, Simberloff and Alexander (1994) conclude that naturally disturbed habitats do not appear to have more introduced species than do pristine habitats. The survival of microorganisms in highly stressed or nutrient-poor environments may be more likely in species-poor communities than in species-

⁵ Effects may include the "lateral transfer" of genetic information from an introduced organism to another species, in which case the risks associated with the recipient organism depend on its survival, proliferation, dispersal, and effects.

⁶ Often, there is a considerable gap between an organism's "physiological range" (i.e., the n-dimensional space along temperature, moisture, nutrient, and other abiotic gradients in which an organism can be expected to survive--generally a laboratory-based measure) and its "ecological range" (i.e., the environmental conditions, including species interactions, in which the organism actually occurs).

rich ones. To persist, herbivores, predators, and parasites require access to suitable host species. Such organisms may have multiple hosts. Salmonella is an example of a zoonotic disease which is naturally transmitted between vertebrate animals and man. Poultry, cattle, sheep, pigs, wild birds, rodents, and reptiles serve as reservoirs but manifest no clinical signs of infection with most human food-poisoning Salmonellas. Host range expansions (i.e., increases in the types of suitable hosts) are also not uncommon in nature, and a *single* genetic alteration might unexpectedly change host specificity (Williamson 1992).⁷

The persistence of biological populations is also sensitive to the number of individuals or propagules present. (Propagules would include seeds, vegetative plant parts capable of taking root, and microbial resting cells such as protozoan cysts.) For each set of environmental conditions in which the organism can survive and reproduce, there exists a minimum viable range of population sizes below which extinction is likely. For several years, the “rule of thumb” for sexually reproducing organisms has been that at least 500 randomly mating individuals would be required to maintain a viable population, but recent simulation modeling results suggest that the number may be 10,000 or more (Culotta 1995).⁸ Every organism also has a range of habitats compatible with survival and reproduction, and the range for survival is generally broader than that for reproduction. However, species may persist as meta-populations with habitats that permit reproduction serving as the source of individuals that are dispersed to lower quality habitats (Pulliam 1988).

Proliferation

Proliferation refers to population growth or multiplication (i.e., increases in population size) or increase in biomass without an increase in number (e.g., growth by filamentous microorganisms such as fungi). Unrestricted proliferation rates can vary enormously among species, and the risks associated with a biological stressor can be particularly sensitive to its proliferation rate when the initial number of individuals or propagules present is small (as is often the case). Generally, the rate is higher for smaller or “weedy” species (i.e., “r-strategist” species). But species that have low maximum reproductive rates (i.e., “K-strategist” species) may produce large ecological effects, and the environmental stress imposed by species with high proliferation potential may be transient. Therefore intrinsic rates of proliferation are not necessarily predictive of the magnitude of environmental effects.

In some cases, accurate population growth prediction is possible, but it can require extensive data collection. Buchanan and Whiting (1997) modeled the survival and growth of

⁷ Host specificity, therefore, may be in contrast to “weediness” which is conventionally (though not necessarily correctly) regarded as a polygenic trait and therefore less prone to surprising outcomes resulting from changes in a single gene (see Wrubel *et al.* 1992).

⁸ Previous estimates of the critical population size failed to consider the fitness constraints necessary for mutations to persist in an evolving population; that is, mutations that negatively effect individual survival and reproduction are less likely to be maintained in the population. To achieve the same amount of genetic variability in the population under this constraint requires more individuals than under unconstrained conditions.

seven food-borne microbial pathogens in protein broths, each under 200-300 abiotic environment combinations (e.g., nutrient, temperature, pH, and salt levels). Their findings suggest the range of variability inherent within microorganism species. For example, the thermal death time of *E. coli* O157:H7 varies over a 3-fold range, depending upon the strain of the microbe.

To complicate matters further, population dynamics of a species introduced into a given environment can follow markedly different trajectories as a result of stochastic or chaotic influences. Ecological population dynamics modeling has generally focused on long-term behavior.⁹ However, Hastings and Higgins (1994) show that simple, long-term population dynamics can have complex transient dynamics that make long-term behavior essentially irrelevant. Their model has transient dynamics that are much longer (on the order of 10^2 - 10^3 years) than the time scale of significant environmental perturbations. The transient dynamics can appear to be the final behavior (either cyclic *or* chaotic), and then the system can quickly change its dynamics without any underlying change in parameters. These “long transients” in population dynamics may play a major role in the highly irregular dynamics of outbreaks of insects (e.g., gypsy moths), species with pelagic larvae (e.g., zooplanktonic copepods associated with *Vibrio cholerae*) or other biological stressors characterized by alternating reproduction and dispersal.

Dispersal

Unlike chemical stressors, some biological stressors are mobile and therefore capable of active dispersal. In other cases, organisms have evolved dispersal mechanisms that take advantage of air or water currents (e.g., “winged” seeds) or the movements of animal vectors (e.g., indigestible fruit seeds or microorganisms that survive digestion by ruminant animals). The dispersal pattern of biological stressors can appear as a gradual diffusion from a single point of origin, as would be estimated by application of chemical transport models. Such models have been applied to estimate the passive dispersal of biological propagules (e.g., de Jong 1992). There are two *key* distinctions, however, between the transport of chemical pollutants in air or water and that of biological stressors. First, passively transported organisms may die or otherwise lose their potential to cause adverse effects *en route*. Secondly, the pattern of dispersal of biological stressors can appear as multiple, separate foci arising by long-distance “jumps” (Pielou 1979).

This capacity for jump-dispersal makes modeling biological stressor dispersal formidable and severely limits the applicability of chemical pollutant transport models. In many cases, the inadvertent, long-distance transport of biological stressors by human activity may be impossible to predict. However, the traffic and commodity loads associated with particular transportation routes provides an indication of their potential to serve as pathways for the introduction of non-indigenous species (Orr et al. 1993). Similarly, the absence or

⁹ Even studies of nonequilibrium behavior, such as cycles or chaos have focused on long-term behavior.

failure of safeguards in transportation, storage, processing, distribution, and preparation provide pathways for microbial pathogens to enter the food system.

Effects

For biological stressors to have any substantial or lasting impact often requires large populations, or at least sufficiently large so as to be infectious or remain viable. Therefore, a threshold may often exist in the “dose-response” relationship for biological stressors. In the case of biological stressors, “dose” refers to the number of organisms, population size, or biomass. In the simplest case, “response” refers to a *direct* effect of the biological stressor on a particular species (such as infection) or ecosystem function (such as nutrient turnover).¹⁰ The number of organisms required to elicit an adverse effect in the average case can vary greatly among species or strains of biological stressors, and there can be considerable variation in the susceptibility or resilience of individuals within species or habitats to effects. Another complication in determining the level at which a biological stressor may have adverse effects is that potentially harmful organisms may be present and viable but not active. This, however, would be analogous to differences in toxicity among chemical species (e.g., organic v. inorganic heavy metals). In most cases, direct dose-response relationships are unavailable for biological stressors. Some quantitative relationships have been developed for a few human pathogens and economically important agricultural and silvicultural pests. For example, Rose and Gerba (1991) estimated the microorganism dose (organisms/100L drinking water) required to yield a 1 percent infection rate for 15 drinking water pathogens, which varied from 0.03 for Rotavirus to 1428 for *Vibrio cholerae*.¹¹

Attempts to predict the effects of non-indigenous species have focused on non-quantitative methods, such as elaborating lists of “weedy” species traits that are conducive to dispersal, establishment, or impact (e.g., Baker 1965).¹² Unlike direct dose-response

¹⁰ A more complex response would involve indirect environmental effects of the biological stressor mediated by the species or functions which it directly affects.

¹¹ However, the population was assumed to be equally susceptible to infection, and infection was indicated by the detection of microorganisms in the feces--not by the manifestation of clinical symptoms. Developing more useful dose-response relationships microbial pathogens would require accurate monitoring of the frequency and causes of gastrointestinal and other illnesses. Unfortunately, morbidity data are consistently underreported, and the specific causative pathogen is not commonly identified, except in the case of outbreaks or mortality. It should be noted, however, that this disconnect between risk assessment measurements and the endpoints of concern is not unique to biological stressors.

¹² An analysis of environmental assessments for field testing transgenic plants reveals that many assessments cite such general principles in determinations of the weediness potential of the transformed crop plant (Wrubel *et al.* 1992), and Orr (1994) argues that certain species characteristics have been shown to be useful in making predictions about invasive species. However, examples can be cited of plants with “weedy” traits that are not weeds and plants lacking weedy traits that are problematic weeds (references in Simberloff and Alexander 1994). It may be possible, however, to improve the predictive performance of “risky traits” lists by developing and applying them in more limited domains. For example, it may be possible to identify characteristic traits of woody plants that are likely to be invasive in the Pacific Northwest (Peter McEvoy, Oregon St. Univ., personal communication).

relationships, these methods aim to assess potential for inter-species or community-level effects. However, evaluating the ecological effects of particular stressors (either chemical or biological) remains problematic. While some admirable efforts have been made to model the effects of perturbations resulting from chemical stressors on aquatic community dynamics (e.g., Bartell et al. 1992), at this point, neither static nor dynamic community ecological models have good predictive performance (Simberloff and Alexander 1994). In fact, some observers are pessimistic that ecology will ever yield broadly generalizable models (see Moffat 1994).

Over the past twenty years, ecologists have fueled this pessimism. May and Oster (1976) demonstrated that *in the absence of disturbance*, systems controlled by completely deterministic processes can exhibit temporal behavior that not only departs from steady state but becomes aperiodic, unpredictable or “chaotic.” Simple systems that are predictable under certain conditions *can be forced* into chaotic behavior through perturbation of model parameters (e.g., O’Neill et al. 1982). Also, an ecosystem can persist in *several alternative stable configurations* (Allen et al. 1977, May 1981), each characterized by different species composition, population sizes, and patterns of energy or material flows. Disturbance, such as exposure to a biological stressor, may force the system from one stable configuration to another, unforeseeable configuration. From the frame of reference of the initial stable state, the system may never recover. Therefore, aside from random variation, some ecological effects at some scales may exhibit dynamics that are inherently unpredictable. However, for particular endpoints in ecological risk analysis, it may be possible to determine the time and space scales for which accurate prediction is feasible.¹³

Negotiated Science

Regardless of whether the stressor of concern is chemical or biological, much of what passes for “science” in risk assessment is, in fact, a negotiated consensus among experts. In many cases, individual studies do not produce conclusive evidence, and analysts attempt to reach consensus by weighing the accumulated evidence. Needless to say, different experts

¹³ Consider, for example, that the viability of prediction may depend crucially on the time scale. For instance, the number of fish measured in a pond today is a pretty good estimate of the number tomorrow, barring a major perturbation or threshold effect. But it is not a good estimate of how many fish there will be in 100 years. Thus, as the forward-prediction time frame progressively expands, the quality of the prediction progressively worsens. This is a characteristic problem with “information-generating systems,” such as ecosystems (Bill Wing, University of Arizona, personal communication). Over short times, the initial information (that was measured) dominates the outcome; but over longer times, the information the system generates internally, regardless of the initial conditions, comes to dominate, and system behavior becomes unpredictable. Another round of measurements, however, may restore predictability -- for a while. The question, then, is over what time frame the quality remains high enough to be useful for decisionmaking. The information generated by ecosystems may also provide clues about the approach of threshold effects as erratic dynamics in particular ecosystem components may precede a systemic threshold change, such as a “jump” to a new stable configuration (references in Simberloff and Alexander 1994). However, it is unclear what frequency of monitoring would be required to detect warnings of threshold dynamics or of major perturbations.

tend to weight data differently, and scientific consensus can be hard to achieve. However, in the cases in which expert consensus has been achieved, or when some credentialed group deems it so, it is easy to lose sight of the fact that what is perceived as a “scientific fact” remains an unvalidated, sometimes untestable, negotiated scientific judgment.

Rules of thumb negotiated by scientists can be helpful benchmarks for decisionmaking, but they remain somewhat arbitrary. One example is the conclusion reached by many in the field of epidemiology that, absent any additional supporting evidence, the observed rate of disease in the study group exposed to a suspected risk factor should be 3 or 4 times that in the unexposed control group for a study to be taken seriously (Gori 1995). But there is no “objective” basis for establishing this range of “relative risk” values as a benchmark.

Negotiated science is not restricted to the conference table; it occurs in the field and lab as well. McEvoy (1996) discusses how the scientific procedures conventionally used by field biologists to predict the host range of potentially harmful non-indigenous species (the organisms that the NIS are likely to attack or use in the field) can be unreliable. For example, host tests for phytophagous (plant-eating) organisms equate vulnerability with suitability for larval development. Host selection, however, is understood to be a hierarchical sequence of opportunities and constraints, of which suitability for development is just one component that may or may not be limiting. The discipline of pathology provides examples of negotiated science in the lab and bears some resemblance to the ancient, now-discredited science of reading goat entrails. The terms lesions, abnormal cellular growths, and benign, pre-cancerous, or malignant tumors are misleadingly precise word models for biological damages that are often hard to categorize. While consensual protocols help ensure the replicability and comparability of different experiments, rules developed for coding laboratory observations are nonetheless often subjective. (See Powell (1996) regarding different interpretations of the pathological evidence on dioxin.)

Future advances in the state of science will tend to reduce current uncertainties as well as reveal our current ignorance. If conservative risk assessment assumptions (i.e., assumptions that systematically overstate risks) are made to fill gaps in the scientific data, then new data on previously assessed hazards will tend to make them seem less risky than they once appeared. The opposite may be true for identifying hazards. As more research is done, we are more likely to find unforeseen hazards (Goldstein 1991). In some cases, research raises more questions than it answers, resulting in increased uncertainty and political conflict (Graham et al. 1988). Thus, science is often a tenuous and shifting foundation for policymaking. When compared to the alternatives bases for policymaking in many parts of the world (e.g., emotion, political threats, and bribery), however, science may be the best alternative.

D. SPS DISPUTE RESOLUTION INSTITUTIONS

Domestic SPS Agencies

Domestic regulatory agencies set national SPS standards and are responsible for analyzing and controlling potential SPS risks associated with imports to the US. In some

cases, they also become involved in assessing the risks and control measures associated with US food and agricultural exports. Domestic regulatory agencies play a dominant role in avoiding SPS trade disputes through bilateral, ministerial negotiations. The domestic regulatory agencies also provide scientific and technical expertise to US delegations to international SPS and trade organizations.

A number of US agencies share regulatory responsibility in the SPS arena. The US Food and Drug Administration (FDA) regulates all food products, except most meat and poultry products and some egg products, which are regulated by the US Department of Agriculture (USDA) Food Safety Inspection Service (FSIS). The US Environmental Protection Agency (EPA) is also responsible for establishing tolerances for pesticide residues on food. The USDA Animal and Plant Health Inspection Service (APHIS) is responsible for guarding against the entry of foreign plants, animals, insects, and diseases that are agricultural, horticultural, or silvicultural pests. The Department of Interior (DOI) Fish and Wildlife Service (FWS) is responsible for controlling the entry of injurious fish and wildlife. All federal land management agencies (including USDA and DOI) are responsible for controlling noxious weeds, including exotics, on federal lands.

World Trade Organization

The WTO is comprised of 131 Members (signatory countries), 30 observer countries, and 8 observers to the General Council. The country delegations and the WTO bureaucracy are predominately trade specialists, not scientists. The highest WTO authority is the Ministerial Conference. In the absence of consensus, the WTO operates on a one country, one vote basis. An interpretation of any of the multilateral trade agreements can be adopted by a three-quarters majority of WTO Members. The WTO General Council, which is comprised of all WTO Members, reports to the Ministerial Conference and supervises the dispute settlement process. Under the WTO Dispute Settlement Understanding (DSU; <http://www.wto.org/wto/dispute/dsu.htm>), Members may challenge perceived violations of any Uruguay Round Trade Agreement through the WTO dispute settlement process and commit themselves to abide by its rules and findings. In the event of a challenge, the WTO General Council convenes as the Dispute Settlement Body (DSB). If a brief period of formal bilateral consultations fails to resolve the dispute, the DSB establishes a review panel. Review panels may form expert review groups to provide advice on scientific or other technical issues of fact. As indicated above, a Member whose standard is challenged under the SPS Agreement must provide scientific evidence (using risk assessment techniques) showing that the SPS measure is not more trade-restrictive than required to achieve the desired level of protection. Furthermore, Members must be able to justify as nonarbitrary any inconsistencies in the levels of protection provided by different SPS standards. The exporting Member has the burden of demonstrating the equivalence of different SPS measures. Appeals under the WTO dispute settlement process are limited to issues of law covered in the panel report and legal interpretations developed by the panel. The DSB (*aka* the General Council) adopts review or appellate panel reports unless there is a consensus to *reject* the report. The

DSB has the authority to authorize retaliatory measures in cases of non-implementation of recommendations.

International SPS Agencies

Under the SPS Agreement, member nations are presumed to be in compliance if they adopt SPS standards set by the Codex Alimentarius Commission, Office International des Epizooties (World Organization for Animal Health), and the International Plant Protection Convention affiliates. These international SPS agencies are also key in establishing recognized procedures and guidelines for conducting SPS risk assessments.

Until recently, Codex, OIE, and the IPPC affiliates operated in technocratic obscurity in large measure because their standards have been voluntary. As Vogel (1995) notes, although Codex standards have occasionally served as a reference point for national regulatory policies, particularly by developing countries seeking access to developed country markets, most nations have not adopted them. Now, however, a country applying more stringent standards runs the risk that the WTO will determine that the standards set exceeded that nation's "appropriate level of protection" and face the concomitant risk of imposition of trade sanctions. Consequently, the international SPS agencies will be subject to increased scrutiny. Environmental and consumer groups are demanding greater access to standard-setting and policy formulating committees.¹⁴ Furthermore, the international SPS agencies are under increasing pressure to consider non-scientific criteria in standard setting. As these agencies have acquired greater standing in international trade law, their historic patterns may not be good predictors of their future behaviors.

Codex

Codex is a joint agency of the United Nation's Food and Agriculture Organization and World Health Organization established in 1962. The location of its meetings alternate between Rome (FAO) and Geneva (WHO). Codex standards cover food commodity standards (similar to FDA standards of identity), food additives, food contaminants, and residues of veterinary drugs in food. Some 150 countries are Members of Codex. In the absence of consensus, Codex operates on a one country, one vote basis. Country delegations to the general assembly, 28 technical committees, and 5 regional committees include representatives from both governmental and non-governmental organizations. Only delegation leaders vote; the others attend as observers. Most Codex participants are government officials--embassy officials (mostly from developing countries), regulatory administrators, scientists, and technical experts. Industry is heavily represented among non-governmental Codex participants, with substantially less representation from consumer and environmental groups (Krissoff et al. 1996; Vandemeulbrouke and Staes 1996).

¹⁴ For example, at the 22nd Session of Codex held in June 1997, consumer groups requested the inclusion of their representatives as observers in the Codex Executive Committee and JECFA, JMPR and other FAO/WHO expert consultations (Codex 1997). The issue will be addressed--if not resolved--at the next Codex Session.

Although the Codex Commission is commonly thought of as an expert agency, it is the vehicle for government acceptance or nonacceptance of the recommendations of its numerous technical committees, two standing expert advisory bodies, and various *ad hoc* FAO/WHO expert consultations. Codex committees set the agenda for expert food safety analyses, review the expert recommendations, and recommend standards to the full Commission. The standing expert advisory bodies are the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). In June 1997, Codex (1997) requested FAO and WHO to convene an international expert advisory body similar to JECFA and JMPR to provide microbial risk assessment support to the Commission.¹⁵ Established in the 1950s, JECFA and JMPR predate Codex. Their primary role is to evaluate toxicological data to determine safe levels of human exposure for non-genotoxic food additives, contaminants, pesticides, veterinary drugs, animal feed additives.¹⁶ FAO and WHO share responsibility for estimating intakes of food additives and contaminants based on food consumption patterns and the assumption of good agricultural, veterinary, and manufacturing practices. The toxicological and exposure data are combined to characterize food safety risks. JECFA, JMPR, and other FAO/WHO expert consultations make recommendations for use by Codex technical committees in developing proposed Codex standards and guidelines.

In formulating recommendations, JECFA and JMPR follow a number of conventional risk assessment policies, such as relying on animal models to predict human effects, using bodyweight scaling for interspecies comparison, and dividing “no observed adverse effect levels” observed in animal studies by a safety factor (typically 100) to account for inter- and intra-species susceptibility differences. JECFA and JMPR evaluations identify a range of levels of non-carcinogens and non-genotoxic carcinogens that the experts regard as safe. (Frequently, these “safe levels” are qualified as being obtained under specific conditions.) Safe levels are not assigned to genotoxic carcinogens. The expert advisory bodies may flag specific food contaminants which present a safety risk under normal practices by recommending that the levels be reduced to levels “as low as reasonably achievable.” In such cases, setting specific standards entails balancing risks and costs. This is a policy decision that is deferred officially to Codex. In some decisions that require balancing, Codex has agreed on specific food safety standards. In other cases, Codex has adopted the narrative standard (as low as reasonably achievable) and left the balancing decision to each member country. As illustrated by the bovine growth hormone case study below, Codex Members are sometimes not in unanimous agreement about potential food safety risks or the appropriate role of science in the standard setting process.

In 1995, in the midst of this dispute and on the heels of the conclusion of the Uruguay Round of trade talks, Codex adopted some *Statements of Principle Concerning The Role of*

¹⁵ The International Commission on Microbiological Specifications for Food (ICMSF) has been periodically invited to advise Codex, but the ICMSF is a private, non-profit scientific organization

¹⁶ Genotoxic carcinogens are capable of initiating cancer, whereas non-genotoxic carcinogens may promote the development of cancer once initiated.

Science in the Codex Decisionmaking Process and the Extent to Which other Factors Are Taken Into Account. Vandemeulbrouke and Staes (1996) suggest that the 1995 Codex assembly at which these principles were debated marked a watershed in the history of the organization: “Before then it was nothing more than a gentleman’s club, in which decisions were reached by consensus.” The US and its allies argued that food safety standards designed to achieve a desired level of human health protection be based solely on scientific analysis and evidence. The Europeans countered that socioeconomic, cultural, and environmental criteria also should be considered. The Europeans had long sought to introduce the “need” standard into the mix--new productivity-enhancing technologies in food and agriculture posing uncertain health risks and adverse impacts on economically marginal farmers are not “needed” in the face of large and persistent surpluses (Kramer 1989). The final Codex science principles state that Codex food standards shall be based on the principle of sound scientific analysis and evidence, and where appropriate, Codex will consider “other legitimate factors” relevant for consumer health protection and the promotion of fair practices in food trade (FAO 1997). What other factors are considered legitimate and the procedures to be used in this regard remain largely undefined and are likely to be revealed implicitly on a case-by-case basis.

IPPC

The International Plant Protection Convention was adopted in 1951. As of 1996, there were 105 Member countries.¹⁷ The IPPC Secretariat was established in 1989 in the FAO Plant Protection Division in Rome. But the Secretariat only initiated activities in 1993. Adoption of the standards reportedly requires consensus endorsement of the FAO Conference, which consists of all FAO Members. The standards are subject to periodic review by a Committee of Experts on Phytosanitary Measures. Under Article IX of the IPPC, disputes over phytosanitary regulations are raised to the Director-General of FAO, who may appoint of committee of experts to review the dispute. The recommendations of the committee, however, are not binding on the Members.

The IPPC Secretariat collaborates with nine Regional Plant Protection Organizations established under the Convention: Asia and Pacific Plant Protection Commission; Caribbean Plant Protection Commission; Comite Regional de Sanidad Vegetal para el Cono Sur; European and Mediterranean Plant Protection Organization; Inter-African Phytosanitary Council; Juda del Acuerdo de Cartagena; North American Plant Protection Organization; Organismo Internacional Regional de Sanidad Agropecuaria; and Pacific Plant Protection Organization. A Near East Plant Protection Organization is also slated for commission under the Convention. The IPPC also collaborates with other regional bodies with phytosanitary programs not established under the IPPC: European Union; Instituto Interamericano de Cooperacion para la Agricultura; and South Pacific Commission (<http://faowfs0a.fao.org/waicent/faoinfo/agricult/agp/agpp/pq/secretar.htm>).

¹⁷ In light of the SPS Agreement, amendments to the Convention were drafted in 1996, and a proposal is currently under review by the FAO Conference of Members.

In comparison to Codex, the IPPC institutions are underdeveloped and decentralized. There also appears to be no procedures for making binding decisions in the absence of unanimous agreement among IPPC Members. This may limit the extent to which the WTO can rely on IPPC institutions to make authoritative, “expert” recommendations for consideration in resolving trade disputes over phytosanitary measures. The IPPC Secretariat is a relatively new organization charged under the SPS Agreement with coordinating the development and harmonization of international phytosanitary measures. The scope of this task is daunting, given the sheer magnitude of international trade in plants and plant parts and the multitude of quarantine plant pests (i.e., those of substantial economic importance). Because the U.N. Food and Agriculture Organization administers the IPPC, its natural focus of attention is on protecting the agricultural sector from phytosanitary risks. As a result, phytosanitary risks with potentially large economic impacts outside the agricultural sector may be neglected.

OIE

The Office International des Epizooties (World Organization for Animal Health) was created in 1924. As of 1996, 144 countries are Members of the OIE. Located in Paris, the OIE is controlled by an International Committee formed by delegates of the Members. In the absence of consensus, the Committee operates on a one country, one vote basis. The OIE International Animal Health Code Commission produces the International Animal Health Code, which defines the animal health conditions which a country should fulfil, depending on the diseases present, before exporting live animals (mammals, birds, and bees), semen, embryos, meat and milk products. There is a separate specialist Commission that addresses Foot and Mouth Disease and other epizootics (i.e., epidemics of animal disease such as bovine spongiform encephalopathy, or BSE). The OIE Standards Commission approves a Manual containing detailed descriptions of the diagnostic techniques and vaccine control methods prescribed by the Animal Health Code. The Fish Diseases Commission approves a Code and Standards Manual for aquatic animals. There are currently OIE working groups on biotechnology, veterinary drugs, and wildlife diseases (<http://www.oie.org>). Because the number of quarantine animal diseases is limited (~60) and due to relatively limited international trade in live animals and animal products, the scope of OIE’s task is arguably more manageable than that of the IPPC organizations.

E. CASE STUDIES

Cattle Growth Hormones

Table A provides a summarized chronology of the dispute between the United States and the European Union over the use of five hormones in livestock production, principally for increasing beef production. Another potential US-EU dispute over hormones used to increase dairy production looms on the horizon.

Table A. Chronology of the US-EU Dispute over Beef Growth Hormones

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- 1979** Investigators reported that young Italian schoolchildren at a school in Milan exhibited precocious sexual development. Meat or poultry treated with illegal growth hormones served in school lunches was the suspected cause.
- 1980** Diethylstilbestrol (DES), a synthetic estrogen that can promote weight gain and muscle development in animals, was detected in baby food samples in Italy. (Human medical use of DES was banned in the US after 1970 when epidemiological evidence linked use by pregnant women to prevent miscarriage to the development of cervical cancer in their daughters. The US banned DES use in livestock production in 1979.) News reports sparked a consumer boycott of veal, and Italy adopted measures to restrict imports of veal from European Community (EC) member states, particularly France, where hormones were authorized.
- 1981** The EC prohibited the use of DES in livestock production but called for further study of five hormones--three natural hormones (estradiol, progesterone, and testosterone) and two synthetic ones (trenbolone, and zeranol). Half of the EC's member states had banned all five disputed substances, while the other six had authorized use of at least one of them.
- 1982** The European Scientific Working Group on Anabolic Agents in Animal Production released an interim report concluding that the three natural hormones would not harm consumer health when used under appropriate conditions and recommending further research on the two synthetic hormones. The Veterinary Committee approved the report.
- 1984** The EC Commission proposed to allow the use of natural hormones, but the EC Council President requested the opinion of the European Parliament.¹⁸
- 1985** The European Scientific Working Group on Anabolic Agents in Animal Production concluded that the two artificial hormones would also not pose a consumer health threat, but the EC Commission canceled the Group's meetings before it could issue its final report. The European Parliament endorsed a ban on zeranol and trenbolone and rejected the proposed authorization of the three natural hormones except for therapeutic purposes. In response, the EC Council issued a directive, scheduled to take effect in 1988, banning the use of natural hormones save for therapeutic purposes and banning the use of synthetic hormones for all purposes. The directive also imposed a trade clause that required EC states to prohibit importation from third countries of animals and or meat treated with hormones.
- 1986** The US raised the EC hormone ban in the Committee on Technical Barriers to Trade ("Standards Code") of the General Agreement on Tariffs and Trade (GATT).

¹⁸ The European Commission is the executive branch of the European Union, formerly the EC. The Commission initiates EU policy and legislation. The Council of Ministers is the decision-making body of the EU. It approves or rejects legislation proposed by the Commission. The European Parliament supervises the Commission and approves the EU budget.

- 1987** The US invoked dispute settlement under the GATT and requested that the matter be referred to a group of technical experts, but the EC blocked formation of the technical expert group. The Joint Food and Agriculture Organization on Food Additives (JECFA), a Codex expert advisory group, recommended Maximum Residue Limits (MRLs) for zeranol and trenbolone and concluded that residues from the natural hormones were unlikely to pose a human health hazard if used in accordance with good veterinary and animal husbandry practices. The Codex Committee on Residues of Veterinary Drugs found no scientific basis for the EC ban. It recommended limits for trenbolone and zeranol and agreed with JECFA that limits were unnecessary for the three natural hormones. The Codex Committee on Food Additives and Contaminants concurred. The EC delayed application of the hormone ban to imports until 1989.
- 1991** The full Codex Commission postponed a decision on the use of hormones while the issue of the role of science in the Codex decisionmaking process was debated.
- 1995** The WTO SPS Agreement was implemented. Codex adopted MRLs for trenbolone and zeranol and decided that MRLs unnecessary for the three natural hormones. The European Union (EU) Scientific Conference on Growth Promotion in Meat Production concluded that there was no evidence of health risk from the five hormones approved for use in the US.
- 1996** The EU reaffirmed its commitment to maintaining the ban, and the US requested the formation of a WTO panel to resolve the dispute.

Sources: Kramer 1989; Vogel 1995; Glickman 1996.

On June 30, 1997, the WTO dispute settlement panel issued its final ruling that the EU beef hormone ban appears inconsistent with SPS Articles 2,3, and 5 (<http://www.wto.org/dispute/horm-us.wp5>).¹⁹ The EU announced that it would file an appeal in late August. Under the WTO dispute settlement process, an appeals panel would then have 60-90 days to rule. If the EU loses on appeal, it would either have to lift the ban or compensate the US (“Final WTO Rule Says EU Ban Illegal,” *Cattlemen on the Hill*, 7/11/97, <http://www.beef.org/hill/fwtorseu.htm>). As noted above, the EU cannot dispute the scientific basis of the ban during appeal. If the panel’s decision is upheld, the US will have satisfactorily demonstrated *under the WTO dispute settlement process* that permitting low levels of bovine growth hormone residues in meat is equivalent to a ban in terms of the level of health protection provided.

Scientific Issues

The biological action of hormones is mediated by binding to specific receptors within cells. Regardless of whether the hormones are natural or synthetically produced, if they bind

¹⁹ The panel also found the EU hormone ban inconsistent with the Agricultural and Technical Barriers to Trade Agreements.

to the same receptor, they are functionally equivalent, though receptor binding affinities and toxicological properties of metabolites may differ.²⁰ Biological activities induced by hormones do not comport with the “one-hit” theory that a single molecule can initiate a sequence of events resulting in a toxic effect such as cancer. Hormonal molecules have to occupy a number of receptor sites before any biological response is seen, and even once activity begins, the cell’s internal regulation system has some capacity to adapt to changing hormonal levels and maintain the mix within the range of tolerance. Therefore, although European officials have argued that an absolute ban on growth hormones is safer than setting low maximum residue levels, there are theoretically safe levels for ingested hormones. The FDA, the European Scientific Working Group on Anabolic Agents in Animal Production, and the Codex expert advisory group JECFA concluded that when properly used, the natural growth hormones would insignificantly increase hormone exposure beyond background levels (even in the most sensitive human populations--prepubertal children and menopausal women) and that the Maximum Residue Levels for the synthetic hormones would produce no harmful effects and provide a margin of safety.²¹ It is noteworthy that in the case of dioxin, which has been characterized as the “Darth Vader” of chemicals and is also mediated by specific receptors within cells, the Europeans have applied the biologically-based approach to risk assessment for many years while American regulatory authorities have been criticized for clinging to an out-dated, overly precautionous set of assumptions (Powell 1996).

Public health advocates remain concerned, however, that hormone abuses might occur more commonly in the absence of a ban (muscle implants produce higher growth rates than ear skin implants but also result in higher concentrations of residues in meat) and that scientific reviewers have analyzed the effects of individual hormones in isolation, whereas they are often administered in combination (Goldman and Wagner 1996). Concerns over the possible synergistic effects of hormone cocktails were heightened by findings published in the prestigious journal *Science* in 1996. The report by Arnold et al. (1996) of synergistic activation of combinations of environmental estrogens added fuel to the fire of scientific and public policy debate environmental hormones (i.e., endocrine disruptors). However, the report was later withdrawn when the original scientists and others were unable to replicate the initial results (McLachlan 1997). This is not to say that multiple hormones do not interact synergistically, only that the 1996 report produced no reliable evidence of synergism.

The Root Causes of the Dispute

Because US meat exports to Europe consisted primarily of specialty meats (e.g., liver, kidney, heart, and tongue used in pate, kidney pies, sausage, tripe, blood pudding, etc.), the value of trade affected by the ban was relatively minor--less than \$100 million a year. Why,

²⁰ The FDA also requires toxicological testing on synthetic hormones to demonstrate that they are not genotoxic.

²¹ One means of providing a margin of safety is to presume that the hormonal residues in meat constitute the effective dose that is biologically available, but the body only absorbs a fraction of ingested hormones.

then, was the scientific basis of the ban ever seriously disputed? Vogel (1995) observes that the economic and political stakes for both the US and the EU extend far beyond the specific dispute over animal growth hormones. In addition to responding to consumer concerns about food safety--particularly with respect to dreaded effects in children, the European ban on hormone use in beef production may have limited the supply of European beef, thereby supporting beef prices and helping to protect small, high-cost producers as well as limiting the producer subsidies supplied under the European Common Agriculture Program. (European subsidies to beef farmers increased by more than 56 percent between 1980 and 1987 (Vogel (1995).)

The US, for its part, feared that the European ban on beef growth hormones could spread to Japan, whose increased imports of American beef were more than offsetting the lost trade in Europe, or give impetus to a consumer advocacy campaign to restrict the use of growth hormones on the home front. Unlike other countries that primarily raise range-fed beef cattle, about two-thirds of American beef cattle spend five months prior to slaughter on a feedlot. According to the National Cattlemen's Beef Association, about 90 percent of US cattle in feedlots raised specifically for beef, rather than milk or breeding, receive growth hormones at some time during their life. The hormone supplement administered in the form of pellets that are implanted behind the ears of cattle reduces by 20-25 days the time required for the steer to reach the desired 1,100 pound weight. More broadly, the US has seen the European beef growth hormone ban as an important test case on multiple fronts. At the broadest level, the US has feared that if the hormone ban were permitted to stand, its trading partners would be emboldened to increase the use non-tariff trade barriers at a time when the US has sought to liberalize global trade. In the food and agriculture sector, the US has viewed the hormone ban as a threat to its comparative advantage in the development and application of profit- and productivity-enhancing technologies—food processing using chemical additives, long-term storage and long-distance distribution of grains and produce enabled by application of postharvest chemicals, and the development of novel foods and agricultural products through biotechnology (Kramer 1989; Vogel 1995).

BST

In a related matter, the European Council instituted a moratorium in 1990 on the commercial use of Bovine Somatotropin (BST) in European dairy herds.²² (The ban was subsequently extended until December 1999.) BST is a hormone produced naturally by dairy cows, and BST supplements increase milk yields. However, only the form produced through biotechnology--recombinant BST (rBST)--is commercially viable.²³ The US Food and Drug Administration has permitted its commercial use since 1994. This decision was based on :

²² Dobson (1996) provides a more thorough BST case study.

²³ BST may be extracted from the pituitary glands of slaughtered cows, but this is not a viable supply for commercial uses. For commercial use, rBST is produced by inserting the cow gene sequence for BST synthesis into *E. coli*, which can then produce large amounts of rBST.

(1) the conclusion by an independent panel appointed by the National Institutes of Health that BST-treated cows produce milk that does not differ in composition or quality from that produced by untreated cows, and (2) the finding that rBST is identical in activity to natural BST.

Some remain concerned, however, with the possible *indirect* health effects of BST treatments. When BST causes a cow to produce more milk, it also increases the risk of the cow developing mastitis, an infection of the mammary glands, which is treated with antibiotics. As a result, drug residues get into the cow's milk. Cows treated with antibiotics are supposed to be removed from the milking line for a sufficient period to allow the antibiotic residuals to be flushed from their systems. Milk containing drug residues above permitted levels is supposed to be discarded. Public health advocates worry that some dairy farmers may fail to comply with the regulations, resulting in elevated levels of drug residues in milk and dairy products. In any event, additional environmental releases of antibiotics (whether through residues in milk discarded or consumed or in animal wastes) may promote the emergence of drug resistant strains of pathogenic bacteria.

Some European environmental, consumer, and animal rights groups have advocated that the European Union ban imports of dairy products produced using rBST. Recently, the European Commission Scientific Committee for Food issued recommendations concerning the substantial scientific information that it deems necessary to support applications for marketing novel food and food ingredients, a category which includes genetically modified products and other novel products developed through non-recombinant biotechnology (ECSCF 1996). Thus, regardless of the outcome of the US challenge of the European ban on beef growth hormones, the dispute over bovine growth hormones may continue.

Mexican Avocados

Mexico currently produces nearly half of the world's avocados, but the US first instituted a quarantine on Mexican avocados in 1917 due to the occurrence of avocado seed weevils. Beginning in 1972, Mexico made a series of requests for approval to export avocados to the US. In July 1993, APHIS permitted avocados grown in Michoacan, the primary avocado-growing region in Mexico, to be imported into Alaska under certain conditions. Motivated by NAFTA negotiations in 1994, Mexico requested that the US permit Michoacan avocados to be imported into the Midwestern and Northeastern states, far from the groves of California and Florida. APHIS conducted a commodity pest risk assessment, and in 1995 proposed to allow entry under certain conditions. US avocado growers (primarily in California, a key electoral state in the 1996 Presidential elections) attacked the scientific basis of the APHIS risk assessment and predicted dire economic consequences from permitting the cheap imports. Mexico argued that while not all insect pests of quarantine significance were proven to be absent from this production region (host-specific pests had been eradicated from Mexican avocado export producing regions and the populations of fruit flies that are citrus pests were low in these areas), protocols for controlling their populations during production, packing, and shipping established a high standard of protection against their introduction and

that limiting distribution to Midwestern and Northeastern US states (where avocado and citrus host species are absent) made any pest risk to US groves negligible. If the US failed to permit the import of the avocados, it would be susceptible to the challenge that it was not complying with NAFTA and WTO trade agreement provisions to allow trade from low pest prevalent areas within countries (Bredahl and Holleran 1997; Patterson 1997).²⁴

In January 1997, experts at a workshop convened by the Harvard Center for Risk Analysis at the request of the California Avocado Growers Association endorsed APHIS's Mexican avocado pest risk analysis (*Risk Policy Report*, 2/21/97, pp. 15-16). On February 5, 1997, USDA published the final rule permitting importation of avocados from Michoacan to 19 Midwestern and northeastern states and the District of Columbia from November through February under USDA oversight and supervision (*Fed. Reg.*, vol. 62, pp. 5293-5315). It would be easy to infer that the APHIS risk analysis and its endorsement by independent scientists played the decisive role in resolving the Mexican avocado dispute. However, another contributing factor to breaking the impasse was the threat that Mexico would retaliate by tightening its own phytosanitary measures against US cherries, apples, and peaches. (Mexico also might have drawn attention to the recent discovery of karnal bunt, a fungal disease that attacks wheat, in southwestern US states by challenging the US quarantine of Mexican wheat on the basis that karnal bunt was established in Mexico.) To some extent, these retaliatory threats split the US agricultural coalition and offset political support for maintaining the avocado ban. At least some US fruit growers seeking to export to the Mexican market judged that the APHIS risk analysis was an adequate scientific basis for the decision to partially lift the ban on Mexican avocados.

For example, in reaction to USDA's final ruling permitting Mexican avocado imports, Kraig Naasz of the Northwest Horticultural Council pointed out the importance of the decision to Northwest fruit growers, particularly considering that Mexico is Washington state's top apple export market. "The USDA decision was based on sound science, and provides adequate safeguards for the California [avocado] industry," Naasz said. "It's critical to note that science was the basis for the ruling. If the U.S. government is to persuade our trade partners to make similar decisions based on science--and not use these issues as protectionist trade barriers--its best to lead by example" (Gibbs 1997).

F. PROJECTING THE FUTURE PATTERN OF SPS DISPUTES

Roberts and DeRemer (1997) surveyed 63 overseas U.S. Department of Agriculture Foreign Agricultural Service posts and identified 315 currently enforced or recently proposed technical trade barriers that appear to violate one or more disciplines of the new multilateral trade agreements. (A measure could be in apparent violation because it is perceived either as an illegitimate protectionist device or as a measure unnecessary to achieve a legitimate objective.) These questionable barriers to U.S. agricultural exports have a total estimated

²⁴ I found no evidence to suggest that the North American Plant Protection Organization or any other IPPC organization played a role in the Mexican avocado dispute.

annual trade impact of \$4.97 billion. (By comparison, the total value of U.S. agricultural, forestry, and fishery exports in 1996 was \$69.7 billion). Over ninety percent of the technical barriers identified in the survey involve SPS issues. (Other technical barriers include labeling and packaging measures.)

Considered individually, many existing or threatened technical barriers to U.S. agricultural exports have modest estimated annual trade impacts. Over 50 percent of the issues have an annual impact of less than \$4 million, and 70 percent have an impact of less than \$10 million. Many of the foreign measures affect specific commodities, such as a single horticultural product. (The largest issue identified in the survey, with an estimated annual trade impact of greater than \$500 million, is Japan's food safety standards that do not permit the use of many synthetic and chemical additives used by the U.S. processed food industry. Each of the many food additives may be considered as a separate issue, however.²⁵) Questionable plant health measures are most numerous, accounting for approximately half of all issues identified in the survey and 43 percent of the trade impact of all SPS measures. Measures currently enforced or proposed under the rationale of food safety account for about 20 percent of the issues in the survey and about 35 percent of the trade impact of questionable SPS measures. Pathogens are most commonly the stated concern of the food safety barriers. Approximately 12 percent of the issues in the survey are animal health measures, but they account for less than 5 percent of the total trade impact of SPS measures.

Biological Hazards

The USDA survey only provides a snapshot of questionable technical barriers to U.S. agricultural exports. (The USDA is currently investigating whether trade barriers to U.S. exports differ from those of other exporting countries (Nicole Ballenger, Economic Research Service, personal communication).) If the U.S. (which is a large market in terms of both exports and imports) is representative, it seems reasonable to infer that the majority of international trade disputes over SPS measures will concern biological stressors, and in particular those organisms that may pose a threat to plant health or food safety.

Because predicting the effects of biological stressors is so fraught with uncertainty, it may be reasonable for countries to act with considerable precaution in setting some SPS standards. On the other hand, the large uncertainties and the relatively immature state of risk assessment for biological hazards combine to form a promising area for countries to deploy protectionist SPS measures. It will likely be difficult and time consuming to generate adequate data and reach a scientific consensus concerning risk assessment for biological stressors. Countries or firms seeking to challenge biological SPS measures as unnecessary trade barriers

²⁵ Roberts and DeRemer (1997) identify the country in question only as "one market in the East Asian region," but the identity of the country is common knowledge. Vogel (1995) notes that Japan permits the use of fewer synthetic and chemical food additives than any other developed nation and that Japanese standards for synthetic or chemical food additives are among the world's strictest. Consequently, it is difficult for American food processors to export processed foods to Japan. Depending on how broadly a chemical additive is defined, between 50 and 200 more synthetic chemicals can legally be added to processed food in the U.S. than in Japan.

may find that they are, in essence, being called upon to finance the start-up costs of a new scientific field. The inevitable delay and high overhead is likely to be a source of frustration and may partially offset incentives for investment in science to resolve SPS disputes.

Setting Precedents?

The USDA survey of trade barriers also suggests that most disputed SPS measures will have insufficient economic trade impacts to attract substantial scientific resources to their resolution. Instead, those with command over scientific and analytical resources may seek to challenge measures that have precedent-setting potential for a broad class of disputes. As the beef growth hormones case study suggests, however, setting precedents in the SPS trade dispute arena may be a slippery objective. The linkage of one SPS dispute to a suite of others raises the stakes of the nominal dispute. Consequently, the weight of scientific evidence necessary to support a position increases out of proportion to the issue at hand. Furthermore, the debate over what factors other than science are legitimate considerations in setting SPS standards has not been resolved permanently. It has merely been shifted from the trade dispute settlement process in WTO to the technical standard setting process in the international SPS agencies such as Codex.

The Promise of Equivalence

One hopeful prospect for resolving international trade disputes over sanitary and phytosanitary measures is that many cases may hinge on establishing the equivalence of alternative SPS risk mitigation measures (i.e., that alternative measures are equally efficacious in reducing risk). This is hopeful for reasons of analytic tractability and of national sovereignty. By focusing on the question of equivalence, many highly uncertain scientific issues become moot. For example, predicting the incidence of fatality and morbidity in a population as a result of food-borne microbial pathogens is beyond current scientific capabilities. It may never be possible to predict the evolution of a benign microbe into a pathogen or the sudden expansion of a plant pest's range of suitable hosts. Such predictions are unnecessary, however, if the key question is whether alternative risk management practices result in equivalent levels of exposure. This framing of the issue still poses considerable technical challenges but tremendously simplifies the scientific analysis. Focusing on equivalence is also protective of national sovereignty because, under Article 4 of the SPS Agreement, it is incumbent upon the exporting country issuing the challenge to demonstrate the equivalence of different SPS measures. However, the promise of equivalence is limited as some SPS disputes will turn on questions of hazard identification or estimated damages from very low levels of exposure to suspected hazards. As suggested by the case studies, the rub will frequently be whether *any* alternative measure can be regarded as equivalent to an outright ban in terms of the level of protection provided.

G. EVALUATING THE WEIGHT OF SCIENTIFIC EVIDENCE

The prospect of international institutions relying on uncertain science to resolve an expected increase in trade disputes over sanitary and phytosanitary measures argues for commonly accepted criteria for use in evaluating the weight of scientific evidence. Scientists have outlined criteria for evaluating the weight of evidence in determining a causal relationship between a stressor and observed effects. For the purposes of resolving trade disputes over SPS measures, however, establishing causality may be insufficient. Under the provisions of the SPS Agreement, it may be necessary in some cases that risk assessments surpass qualitative hazard identification and estimate the magnitude of potential damages. This paper concludes with a brief discussion of the existing criteria for evaluating causality and a narrative set of weight of evidence criteria for evaluating the strength of damage estimates. The criteria for damage estimates is raised as a strawman to invoke needed discussions about more refined criteria for the SPS setting.

Criteria for Causality

Hill, Susser, Koch, Fox and others have outlined weight of evidence criteria for determining causality (see discussion in EPA 1996). As more of the criteria are satisfied, the greater the weight of evidence indicating a causal relationship between a potential stressor and an observed effect. Failure to satisfy the criteria, however, does not necessarily rule out causality.

Strength of Association

In general, the weight of evidence is greater if a strong or severe biological response is observed instead of a weak one. Of course, for any association to be drawn, there must be some evidence that the organism manifesting a response is exposed to the hypothesized stressor, and there must be some level of confidence in the diagnosis.

Stressor-Response Relationship

The evidence of causality is strengthened if there is an observable relationship between the level of the stressor and the magnitude of the biological response. Typically, the frequency of adverse effects would increase with the level of exposure to a stressor, but the relationship need not be linear or even monotonic. For example, a parabolic relationship would hold if a non-indigenous pest species is introduced at densities so great that there are insufficient resources at the port of entry to maintain a viable population.

Temporal Plausibility

In order to cause the effect, the hypothesized stressor must precede the observed response in time. A stressor may be present but undetected prior to the observed response. Therefore, sensitive indicators of exposure may be necessary to establish temporal implausibility.

Consistent Findings

The evidence of causality is strengthened if the association between a stressor and an effect is repeatedly observed using different methods (e.g., field and experimental studies) and by different investigators. The case for causality is further strengthened if the same stressor is associated with effects in different populations, species, or ecosystems. If a stressor is present without the expected effect, this may weaken the evidence of causality, but is not necessarily strong evidence against causality. There may be a long time-lag between exposure and the manifestation of effects. A stressor also may be neutralized or potentiated under some circumstances but not in others. For example, an exotic pest species may have an undetectable effect if introduced into an environment where there is a predator or pathogen to keep it in check, or it may cause extensive damage in the absence of biological controls. Similarly, a co-factor may be required to cause an adverse response to exposure.

Biological Plausibility

The hypothesized causal relationship is consistent with the current state of biological science. This, of course, is maddeningly subject to change.

Specificity of Association

Many stressors have multiple effects, and many effects have multiple causes. Evidence of causality is strengthened, however, if the effects are diagnostic (the stressor has a peculiar response) or localized.

Criteria for Damage Estimates

Expert Opinion

Ordinal (high, medium, low) damage estimates derived from simple “opinion” surveys of a limited number of experts form the weakest basis for estimating the damages from sanitary and phytosanitary risks. Unfortunately, for some biological stressors such as little-studied exotic species, this may often provide the best available scientific information.

Expert Judgment

Somewhat stronger evidence is provided by more sophisticated means of eliciting expert judgment. (These include disaggregating the estimation problem into manageable subcomponents that are evaluated separately, requiring the experts to explain the basis of their judgments, and taking into consideration the tendency of experts toward overconfidence and the potential for motivational biases to creep into elicited responses.)

Empirical-Judgment

A combination of relevant empirical data and expert judgment to fill data gaps forms the strongest class of damage estimates. The weight of evidence increases with the empirical

database, but there is no imaginable risk assessment situation that would not require some expert judgment. The most relevant data--rarely available--are derived from large, long-term studies of the species and exposure conditions of concern. The weightiest judgments are explicit, well-documented, and consider the full range of biologically plausible models.

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