ARTICLES

THE INFLUENCE OF CARCINOGENICITY CLASSIFICATION AND MODE OF ACTION CHARACTERIZATION ON DISTINGUISHING "LIKE PRODUCTS" UNDER ARTICLE III:4 OF THE GATT AND ARTICLE 2.1 OF THE TBT AGREEMENT

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INTRODUCTION

Over 80,000 chemicals are registered for use in the United States marketplace; however, the health risks posed by these chemicals are not fully understood.[1] Many of the chemicals that were once considered safe have been identified as capable of causing cancer or other adverse health effects. To take just two examples, benzene has been linked to acute myelogenous leukemia, and mercury to neurological deficits.[2] In response to this problem, countries around the world have established agencies to identify chemical carcinogens, characterize their relevance to humans, and in some cases, establish safe levels of exposure through development of peer-reviewed health assessments. The most influential and most widely recognized of these organizations are the International Agency for Research on Cancer (IARC), the U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS), and the U.S. National Toxicology Program (U.S. NTP).

Each of these agencies has an established process by which it develops its specific documents and classifies chemicals as to their ability to cause cancer in humans. The final determination as to a chemical's propensity to cause cancer is published and utilized for determining the level of regulation needed in the workplace and the environment to ensure an adequate level of protection for the public's health. However, these agencies' processes and their classification schemes differ, sometimes quite significantly. As a result, one agency may classify a chemical as a human carcinogen

[*] **DISCLAIMER**: The research described herein was developed by the authors, employees of the U.S. Environmental Protection Agency (EPA), on their own time. It was conducted independent of EPA employment and has not been subjected to the Agency's peer and administrative review. Therefore, the conclusions and opinions drawn are solely those of the authors and are not necessarily the views of the Agency, EPA/600/9-91/004 at Appendix F Disclaimers and Other Notices. For discussion, see Todd Stedeford, *Prior Restraint and Censorship: Acknowledged Occupational Hazards for Government Scientists*, 31 WM. & MARY ENVTL. L. & POL'Y REV. 1 (2007).

[1] NATIONAL TOXICOLOGY PROGRAM, CURRENT DIRECTIONS AND EVOLVING STRATEGIES 4 (2006), *available at* http://ntp.niehs.nih.gov/files/NTP_CurrDir2006.pdf.

[2] U.S. EPA, Integrated Risk Information System, Benzene (CARSN 71-43-2), http://www.epa.gov/iris/subst/0276.htm (last visited May 1, 2007); U.S. EPA, Integrated Risk Information System, Mercury, elemental (CARSN 9439-97-6), http://www.epa.gov/iris/subst/0370.htm (last visited May 1, 2007).

while another does not. Moreover, some agencies provide only qualitative evaluations while others provide quantitative assessments as well. Finally, even if agencies agree that a chemical is a carcinogen, they may differ about its "mode of action." A chemical's mode of action is the sequence of events leading from exposure to cancer.[3] One agency may make specific findings as to a particular chemical's mode of action, suggesting that the chemical poses a threat only via particular exposure pathways and only in particular amounts, while another agency may make conflicting findings or no such findings at all.

Mode of action determinations are of particular importance when assessing whether a chemical poses a risk to human health in small concentrations.[4] Along a particular exposure pathway and mode of action, a chemical may pose a threat to human health even in minute concentrations. Where the level of adverse effects is proportional to the concentration of the chemical and where even small concentrations may be harmful, the mode of action is deemed to be "linear."[5] For other modes of action, it may be unlikely that a chemical will pose a threat below a certain threshold exposure concentration. Where adverse human health effects are observed only above a certain threshold concentration and where minute exposure concentrations may not have an observed effect, the mode of action is deemed to be "non-linear."[6] So, more precise determinations of the mode(s) of action by which a chemical causes adverse health effects may help to determine whether it is a linear or non-linear carcinogen.

In the face of disparate agency findings and uncertainty about the health risks posed by a chemical, it may be difficult for a country to decide on an appropriate regulatory response. The regulatory decisions are further complicated by international trade law. Since products that contain these chemicals enter a global marketplace, a country's authority to regulate or ban such products may be called into question. For example, if a country wishes to

[3] U.S. EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT 1-10 n.2 (2005), *available at* http://www.epa.gov/iris/cancer032505.pdf (defining mode of action as "a sequence of key events and processes, starting with interaction of an agent with a cell, proceeding through operational and anatomical changes, and resulting in cancer formation").

[4] *See id.* at 1-11.

[5] *See id.* at 1-11 n.3.

[6] *Id.*

regulate formaldehyde as a known human carcinogen and to impose stringent standards for the quantity of formaldehyde that a product may contain if produced within or entering its borders, it will need to defend this decision within the framework provided by a number of international agreements.

Several multilateral environmental agreements facilitate and encourage regulation of some of the more pernicious chemicals in the world, such as hazardous wastes and persistent organic pollutants.[7] However, they are, in effect, nothing more than paper tigers when it comes to enforcement, especially when dealing with a country that has not ratified the agreement.[8] In contrast, when issues involving chemicals and trade arise, the World Trade Organization (WTO) is often called upon to resolve disputes between its members. Unlike the multilateral environmental agreements, the WTO's enforcement mechanism is enabled with unprecedented powers, which include authorizing countries to impose financial sanctions on countries that establish barriers to trade.

In light of the foregoing, three issues stand out as important in the areas of international environmental law and trade law. First, what processes are used by international agencies to determine whether a chemical is a human carcinogen? Second, in general, how does international trade law constrain a state's regulatory options? Third, how does inconsistency and uncertainty in the classification of carcinogens affect the application of international trade law?

To address the first question, Section II provides a brief introduction to three agencies that classify chemicals as carcinogens and the systems they use. Addressing the second question, Section III presents a brief overview of the General Agreement on Tariffs and Trade (GATT) and the Technical Barriers to Trade (TBT) Agreement. The emphasis of this article

[7] *See, e.g.*, Basel Convention on the Control of Transboundary Movement of Hazardous Wastes and Their Disposal, Mar. 22, 1989, 1673 U.N.T.S. 125; Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, Sept. 11, 1998, 38 I.L.M. 1; Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 40 I.L.M. 532.

[8] *See* Vienna Convention on the Law of Treaties art. 34, May 23, 1969, 1155 U.N.T.S. 331, *available at* http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf ("General rule regarding third States: A treaty does not create either obligations or rights for a third State without its consent.").

is on addressing the third question. Sections IV to VI focus on the third question. Section IV focuses on a crucial issue in challenges to WTO Member State taxes and regulations under Article III of the GATT, the issue of whether the challenged measure treats "like products" differently. The decision of the Appellate Body in the *EC-Asbestos* case is discussed in depth, as this decision shows the importance of carcinogenicity classification to the "like products" analysis. Section V considers the possibility of defending trade-restrictive measures under the Article XX exceptions to the GATT, focusing again on the treatment of Article XX(b) in *EC-Asbestos*. Then, in Section VI, we turn to another potential basis for challenges to state regulations, the TBT Agreement. We focus on the threshold inquiry of what constitutes a "technical regulation" and then on the "like products" analysis under Article 2.1 of the TBT Agreement. Finally, this study concludes with a discussion of issues that will likely be the subject of future WTO disputes involving carcinogenicity classification and mode of action characterization of chemicals.

I. INTERNATIONAL AGENCIES AND CARCINOGENICITY CLASSIFICATIONS

Countries seeking to regulate the manufacture or trade of chemicals strive to ensure that the chemicals and the products containing them do not pose unnecessary risks of cancer or other adverse effects. In their decision-making process, regulatory bodies may rely on their own research or on existing evaluations by other recognized agencies, either national or international. The results of these evaluations may differ as there is no universal system for classifying chemicals in terms of potential carcinogenicity. In general, agencies evaluate the available information, rank it based on the level or weight-of-evidence, and express their findings in terms of a descriptive categorization. Although many agencies evaluate chemicals for their carcinogenic potential, IARC generally serves as the international benchmark. When governments or private entities evaluate a chemical's carcinogenicity, they often rely on IARC evaluations considered together with descriptors from IRIS and the U.S. NTP. In order to understand the important differences between IARC, IRIS, and U.S. NTP evaluations, a brief description of each agency, along

with the weight-of-evidence descriptors used by each, is provided below.[9]

A. *International Agency for Research on Cancer*

In 1965, in order to promote international collaboration in cancer research, the 18th World Health Assembly established the International Agency for Research on Cancer as an extension of the World Health Organization.[10] IARC's mission is to identify cancer etiology and develop preventative measures or, in other words, to coordinate and conduct "cancer research for cancer control."[11] IARC first developed criteria for evaluating carcinogenic risk to humans in 1971.[12] Since that time these criteria have undergone several revisions spearheaded by ad-hoc working groups.[13] In the 1980s, IARC expanded its program from evaluating the human carcinogenic risk of individual chemicals to assessing risks associated with exposures to complex mixtures and other agents such as radiation and viruses.[14]

IARC classifies chemicals into one of five categories based on the level of carcinogenic risk to humans. Unlike other classification systems, the IARC system involves independently weighing evidence from human and animal studies before classifying chemicals based on the overall weight of evidence.[15]

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[9] For an in-depth discussion of these agencies, the similarities and differences between the weight-of-evidence descriptors used by each, and an analysis of the common chemicals that each has evaluated, see Amanda S. Persad, Todd Stedeford & Michael Dourson, *Classifying Chemicals as Carcinogens: An Analysis of the Weight-of-Evidence Descriptors Used by IARC, IRIS, and NTP*, 1 APPALACHIAN NAT. RESOURCES L.J. (forthcoming 2007).

[10] International Agency for Research on Cancer, IARC Membership, http://www.iarc.fr/ENG/General/membership.php (last visited June 1, 2007); International Agency for Research on Cancer, IARC's Mission: Cancer Research for Cancer Control, http://www.iarc.fr/ENG/General/index.php (last visited June 1, 2007). *See also* Peter Boyle, *Global Player in Cancer Research: IARC Celebrates Its 40th Anniversary*, 97 J. NAT'L CANCER INST. 1400 (2005).

[11] International Agency for Research on Cancer, IARC's Mission: Cancer Research for Cancer Control, http://www.iarc.fr/ENG/General/index.php (last visited June 1, 2007).

[12] INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, PREAMBLE TO THE IARC MONOGRAPHS ON THE EVALUATION OF CARCINOGENIC RISKS TO HUMANS 19–23 (2006), *available at* http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf.

[13] *Id.*

[14] *Id.*

[15] *Id.*

As there are differences in classification methodology, weight of evidence descriptors by IARC may not be equivalent to designations by other agencies. Table 1 outlines the classification system used by IARC.

TABLE 1: WEIGHT OF EVIDENCE DESCRIPTORS USED BY IARC[16]

Descriptor	Use
Group 1: Carcinogenic to Humans	Sufficient evidence of carcinogenicity in humans, or less than sufficient evidence of human carcinogenicity but sufficient evidence of carcinogenicity in experimental animals and strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity
Group 2A: Probably Carcinogenic to Humans	Limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals
Group 2B: Possibly Carcinogenic to Humans	Limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals
Group 3: Not Classifiable as to Human Carcinogenicity	Evidence of carcinogenicity is inadequate in humans and inadequate or limited in experimental animals
Group 4: Probably Not Carcinogenic to Humans	Evidence suggesting lack of carcinogenicity in humans and in experimental animals

To date, IARC has evaluated the carcinogenicity of over 900 substances.[17] Of these, 100 substances have been listed as carcinogenic to humans.[18] Sixty-eight substances have been listed as "probably carcinogenic to humans," 246 substances as "possibly

[16] *Id.* at 22–23.

[17] *See* International Agency for Research on Cancer, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Overall Evaluations of Carcinogenicity to Humans, http://monographs.iarc.fr/ENG/Classification/crthall.php (last visited Apr. 12, 2007) [hereinafter IARC Overall Evaluations]; INTERNATIONAL AGENCY FOR RESEARCH ON CANCER, AGENTS REVIEWED BY THE IARC MONOGRAPHS: VOLUMES 1–95 (ALPHABETICAL ORDER), *available at* http://monographs.iarc.fr/ENG/Classification/Listagentsalphorder.pdf [hereinafter IARC AGENTS REVIEWED].

[18] *See* IARC Overall Evaluations, *supra* note 17; IARC AGENTS REVIEWED, *supra* note 17.

carcinogenic to humans," and 516 substances as "not classifiable as to human carcinogenicity."[19] Just one substance has been deemed "probably not carcinogenic to humans."[20]

B. *Integrated Risk Information System*

Originally designed for internal use at the U.S. Environmental Protection Agency (U.S. EPA), IRIS is now recognized worldwide as a repository of health effects information on hundreds of chemical substances in the environment. IRIS was originally intended to ensure internal consistency among the health assessments developed by various U.S. EPA Regions and Offices.[21] Public usage of IRIS expanded when it was made publicly available, first via email in 1988 and more recently on the internet.[22]

IRIS provides qualitative and quantitative chronic health information on specific chemicals. Assessments were originally released in the form of an IRIS Summary of each chemical, but more recently a detailed Toxicological Review of each chemical assessed has been composed. A particular chemical's review consists of a qualitative carcinogen classification, along with a variety of quantitative data used to evaluate public health risks. These values are used for evaluating potential public health risks from environmental contaminants as well as decision-making and regulatory activities.

Currently, the IRIS database contains over 500 chemicals, about half of which have been reviewed with regard to their carcinogenic potential.[23] Unlike IARC, the IRIS classification

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[19] *See* IARC Overall Evaluations, *supra* note 17; IARC AGENTS REVIEWED, *supra* note 17.

[20] *See* IARC Overall Evaluations, *supra* note 17; IARC AGENTS REVIEWED, *supra* note 17.

[21] Amy Mills & Gary L. Foureman, *US EPA's IRIS Pilot Program: Establishing IRIS as a Centralized, Peer-Reviewed Data Base with Agency Consensus*, 127 TOXICOLOGY 85, 86 (1998).

[22] *Id.* at 86–87. Direct access to IRIS is available at U.S. EPA, Integrated Risk Information System, http://www.epa.gov/iris/ (last visited Apr. 12, 2007).

[23] Searching IRIS reveals a total of 282 assessments with information on carcinogenic potential. These assessments cover 246 chemicals that have been reassessed based on the implementation of updated Guidelines for Carcinogen Risk Assessment, or carcinogen potential was assessed by different routes of exposure (oral versus inhalation). *See* Search IRIS, http://www.epa.gov/iris/search.htm (select all guidelines classifications under the "Search IRIS by Evidence for Human Carcinogenicity" heading and click on the

system for carcinogenic potential has undergone several revisions in the last 20 years.[24] A chemical assessed under an older guideline is not necessarily assigned a new weight of evidence descriptor with each revision of the classification system. Thus, a chemical assessed during IRIS' infancy may still carry a carcinogenicity potential descriptor based on the 1986 cancer guidelines, while a recently assessed chemical may have a descriptor based on the 2005 cancer guidelines. The vast majority of carcinogenicity assessments were conducted using the 1986 cancer guidelines (231 of 282 assessments).[25] Twenty-seven chemicals were assessed for carcinogenicity under the 1996 proposed guidelines, twenty under the review draft 1999 cancer guidelines, and four chemicals were under the final 2005 cancer guidelines.[26] Table 2 outlines the historical classification systems used by IRIS, while Table 3 presents the current classification system. For most classification categories, there is no straightforward parallel to a classification under another guideline, so there is no precise method for translating a chemical's cancer classification based on one cancer guideline to another. Thus, chemical carcinogenicity potential is accompanied by the classification system that was in force at the time of in its evaluation.

"Go" hyperlink) (last visited Apr. 28, 2007).

[24] *See* U.S. EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, 51 Fed. Reg. 33,992–34,003 (Sept. 24, 1986), *available at* http://www.epa.gov/ncea/raf/car2sab/guidelines_1986.pdf; U.S. EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, 61 Fed. Reg. 17,960–18,011 (Apr. 23, 1996), *available at* http://www.epa.gov/ncea/raf/pdfs/propcra_1996.pdf; U.S. EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (Review Draft) (1999), *available at* http://www.epa.gov/iris/cancer_gls.pdf; U.S. EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (2005), *available at* http://www.epa.gov/iris/cancer032505-final.pdf.

[25] *See* Search IRIS, http://www.epa.gov/iris/search.htm (select all 1986 guidelines classifications under the "Search IRIS by Evidence for Human Carcinogenicity" heading and click on the "Go" hyperlink) (last visited Apr. 28, 2007).

[26] *See* Search IRIS, http://www.epa.gov/iris/search.htm (select all guidelines classifications under the "Search IRIS by Evidence for Human Carcinogenicity" and click on the "Go" hyperlink) (last visited Apr. 28, 2007).

TABLE 2: WEIGHT OF EVIDENCE DESCRIPTORS BASED ON THE 1986[27], DRAFT 1996,[28] AND FINAL DRAFT 1999[29]
EPA CANCER GUIDELINES

1986 Cancer Guideline	1996 Draft Cancer Guideline	1999 Final Draft Cancer Guideline
A: Human Carcinogen - sufficient evidence from epidemiologic studies to support a causal association between exposure to the agents and cancer.	**"Known/Likely"** - available tumor effects and other key data are adequate to convincingly demonstrate carcinogenic potential for humans	**Carcinogenic to Humans** - convincing epidemiologic evidence demonstrating causality between human exposure and cancer
B1: Probable Human Carcinogen - the weight of evidence of human carcinogenicity based on epidemiologic studies is "limited."		**Likely to be Carcinogenic to Humans** - available tumor effects and other key data are adequate to demonstrate carcinogenic potential to humans
B2: Probable Human Carcinogen - sufficient evidence from animal studies and for which there is inadequate evidence or no data from epidemiologic studies		**Suggestive Evidence of Carcinogenicity** - evidence from human or animal data is suggestive of carcinogenicity, which raises a concern for carcinogenic effects but is judged not sufficient for a conclusion as to human carcinogenic potential
C: Possible Human Carcinogen - limited evidence of carcinogenicity in animals in the absence of human data.		

[27] U.S. EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, 51 Fed. Reg. 33,992, 34,000 (Sept. 24, 1986), *available at* http://www.epa.gov/ncea/raf/car2sab/guidelines_1986.pdf.

[28] U.S. EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, 61 Fed. Reg. 17,960, 17,985–86 (Apr. 23, 1996), *available at* http://www.epa.gov/ncea/raf/pdfs/propcra_1996.pdf.

[29] U.S. EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (Review Draft) at 2-43 to 2-45 (1999), *available at* http://www.epa.gov/iris/cancer_gls.pdf.

1986 Cancer Guideline	1996 Draft Cancer Guideline	1999 Final Draft Cancer Guideline
D: Not Classifiable as to Human Carcinogenicity - inadequate human and animal evidence of carcinogenicity or for which no data are available	**"Cannot be Determined"** - available tumor effects or other key data are suggestive or conflicting or limited in quantity and, thus, are not adequate to convincingly demonstrate carcinogenic potential for humans	**Data Inadequate for an Assessment of Human Carcinogenic Potential** - available data are judged inadequate to perform an assessment
E: Evidence of Non-carcinogenicity for Humans - no evidence for carcinogenicity in at least two adequate animal tests in different species or in both adequate epidemiologic and animal studies.	**"Not Likely"** – in the absence of human data suggesting a potential for cancer effects, experimental evidence is satisfactory for deciding that there is no basis for human hazard concern	**Not Likely to be Carcinogenic to Humans** - available data are considered robust for deciding that there is no basis for human hazard concern

TABLE 3: WEIGHT OF EVIDENCE DESCRIPTORS BASED ON THE 2005 EPA CANCER GUIDELINES[30]

Descriptor	Use
Carcinogenic to Humans	Strong evidence of human carcinogenicity
Likely to be Carcinogenic to Humans	The weight of the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence above descriptor
Suggestive Evidence of Carcinogenic Potential	A concern for potential carcinogenic effects in humans is raised, but the data are judged not sufficient for a stronger conclusion
Inadequate Information to Assess Human Carcinogenic Potential	Available data are judged inadequate for applying one of the other descriptors
Not Likely to be Carcinogenic to Humans	Available data are considered robust for deciding that there is no basis for human hazard concern

C. *National Toxicology Program*

Born out of the increasing scientific, regulatory, and Congressional concern about the human health effects of chemicals in the environment, the U.S. NTP was established in 1978 by the Secretary of Health, Education and Welfare (now the U.S. Department of Health and Human Services) to "coordinate toxicology testing programs within the federal government."[31] The U.S. NTP is also responsible for strengthening scientific knowledge about tested substances, developing and validating improved testing methods, and providing information about potentially toxic substances to its stakeholders, which include health, regulatory, and research agencies as well as the public.[32]

[30] U.S. EPA, Guidelines for Carcinogen Risk Assessment at 2-54 to 2-58 (2005), http://www.epa.gov/iris/cancer032505-final.pdf.

[31] Nat'l Toxicology Program, NTP: History of the NTP, http://ntp-server.niehs.nih.gov/ntpweb/index.cfm (follow "History of the NTP" hyperlink) (last visited June 1, 2007); Nat'l Toxicology Program, Toxicology in the 21st Century: The Role of the National Toxicology Program (Feb. 24, 2004), http://ntp-server.niehs.nih.gov/ntp/main_pages/NTPVision.pdf.

[32] Nat'l Toxicology Program, NTP: History of the NTP, http://ntp-server.niehs.nih.gov/ntpweb/index.cfm (follow "History of the NTP" hyperlink) (last visited June 1, 2007); Nat'l Toxicology Program, Toxicology in the 21st Century: The Role of the National Toxicology Program (Feb. 24, 2004),

Policy oversight is handled by the U.S. NTP Executive Committee, which includes representatives from these agencies as well as from the U.S. Agency for Toxic Substances and Disease Registry, the U.S. Consumer Product Safety Commission, U.S. EPA, the U.S. National Cancer Institute, and the U.S. Occupational Safety and Health Administration.[33] External scientific oversights and peer-review for the program are entrusted to the Scientific Advisory Committee on Alternative Toxicological Methods and the U.S. NTP Board of Scientific Counselors.[34] The latter body is comprised of a subgroup known as the Report on Carcinogens Subcommittee, which biennially issues the congressionally mandated Report on Carcinogens (RoC).[35] This document provides a list of known human carcinogens and substances that are anticipated to be human carcinogens, as well as brief profiles for each substance. The 11th RoC lists 58 "known" human carcinogens and 188 "reasonably anticipated" carcinogenic substances.[36] A summary of the classification criteria used in the 11th RoC is provided in Table 4.

http://ntp-server.niehs.nih.gov/ntp/main_pages/NTPVision.pdf.

[33] Nat'l Toxicology Program, NTP: Organization, http://ntp-server.niehs.nih.gov/ntpweb/index.cfm (follow "Organization" hyperlink) (last visited Apr. 19, 2007).

[34] *Id.*

[35] Nat'l Toxicology Program, NTP: Report on Carcinogens, http://ntp-server.niehs.nih.gov/ntpweb/index.cfm (follow "Report on Carcinogens" hyperlink) (last visited May 1, 2007).

[36] *Id.*

TABLE 4: LISTING CRITERIA FOR SUBSTANCES IN THE 11TH REPORT ON CARCINOGENS[37]

Descriptor	Use
Known to be Carcinogenic to Humans	Sufficient evidence of carcinogenicity from studies in humans which indicates a causal relationship between exposure to the agent, substance, or mixture, and human cancer
Reasonably Anticipated to be a Human Carcinogen	Either: • Limited evidence of carcinogenicity from studies in humans which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding factors, could not adequately be excluded • Sufficient evidence of carcinogenicity from studies in experimental animals, which indicates there is an increased incidence of malignant and/or a combination of malignant and benign tumors (1) in multiple species or at multiple tissue sites, or (2) by multiple routes of exposure, or (3) to an unusual degree with regard to incidence, site, or type of tumor, or age at onset • Less than sufficient evidence of carcinogenicity in humans or laboratory animals; however, the agent, substance, or mixture belongs to a well-defined, structurally related class of substances whose members are listed in a previous Report on Carcinogens as either known to be a human carcinogen or reasonably anticipated to be a human carcinogen, or there is convincing relevant information that the agent acts through mechanisms indicating it would likely cause cancer in humans

[37] *Id.*

D. *Summary*

Without a universal carcinogenicity classification system, agencies may and do classify chemicals differently. In some cases, IARC has found a greater risk of carcinogenicity than IRIS. For example, three chemicals, namely beryllium, cadmium, and formaldehyde, were designated as "carcinogenic to humans" by IARC, but only as "probable human carcinogens" by IRIS.[38] Additionally, IARC ranks nitrobenzene and ethylbenzene under its Group 2B as "possibly carcinogenic to humans," whereas IRIS classified these chemicals in its Category D as "not classifiable as to human carcinogenicity."[39] In other cases, IARC has found a lesser risk than IRIS and U.S. NTP. For example, IRIS has classified 1,3-butadiene as "carcinogenic to humans" under EPA's 1999 Guidelines,[40] and U.S. NTP has classified it as "known to be a human carcinogen,"[41] whereas IARC has listed it only as

[38] *See* IARC, Summary of Data Reported and Evaluation, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 58: Beryllium, Cadmium, Mercury, and Exposures in the Glass Manufacturing Industry (Aug. 22, 1997), http://monographs.iarc.fr/ENG/Monographs/vol58/volume58.pdf; IARC, Summary of Data Reported and Evaluation, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 88: Formaldehyde (2006), http://monographs.iarc.fr/ENG/Monographs/vol88/volume88.pdf; U.S. EPA, Integrated Risk Information System, Beryllium and Compounds (CASRN 7440-41-7), http://www.epa.gov/iris/subst/0012.htm (last visited June 1, 2007); U.S. EPA, Integrated Risk Information System, Cadmium (CASRN 7440-43-9), http://www.epa.gov/iris/subst/0141.htm (last visited June 1, 2007); U.S. EPA, Integrated Risk Information System, Formaldehyde (CASRN 50-00-00), http://www.epa.gov/iris/subst/0419.htm (last visited June 1, 2007). IRIS is currently re-evaluating each of these compounds.

[39] IARC, Summary of Data Reported and Evaluation, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 65: Printing Processes and Printing Inks, Carbon Black and Some Nitro Compounds (Aug. 13, 1997), http://monographs.iarc.fr/ENG/Monographs/vol65/volume65.pdf (summarizing the classification of nitrobenzene); IARC, Summary of Data Reported and Evaluation, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 77: Some Industrial Chemicals (Aug. 22, 2000), http://monographs.iarc.fr/ENG/Monographs/vol77/volume77.pdf (summarizing the classification of ethylbenzene); U.S. EPA, Integrated Risk Information System, Nitrobenzene (CASRN 98-95-3), http://www.epa.gov/iris/subst/0079.htm (last visited June 1, 2007); U.S. EPA, Integrated Risk Information System, Ethylbenzene (CASRN 100-41-4), http://www.epa.gov/iris/subst/0051.htm (last visited March 7, 2007).

[40] U.S. EPA, Integrated Risk Information System, 1,3-Butadiene (CASRN 106-99-0), http://www.epa.gov/iris/subst/0139.htm (last visited June 1, 2007).

[41] U.S. DEPT. OF HEALTH & HUMAN SERVICES, NAT'L TOXICOLOGY PROGRAM, *1,3-Butadiene*, *in* 11TH REPORT ON CARCINOGENS (2005), *available at* http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s025buta.pdf.

"probably carcinogenic to humans."[42] Similarly, IRIS has classified 1,3-dichloropropene and chlordane as a "likely carcinogen,"[43] whereas IARC has described both as only "possibly carcinogenic to humans."[44]

In addition, problems can arise even where IARC, IRIS, and the U.S. NTP use a similar qualitative descriptor for a chemical. The potential risk from *de minimis* quantities of a chemical is typically unknown, but it is sometimes computed through low dose extrapolations performed with the assumption of a linear relationship between chemical concentration and potential risk. In other words, it has sometimes been assumed that the dose or concentration of the chemical is proportional to the level of risk, so that the chemical is deemed harmful even at *de minimis* quantities. But this assumption may not be true, as is reflected in some recent IRIS assessments. For instance, IARC and IRIS classify chloroform as a possible or probable human carcinogen, respectively,[45] but IRIS has gone one step further and categorized the carcinogenic mode of action as non-linear, suggesting that minute quantities are not carcinogenic.[46] Given that mode of

[42] IARC, Summary of Data Reported and Evaluation, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 71: Re-Evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide, (Apr. 9, 1999), http://monographs.iarc.fr/ENG/Monographs/vol71/volume71.pdf (summarizing the IARC classification of 1,3-Butadiene).

[43] U.S. EPA, Integrated Risk Information System, 1,3-Dichloropropene (DCP) (CARSN 542-75-6), http://www.epa.gov/iris/subst/0224.htm (last visited June 11, 2007); U.S. EPA, Integrated Risk Information System, Chlordane (Technical) (CASRN 12789-03-6), http://www.epa.gov/iris/subst/0142.htm (last visited June 11, 2007).

[44] IARC, Summary of Data Reported and Evaluation, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 71: Re-Evaluation of Some Organic Chemicals, Hydrazine and Hydrogen Peroxide, (Apr. 9, 1999), http://monographs.iarc.fr/ENG/Monographs/vol71/volume71.pdf (summarizing the IARC classification of 1,3-Dichloropropene); IARC, Summary of Data Reported and Evaluation, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 79: Some Thyrotropic Agents (Sept. 25, 2001), http://monographs.iarc.fr/ENG/Monographs/vol79/volume79.pdf (categorizing chlordane).

[45] IARC, Summary of Data Reported and Evaluation, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 73: Some Chemicals That Cause Tumors of the Kidney or Urinary Bladder in Rodents and Some Other Substances (Sept. 29, 1999), http://monographs.iarc.fr/ENG/Monographs/vol73/volume73.pdf; U.S. EPA, Integrated Risk Information System, Chloroform (CASRN 67-66-3), http://www.epa.gov/iris/subst/0025.htm (last visited June 11, 2007).

[46] U.S. EPA, Integrated Risk Information System, Chloroform (CASRN 67-

action characterization provides greater insight on the true cancer risk, it is very likely that countries will want to use such determinations for standard setting of acceptable risks from products entering or produced within their borders. However, at this point, detailed mode of action classifications will often conflict with those assessments that assume a linear threat.

In sum, the national and international agencies that assess chemical carcinogenicity follow different processes, and there is no universal classification system for chemical carcinogenicity. As a result, chemicals may be classified differently by different countries. As we will see, this can pose a problem in international trade disputes. A recent WTO appellate body decision suggests that chemical carcinogenicity may be used to justify regulations affecting trade.[47] However, without some level of consistency in assessments of carcinogenicity, the attribution of chemical carcinogenicity may be challenged in international trade disputes.

II. INTERNATIONAL TRADE AND THE ENVIRONMENT

When regulating carcinogens, countries must not only decide which agency classification system to rely on, they must also consider the constraints posed by international trade law. This is especially true for members of the WTO. In particular, regulatory decision making must take account of the General Agreement on Tariffs and Trade (GATT) and the Technical Barriers to Trade (TBT) Agreement. This section briefly introduces the GATT/WTO system along with specific aspects of the GATT and TBT that may impact a member state's choice of establishing a health protective, yet trade restrictive measure.

A. *The GATT/WTO System*

At the end of World War II, three economic institutions (the World Bank, the International Monetary Fund, and the GATT)

66-3), http://www.epa.gov/iris/subst/0025.htm (last visited June 11, 2007). "The weight of the evidence supports the conclusion that chloroform-induced tumors in liver and kidney are produced only at dose levels that result in repeated or sustained cytotoxicity and regenerative cell proliferation. . . . The proposed dose-response relationship for chloroform tumorogenesis . . . will be nonlinear." Byron E. Butterworth, *A Classification Framework and Practical Guidance for Establishing a Mode of Action for Chemical Carcinogens*, 45 REG. TOXICOLOGY & PHARMACOLOGY 9 (2006).

[47] *See* discussion *infra* Parts IV–VI.

were established by the international community.[48] This decision was based on the premise that mutual economic dependency will foster relationships between countries so that disputes will be resolved amicably, rather than through armed conflict.[49]

In 1947, the GATT negotiations were concluded and the GATT entered into force provisionally in January 1948.[50] Originally, the GATT was intended to be only a portion of a larger agreement that would establish an International Trade Organization, but the negotiations for the Organization fell through when the U.S. Congress refused to ratify the agreement, a move that stifled the formation of an administrative structure for the GATT.[51] However, through decades of practice and a series of agreements, the GATT evolved from an agreement to an institution with a Council, Secretariat, and Committees.[52] In 1995, after the 1986–1994 Uruguay Round negotiations, major revisions were made to the original GATT leading to the establishment of the World Trade Organization (WTO).[53] Now over a decade old, the WTO continues to work towards its goal of "improv[ing] the welfare of the peoples of the member countries"[54] with the GATT being the principle rulebook for trade in goods.

The basic premise of the GATT is to ensure that goods and, more recently, services, are not discriminated against based on their national origin.[55] As stated above, this goal also has the underlying diplomatic objective of establishing an economic interdependency between countries that will also ensure international security.[56] The core principles of the GATT are

[48] *See* DAVID HUNTER ET AL., INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 1255 (3d ed. 2007).

[49] *Id.* at 1256.

[50] General Agreement on Tariffs and Trade, Oct. 30, 1947, pmbl., 61 Stat. A3, 55 U.N.T.S. 194, *available at* http://www.wto.org/english/docs_e/legal_e/gatt47_e.pdf [hereinafter GATT].

[51] HUNTER ET AL., *supra* note 48, at 1256.

[52] *Id.*

[53] WORLD TRADE ORGANIZATION, THE WORLD TRADE ORGANIZATION . . . IN BRIEF (2005), http://www.wto.org/english/res_e/doload_e/inbr_e.pdf.

[54] *Id.*

[55] HUNTER ET AL., *supra* note 48, at 1256.

[56] *Id.* ("It was widely believed by the GATT's architects that the spiraling protectionism of the 1930s had directly contributed to the economic instability accompanying the rise of fascism. Just two years after the bloodiest war in human history, protectionist trade barriers represented far more than mere commercial preferences.")

found in Article I's "Most Favored Nation"[57] obligation and Article III's "National Treatment"[58] obligation. The former requires member states to treat products from all other member states alike. Thus, if a member state wanted to waive a tax on products from one particular state, it would have to similarly waive the tax on "like products" from all other member states. Article III's "national treatment" obligation requires member states to treat the products of another state just as they treat their own "like products." So, for example, member states may not impose taxes on foreign products in excess of those imposed on domestically produced "like products."

While the obligations of Articles I and III generally admonish trade discrimination, measures inconsistent with these articles are sometimes permissible under Article XX's "general exceptions." Specifically, Article XX(b) allows trade restrictive measures "necessary to protect human, animal or plant life or health."[59]

B. *TBT Agreement*

In addition to establishing the WTO, the Uruguay Round also produced a number of companion agreements to be enforced along with the GATT. Of particular interest here is the Technical Barriers to Trade (TBT) Agreement. The TBT is aimed at minimizing trade distortions that can result when different countries establish different product standards.[60] Inconsistent standards for quality, safety and performance of products can make it difficult for the "like products" of one state to be sold in another. The TBT Agreement seeks to remove this obstacle by establishing both procedural and substantive requirements for such domestic regulations.

The TBT Agreement covers two categories of product regulation: "regulations" and "standards." Within the meaning of the agreement, both lay down criteria for product characteristics, including processes and production methods, and both "may also include or deal exclusively with terminology, symbols, packaging,

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[57] GATT, *supra* note 50, art. 1, ¶ 1.

[58] GATT, *supra* note 50, art. III, ¶¶ 1–4.

[59] *Id.* art. XX.

[60] *See* Agreement on Technical Barriers to Trade, pmbl., art 2.1, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120, *available at* http://www.wto.org/english/docs_e/legal_e/17-tbt.pdf [hereinafter TBT Agreement].

marking or labeling requirements . . . ."[61] The difference, however, is that compliance with technical regulations is mandatory, whereas compliance with technical standards is voluntary.[62] So, typically, a product must meet all relevant domestic technical regulations to enter a country's market, whereas it may only have to meet a domestic technical standard if its producer wishes to label and advertise it as meeting that standard.

Since the TBT Agreement is a part of the WTO agreement, it is binding on all WTO members. Thus, it must also be evaluated for its potential to limit a state's ability to regulate carcinogenic chemicals.

C. *"Like Products"*

This brief review of relevant trade law shows that the concept of "like products" plays a central role in international trade law administered by the WTO. States attempting to regulate carcinogenic products will want to be able to show that the targeted products are not "like" those products that are not subject to the regulation. Thus, a state's authority to regulate carcinogens, as well as other potentially harmful products, may depend on the interpretation of the phrase "like products" in Articles I and III of the GATT and in the TBT Agreement. If a state cannot defend its regulation from an Article I or Article III challenge, it will need to seek the protection of an Article XX exception. Thus, it becomes necessary to consider the appropriate interpretation of the Article XX exceptions.

In light of this, the next three parts of this paper look more closely at the interpretation of "like products" in Article III of the GATT, the applicability of the Article XX exceptions, and the interpretation of "like products" in the TBT Agreement. On each of these topics, we focus on the Appellate Body's recent decision in *EC-Asbestos*, which is particularly instructive when it comes to health-based regulations.

III. "LIKE PRODUCTS" UNDER ARTICLE III OF THE GATT 1994

The "like products" requirements of Articles I and III have

[61] *Id.* Annex 1 ¶¶ 1–2.
[62] *Id.*

stirred a considerable amount of debate between members of the trade community and environmentalists. The crux of this debate is whether the "likeness" of two products should depend only on their having similar physical characteristics and uses or whether it should also depend on the processes and production methods (PPMs) by which they are made.[63] As noted by Hunter, Salzman, and Zaelke,

> Clarifying the PPM issue is one of the most important and difficult challenges in the trade and environment debate. Environmentalists argue that the existing rules fail to provide policy-makers with sufficient clarity about the kinds of measures governments may take to address environmental impacts. Preventing or limiting countries from distinguishing between goods according to the environmental impact of their production gives foreign countries a competitive edge and places downward pressure on domestic environmental standards. It also forces importing countries to import and consume unsustainably produced goods. Trade theorists respond that differing countries may set their own environmental standards and that different preferences for environmental quality are a valid source of 'competitive advantage.'[64]

Notwithstanding the debate about the meaning of "like products" based on PPMs, the focus of the "like products" debate in the context of the regulation of carcinogens has been based on a product's physical characteristics and uses.

Despite the importance of the term "like products," the GATT and other WTO agreements do not define it. Instead, dispute settlement panels and other trade bodies have determined "likeness" on a case-by-case basis. The Contracting Parties expressly advocated this approach in 1970 with the adoption of the Report by the Working Party on Border Tax Adjustments.[65]

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[63] *See, e.g.*, Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 2, WT/DS58/AB/R (Oct. 12, 1998), *available at* http://www.wto.org/english/tratop_e/dispu_e/58abr.pdf. (The U.S. placed a ban on imported shrimp and shrimp products that were harvested from waters occupied by sea turtles if the shrimp trawlers did not use "turtle excluder devices" (TEDs) in their nets. Although shrimp and shrimp products harvested with or without TEDs are indistinguishable, the U.S. requirement distinguished shrimp products based on PPMs—that is, whether the shrimp was harvested with or without the use of TEDs.)

[64] HUNTER ET AL., *supra* note 48, at 1274–75.

[65] Report by the Working Party on Border Tax Adjustments, ¶ 18, L/3464,

However, this Report also provided some guidance by identifying three criteria to consider in carrying out the case-by-case interpretation of "like or similar products":

> [P]roblems arising from the interpretation of the term should be examined on a case-by-case basis. This would allow a fair assessment in each case of the different elements that constitute a "similar" product. Some criteria were suggested for determining, on a case-by-case basis, whether a product is "similar": the product's end-uses in a given market; consumers' tastes and habits, which change from country to country; the product's properties, nature and quality.[66]

Since the 1970s, the GATT and WTO panels and the Appellate Body have focused on and refined the interpretation of these three Working Party criteria: physical characteristics, consumer tastes and preferences, and the product's end uses.[67] In addition, they have added a fourth factor for assessing product similarity: tariff classification.[68]

With regard to chemical carcinogens, the *EC-Asbestos* case is directly on point and provides a detailed evaluation of how the GATT Panel and the Appellate Body weigh the carcinogenicity of a product in the "like products" analysis under Article III of the GATT. The *EC-Asbestos* case tested a French regulation forbidding the sale of chrysotile asbestos and most products containing such asbestos.[69] Canada challenged this measure, arguing that chrysotile fibers were "like" certain other fibers sold in the French marketplace, namely polyvinyl alcohol fibers (PVA) and cellulose & glass fibers (hereinafter, PVA and cellulose &

(Dec. 2, 1970), GATT B.I.S.D. (18th Supp.) at 97 (1970), *available at* http://www.wto.org/gatt_docs/English/SULPDF/90840088.pdf.

[66] *Id.*

[67] *See, e.g.*, Report of the Panel, *Spain—Tariff Treatment of Unroasted Coffee*, ¶ 4.5, L/5135, (adopted June 11, 1981), GATT B.I.S.D. (28th Supp.) at 102 (1981), *available at* http://www.worldtradelaw.net/reports/gattpanels/spaincoffee.pdf; Report of the Panel, *Japan-Customs Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages*, ¶ 5.6, L/6216, (adopted Nov. 10, 1987), GATT B.I.S.D. (34th Supp.) at 83 (1987), *available at* http://www.worldtradelaw.net/reports/gattpanels/japanliquor.pdf.

[68] *See, e.g.*, Report of the Panel, *EEC Measures on Animal Feed Proteins*, L/4599 (Mar. 14, 1978), GATT B.I.S.D. (25th Supp.) at 49 (1978), *available at* http://www.wto.org/gatt_docs/English/SULPDF/90940259.pdf.

[69] Apellate Body Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶¶ 1–2, WT/DS135/AB/R (Mar. 12, 2001), *available at* http://www.wto.org/english/tratop_e/dispu_e/135abr_e.pdf [hereinafter EC-Asbestos].

glass fibers are referred to as 'PCG fibers'). The Panel established by the Dispute Settlement Body of the WTO sided with Canada on this issue, finding that chrysotile asbestos fibers and PCG fibers are "like products" under Article III:4 and that asbestos-based cements are "like" PCG-based cements.[70] In making this determination, the Panel based its approach on the four Working Party criteria.[71] However, the Panel declined to consider the comparative risks posed by the products, either as an independent criteria for likeness or under any of the other likeness criteria.[72]

On appeal, the European Communities requested that the Appellate Body "reverse the Panel's findings that the two sets of products were 'like products' under Article III:4."[73] They argued that the Panel erred in its "like products" analysis by excluding the health risks posed by chrysotile fibers. According to the European Communities' interpretation, Article III:4 requires consideration of the health objective of the regulatory distinction between chrysotile asbestos products and non-asbestos products.[74] In addition, the European Communities argued that under Article III:4 products should not be considered "like" unless the regulatory distinction at issue grants favor to domestic products over imported products.[75] Thus the crux of the European Communities' appeal turned on the phrase "like products" in the following passage of Article III:4: "[t]he products of the territory of any Member imported into the territory of any other Member shall be accorded treatment no less favourable than that accorded to like products of national origin . . . ."[76]

The Appellate Body stated that "like products" must be interpreted based on the context, including the object and purpose of the specific provision at issue (*i.e.*, Article III:4), as well as the GATT as a whole.[77] Following this method, the Appellate Body began its interpretation of "like products" by addressing a key

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[70] Panel Report, *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products*, ¶¶ 8.144, 8.150, WT/DS135/R (Sept. 18, 2000) [hereinafter Asbestos Panel Report].

[71] EC-Asbestos, *supra* note 69, ¶ 85.

[72] Asbestos Panel Report, *supra* note 70, ¶¶ 8.130, 8.132.

[73] EC-Asbestos, *supra* note 69, ¶ 86.

[74] *Id.*

[75] *Id.*

[76] *Id.* ¶¶ 87–88.

[77] *Id.*

argument about the scope of "like products" in Article III:4. The phrase "like products" occurs in Article III:2 as well as Article III:4. In prior decisions interpreting Article III:2, the Appellate Body had held that "like products" was to be construed "narrowly."[78] In *EC-Asbestos*, however, the Appellate Body concluded that a similarly narrow interpretation was not required for Article III:4.

To reach this conclusion, the Appellate Body argued first that the general principle of Article III:1 "informs the rest of Article III and acts as a guide to understanding and interpreting the specific obligations contained" in each provision of Article III.[79] That general principle, it explained, is one of "prevent[ing] Members from applying internal taxes and regulations in a manner which affects the competitive relationship, in the marketplace, *between the domestic and imported products involved*, 'so as to afford protection to domestic production.'"[80] Second, it noted a contrast between Article III:2 and Article III:4. The first sentence of Article III:2 addresses the obligations of member states with respect to "like products," while the second sentence of Article III:2 addresses the obligations of member states with respect to "directly competitive or substitutable" products.[81] In contrast, Article III:4 applies only to "like products" and lacks a provision covering "directly competitive or substitutable products."[82] So, in Article III:2 the two contrasting provisions can complement each other in giving expression to the general principle of Article III. In Article III:2, "like products" need only cover what is not covered by "directly competitive or substitutable" products. But when it comes to Article III:4, "the term 'like product' . . . must be interpreted to give proper scope and meaning to this principle."[83] Thus, the phrase may need to be interpreted more broadly than in Article III:2.

Reasoning from the general principle provided in Article III:1,

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[78] *See e.g.*, Appellate Body Report, *Japan—Taxes on Alcoholic Beverages*, 19-20 H(1)(a), WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (Nov. 1, 1996), *available at* http://www.worldtradelaw.net/reports/wtoab/japan-alcohol(ab).pdf.

[79] EC-Asbestos, *supra* note 69, ¶ 93 (internal quotations omitted).

[80] *Id.* ¶ 98.

[81] *Id.* ¶ 94.

[82] *Id.*

[83] *Id.* ¶ 98.

the Appellate Body then concluded that "a determination of 'likeness' under Article III:4 is, fundamentally, a determination about the nature and extent of a competitive relationship between and among products."[84] However, it declined to rule on the precise scope of "like products" under Article III:4.[85] It concluded only that the scope was broader than that of "like products" in the first sentence of Article III:2, but "certainly *not* broader than the *combined* product scope of the *two* sentences of Article III:2 of the GATT 1994."[86]

The Appellate Body then undertook the application of "like products" to the case before it by using the same four criteria derived from the Working Party Report and used by the Dispute Settlement Body's Panel: (1) the properties, nature and quality of the products; (2) the end-uses of the products; (3) consumers' tastes and habits; and (4) the tariff classification of the products.

In addressing the first criteria—*i.e.*, properties, nature, and quality of the products—the Appellate Body criticized the Panel's discussion below. The Panel had noted the unique properties of chrysotile asbestos fibers in the course of its examination.[87] But it then suggested that since the relevant products have some applications that are similar and can replace each other, "their properties are . . . equivalent, if not identical."[88] The Appellate Body viewed this as an inappropriate means of determining "likeness" under the "property, nature and quality" criterion, holding that the "end-uses" criterion should be treated as an independent inquiry.[89] In addition, the Appellate Body disagreed with the Panel's reasoning linking shared end uses to shared properties.[90] The Appellate Body argued that products with different physical properties may have similar or identical end-uses and that the equivalence of use does not remove differences in the underlying physical properties of the products.[91]

In its own consideration of the properties, nature, and quality criterion, the Appellate Body held that chrysotile asbestos fibers

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[84] *Id.* ¶ 99.
[85] *Id.*
[86] *Id.*
[87] Asbestos Panel Report, *supra* note 70, ¶ 8.123.
[88] EC-Asbestos, *supra* note 69, ¶ 110.
[89] *Id.* ¶ 111.
[90] *Id.* ¶ 112.
[91] *Id.*

and PCG fibers are significantly different. In particular, it viewed carcinogenicity as a "defining aspect of the physical properties of chrysotile asbestos fibres" not shared by PCG fibers,[92] and it stated in strong terms that when products differ sharply in terms of carcinogenicity, this difference must be relevant under this criterion.[93] In addition, the Appellate Body dismissed the argument that considering a product's tendency to cause adverse health effects under Article III:4 would remove the purpose of the Article XX(b) exception, arguing that the inquiries under the two provisions are quite different.[94] Thus, the Appellate Body's application of the first criterion clearly supports the idea that carcinogenicity may distinguish otherwise similar products, justifying differential regulation by states.

Before evaluating the second and third criteria for "likeness"—*i.e.*, the end-uses of products and consumers' tastes and habits, respectively—the Appellate Body noted that these two criteria are particularly closely tied to the competitive relationship between products.[95] Where products have similar end-uses and where consumers' tastes and habits suggest that they are in fact interchangeable, this strongly suggests the existence of a competitive relationship between the products. Because Article III:4 is concerned precisely with the competitive relationship between products, the Appellate Body reasonably concluded that evidence supporting substitutability of products based on "end-uses" and "consumers' tastes and habits" is particularly important for evaluating the "likeness" of products.[96] The Appellate Body also added that such evidence is especially important when the products at issue in a case have been found to have quite different physical characteristics.[97]

While evaluating the end-uses criterion, the Appellate Body determined that the Panel had provided an incomplete picture for the end-uses of chrysotile asbestos fibers compared to PCG

[92] *Id.* ¶ 114.

[93] *Id.* ("We do not see how this highly significant physical difference *cannot* be a consideration in examining the physical properties of a product as part of a determination of "likeness" under Article III:4 of the GATT 1994.")

[94] *Id.* ¶ 115.

[95] *Id.* ¶ 117.

[96] *Id.*

[97] *Id.* ¶ 118.

fibers.[98] In addition to failing to distinguish the end-uses criterion from the physical characteristics criterion, the Panel had focused on a limited number of applications where the products are substitutable.[99] The Appellate Body felt that the Panel should have evaluated other different end-uses of the products and that only through an analysis of end-uses in their totality could the Panel assess the significance of the small number of applications shared by the products.[100]

For the third criterion—consumers' tastes and habits—the Panel had stated that this criterion "would not provide clear results" and declined to examine or make findings relating to it.[101] The Appellate Body noted that few situations will provide clear results and questioned how the Panel could make such a determination, considering the Panel did not examine any information for this criterion.[102] The Appellate Body was especially persuaded in this case that "evidence relating to consumers' tastes and habits would establish that the health risks associated with chrysotile asbestos fibres influence consumers' behaviour with respect to the different fibres at issue."[103] Canada argued that this criterion was irrelevant in this case because the French regulation had disturbed the competitive nature of these products.[104] The Appellate Body disagreed with this reasoning and stated that "the existence of the measure does not render consumers' tastes and habits irrelevant."[105]

Finally, addressing the fourth criterion—tariff classifications—the Appellate Body noted that the tariff classifications for the fiber types at issue were different, and although the criterion by itself is not decisive, they viewed the tariff classifications as supporting the proposition that the chrysotile asbestos fibers and PCG fibers were not "like products."[106]

Based on the analysis of all four criteria, the Appellate Body

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[98] *Id.* ¶ 119.
[99] *Id.*
[100] *Id.*
[101] *Id.* ¶ 120.
[102] *Id.*
[103] *Id.* ¶ 122.
[104] *Id.* ¶ 123.
[105] *Id.*
[106] *Id.* ¶ 140.

ruled that "[t]aken together, in our view, all of this evidence is certainly far from sufficient to satisfy Canada's burden of proving that chrysotile asbestos fibres are 'like' PCG fibres under Article III:4 of the GATT 1994. Indeed, this evidence rather tends to suggest that these products are not 'like products' for the purposes of Article III:4 of the GATT 1994."[107]

EC-Asbestos clearly supports the importance of carcinogenicity to the "like products" analysis under Article III. The decision shows that the carcinogenicity of a product, when known, can provide a clear basis for finding that two products have different properties under the first criterion for "likeness." In addition, it shows that such a finding will make it particularly difficult for a state to establish that the carcinogenic product is "like" a non-carcinogenic product. However, this tends to highlight how easily discrepancies with regard to carcinogenicity classification could impact the "like product" analysis for trade purposes. If the carcinogenicity of chrysotile asbestos fibers had not been supported by a consensus among the experts, there is little assurance that the Appellate Body would have concluded that they were different than PCG fibers. A state that could not rely on such a consensus to support its regulation of a suspected carcinogen may be forced to rely on the Article XX(b) exception allowing trade-restrictive measures aimed at protecting human health. Thus, we consider these exceptions next.

IV. ARTICLE XX EXCEPTIONS

Article XX of the GATT permits member states to apply certain measures that are inconsistent with other provisions of the GATT. The relevant exception here, Article XX(b), permits a state to regulate products to the extent "necessary to protect human, animal or plant life or health." Article XX provides in pertinent part:

> Subject to the requirements that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (b) necessary to protect human, animal or plant life

[107] *Id.* ¶ 141.

or health.[108]

A member state seeking to defend a regulation under an Article XX exception bears the burden of showing that the exception applies. For example, if, in order to protect human health, a member state wishes to implement a ban on a product that contains a specific chemical, the member will bear the burden of demonstrating that there is no alternative measure consistent with the GATT, or less inconsistent with the GATT, for the member to achieve its health policy objectives.[109] In the absence of such a showing, the measure in question will fail to meet the "necessity" requirement within the terms of Article XX(b).

An interesting outcome of the *EC-Asbestos* case was the Appellate Body's affirmation of the Panel's finding that Article XX(b) of the GATT 1994 permitted the French to ban chrysotile asbestos in order to "halt" asbestos-induced disease. Though the Panel had found that the French decree was inconsistent with Article III:4 of the GATT 1994, it went on to find that 1) asbestos poses a risk to human health, and 2) the French decree was necessary to protect human life or health.[110] Thus, the Panel concluded that the measure was permissible under the Article XX(b) exception. On appeal, Canada challenged both of the findings supporting this conclusion.

The Appellate Body first evaluated whether the Panel accurately assessed the evidence to evaluate health risks posed by chrysotile-cement products.[111] Citing its own earlier decisions, the Appellate Body noted that it reviews a Panel's factual findings according to a deferential standard.[112] These decisions made clear that the Appellate Body will not interfere with the Panel's factual findings unless they are "satisfied that the panel has *exceeded the bounds of its discretion*, as the trier of facts, in its appreciation of

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[108] GATT, *supra* note 50, art. XX.

[109] Report of the Panel, *United States – Restrictions on Imports of Tuna*, ¶ 5.22, DS21/R-39S/155 (citing GATT Panel Report, *Canada – Administration of the Foreign Investment Review Act*, ¶ 5.20, L/5504 (adopted February 7, 1984), GATT B.I.S.D., (30th Supp.) at 140 (1984)), *available at* http://www.worldtradelaw.net/reports/gattpanels/tunadolphinI.pdf; Panel Report, *Thailand—Restrictions on Importation of and Internal Taxes on Cigarettes*, ¶ 75, DS10/R (adopted Nov. 7, 1990) GATT B.I.S.D. (37th Supp.) at 200 (1990), *available at* http://www.worldtradelaw.net/reports/gattpanels/thaicigarettes.pdf.

[110] EC-Asbestos, *supra* note 69, ¶ 155.

[111] *See id.* ¶¶ 157–63.

[112] *Id.* ¶¶ 159–60.

the evidence."[113] The Appellate Body found that the Panel had relied on the concurring testimony of all of the expert witnesses it consulted, and that Panel's findings were faithful to their testimony.[114] The Panel dismissed Canada's arguments as attacks on the Panel's decision to find these experts credible and, thus, as inappropriate grounds for reversal under the deferential standard of review.[115]

Upholding the determination that chrysotile asbestos and asbestos products pose a health risk, the Appellate Body turned to the second part of the evaluation: whether the French prohibition was *necessary* to protect public health.[116] In addressing the arguments put forth by Canada on appeal, the Appellate Body made findings quite favorable to the authority of Member States to address health risks. First, Canada had argued that "the Panel had an obligation to 'quantify' . . . the risk associated with chrysotile-cement products and that it could not simply 'rely' on the 'hypotheses' of the French authorities."[117] Dismissing this argument, the Appellate Body noted that Article XX(b) does not require that the risks to human life or health be quantified, and that risk may be assessed in either qualitative or quantitative terms.[118] The Appellate Body then found that, in this case, the Panel had adequately characterized the nature of the risk by finding that "no minimum threshold level of exposure or duration of exposure has been identified with regard to the risk of [lung cancer and mesothelioma] associated with chrysotile [asbestos]."[119] Second, Canada had argued that "the Panel erred by postulating that the level of protection of health inherent in the Decree is a halt to the spread of asbestos-related health risks."[120] The Appellate Body dismissed this argument by holding that "WTO Members have the right to establish the level of protection of health that they consider

[113] *Id.* ¶ 162 (quoting Appellate Body Report, *United States—Definitive Safeguard Measures on Imports of Wheat Gluten from the European Communities*, ¶ 151, WT/DS166/AB/R, (Sept. 26, 2000), *available at* http://www.worldtradelaw.net/na/ds166-7(na).pdf).

[114] *Id.* ¶ 162.

[115] *Id.* ¶ 162.

[116] *See id.* ¶¶ 164–75.

[117] *Id.* ¶ 165.

[118] *Id.* ¶ 167.

[119] *Id.*

[120] *Id.* ¶ 165.

appropriate in a given situation."[121] More narrowly, the Appellate Body held that it is "perfectly legitimate for a Member to seek to halt the spread of a highly risky product while allowing the use of a less risky product in its place."[122] Finally, Canada had argued that "the Panel erred in finding that 'controlled use' is not a reasonably available alternative to the Decree."[123] The Appellate Body agreed with the Panel that "controlled use" was inappropriate given that "France could not reasonably be expected to employ *any* alternative measure if that measure would involve a continuation of the very risk that the Decree seeks to 'halt.'"[124] Thus, the Appellate Body held that in response to a finding that a chemical poses a non-threshold or "linear" health risk, Article XX(b) permits a Member State to attempt to remove the risk entirely by prohibiting products containing the chemical.

The outcome in *EC-Asbestos* seems to set the stage for future measures that may aggressively exclude carcinogenic substances from products entering the enforcing Member's borders. However, the Appellate Body's support for a complete ban turned on the fact that no threshold had been found below which chrysotile asbestos could be said to be safe. Thus, the *EC-Asbestos* case, up to this point, may not support a complete ban for a non-linear carcinogen. For a non-linear carcinogen, controlled-use may remove the health risks posed by products that contain non-linear carcinogens. With the increasing trend among international agencies toward assessing not only the carcinogenic potential of a substance, but also the mode of action by which it causes cancer, the rationale supporting the French decree may be called into question in future cases, where one or more agencies find that a chemical is a non-linear health risk.[125]

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[121] *Id.* ¶ 168.

[122] *Id.*

[123] EC-Asbestos, *supra* note 69, ¶ 165. Canada also argued that the Panel erred in finding, on the basis of the scientific evidence before it, that chrysotile-cement products pose a risk to human health; however, the Appellate Body noted simply that it had already dismissed this contention in the first part of the evaluation. *Id.* ¶¶ 165–66.

[124] *Id.* ¶ 174.

[125] *See, e.g.*, U.S. EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT, *supra* note 3, at 2-14; Alan R. Boobis et al., *IPCS Framework for Analyzing the Relevance of a Cancer Mode of Action for Humans*, 36 CRITICAL REVIEWS IN TOXICOLOGY 781 (2006); INT'L PROGRAMME OF CHEMICAL SAFETY, IPCS FRAMEWORK FOR ANALYSING THE RELEVANCE OF A CANCER MODE OF ACTION FOR HUMANS (2006), *available at* http://www.who.int/entity/

Fortunately, some guidance on how scientific evidence is weighted and how to deal with divergent scientific opinion was provided by way of the Appellate Body's discussion of Canada's final argument under Article XX(b). According to Canada, Article 11 of the Dispute Settlement Understanding (DSU) required the Panel to assess the scientific evidence "in accordance with the principle of the balance of the probabilities."[126] In addition, Canada asserted that when the evidence is "divergent or contradictory," a panel must follow the "principle of the preponderance of evidence" and take a weight of the evidence approach for evaluating evidence.[127] In response to this claim, the Appellate Body once again recognized that Canada was challenging the Panel's "exercise of discretion in assessing and weighing the evidence."[128] The Appellate Body reiterated that such interpretations would only be questioned if it seemed that the Panel has abused its discretion as the trier of fact, which in this case, it had not.[129] However, the Appellate Body went further to hold that Member States may rely on non-unanimous and even minority scientific opinion to justify a health related measure:

> In justifying a measure under Article XX(b) of the GATT 1994, a Member may also rely, in good faith, on scientific sources which, at that time, may represent a divergent, but qualified and respected, opinion. A Member is not obliged, in setting health policy, automatically to follow what, at a given time, may constitute a majority scientific opinion.[130]

From this, the Appellate Body concluded that the Panel did

ipcs/methods/harmonization/areas/poster.pdf.

[126] EC-Asbestos, *supra* note 69, ¶ 176. *See also*, Understanding on Rules and Procedures Governing the Settlement of Disputes art. 11, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2 33 I.L.M. 1125, 1226 (1994), *available at* http://www.wto.int/english/docs_e/legal_e/28-dsu.pdf ("The function of panels is to assist the DSB in discharging its responsibilities under this Understanding and the covered agreements. Accordingly, a panel should make an objective assessment of the matter before it, including an objective assessment of the facts of the case and the applicability of and conformity with the relevant covered agreements, and make such other findings as will assist the DSB in making the recommendations or in giving the rulings provided for in the covered agreements. Panels should consult regularly with the parties to the dispute and give them adequate opportunity to develop a mutually satisfactory solution.").

[127] EC-Asbestos, *supra* note 69, ¶ 176.

[128] *Id.* ¶ 177.

[129] *Id.*

[130] *Id.* ¶ 178.

not need to base its conclusions under Article XX(b) on the preponderance of the evidence.[131]

The above finding supports the notion that a Member may choose to base a measure on a minority view within the scientific community. However, given that the scientific experts and international bodies relied upon were in agreement that chrysotile asbestos fibers and chrysotile-cement products present a risk to human health,[132] it may be considered dicta. Additionally, the Appellate Body's statements here do not address how future panels or appellate bodies may interpret evidence based on a minority view that is outdated or possibly "cutting edge." At present, the Appellate Body's view that a panel need not reach a decision based on the preponderance of the weight of evidence is reasonable for settling the scientific aspects of an Article XX(b) defense. While many questions remain, the Appellate Body's treatment of Article XX(b) provides significant support for the authority of WTO Members to regulate carcinogenic chemicals, even in the face of scientific uncertainty. However, many measures to control carcinogenic chemicals can also be challenged under the TBT Agreement, to which the Article XX(b) exception does not apply. So, we must consider the applicability of the TBT Agreement next.

V. AGREEMENT ON TECHNICAL BARRIERS TO TRADE

As discussed previously, a Member may attempt to challenge measures not only under Article III of the GATT, but also as technical regulations under Article 2 of the TBT Agreement. Article 2.1 of the TBT Agreement imposes an obligation quite similar to Article III. Members are required to ensure that their "technical regulations" do not cause imported products to be accorded treatment less favorable than that accorded to "like products" of national origin or to "like products" originating from another country.[133] There are two important differences between this obligation and the obligations imposed by Article III of the GATT. First, it applies only to "technical regulations," so it is crucial to understand this term. Second, while a measure that is inconsistent with Article III of the GATT may be justified under

[131] *Id.*

[132] *Id.* ¶ 162.

[133] TBT Agreement, *supra* note 60, art. 2.1.

the general exceptions of Article XX, the TBT Agreement lacks such a safe harbor provision. So, in order to defend a "technical regulation" a member state will need to show that it does not discriminate between "like products."

Unlike Article III of the GATT, the TBT Agreement integrates consideration of the states' authority to control human health hazards throughout its other restrictions on technical regulations. In addition to the obligations of Article 2.1, the TBT Agreement includes obligations on WTO Members aimed at "harmonizing" product standards.[134] To accomplish harmonization, the TBT Agreement requires WTO members to establish technical regulations that are "no more trade-restrictive than necessary to fulfill legitimate objectives," which may include: "national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment."[135] These legitimate objectives are weighed against the risks that non-fulfillment would create, and are to be assessed based on "available scientific and technical information, related processing technology or intended end-uses of products."[136] Moreover, Members are to base their technical regulations on available international standards, established by international standard-setting bodies.[137] However, when the available international standard "would be an ineffective or inappropriate means for the fulfillment of" legitimate objectives, Members are not required to base their technical regulations on such standards.[138] Article 2.4 of the TBT agreement articulates several examples of factors that may make an international standard inappropriate for a particular Member State, including "fundamental climatic or geographical factors or fundamental technological problems."[139] While this consideration of a Member's interest in regulating health risks and other "legitimate objectives" limits the scope of these harmonizing obligations, it appears absent from Article 2.1's national treatment and most favored nation obligations.

It is important to note that Article 2.1 of the TBT Agreement,

134 *Id.* arts. 2.2–2.6.
135 *Id.* art. 2.2.
136 *Id.*
137 *Id.* art. 2.4.
138 *Id.*
139 *Id.*

like the GATT, does not explain the scope of the terms "like products." Therefore, the interpretation may be coextensive with "like products" under GATT Article III:2, with "like products" under GATT Article III:4, or entirely different. In *EC-Asbestos*, the Appellate Body also determined that the French ban on asbestos and asbestos products constituted a technical regulation within the meaning of the TBT Agreement. However, the Appellate Body never revisited the "like product" issue within Article 2.1 of the TBT Agreement. Still, their interpretation of what constituted a technical regulation was the first of its kind. Since the issue of whether a measure is a technical regulation is a threshold inquiry in a challenge under the TBT Agreement, the Appellate Body's treatment of the issue is discussed below. We will then discern what we can about the meaning of "like products" in Article 2.1 of the TBT Agreement.

A. EC-Asbestos

In addition to arguing that the French measure prohibiting the use of chrysotile asbestos fibers in products entering its borders violated Article III of the GATT 1994, Canada argued that the measure was inconsistent with Article 2, paragraphs 1, 2, 4, and 8 of the TBT Agreement.[140] The Panel analyzed the application of the TBT agreement to the French decree in two stages. First, the Panel evaluated the part of the decree that prohibits the marketing of asbestos and asbestos-containing products.[141] Second, the Panel evaluated the exceptions portion of the French decree.[142] The Panel found that the prohibition was not a "technical regulation," but the exceptions did constitute a "technical regulation."[143] Since the Panel viewed Canada's complaints as arising under the prohibition section of the French decree, the Panel did not evaluate Canada's Article 2 claims under the TBT Agreement.[144]

On appeal, Canada challenged the Panel's finding that the French decree was not a "technical regulation" as defined in Annex 1 of the TBT Agreement, and it restated its arguments under Article 2.[145] The Appellate Body viewed the interpretation

[140] EC-Asbestos, *supra* note 69, ¶ 10.
[141] *Id.* ¶ 60.
[142] *Id.*
[143] *Id.*
[144] *Id.*
[145] *Id.* ¶ 14.

of "technical regulation" as the threshold issue for determining whether to proceed to Canada's Article 2 arguments.[146]

The Appellate Body rejected the Panel's two-stage interpretation of the decree, stating, "the proper legal character of the measure at issue cannot be determined unless the measure is examined as a whole."[147] The Appellate Body then went on to determine whether the decree was consistent with the definition of a "technical regulation" under Annex 1 of the TBT Agreement.[148] It noted that Annex 1 of the TBT Agreement defines a "technical regulation" as a:

> Document which lays down *product characteristics* or their related processes and production methods, including the *applicable administrative provisions*, with which *compliance is mandatory*. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling [*sic*] requirements as they apply to a product, process or production method.[149]

Analyzing this definition, the Appellate Body first noted that a technical regulation is fundamentally a document that lays down "product characteristics."[150] It then expanded on the meaning of the phrase "product characteristics." In their view, a product's characteristics include "any objectively definable 'features', 'qualities', 'attributes' or other 'distinguishing mark' of a product."[151] Second, the Appellate Body stressed that compliance with a technical regulation's description of a product's characteristics must be mandatory.[152] Combining these two requirements, the Appellate Body noted that technical regulations either affirmatively require products to have certain characteristics or, negatively, mandate that they not have certain characteristics.[153]

Additionally, the Appellate Body noted the practical importance of being able to identify the products to which the

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[146] *Id.* ¶ 59.
[147] *Id.* ¶ 64.
[148] *Id.* ¶ 66.
[149] *Id.* ¶ 66 (quoting TBT Agreement, *supra* note 60, Annex 1.1) (emphasis supplied by the Appellate Body).
[150] *Id.* ¶ 67
[151] *Id.*
[152] *Id.* ¶ 68.
[153] *Id.* ¶ 69.

regulation applied.[154] However, it noted that nothing in the TBT Agreement expressly states that the covered products must be named or identified in the technical regulation and that legitimate administrative reasons may obviate the naming of products, so long as they are identifiable based on characteristics that are the subject of the regulation.[155]

Based on the above considerations, the Appellate Body determined that the French decree was a technical regulation because it laid down mandatory product characteristics for all products that might contain asbestos.[156] Specifically, it required that they not contain asbestos. In addition, in considering the measure's exceptions, the Appellate Body noted the appropriate administrative provisions were laid out for exceptions to the prohibition, as required by the definition.[157] The Appellate Body emphasized, however, that their interpretation of the French decree as a technical regulation did not transform "*all* internal measures covered by Article III:4 of the GATT 1994 'affecting' the 'sale, offering for sale, purchase, transportation, distribution or use'" of a product into "technical regulations" within the meaning of the TBT Agreement.[158]

Though the Appellate Body found that the threshold inquiry was satisfied, and that the French measure was therefore subject to the requirements of the TBT Agreement, the Appellate Body declined to examine Canada's claims under Article 2 of the TBT Agreement.[159] Because the Panel had reached the opposite conclusion on the threshold question, it did not explore Canada's claims under Article 2 of the TBT agreement further. In light of the limited facts on the record and the lack of prior legal findings, both in the Panel's decision and in earlier cases, the Appellate Body held that addressing these claims for the first time on appeal was not appropriate.[160] Similarly, when the Appellate Body had opportunity to revisit this issue in *EC-Sardines*, they again declined to embark on uncharted territory, although they upheld the *EC-Asbestos* ruling as to what constitutes a "technical

[154] *Id.* ¶ 70.
[155] *Id.*
[156] *Id.* ¶ 75.
[157] *Id.* ¶¶ 73–75.
[158] *Id.* ¶ 77.
[159] *Id.* ¶¶ 78–83.
[160] *Id.* ¶ 82–83.

regulation."[161]

B. *"Like Products" Under Article 2.1*

Although the Appellate Body determined what constitutes a technical regulation under the TBT Agreement in *EC-Asbestos*, the scope of the term "like products" in Article 2.1 of the TBT Agreement has yet to be defined. On appeal from the Panel decision in *EC-Asbestos*, Canada argued that since the principle of national treatment in Article 2.1 of the TBT Agreement was a specific expression of Article III:4 of the GATT 1994, the scope of the term "like products" under Article 2.1 was identical to that conveyed in Article III:4.[162] Though the Appellate Body did not address this argument, it has some textual basis. Both Article 2.1 and Article III:4 state that products imported from the territory of a Member "shall be accorded treatment no less favourable than that accorded to like products of national origin . . . ."[163] The direct use of this language in both articles with regard to the same object and purpose suggests that the intended meaning of "like products" in Article 2.1 of the TBT agreement is the same as that described for "like products" under Article III:4 of the GATT 1994.

Assuming that the "like products" standard has the same scope in both Article III:4 of the GATT and Article 2.1 of the TBT Agreement, a great deal may still turn on the threshold inquiry as to whether a measure constitutes a "technical regulation." In particular, if the challenging country succeeds in showing that the measure discriminates between its products and the "like products" of national origin, then the threshold inquiry may determine the regulating country's options for defending the measure. If the measure is not viewed as a technical regulation, then a Member may be able to defend the measure adequately under an Article XX exception. However, if the measure is viewed as a technical regulation and thus in conflict with the national treatment obligation in Article 2.1 of the TBT Agreement, there is no equivalent Article XX-type exception with which a Member may justify the measure.

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[161] Appellate Body Report, *European Communities—Trade Description of Sardines* ¶¶ 195, 315, WT/DS231/AB/R (Sept. 26, 2002), http://www.worldtradelaw.net/reports/wtoab/ec-sardines(ab).pdf.

[162] EC-Asbestos, *supra* note 69, ¶ 15.

[163] GATT, *supra* note 50, art. III ¶ 4; TBT Agreement, *supra* note 60, art. 2.1.

VI. DISCUSSION

At first glance, the classification of chemicals as carcinogens by international regulatory and public health agencies may appear far removed from trade law jurisprudence. However, as outlined in this article, risk assessment decisions with regard to carcinogenicity classification and mode of action characterization may become central in future trade law disputes, particularly when DSB panels and appellate bodies must apply the "like products" standard. First, by examining the processes used by international agencies to determine chemical carcinogenicity, we found that there is no universal classification system. The criteria used to designate a chemical's potential carcinogenicity and its mode of action varies between agencies. Second, through a careful reading of the Appellate Body's *EC-Asbestos* opinion, we considered how a country may implement health protective measures that impact trade without being sanctioned by the WTO. We noted that the absence of a universal carcinogenicity classification system may complicate disputes over the weight to be given to evidence of carcinogenicity in determining "likeness" of products. These disputes have the potential to determine the outcome of a challenge to a measure under Article III:4 of the GATT or a technical regulation under Article 2.1 of TBT Agreement.

EC-Asbestos demonstrates that the Appellate Body of the WTO is attuned to environmental and health concerns, however, much remains uncertain about how the WTO DSB will resolve future trade cases involving carcinogens. This uncertainty is most acute regarding the "like products" analysis required by Article 2.1 of the TBT Agreement, which the Appellate Body has thus far avoided. However, as we have noted above, there is also significant uncertainty about how to handle cases under both Article III and the TBT Agreement when there is no uniform consensus scientific regarding a chemical's carcinogenicity and its mode of action. The remainder of this closing discussion highlights some important consequences for these future cases.

With regard to the "like product" analysis under Article III of the GATT 1994, three critical outcomes of the *EC-Asbestos* case warrant additional discussion. First, while the Appellate Body's inclusion of a product's health effects as a component of its physical characteristics was a milestone in itself, its basis for making this decision suggests that Member States may look quite

far "downstream" to show that a product may have an adverse effect on health. The Appellate Body found not only that the carcinogenicity of chrysotile asbestos fibers distinguished them from PCG fibers, but also that it distinguished cement containing asbestos fibers from cement containing PCG.[164] In doing so, it cited with approval the Panel's finding that "there is an undeniable public health risk in relation to chrysotile contained in high-density chrysotile-cement products."[165] As the risk of exposure posed by chrysotile-cement products comes largely during "construction, repair and demolition" and "transportation and disposal,"[166] this suggests that both the Panel and the Appellate Body recognized the health risks of a product later in its life cycle and not simply during its immediate intended use. If so, this may empower Member Countries with the option of banning or taxing products posing a health threat during not only on their immediate intended uses, but also during downstream activities including "transportation and disposal."

Second, the Appellate Body's decision may offer some momentum to the argument that "likeness" of products is based not only on the physical characteristics, as stated above, but also on processes and production methods (PPMs). The Appellate Body's decisions to evaluate health risks as part of the physical characteristics component of "likeness," and its willingness to consider health risks created throughout a product's life-cycle, may make it possible for states to regulate and tax some products that differ primarily in terms of their PPMs. For example, a major application for formaldehyde is its use in the wood industry, particularly as a resin in the manufacture of plywood and particleboard.[167] The resin, however, continues to emit formaldehyde after installation and constitutes a persistent source of emission.[168] The IARC classifies formaldehyde as a known

[164] EC-Asbestos, *supra* note 69, ¶¶ 114, 128.

[165] *Id.* ¶ 128.

[166] INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY, ENVIRONMENTAL HEALTH CRITERIA 203: CHRYSOTILE ASBESTOS (1998), *available at* http://www.inchem.org/documents/ehc/ehc/ehc203.htm.

[167] *See* Kristen Ebbert, Children's Health Environmental Coalition, *A Sane Home: In a Plywood, Particleboard & Pressure-Treated Wood World*, http://www.checnet.org/healthehouse/education/articles-detail.asp?Main_ID=151 (last visited Apr. 18, 2007).

[168] *See id.*; GREEN SEAL, GREEN REPORT: PARTICLEBOARD AND MEDIUM-DENSITY FIBERBOARD 1, 3 (Oct. 2001), *available at*

human carcinogen.[169] Therefore, the Appellate Body's decision in *EC-Asbestos* supports the notion that Article III permits a Member Country to ban, tax, or stiffly regulate wood products treated with formaldehyde resins but not those treated with other, less toxic resins. Based on the Appellate Body's decision, the formaldehyde-free product should not be considered a "like product" to formaldehyde-treated products, since the latter product contains a known human carcinogen that is released over time while in its immediate intended use and, ultimately, after disposal. Essentially, the rationale of *EC-Asbestos* offers one way of justifying regulations that primarily affect the way products are manufactured and processed. Such measures should not only have a positive impact on the manufacturing process of the Member Country that enacted it, but also on those of Member Countries wishing to export products there.

Finally, the Appellate Body's observation that consumers' tastes and habits "are very likely to be shaped by the health risks associated with a product which is known to be highly carcinogenic" is also of profound importance.[170] In *EC-Asbestos*, the Appellate Body stated the following:

> Consumers' tastes and habits regarding *fibres*, even in the case of commercial parties, such as manufacturers, are very likely to be shaped by the health risks associated with a product which is known to be highly carcinogenic. A manufacturer cannot, for instance, ignore the preferences of the ultimate consumer of its products. If the risks posed by a particular product are sufficiently great, the ultimate consumer may simply cease to buy that product. This would, undoubtedly, affect a manufacturer's decisions in the marketplace. Moreover, in the case of products posing risks to human health, we think it likely that manufacturers' decisions will be influenced by other factors, such as the potential civil liability that might flow from marketing products posing a health risk to the ultimate consumer, or the additional costs associated with safety procedures required to use products in the manufacturing

http://www.greenseal.org/resources/reports/CGR_particleboard.pdf.

[169] IARC, Summary of Data Reported and Evaluation, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 88: Formaldehyde (2006), http://monographs.iarc.fr/ENG/Monographs/vol88/volume88.pdf (last visited April 30, 2007).

[170] EC-Asbestos, *supra* note 69, ¶ 122.

process.[171]

The Appellate Body's claims here are illustrated by the recent reaction to findings that perfluorooctanoic acid (PFOA) is ubiquitous in the environment and measurable in the blood of individuals throughout the U.S.[172] Though no international regulatory agency has formally classified the carcinogenicity of PFOA, animal tests demonstrate its potential to cause cancer and developmental abnormalities.[173] The conveyance of this information to the public has caused a movement away from Teflon® products.[174] The 3M Company, once a leading manufacturer of PFOA, no longer sells or manufactures it, and in 2002 3M announced the completion of its phaseout of a related fluoropolymer, PFOS.[175] In addition, in February 2005, DuPont Chemical Company, another manufacturer of PFOA, settled a $107.6 million dollar class-action lawsuit with residents of a community that DuPont had polluted with PFOA.[176]

This point calls attention to the importance of public awareness of the potential hazards that exist in products, particularly those products a Member Country wishes to limit or ban. Because this information has the potential to shape both consumer and manufacturer preferences, it may have an impact on its own. But because these preferences are relevant to the determination of "like products" under Article III, public education may help a state to protect its regulations and taxes from challenges before the WTO.

If, as suggested in Section VI, the like products analyses under Article III:4 of the GATT and Article 2.1 of the TBT Agreement are equivalent, then each of the above arguments

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[171] *Id.* ¶ 122.

[172] Antonia M. Calafat, et al., *Serum Concentrations of 11 Polyfluoroalkyl Compounds in the U.S. Population: Data from the National Health and Nutrition Examination Survey (NHANES)*, 41 ENVTL. SCI. & TECH. 2237 (2007).

[173] Gerald L. Kennedy et al., *The Toxicology of Perfluorooctanoate*, 34 CRITICAL REVIEWS IN TOXICOLOGY 351 (2005); Sally S. White, et al., *Gestational PFOA Exposure of Mice is Associated with Altered Mammary Gland Development in DAMS and Female Offspring*, 96 TOXICOLOGY SCI. 133 (2007).

[174] Chris Summers, *Teflon's Sticky Situation*, BBC NEWS ONLINE, Oct. 7, 2004, http://news.bbc.co.uk/1/hi/magazine/3697324.stm.

[175] 3M, What is 3M Doing?, http://solutions.3m.com/wps/portal/3M/en_US/PFOS/PFOA/Information/Action (last visited Apr. 18, 2007).

[176] *EPA, DuPont Settle Teflon Lawsuit*, CBSNews.com, Nov. 29, 2005, http://www.cbsnews.com/stories/2005/11/29/business/main1083164.shtml.

should apply to challenges involving Article 2.1 of the TBT Agreement as well.

Interestingly, the importance of designating products as "like" has implications, which go beyond the Article III analyses. For instance, under the "like product" distinction of Article 2.1 of the TBT Agreement, problems may arise when a consensus exists that two chemicals are carcinogens, but there is disagreement about whether the chemicals are linear carcinogens or non-linear carcinogens. Products containing either chemical may be viewed as "like products" under Article 2.1 of the TBT Agreement, in so far as the chemicals have the same carcinogenicity classification. However, if WTO panels or the appellate body do not consider whether they differ in terms of being linear and non-linear carcinogens during the "like products" analysis, then a technical regulation may be regarded as inconsistent with Article 2.1 if the regulation lays down product characteristics, which include mode of action considerations.

In conclusion, the "like product" analysis based on carcinogenicity classification may have favorable outcomes as discussed above with the example of formaldehyde containing wood products and PPMs. However, with the increasing emphasis for developing health assessments and characterizing not only the carcinogenicity of a chemical but also its mode of action (e.g., linear or non-linear), it is very likely that this latter criterion (mode of action) will have detrimental effects on measures viewed under Article III:4 of the GATT that are determined to be "technical regulations" or those challenged directly under Article 2.1 of the TBT Agreement, if mode of action is not considered as part of the "like products" analysis. Problems may arise when a product contains substances identically classified by agencies with regard to carcinogenicity, but differ by mode of action, since there is no exception for measures that violate the national treatment obligation for "like products" under Article 2.1 of the TBT Agreement, as there is for measures that violate the national treatment obligation under Article III:4 of the GATT.