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Precautionary Principle Will 'Run In Place' In 2007, Trade Expert Predicts

The precautionary principle reverses the burden of proof in any regulatory regime from government to industry and requires the elimination or substitution of "lower-risk" products. Lawrence Kogan says it can significantly drive up costs related to, and diminish the value of, tangible assets, as well as intangible assets, processes and technologies.

The recent enactment of precautionary chemical regulations in Europe does not mean that 2007 will be remembered as the most significant year for global adoption of the precautionary principle, says international trade and regulatory attorney Lawrence Kogan.

Kogan is CEO of the Institute for Trade, Standards and Sustainable Development, a N.J.-based think tank whose mission includes the promotion of, among other things, economic growth, free markets, and intellectual property rights in support of "a positive global paradigm of sustainable development."

The precautionary principle, which has more than one definition, has been generally defined as a policy directing governments to restrict the use of substances regarded as potentially serious threats to public health – unless scientific evidence to the contrary is provided to regulatory authorities.

Already guiding environmental policy in the European Union, the precautionary principle has been proposed in the United States as a defining legal standard in a handful of states and municipalities – although few of these proposals have been adopted, so far (see *Insider*, Vol. 2, No. 11, "Precautionary Principle Pushed In United States," June 7, 2005).

The most recent manifestation of European adherence to the principle was the EU adoption the Registration, Evaluation and Authorization of Chemicals (REACH) Regulation, which was passed by the European Parliament on Dec. 13, and approved by the European Council of Ministers on Dec. 18.

However, just weeks before enactment of REACH, the European Communities (EC) accepted a World Trade Organization decision against a precautionary, European Union (EU) moratorium on regulatory approvals for genetically modified organisms (GMOs), such as engineered food and seed.

The complaint against the moratorium was brought to the WTO by Argentina, Canada and the United States in 2003. On Nov. 21, the EC decided against appealing the Sept. 29 EC Biotech Products decision from the WTO – but Austria has since refused to lift its moratorium.

It's unclear what measures the EC could, or would, pursue to force Austrian observance of the WTO decision. Kogan points out that the EU could face sanctions if Austria doesn't fall in line, and adds that Hungary is poised to adopt the toughest GMO ban in Europe.

Kogan predicts that, despite the political shift in Congress, 2007 will not usher in precautionary principle enactments on this side of the Atlantic. However, he feels that 2008 may be more pivotal for the precautionary principle in the United States. He also argues that adoption of the principle would threaten, among other things, U.S. protections for intellectual property rights.

THE BIOTECH DISPUTE

Besides their challenge against the de facto EU regional moratorium blocking approvals of their biotech products, Argentina, Canada and the United States also accused individual EU member states – Austria, France, Germany, Greece, Italy and Luxembourg – of violating WTO agreements by adopting biotech product bans before the EU moratorium was adopted in 1998.

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Under Article 12 of the General Agreement on Tariffs and Trade (GATT), governments may regulate trade to protect human health, or animal or plant life, provided the regulations don't discriminate or serve protectionist ends.

To ensure that the food in trade is safe, the WTO Sanitary and Phytosanitary Agreement (SPS) allows member nations to impose scientifically based restrictions as long as their SPS safeguard measures don't violate the anti-protectionist language of Article 12.

Under the SPS Agreement, nations may rely on international standards, guidelines or recommendations – like those from the Codex Alimentarius – to set SPS safeguard measures; or, they may establish their own SPS standards if they demonstrate that there is scientific justification for tougher restrictions.

The complaining countries argued, among other things, that the EU biotech-approval moratorium, along with the product-specific bans of the EU-member nations, all violated the SPS.

THE WTO DECISION

In its decision, "European Communities – Measures Affecting the Approval and Marketing of Biotech Products," the WTO dispute resolution panel addressed the accusations from each of the three countries individually. Unlike the United States' challenge, the complaints from Argentina and Canada included allegations that the EU and its member states violated the GATT and the WTO Technical Barriers to Trade Agreement (TBT), which seeks to, among other things, preserve the regulatory autonomy of individual nations while, at the same time, encouraging countries to

accept each other's standards if the standards aren't based on international norms.

The dispute resolution panel did not delve into the GATT and TBT claims. In its general findings, however, the panel said, "[B]oth the evidence provided by the European Communities and the advice provided to the Panel by the experts advising it indicate that many of the identified concerns are highly unlikely to occur in practice (e.g., the transfer of antibiotic resistance from marker genes used in the production of some biotech plants to bacteria in the human gut). On the other hand, other identified concerns, such as those relating to the development of pesticide-resistance in target insects through exposure to pesticides (including those incorporated into biotech plants) have indeed been documented to occur" – i.e., if they did not perform "adequate risk assessments" for purposes of the SPS Agreement.

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But, the panel also determined that the EU moratorium led to "undue delays" in the approval process, thereby violating the SPS agreement; that the safeguard measures of the individual nations were "inconsistent with the European Communities' WTO obligations"; that "sufficient scientific evidence was available to permit a risk assessment [for the safeguard measures] as required by the SPS agreement"; and, that the risk assessments which were performed, to some extent for some of the banned GMO's, did not "provide reasonable support for a prohibition of the biotech products at issue."

PRECAUTIONARY APPROACH

Kogan believes that the decision of the dispute resolution panel underscores the distinction between Europe's precautionary principle and a similar, but not identical, concept known as the precautionary approach – which was defined in the Declaration that emerged from the 1992 United Nations Conference on Environment and Development (a.k.a., the Rio "Earth Summit").

The complaining countries argued, among other things, that the EU biotech-approval moratorium, along with the product-specific bans of the EU-member nations, all violated the SPS.

Under Principle 15 of the Declaration, "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

"National authorities," the Declaration continues in Principle 16, "should endeavor to promote the internalization of environmental costs and the use of economic instruments, taking into account the approach that the polluter should, in principle, bear the cost of pollution, with due regard to the public interest and without distorting international trade and investment."

Under the European expression of the precautionary principle, as opposed to the precautionary approach, there isn't any consideration of "trade" or "cost-effective" response to environmental degradation.

Kogan says the WTO decision "is significant because it emphasizes that there was a technical and legal distinction between the term precautionary approach, which is embedded in many different multilateral environmental treaties, and what European governments and trans-Atlantic activist groups refer to as the precautionary principle.

"The precautionary approach," Kogan continued, "is pretty much a fact-and-context-based notion that takes into account scientific and empirical evidence to evaluate whether an adequate risk assessment was performed. The precautionary principle considers empirical risk-evaluation only after a substance has already been identified, characterized and stigmatized as posing a potential health or environmental hazard, based on non-empirical data of harm.

"The panel," Kogan added, "distinguished between the precautionary approach, which is found in Article 57 of the SPS Agreement, and the precautionary principle, which is outside the entire WTO regime.

"The WTO decision basically said," Kogan went on, "that, unless you have conducted an adequate risk assessment, you are unable to reach the point of evaluating whether you're entitled to employ precautionary measures to ban substances, products or processes of concern under SPS Article 5.7. In essence, this decision is important because it says that scientists – not legislators – determine whether a risk of health or environmental damage exists, and the level of those risks."

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TREATY ISSUES

In a Nov. 22 press release, Steve Suppan, a senior policy analyst at the Institute for Agriculture and Trade Policy, said the EC defended its biotech moratorium by reference to the UN's Cartegena Protocol on Biosafety, which has been ratified by 130 countries – and which, the IATP points out, "authorizes signatories to take a precautionary approach to regulating GE crops when there is scientific uncertainty or insufficient data about a product.

"The WTO panel ruled," the IATP continues, "that, because the U.S., Argentina and Canada have not ratified the Protocol, the EC could not use a Protocol-based defense."

"Only a diplomatic conference," said Suppan, "could reconcile commitments to divergent international treaties. By declining to appeal, the EC has allowed a very bad precedent to become a foundation for rulings on disputes about trade vs. [multilateral environmental agreements]; for example, disputes about the regulation of synthetic biology or agri-nanotechnology products."

Asked to what extent, if any, the signatories to multilateral treaties are affected by the interests of countries which are not signatories, Kogan said, "It is important that the WTO stressed, in this case, the fact that non-WTO norms such as the precautionary principle cannot be used to interpret WTO law. And, that is because the Unites States is neither a party to the Convention on Biological Diversity, nor a party to the Biosafety Protocol; therefore, the WTO panel ruled that the United States cannot be held, even for reasons of interpretation, to non-WTO norms like the precautionary principle."

AUSTRIA

If WTO agreements trump the treaties to which the EU members are signatories, will the Austrian refusal to abide by the WTO decision stand?

"Essentially," Kogan replied, "the EU is a confederation, not a federation, of states, which means that each state retains some national sovereignty while complying with a common, regional, legal framework. So, not everything is susceptible to determinations by the EC or the European Parliament.

"The EC," Kogan continued, "is aware, and willing, and actually wants to abide by the WTO decision; it has long fought those EU member states which have unilaterally decided to buck WTO laws. Austria's decision to ban GMO's, to the extent that their decision is not based on an adequate scientific risk assessment, is a violation of the WTO rules, and the EC is worried about that because it could be dragged, along with Austria, before the WTO and face sanctions, such as retaliatory tariffs, if Austria decides to continue banning GMOs.

"In 2005," Kogan added, "when the EU adopted regional GMO regulations on pre-market authorization, traceability and labeling, that whole regulatory regime was based on the notion of a quid pro quo: if the member states would drop their de facto GMO bans, then the EC would adopt this regulatory regime. The EC did adopt the regulatory regime and, obviously, the EU member states are not living up to their end of the bargain. They're being pushed this way by environmental extremists who do not respect the WTO and want to destroy it as an institution."

Meanwhile, Kogan pointed out, "Hungary has blocked some GMO seed products – based not on scientific evidence but on social and political concerns. I don't know if they will fall in line with the WTO decision, but it is my understanding that Hungary is preparing to adopt the strongest, most vociferous anti-GMO legislation in all of Europe."

CHINA

Kogan says it will be interesting to observe the Chinese response to pressures for conformity with Europe's precautionary principle.

"They are a pragmatic people," he said. "They aren't going to do what

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goes against their interests. They are likely to pay lip service to sustainable development to the extent it allows them to reap the political and technological rewards of European engagement; at the same time, however, the Chinese realize that, to maintain the growth of their economy, they must continue to develop at a very fast pace, so they are looking for any way to find a compromise paradigm for sustainable development, one that will allow them to ensure public health and environmental protection without jeopardizing their economic policies and hurting their economy. So, I see the Chinese as straddling or sitting on the fence, so to speak, and employing a 'Chinese menu' approach to sustainable development."

REACH

The REACH Regulation, which will enter into force on June 1, expressly incorporates, Kogan says, an aspect of the precautionary principle which "provides for a precedent-setting reversal of the burden of proof from government to industry."

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Under its Authorization Title, persistent bioaccumulative toxics; carcinogenic, mutagenic or reproductive toxics; and very persistent, and very bioaccumulative substances, will be banned from EU markets unless their manufacturers demonstrate that mitigation measures would reduce their risks – or that their economic and sociological benefits exceed their risks (see *Insider*, Vol. 3, No. 12, "REACH Could Require European Registrations For U.S. Inerts Exporters," Nov. 7, 2006).

According to Kogan, however, "This is not the same thing as the government undertaking a cost-benefit analysis prior to enacting a regulation – a process to which many regulations in the United States are subject. Europe has no such formal mechanism."

EU nations would submit proposals for restrictions, if any, on chemicals proposed for Authorization – with the EC making the final decisions on bans. Those decisions could go against chemicals of "very high concern" if the EC – applying the precautionary principle – determines that the chemicals are too risky for Authorization, and the data supporting their Authorization wouldn't be available for a long period of time.

Kogan maintains that, "One of the most blatant deficiencies of the REACH Regulation is not only its extra-territoriality, but also its implied choice of alternative risk management approaches. REACH is based on the notion that industry has the greatest amount of information about the products, and that this information must be publicly shared for the government to determine the risks surrounding the use of the substances and products containing them.

"Did the governments within Europe actually consider less trade-restrictive alternatives to REACH when deciding upon this regulation, and

this risk management strategy, to address these potential hazards?" Kogan continued. "If they did, which I seriously doubt, I don't think that any adequate risk assessments have been performed on the substances that they have identified as potentially harmful.

"The most insidious aspect of REACH," Kogan argues, "is its attempt to reverse the burden of proof. And, when you reverse the burden of proof and shift it from government to industry, you're demanding that industries prove that their products are, practically speaking, 100% safe. That means industry will have to prove a negative, and you cannot prove a negative, so the burden of proof will never be satisfied, and, as a result, a number of products and substances will be taken off the market and substitutes demanded in their place. There will also be various types of legal liability triggered."

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Kogan asserts that "the precautionary principle is the lever with which a reversal of the burden of proof can be achieved. If you look at the WTO EC Biotech Products case, two things are obvious: one, the EU and individual members sought to reverse the burden of proof, a priori, and without any scientific basis: they failed to provide any scientific or empirical data to demonstrate the existence and magnitude of the alleged risks from the biotech products. And, two, they failed to consider any less trade-restrictive alternatives that could have been adopted in place of the moratoria. There are a number of [WTO] panel decisions that talk about least trade-restrictive alternatives, and the other side knows that they exist, which is why they are concerned, and why they have written in the past about these alternatives being the death knell for the precautionary principle."

INTELLECTUAL PROPERTY TAKINGS

> "The most insidious aspect of REACH is its attempt to reverse the burden of proof." *Lawrence Kogan, Regulatory Attorney*

As the precautionary principle becomes more entrenched in regulatory regimes, Kogan warns, there will be a concomitant increase in the threat to intellectual property (IP) from government takings.

"Precautionary-principle based regulations will have direct and indirect effects on private property," Kogan said. "For the precautionary principle to be the basis of regulatory regimes requiring a reversal of the burden of proof, and the elimination or substitution of products, the precautionary principle can significantly drive up costs related to, and diminish the value of, fixed, tangible assets, as well as intangible assets and intangible processes and technologies. This will arise to the extent that new investments must be made and old investments must be written off to comply with the regulatory regime.

"In addition," Kogan continued, "adoption of the precautionary principle will affect the types and quality of the information that companies provide to regulators in advance as part of a substance or product dossier that regulators look at to determine the harmfulness or safety of

particular substances or products. This information is usually required as a condition precedent to obtaining market authorization. There are inadequate provisions within these laws to protect private intellectual property – copyrights and patents and trade secrets. In the case of pharmaceuticals and biotech products, it is often the case that government regulators do not abide by trade secret declarations and pass this information on to competing domestic industries, to academics, to consultants, to activists, and perhaps even to foreign competitors.

"With respect to REACH," Kogan added, "there are inadequate protections to prevent the disclosure by regulators of this proprietary information because the information they seek must be in the form of supply chain dossiers, meaning different companies along the product supply chain have to put the information in a compiled form for submission. So, there have to be [non-disclosure] agreements among the companies themselves, and they have to hope that the EU Commission and European governments will abide by those agreements and trade secret notifications to protect the information."

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Europe, Kogan said, "has a different notion of what is public and what is private information, let alone what is public versus private property. They don't believe a lot of this information is private property, as such – even though its generation required major investments of time, labor and money. Here, in the United States, we have a legal foundation for private-property-based IP, whereas, in Europe, they have a greater notion of public, international goods.

"In the United States," Kogan continued, "the Supreme Court decided, back in its 1984 opinion in [*Ruckelshaus v. Monsanto Co.*], that proprietary data recognized by state law is protected under the Fifth Amendment of the Bill of Rights. So, in The United States, if private property, including IP, is taken by the government without payment of just compensation, then the Bill of Rights is violated."

FIFRA provides for compensation in the event the government "takes" proprietary information for a "public use." REACH does not provide any of the data compensation provisions of FIFRA because, Kogan says, "the same people who promote REACH also promote compulsory licensing and other anti-IP flexibilities in the WTO [Trade-Related Intellectual Property Rights, or TRIPS] agreement. They believe that proprietary data is subject to public-interest demands. They want to reverse the burden of proof and private property ownership internationally, as well."

SUSTAINABLE DEVELOPMENT

According to Kogan, "the international advocacy for the precautionary principle, both by national governments and the activist community, is rooted in an extreme interpretation of the Rio notion of sustainable development that is characterized by negativity. As these parties have

deemed it, sustainable development seeks to remedy everything in the marketplace that is potentially harmful to society at large, including private property ownership, especially when exploited by industry; i.e., multinational companies. Therefore, in their minds, environment-centric sustainable development is the national answer to the extreme negatives of globalization.

"That's more or less the 'micro' view of where we are with the advocacy for the precautionary principle," Kogan continued. "Moving to the macro level, advocates of negative sustainable development believe that U.S.-based globalization is the cause of global inequity, the cause of global poverty and runaway materialism, as well as the cause of global environmental and social degradation. It's the cause of so-called global homogenization, American style, and, as the French have argued, it also threatens their cultural diversity. All of these things seem to evolve around this notion of sustainable development, which is based in the UN, and is hailed as the panacea for all of the negatives that you see in the world.

"These advocates believe," Kogan added, "that the precautionary principle is the indispensable lever to stop progress as we know it; to stop the way we conduct our affairs; and to change, to slow down, to stop the use of certain substances and products; to stop being wasteful; and, for civil society to have a greater say in private lives."

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TRANSITIONAL YEAR

Notwithstanding REACH implementation, 2007, Kogan predicts, will be a 'transitional year' for the precautionary principle.

"It won't necessarily be the most significant year yet to come," he said. "I think 2008 will become much more significant as we approach the presidential election. So, 2007 will be kind of a 'running-in-place' year – a changing of the framework or perspective from which we think about and look at these types of issues. Until 9/11, we all pretty much viewed the world through the post-World War II perspective. The institutions we had developed obviously needed to be updated and adjusted, and new and evolving issues needed to be addressed. Free markets, private property, and economic growth were all viewed as good things in themselves that required periodic monitoring and adjustment.

"The new framework in 2007," Kogan continued, "particularly with the new Congress in power, will increasingly become UN sustainable-development focused, and this, by necessity, will bring the precautionary principle into play within a greater number of regulatory issues. That's why you see states like California and [Gov. Arnold] Schwarzenegger shifting their position on a number of environmental issues."

Schwarzenegger, Kogan said, "wants to redeem the U.S. 'brand' abroad. In a September 23rd *Washington Post* article, he was quoted as saying that

'they' – meaning the Europeans – will 'love us' if we become more environmentally engaged, which I thought was a phenomenal statement since Mr. Schwarzenegger is Austrian by birth. Is he saying that, in order to redeem our global image, and our image before Europe, including Austria, his birthplace, that the United States must become a party to UN precautionary principle-based environmental treaties which potentially threaten our national interests and private property rights?

"Is he saying," Kogan continued, "that we should pursue multilateral rather than unilateral or international solutions to potential U.S. and/or global problems? To what extent are his state-level actions constitutionally permissible? California has the reputation for being the bellwether state for the United States, especially as concerns environmental law. Will it now serve as the 28th member of the EU as a multilateral bridge for purposes of ushering in the precautionary principle as U.S. law?"

Beyond California, Kogan observed, "there are regulatory winds of change out there. And the issues they cover range anywhere from GMO's to chemicals to antibiotics to biocides to global warming. All of these regimes are based on UN Agenda 21, which is the road map for negative sustainable development, and which, of course, requires the adoption of the precautionary principle."

The full report of the WTO dispute resolution panel investigating the charges against EU restrictions against biotech products is available at http://www.wto.org/english/news_e/news06_e/291r_e.htm.

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