

**COMMENTS TO THE APPELLATE BODY
OF THE
WORLD TRADE ORGANIZATION**

CONCERNING

European Communities -- Measures Concerning Meat and Meat Products (Hormones)

Submitted on Behalf of

**Public Citizen
Institute for Agriculture and Trade Policy
Cancer Prevention Coalition
Community Nutrition Institute**

EARTHJUSTICE LEGAL DEFENSE FUND

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October 31, 1997

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The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) broke new ground in allowing WTO panels to consider the legitimacy of nondiscriminatory sanitary measures. The first WTO decision applying the SPS Agreement -- *EC Measures Concerning Meat and Meat Products (Hormones)* -- has made clear that WTO dispute resolution panels will directly affect government decisionmaking concerning matters of fundamental public policy that directly affect the lives of billions of people. As a result, each WTO decision concerning such measures will be closely scrutinized by people all around the world and will have a profound effect on the public perception of the World Trade Organization. Therefore, as panels interpret and apply the SPS rules, they must be careful to remain within the bounds of the WTO's competence and legitimacy. Otherwise, they risk undermining public confidence in the WTO as an institution.

The fundamental goal of the SPS Agreement is to prevent false claims of the need to protect health from being used as a cover for trade restrictions without impairing the ability of countries to protect health where the need to do so is scientifically justified. These two objectives are established in the very first paragraph of the Preamble to the Agreement, which reaffirms

that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade.

These objectives are achieved through requirements that sanitary measures be based on a scientific justification¹ and the protection of the right of governments to establish the level of

¹ *Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)*, Art. 2.2 (measures must be applied and maintained on the basis of "scientific principles" and "scientific evidence"), Art. 3.3 (measures

protection against risk that they consider appropriate, without outside interference.² Indeed, even during negotiation of the SPS Agreement, it was recognized that

[t]he basic aim of the SPS Agreement is to maintain the sovereign right of any government to provide the level of health protection it deems appropriate, but to ensure that these sovereign rights are not misused for protectionist purposes and do not result in unnecessary barriers to international trade.³

Rather than carefully limiting its role to determining whether the EC sanitary measures at issue are a cover for restrictions on international trade, however, the Panel took on the task -- more appropriate to a government body directly responsible to the people affected -- of determining the appropriate standards for protecting human health. In addition, in its zeal to set health standards, the Panel addressed a number of issues unnecessary to the resolution of the dispute before it. Unless the Appellate Panel limits the original Panel's decision to only those conclusions necessary to determine whether the EC measures at issue are a cover for trade restrictions and corrects the numerous errors in the Panel Report arising out of the Panel's misinterpretation of its role and of the provisions of the SPS Agreement, the Hormone decision will make the SPS Agreement an obstacle to governments' exercise of their right to take action to protect against risks to human health and will undermine public confidence in WTO review of sanitary or phytosanitary measures and weaken the WTO's legitimacy.

THE PANEL'S RESOLUTION OF UNNECESSARY ISSUES

The resolution of this case will establish rules that the WTO will apply in future challenges under the SPS Agreement. As previously noted, the resolution of these challenges will affect people around the world. It is of special concern, therefore, that the SPS Agreement not be interpreted or applied without full and careful consideration of the issues at stake. A common protection against unconsidered development of legal rules is the principle that judicial bodies should only address the issues that are essential to resolving the dispute before them. When a judicial body reaches out to decide issues that are not essential, it risks developing rules without the benefit of full and vigorous presentation of all relevant arguments for and against the rules.

The Hormone Panel found that the EC did not satisfy "procedural" requirements necessary to maintain sanitary measures; the risk assessments that exist did not provide sufficient scientific justification for the measures; and distinctions in levels of protection applied by the EC

resulting in a higher level of protection than would be achieved through international standards must have a "scientific justification"), Art. 5 (requiring SPS measures to be based on a risk assessment that takes into account scientific evidence).

² See *id.*, *Preamble* (expressing desire to further harmonization of SPS standards "without requiring Members to change their appropriate level of protection"), Art. 3.3 (permitting measures resulting in higher level of protection than would be achieved through international standards "as a consequence of the level of the level of sanitary or phytosanitary protection a Member determines to be appropriate").

³ *Undertaking the Agreement on Sanitary and Phytosanitary Measures*, Background Paper, GATT Secretariat, 28 Jan. 1994, p. 1.

in certain circumstances were unjustified and therefore violated the SPS Agreement. As the Panel noted, any of these findings would have been sufficient to conclude that the EC measures violated the SPS Agreement. The Panel also established rules concerning the relevance of the precautionary principle to SPS disputes, despite the fact that the precautionary principle is irrelevant if, as the Panel found, there is no risk against which to take precautionary measures.

Although the Panel recognized that it did not need to address every issue raised by the parties (for example, it correctly concluded that its findings on the issues enumerated above made it unnecessary to consider whether the measures at issue were more trade restrictive than necessary), it nevertheless addressed a number of issues that were not essential to the resolution of this dispute. In doing so, the Panel developed rules, discussed below, that are inconsistent with the purpose and goals of the SPS Agreement.

The Panel's creation of procedural risk assessment requirements is an example of the danger of deciding unnecessary issues. Because, as demonstrated below, the SPS Agreement does not require the procedures created by the Panel, the primary focus of the parties' arguments was the presence or absence of a substantive scientific justification for the measures. Without the benefit of vigorous argument concerning whether the SPS Agreement imposes procedural requirements, the Panel developed a rule that will interfere with the ability of governments to protect human health and that are therefore inconsistent with the goals of the SPS Agreement.

The Appellate Panel should prevent errors of this type by limiting dispute resolution panels to only the issues that are essential to resolving the cases before them.

THE PANEL'S "PROCEDURAL" RISK ASSESSMENT REQUIREMENTS

The SPS Agreement prevents false health concerns from being used as a cover for trade restrictions by requiring that measures implemented in the name of health protection have a "scientific justification." The Agreement requires that the scientific justification for the measures be "based on" a risk assessment that "take[s] into account" certain kinds of evidence that are relevant to determining risk. When risk assessments indicate that there is a risk, then the measure is scientifically justified.

The Hormone Panel found that studies submitted by the EC were risk assessments. Instead of limiting its inquiry to whether these risk assessments provided scientific justification for the EC measures, however, the Panel created a set of "procedural" requirements for risk assessment that are unrealistic and unsupported by the SPS Agreement. On the ground that there was no evidence that the EC actually considered certain assessments in existence when the EC implemented its ban, the Panel refused to consider whether those assessments provided scientific justification for the ban. The Panel suggested that the EC Parliament should have "mention[ed] the scientific studies" in the preamble to the measures themselves. Taking its procedural requirements to their extreme, the Panel then stated that articles and opinions of scientists published after the measures were implemented

cannot . . . be considered as part of a risk assessment on which the European Communities based its measures unless there would be some evidence that the competent

EC institutions actually considered these articles and opinions or reexamined the potential risks related to the specific substances at issue in light of these articles and opinions.⁴

The Panel's elevation of form over substance runs counter to the purpose and language of the SPS Agreement, as well as the realities of the scientific process, which make the existence of a scientific justification, no matter how or when it is recognized, the dispositive issue. As noted above, the focus of the SPS Agreement with respect to risk assessment is whether there is a scientific justification for the measure in question. By applying this requirement to the "maintenance" of SPS measures in addition to their introduction,⁵ the Agreement makes clear that when previously implemented measures are challenged, the existence of a scientific justification is to be determined with respect to their *maintenance -- i.e., as of the time of the challenge*. If the focus of the dispute were only on scientific justification at the time of introduction, there would be no need to specify that "maintenance" of a measure also requires justification.

This is consistent with the SPS Agreement's goal of permitting governments to implement protective measures that are scientifically justified. Scientific research is an ongoing process and new studies are constantly being completed. The Panel's requirements mean that challenges to SPS measures will be evaluated on the basis of fiction -- what the scientific evidence was when the government last undertook a formal evaluation -- rather than the real state of scientific understanding when the measure is being evaluated. This could mean that a measure that is unarguably justified by scientific evidence when it is challenged would be invalidated because the evidence was less strong when the measure was introduced. Furthermore, another country could maintain the same measure simply because it happened to have implemented it later, and so considered the new, stronger evidence in adopting the measure.

The Panel's procedural requirements also interfere with the sovereign political prerogatives of governments. The Panel has specified certain procedures that governments must follow in introducing or maintaining sanitary measures. These requirements would mean that a government must systematically reevaluate its health measures in light of each new scientific study relating to any measure it has implemented and formally announce its conclusions. Not only is such interference beyond the authority of a WTO panel, the procedures required by the Panel are inconsistent with governmental practices recognized as legitimate by most Members. For example, the Panel's requirements would invalidate SPS measures initiated through popular referenda, even if those measures are fully justified by science. The SPS Agreement certainly was not intended to prescribe or prohibit certain methods of making essential political decisions.

For all of these reasons, to achieve the SPS Agreement's goal of allowing governments to protect against real risks to health, *the focus of a WTO panel's analysis should be on the existence of a scientific justification at the time of the challenge, not on how or when the*

⁴ *EC Measures Concerning Meat and Meat Products (Hormones), Complaint by the United States, Report of the Panel (Panel Report (US))*, WT/DS26/R/USA, 18 Aug. 1997, para. 8.115.

⁵ *SPS Agreement*, Art. 2.2 (requiring sanitary measures to be "based on scientific principles" and "not maintained without sufficient scientific evidence").

government in question became aware of that justification. If the Appellate Panel allows the Hormone Panel to add its procedural requirements to the provisions of the SPS Agreement, it will intrude into the ability of governments to take action to protect against health risks and, in so doing, will severely undermine public confidence in WTO processes.

THE PANEL’S CONSIDERATION OF SCIENTIFIC ISSUES

Several provisions of the SPS Agreement make scientific issues relevant to resolving challenges to SPS measures. It is essential to the integrity of the dispute resolution process, however, as well as to public confidence in panel decisions, that the panel not evaluate decisions that are outside its proper scope of review. Likewise, although the SPS Agreement and the Dispute Settlement Understanding allow panels to seek advice from experts in disputes “involving scientific or technical issues,” the role of a scientific advisory group can be no greater than the panel’s authority to address scientific issues. Unfortunately, the Hormone Panel misconstrued its own role and that of its expert advisers, thereby undermining the credibility of its decision. In addition, the Panel failed to take several procedural steps necessary to ensuring the competency and legitimacy of the advice it received from its experts.

The Panel’s Role in Considering Scientific Issues

The SPS Agreement makes scientific and technical issues relevant in the following areas:

- The application of sanitary measures, which must be “*based on scientific principles*” and the maintenance of such measures, which requires “*sufficient scientific evidence*”⁶;
- The decision to use measures intended to result in a higher level of protection than would be achieved by measures based on international standards: As the Hormone Panel noted,⁷ Members may make this decision if there is “*a scientific justification*”⁸ or if, “*on the basis of an examination and evaluation of available scientific information,*” the “*Member determines*” that the relevant international standards will not achieve its desired level of protection⁹; and
- Risk assessment: Members are to “*take into account available scientific evidence*” and other technical issues.¹⁰

Although the SPS Agreement requires that measures be based on “scientific principles,” it does not require that those principles be the *best* principles or even those that are predominantly accepted in the scientific community. Likewise, where the Agreement requires

⁶ *SPS Agreement*, Art. 2.2 (emphasis added).

⁷ *Panel Report (US)*, para. 8.79.

⁸ *SPS Agreement*, Art. 3.3 (emphasis added).

⁹ *Id.*, Art. 3.3 n.2 (emphasis added).

¹⁰ *Id.*, Art. 5.2 (emphasis added).

scientific justification, it requires “a” justification, not the best one or the one accepted by the largest number of scientists. Finally, the Agreement requires that Members “take into account,” “examin[e]” and “evaluat[e]” scientific information and that ongoing measures be supported by “sufficient” scientific evidence; it does not, however, require that the measures be supported by the weight of the available scientific evidence or specify any other standard by which Members must choose between competing scientific claims.

These provisions of the SPS Agreement reflect a recognition that scientific certainty is rare and that advancements in scientific knowledge -- including knowledge of previously unknown risks -- nearly always begin as controversial theories held by a minority of the scientific community. If the Agreement required a country to base its measures on the scientific principles accepted as “best” by the majority of scientists or supported by the “most” scientific evidence, countries would be unable to take precautionary measures to protect against risks suggested by new or controversial evidence.

The unequivocal protection that the SPS Agreement gives to the right of countries to choose their own levels of protection also emphasizes the limited role of dispute resolution panels with respect to scientific issues. A very high level of protection is likely to necessitate measures to protect against risks revealed by new, and frequently controversial, scientific evidence.¹¹ For that reason, the SPS Agreement leaves to the country implementing a sanitary measure the responsibility to make any judgments required by the existence of conflicting evidence or different scientific principles. If dispute panels were permitted to judge what they believe to be the “correct” or “best” or “most accepted” science, they would unavoidably interfere with the freedom of countries to choose their own levels of protection.¹²

¹¹ This point can be illustrated by the following example. Suppose two people are preparing to leave their homes to go to the office in the morning and each checks several weather forecasts before doing so to determine whether to take precautions against getting wet from rain. Assume further that these people are seeking to achieve different levels of protection: one is willing to suffer a little wetness but would prefer not to get extremely wet; the other considers it extremely important to avoid getting wet (*i.e.*, has chosen a higher level of protection). Four out of five forecasts indicate that it is most likely not going to rain during the day, but the fifth, using a new and controversial forecasting method, indicates that it is likely to rain. The person who is willing to get a little wet is likely to take fewer precautions against rain on the chance that the new forecasting method is not as reliable as the method used by the other four forecasts. The person with the higher level of protection is more likely to consider the possibility that the new method may be accurate and take precautions against rain. Forcing the second person to act on the basis of the majority of the evidence effectively lowers the level of protection that she is permitted to choose.

That is not to say, however, that scientific experts have no role in this scenario. As under the SPS Agreement, scientific experts could offer an opinion as to whether the new forecasting method is based on a minimally scientific inquiry concerning the weather (in which case, the SPS Agreement would require that the individual be permitted to decide whether to take precautions based on the forecast) or is based on something unscientific, such as astrological predictions.

¹² The United States and the European Community have each expressed their agreement with these principles. The United States has stated:

It is clear that the requirement in the [SPS] Agreement that measures be based on scientific principles and not be maintained “without sufficient scientific evidence” would *not* authorize a dispute settlement panel to substitute its scientific judgment for that of the government maintaining the [SPS] measure. For example, by requiring measures to be based on scientific principles (rather than, for instance, requiring measures to be based on the “best” science) and not to be maintained without sufficient scientific evidence (rather than,

Because of the deference the SPS Agreement accords countries with respect to decisions concerning conflicting science, a dispute resolution panel's role should be limited to ensuring that the "evidence" considered, the "principles" used and the "justification" derived by the country in selecting and implementing its sanitary measure are minimally scientific in nature by virtue of having been derived by the application of scientific methods and procedures. *The scientific role of dispute panels should therefore be limited to determining whether the science underlying the sanitary measure has the minimal attributes of scientific inquiry and should not include consideration of whether that science is accurate or correct.* Such an analysis will ensure that sanitary measures are not disguised restrictions on international trade without jeopardizing the panel's credibility by purporting to judge decisions properly left to the discretion of the country implementing the measure.

Despite these clear limitations, however, the Hormone Panel went far beyond its authority by attempting to resolve conflicts in scientific evidence, as well as nonscientific matters. This is most clear in the Panel's consideration of the evidence presented by the EC in support of the EC's conclusion that there is a potential for harm from hormone-treated meat. Rather than considering whether this evidence was derived through the use of legitimate scientific methods and therefore was legitimate evidence to be considered in an assessment of risk, the Panel purported to determine whether the evidence proved that harm would occur.

For example, the Panel rejected evidence of the genotoxic effects of hormones because the studies showing such effects were based on elevated doses of hormones and the "relevance of these high dose effects of potential risks related to the low levels of oestrogens in meat from growth promoted animals *has not yet been evaluated.*"¹³ The Panel noted that the studies demonstrating genotoxicity at high doses "do not yet contain *conclusive evidence* of an identifiable risk."¹⁴

However, the fact that evidence is not *conclusive* does not mean that it is not *probative*. For decades, human health regulations have been based on animal studies, even when there was no conclusive evidence that the regulated substances cause the same harm in humans that they

for instance, requiring an examination of the "weight of the evidence"), the [SPS] Agreement recognizes the fact that scientific certainty is rare and many scientific determinations require judgments between differing scientific views. The [SPS] Agreement preserves the ability of governments to make such judgments.

The Uruguay Round Agreements Act, Statement of Administrative Action at 90, 95 (emphasis in original). See also Report on US Food Safety and the Uruguay Round, Protecting Consumers and Promoting US Exports (USTR Report on Food Safety) at 8 (USTR June 1994) at ii; *id.* at 15 ("[D]ispute settlement panels will not be responsible for choosing among competing scientific views, but will only determine whether a particular SPS measure has a scientific basis" (emphasis added)).

The European Community expressed its agreement with these principles in the Written Version of the European Community's Oral Statement at the Second Substantive Meeting of [the Hormone Panel], pp. 34-35, and in its Second Written Submission (Rebuttal) to the Hormone Panel, pp. 17-18.

¹³ *Panel Report (US)*, para. 8.131 (emphasis added).

¹⁴ *Id.*, para. 8.131, n. 342 (emphasis added).

did in animals. These regulations are based on the reasonable assumption that effects on animals are probative evidence -- not conclusive proof -- of potential effects in humans. Likewise, studies showing harm at high doses are at least *evidence* of the possibility of -- or potential for -- the harm at low doses. Although they may not *prove* that harm will occur, they *support the conclusion* that there is a *risk*.

The Hormone Panel also refused to recognize the relevance of evidence of the *general* carcinogenic or genotoxic effects of the hormones in question, insisting instead that the EC demonstrate that such evidence “would indicate that an identifiable risk arises for human health from the use of these hormones for growth promotion purposes if good practice is followed.”¹⁵ Again, evidence of general harm is *probative* of a potential for harm at low doses. The Panel’s insistence on evidence of an “identifiable risk” indicates its refusal to recognize the relevance of inconclusive evidence in assessing risk.

The Panel’s addition of the term “identifiable” -- a phrase that is not part of the SPS Agreement’s discussion of risk or risk assessment -- to the Agreement’s fully complete definition of “risk” as the “potential for adverse effects,” is an important error that the Appellate Panel should correct. Although the Panel uses the phrase “identifiable *risk*,” the fact that it refuses to consider probative but inconclusive evidence of potential harm reveals that it intends “identifiable risk” to mean evidence of nearly certain harm. If the Panel had intended “identifiable risk” to mean an identifiable potential for adverse effects, it would not have refused to consider evidence that is so clearly probative of such effects.

The Panel’s refusal to consider inconclusive or controversial evidence and its implicit requirement that a country maintaining an SPS measure must show conclusive evidence of nearly certain harm are completely inconsistent with the SPS Agreement’s risk assessment requirement. An assessment that considers only fully accepted scientific theories or conclusive scientific evidence will not result in a determination of *risk*, which is, according to the SPS Agreement, “the *potential* for adverse effects.”¹⁶ *Therefore, it is only by taking into account controversial and inconclusive scientific evidence that a true assessment of risk -- as opposed to certain harm -- is possible.* As noted above, therefore, a WTO panel’s role must be limited to determining whether the evidence supporting an SPS measure is scientific, meaning that it has been developed through the application of scientific methods.

The right of countries to consider probative controversial or inconclusive scientific evidence is also supported by the precautionary principle. The Hormone Panel concluded that for the precautionary principle to apply in this case, it would have to “*override* the explicit

¹⁵ *Id.*, para. 8.134. *See also id.*, para. 8.127 (rejecting evidence included in IARC studies because the studies “do not specifically evaluate . . . the potential for adverse effects arising from the presence *in food (in casu* meat or meat products) of residues of the hormones in dispute or from residue levels comparable to those present in food”); *id.*, para. 8.130 (rejecting the articles and opinions of individual scientists dealing with carcinogenic or genotoxic potential of hormones for the same reason).

¹⁶ *SPS Agreement*, Annex A, para. 4 (emphasis added). The SPS Agreement’s definition of “risk” as the “potential for adverse effects” agrees with the common understanding of that phrase as meaning “exposure to the chance of injury or loss.” *Random House Dictionary of the English Language* 1660 (2d ed. unabridged 1987).

wording of Articles 5.1 and 5.2” of the SPS Agreement.¹⁷ However, the preceding discussion indicates that the precautionary principle is not only consistent with the concept of risk assessment set forth in Articles 5.1 and 5.2, it is essential to any real assessment of risk.

The precautionary principle is based on the premise that science does not always provide the information or insights necessary to take protective action effectively or in a timely manner and that undesirable and potentially irreversible effects may result if action is not taken until science does provide such insights.¹⁸ Pursuant to the principle, countries have the right to regulate activities and substances that may be harmful to human health even if the scientific evidence concerning the connection between the activity or substance and the harm is inadequate or inconclusive -- that is, even if scientists do not agree or cannot explain exactly whether, how or to what degree the harm is caused.¹⁹ This principle has been a part of domestic and international law for several decades and has become a “broadly accepted basis for international action.”²⁰

As described above, a real assessment of risk requires taking into account all probative scientific evidence, even if it is inconclusive or controversial. Thus, the precautionary principle acts as additional insurance that health measures will be based on an accurate “evaluation of the potential for adverse effects.”

The Panel’s Allocation of the Burden of Proof

¹⁷ *Panel Report (US)*, paras. 8.157-8.158 (emphasis added).

¹⁸ See E. Hey, *The Precautionary Principle in Environmental Policy and Law: Institutionalizing Caution*, 4 *Geo. Int’l Env’t L. Rev.* 303, 308-09 (1992).

¹⁹ The precautionary principle has been included in numerous multilateral international treaties and declarations. Examples of these include the *Rio Declaration on Environment and Development*, UN Conference on Environment and Development, U.N. Doc. A/CONF.151/5/Rev.1 (1992), reprinted in 31 *I.L.M.* 874 (1992) (“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.”); the *Framework Convention on Climate Change*, U.N. Doc. A/AC.237/18 (Part II)/Add.1 (1992), reprinted in 31 *I.L.M.* 849 (“The Parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures”); the *Ministerial Declaration of the Second World Climate Conference*, Nov. 7, 1990, reprinted in 1 *Y.B. Int’l Env’t L.* 473 (1990) (ministers and representatives of 137 countries agree to “protect the ozone layer by taking precautionary measures to control . . . emission of substances that deplete it”); the *Second International Conference on the Protection of the North Sea, Ministerial Declaration I* (1987) (ministers of the EEC and eight countries agree that the North Sea ecosystem should be protected through the reduction of pollution “even where there is no scientific evidence to prove a causal link between emissions and effects (‘the principle of precautionary action’)”); the *World Charter for Nature*, G.A. Res. 37/7, U.N. GAOR, 37th Sess., Supp. No. 51, U.N. Doc. A/Res/37/7 (1982), reprinted in 22 *I.L.M.* 455 (1983) (“Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effects are not fully understood, the activities should not proceed.”).

²⁰ Philippe Sands, *The Greening of International Law: Emerging Principles and Rules*, 1 *Global Legal Studies J.* 293, 301 (1994). See generally *Interpreting the Precautionary Principle* 262 (Tim O’Riordan & James Cameron eds. 1994).

The rules established by the Hormone Panel concerning burden of proof are also inconsistent with the SPS Agreement's intention of preserving the ability of governments to protect against health risks. The Panel stated that it is not the responsibility of the country challenging an SPS measure "to prove that there is *no risk*."²¹ The Panel correctly noted that science is "not . . . capable of assuring that no risks will ever arise from a substance."²² However, as the Panel's treatment of probative inconclusive evidence demonstrates, the Panel essentially placed on the EC the burden of proving that harm was virtually certain to occur.

The SPS Agreement requires only a scientifically-based finding of *risk*. Thus, *a country maintaining a sanitary measure should only have to prove the existence of evidence that has been derived through the application of legitimate scientific methods and procedures, and that is probative of a potential for adverse effects*. This is true even if the evidence is controversial or inconclusive. Once a WTO panel has confirmed that the evidence is scientific and probative, it must uphold the measure.

The Panel's Use of Expert Advisers

As noted above, the issues of human health raised by this case go to the heart of public concern and the Panel's decision will be under great public scrutiny. The United States and the EC agreed that the manner in which the Panel used scientific experts would affect the integrity of the dispute settlement process and public confidence in the outcome of the dispute.²³ There are four elements that are essential to ensuring the integrity of the use of experts and public confidence in the panel decisions that rely on expert advice. The most fundamental criterion for ensuring integrity and public confidence is transparency in the Panel's use of experts. In addition, the experts must be independent and impartial, they must be qualified to render advice in the areas at issue, and they must have access to all relevant information.

Transparency

If the public is to trust the Panel's use of expert advisers, it must be assured that the advisers are impartial and qualified to address the questions at issue. Because the public is excluded from the dispute resolution process until the final report is issued, it is critical that the report include all information necessary to assure the public of the legitimacy of the advisory process. The Hormone Panel's record in this respect is mixed. On the one hand, the Panel should be commended for including in its Report the questions that it asked the experts and a summary of their responses, as well as the transcript of its meeting with the experts. However, the Panel's report omitted some of the most important information. For example, the Panel's report did not include any information concerning the experts' qualifications and did not provide any means of assuring the public that the experts were impartial. To this end, the Panel should have appended the experts' curricula vitae to the Report.

²¹ *Panel Report (US)*, para. 8.151.

²² *Id.*, para. 8.153.

²³ *Id.*, paras. 6.1, 6.3.

Another reason for transparency is to assure the public of the scientific legitimacy of the opinions conveyed to the Panel. One element of such legitimacy, discussed below, is to require the experts to identify the scientific bases for their opinions. However, the Panel should also have made public the experts' written submissions to the Panel. This would ensure the public that serious mistakes in the experts' opinions could be corrected by other scientists with similar, or greater, expertise. Again, the information provided by the Panel concerning the experts' opinions was helpful, but especially in light of the Panel's heavy reliance on those opinions, full transparency would have provided greater assurance to the public that the experts did not make serious errors or overlook important evidence.

Independence and Impartiality of Experts

The United States and the EC agreed that the Panel's use of experts should be free of conflicts of interest.²⁴ The advice provided by the experts -- and therefore of any panel decision that uses that advice -- can only be credible if the choice of experts ensures that the experts will be able to consider the information before them objectively and provide unbiased advice. For this reason, the experts must be independent and impartial.

The Panel's report does not make clear what standards, if any, standards it applied to ensure that its experts were independent and impartial. For example, the Panel provided no indication that it considered whether the experts had financial or other links to industries that have a stake in the dispute, such as pharmaceutical and livestock industries, and did not provide any information to allow the public to reassure itself that no such ties existed.

The Panel's close collaboration with the Codex Alimentarius Commission created a perception of conflict that threatens to taint the Panel's entire Report. Under the circumstances of this case, in which the experts will be asked to consider the science underlying the European Community's consideration of issues previously addressed by the Codex Alimentarius Commission, the advisers should not have participated in the Codex deliberations, as they may be inclined -- either actually or in popular perception -- to reaffirm Codex's previous conclusions. Codex has addressed the issues considered by the panel several times, including in a 1988 report that the United States cited in support of its position in the dispute and that the European Communities argued was incorrect. Because Codex has taken a public position with respect to the issues before the Panel, it is inappropriate for Codex or experts who have participated in its deliberations to participate in the advisory panel. Despite this obvious concern, Codex influence permeated the advisory process.

According to the Panel Report, the Panel selected at least two of its five experts from lists provided by Codex and the International Agency for Research on Cancer.²⁵ Although the Panel provided very little background information on the experts that it chose, there has been some suggestion that at least one of the two experts chosen from the Codex/IARC lists -- Dr. Jock

²⁴ *Id.*

²⁵ *Id.*, paras. 6.6, 6.7.

McLean -- was actually a member of the Codex group that produced the 1988 report relied on by the United States. In addition to choosing its experts from a list provided by Codex, the Panel submitted written questions to the Codex Commission secretariat and involved a sixth expert, who represented the Codex secretariat, in its expert deliberations.²⁶ Using individuals associated with the Codex deliberations or recommended by Codex creates, at a minimum, an appearance of lack of independence and may thereby raise doubts concerning the Panel's dependence on those the experts in resolving the dispute.

In addition to avoiding individuals involved in groups like Codex that have a stake in the outcome of the dispute, the Panel should not have included experts with close ties to governments with a stake in the outcome, particularly governments party to the disputes at issue. Two members, Drs. Arnold and Lucier, are employed by governments involved in the dispute. In addition, there is information suggesting that Dr. Ritter has served for considerable time as an official of the Canadian government. These connections raise suspicions concerning the ability of the experts to provide impartial input to the Panel.

If the Panel found that it was unable to avoid including experts with the kinds of problematic connections described above, it should at least have taken steps to ensure that the expert group included a balance of perspectives concerning the scientific issues in dispute. It is clear from the statements of the scientists who participated in the Panel's Joint Meeting with Experts that the Panel could have found scientists with opinions that differ greatly from those of the scientists chosen by the Panel.

As we stated earlier, the Panel did not provide sufficient information to assure the public of the experts' independence and impartiality. The information that is available, however, creates the perception that the Panel may not have received balanced, unbiased advice from its experts. Such a perception undermines the credibility of the Panel's report.

The Experts' Qualifications

It should go without saying that the legitimacy of and public confidence in the Panel's use of expert advisers depends heavily on the qualifications of its advisers. As noted above, the Panel's scientific role is limited to evaluating whether the science underlying the EC's sanitary measures has the minimal attributes of scientific inquiry. The experts that the Panel used to make this evaluation must be qualified to do so.

The Panel should have provided curricula vitae for all of its experts and should have identified the areas with respect to which each was considered an expert. The Panel should also have addressed each of its questions only to those advisers who were truly experts in the area of inquiry at issue.

We have expressed above our concern that the Panel used its experts to address issues far beyond the Panel's authority under the SPS Agreement. However, even if the Panel's broad

²⁶ *Id.*, paras. 6.7, 6.10; *Transcript of Joint Meeting with Experts, held on 17 and 18 February 1997 (Joint Meeting Transcript), Panel Report (US), Annex*, para. 26.

questions were appropriate, it appears that the members of the advisory group were not qualified to address many of those questions. In several instances, the group members themselves expressed concern about their qualifications to address the questions.²⁷ Even when the experts did not expressly indicate their lack of expertise, it is hard to believe that all of them -- and in some cases *any* of them -- are qualified to provide *expert* advice concerning many of the questions that they answered. For example, the Panel asked the experts to address the feasibility of labeling products containing meat from hormone-treated animals. There is no indication that any of the Panel's advisers has any expertise that relates to labeling.

The Panel also requested the experts to address the question of the relative ability of governments to control the abuse of growth hormones and ensure the use of good veterinary practices when all hormones are banned as compared to when some are permitted. Once again, it appears that most of the expert advisers had no expertise on this subject. Dr. Arnold stated that he was "reluctant" to answer the question because it was "subject to speculation," but nevertheless provided an answer based on several assumptions.²⁸ Dr. Lucier also explained that his answer to the question was only "speculation," based on his "feeling" and a "guess."²⁹ Despite these express reservations, the Panel concluded that "the experts advising the Panel *made clear* that the potential for abuse under both regimes would be comparable. . . . In this context, we note, therefore, that banning the use of a substance does not necessarily offer better protection of human health than other means of regulating its use."³⁰

More problematic, however, is the Panel's omission of the fact that at least one expert actually reached the opposite conclusion on this issue, stating that experience in his country had shown that abuse increased when some use of growth hormones was allowed and expressing his opinion that "the authorization, legalization, of these compounds had no effect, real effect on some black market," and that control of the use of some hormones was easier when all were banned.³¹ The Panel's use of speculative statements from its experts, as well as its omission of the conflicting statements of one expert, place the legitimacy of the Panel's conclusions in doubt and undermines the credibility of those aspects of its decision that rely on expert input.

Another serious omission that undermines the credibility of the Panel's use of expert advisers is the Panel's failure to demand support for the experts' "opinions." The Panel apparently did not require that the experts indicate whether there was a scientific basis for each answer (and if so, what that basis was), nor did it require the experts to distinguish between their

²⁷ For example, Dr. Lucier explained that he had "little expertise" in the area of good animal husbandry practice addressed by Question 1. *Panel Report (US)*, para. 6.17. Nevertheless, Dr. Lucier apparently considered it appropriate to express an opinion based on what appeared to him to "seem[] reasonable to assume." *Id.* Other advisers similarly answered questions despite their admitted lack of expertise. *See, e.g., id.*, paras. 6.203 and 6.234 (in which Dr. André expresses belief that Questions 23 and 28 are "not related to scientific expertise" but nevertheless answers "from a personal point of view"), 6.210 (Dr. Ritter has "no expertise" in the area of enforcement, but provides his opinion).

²⁸ *Joint Meeting Transcript, Panel Report (US)*, Annex, para. 269.

²⁹ *Id.*, para. 274.

³⁰ *Panel Report (US)*, para. 8.146.

³¹ *Joint Meeting Transcript, Panel Report (US)*, Annex, paras. 168, 362.

personal opinions and conclusions drawn on the basis of data or peer-reviewed scientific studies. No scientific opinion is credible without proof that it is actually based on scientific evidence. Even when the experts did not explicitly express the speculative nature of their opinions, the Panel required nothing to assure it -- or the public -- that the experts' opinions were grounded in the scientific method and had been confirmed through the process of peer review. Without such assurances, the legitimacy of the Panel's entire report is questionable.

The Experts' Access to Relevant Information

Another essential test of the validity of the experts' opinions is whether they have considered all of the relevant information pertaining to the scientific or technical issues before them. Without the opportunity to examine all relevant information, the experts' conclusions will be meaningless, and the Panel's reliance on them is suspect.

Simply allowing the experts to review the record in the dispute was not sufficient to ensure that the experts will have access to all relevant information. The parties to the dispute may not have had access to all relevant information or may have chosen not to submit even valuable information to the Panel for political or strategic reasons, such as not wanting to establish a precedent that would undercut their position in an unrelated dispute.

To ensure that the experts are able to consider all relevant information, the panel should have notified the public of its decision to use expert advisers and of the experts' mandate. Such notice should have include the identity of the experts and what information they were provided. In addition, the public should have been invited to provide information that was relevant to the experts' mandate -- that is, information that bears on whether the EC used valid scientific methods and procedures in implementing and maintaining the sanitary measures at issue.

The experts should also have been encouraged to request information on this issue from outside sources of their choosing and to serve as conduits for information from the scientific community.³² The scientific process depends on constant exchange of ideas among scientists and the experts are likely to have been aware of valuable sources of information that might not otherwise be made available to them. Without the opportunity to consider information from other scientists and the public, the conclusions of the expert advisers are likely to be incomplete and may be considered untrustworthy.

THE PANEL'S INTERFERENCE WITH THE RIGHT OF THE EUROPEAN COMMUNITY TO CHOOSE A LEVEL OF PROTECTION THROUGH ITS MISINTERPRETATION OF ARTICLE 5.5

As noted above, one of the most important ways in which the SPS Agreement protects the ability of governments to take action against health risks is through its explicit protection of each country's freedom to choose the level of protection it considers appropriate. In addition to

³² The provisions of the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes concerning Expert Review Groups (Appendix 4, para. 4) provides that "expert review groups may consult and seek information and technical advice from any source they deem appropriate."

taking on the responsibility of resolving conflicts in scientific evidence, the Hormone Panel's interpretation of Article 5.5 of the SPS Agreement further undermined this freedom.

As part of the overall goal of the SPS Agreement to prevent trade protective measures, the Agreement attempts to ensure that a country's choice of a level of protection is not really a cover for such a measure. To this end, Article 5.5 requires each Member to

avoid arbitrary or unjustifiable distinctions in the levels [of protection] it considers appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade.

The Hormone Panel analyzed several "distinctions" in the EC's levels of protection and concluded that each one resulted in discrimination or a disguised restriction on international trade. Two of the distinctions that the Panel addressed involved comparing the use of growth hormones with the natural presence of hormones in meat and other foods. The Panel concluded that because the EC bans the use of growth hormones, but takes no action to prevent the consumption of untreated foods containing hormones, the distinction was arbitrary or unjustifiable. This conclusion ignored the fact that *risk is only one of many factors to be considered in determining the appropriate level of protection.*

When a nation identifies a potential risk to human health, it must decide whether and to what extent to take steps to protect against that risk. While science plays an important role in identifying the existence of a risk, the decision concerning the appropriate response to that risk is political. It requires weighing the evidence, which may be conflicting, that the risk exists. More significantly, it requires weighing how much the citizens of the country fear the particular risk and how much, if at all, they value the benefits that the activity or substance provides.

By balancing concern about the risk against the value of the substance that poses the risk, the government of a country can determine what amount of that risk is acceptable to its citizens and, therefore, what level of protection against that risk it must strive to attain. This decision goes to the heart of what governments do -- determine appropriate actions based on the fears and values of citizens.³³ Because of the essentially political nature of the choice of a level of protection against risk, customary international law and the SPS Agreement protect the right of countries to make this choice.

³³ The United States has recognized that the SPS Agreement's definition of appropriate level of protection explicitly affirms the right of each government to choose its levels of protection, including a "zero risk" level if it so chooses. A government may establish its level of protection by any means available under its law, including by referendum. In the end, the choice of the appropriate level of protection is a societal value judgment. The Agreement imposes no requirement to establish a scientific basis for the chosen level of protection because the choice is not a scientific judgment.

The Uruguay Round Agreements Act, Statement of Administrative Action at 89. See also *USTR Report on Food Safety* at 4, 6 ("**[T]he requirement for a scientific basis applies to SPS measures; it does not apply to the level of food safety that those measures are designed to achieve. . . . [T]he Agreement specifically preserves the right of governments to choose the level of risk they find acceptable**" (emphases (both bold and underline) in original)).

In comparing levels of protection for the purposes of Article 5.5, therefore, it is important to consider *all* factors that could justify apparently different levels of protection, not just the amount of risk at issue. For example, it may be that the benefit to be obtained from one potentially carcinogenic activity (such as the use of x-rays) is considered to be greater, and thus to justify a greater risk, than the benefit from another potentially carcinogenic activity (such as using DDT). In addition, the benefit to be obtained from a potentially risky activity may carry more weight if there are few or no safer alternative means of obtaining that benefit. It is important that Article 5.5 not be interpreted as limiting the relevant factors to the amount of risk to which allegedly different levels of protection correspond.

Another mistake that the Panel made in its analysis of the EC measures under Article 5.5 was the significance that it placed on “objectives (other than the protection of human health) that the [EC] had in mind when enacting or maintaining the EC ban” as an “additional factor” in finding that the EC distinctions resulted in discrimination.³⁴ As noted above, the fundamental goal of the SPS Agreement is to prevent false claims of the need to protect health from being used as a cover for trade restrictions without impairing the ability of countries to protect health where the need to do so is scientifically justified. If both objectives of this goal are to be met, *the only possibly relevant question concerning objectives underlying an SPS measure is whether there is a legitimate scientific justification*. If a scientific justification exists, it should not matter that the measure achieves other goals.

Political decisions are nearly always the result of compromises made by decisionmakers with numerous -- and sometimes conflicting -- concerns. Even if it were possible for dispute resolution panels to untangle this web of motives to identify a single “real” one, attempting to do so would interfere in countries’ sovereign political processes. The Appellate Panel should not permit the Panel’s consideration of the EC’s “other objectives” to remain a basis for concluding that the EC’s level of protection results in discrimination.

The Panel’s second “additional factor” is also based on an erroneous interpretation of Article 5.5. The Panel considered the fact that the percentage of animals treated with growth hormones before the EC ban came into force was significantly lower in the EC than in the United States. The Panel then concluded that a ban on the sale and import of meat treated with growth hormones “*de facto* discriminates against US meat in favour of EC meat” and, “in this sense, the difference in levels of protection . . . could be said to result in ‘discrimination or a disguised restriction on international trade.’”³⁵ This kind of disparate impact analysis has already been rejected by a GATT dispute resolution panel.

In *United States -- Taxes on Automobiles*, the panel considered whether taxes that had a disparate impact on like foreign and domestic products created a distinction drawn “so as to afford protection” to the domestic products. The panel rejected repeated arguments by the EC that the taxes’ disparate impact was evidence of an intent to protect domestic products. As the panel noted, because the taxes had a legitimate purpose and were neutral on their face, “the fact

³⁴ *Panel Report (US)*, para. 8.204.

³⁵ *Id.*, para. 8.205.

that the EC automobiles bore most of the burden of the tax did not mean that the measure had the effect of affording protection to United States production.”

The same is true in the present case. It would be a dangerous precedent to find facially nondiscriminatory health measures to be an unfair trade barrier simply because they have a disparate impact. If the measures are scientifically justified, that should end the inquiry.

CONCLUSION

The SPS Agreement requires WTO dispute panels to make decisions that directly affect the efforts of governments to protect the health and well-being of billions of people. Therefore, public health and public confidence in the WTO depend on the panels’ ability to remain within the bounds of their competence under the Agreement.

The SPS Agreement is intended to prevent false health claims from being used to disguise trade restrictions without interfering with the ability of governments to protect against real threats to health. To achieve both of these objectives, it is essential that dispute resolution panels applying the Agreement carefully limit their role to determining whether the sanitary measures at issue are a cover for restrictions on international trade.

Unfortunately, the panel that considered the challenge to the EC’s ban on trade in hormone-treated meat went beyond this role, attempting instead to determine the appropriate standards for protecting human health. In the process, the Panel addressed many unnecessary issues and developed rules that will impair the ability of governments to protect their citizens against health risks. Unless the Appellate Panel corrects these mistakes, public confidence in the legitimacy of the WTO severely weakened and the WTO will undermine countries’ sovereign prerogatives to protect their citizens.