HARMONIZATION ALERT

Vol. 2 No. 8 www.harmonizationalert.org November 2001 - February 2002

HARMONIZATION ALERT, a publication of Public Citizen, seeks to promote open and accountable policy-making relating to public health, natural resources, consumer safety, and economic justice standards in the era of globalization.

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NAFTA INVESTOR-TO-STATE CASES

Topic: *U.S. Investor Uses Dual Strategy to Combat Canadian Pesticide Restriction*

Contact: Andre Lemay, Deputy Director for Trade, Canadian Department of Foreign Affairs and International Trade, 613-995-1874. Karen Ras, Communications Manager, Crompton Corporation, 519-669-1671, x 386.

On November 6, 2001, the U.S.-based Crompton Corporation filed a notice with the Canadian government that it intended to bring a suit using the "investor-to-state" mechanism of the North American Free Trade Agreement (NAFTA). The company was demanding $100 million in damages due to Canadian actions to restrict the hazardous pesticide known as lindane.[1]

This case is drawing special notice for two reasons. First, the company involved is using a dual strategy, filing its NAFTA case while pursuing a similar claim in Canadian federal court. Second, the case involves a pesticide that has been at the center of a public health controversy for some time.

Since NAFTA's enactment in 1994, corporate investors in all three NAFTA countries sought to enforce unprecedented new rights and privileges granted to them by NAFTA's investment chapter (Chapter 11). To do so they have challenged a variety of national, state and local environmental and public health policies, and even domestic judicial decisions as NAFTA violations. While most of these NAFTA cases are still pending, some companies already have succeeded with these challenges.

NAFTA provides an enforcement system that allows investors to privately enforce their new investor rights outside the domestic court systems of the NAFTA member nations. Called investor-to-state dispute resolution, this mechanism empowers private investors and corporations to sue NAFTA-signatory governments in special tribunals to obtain cash compensation for government policies or actions that investors believe violate their new NAFTA rights. If a corporation wins its case, it can be awarded an unlimited amount of taxpayer dollars from the treasury of the offending nation even though it has gone around the country's domestic court system and domestic laws to obtain such an award.

Crompton Corporation's NAFTA complaint challenges Canadian restrictions on a pesticide with a long history. In technical terms, lindane is known as gamma-hexachlorocyclyhexane (g-HCH). It is used for preventing fungus on seeds, as an insecticide on foliage of fruit and nut trees, for killing insects in wood and for the eradication of lice and scabies on humans and animals.

Lindane is one of the few chemicals still remaining on the market in the same chemical class as DDT. Both are persistent organic pollutants (POPs) in the organochlorine class.[2] In June 2001, President Bush signed the Stockholm POPs Convention which is an international commitment to rid the world of the 12 worst POP chemicals including PCBs and DDT. Lindane narrowly avoided being included on the initial list.[3] The treaty provides for an on-going assessment process of old and new POP chemicals. Lindane is currently a candidate for review under the POPs treaty once the agreement is ratified by a sufficient number of nations.

Lindane has been on Pesticide Action Network's (PAN) international list of "Dirty Dozen" pesticides since 1985.[4] PAN describes lindane as "persistent in the environment, highly toxic, a suspected endocrine disruptor" that has been "linked to breast cancer."[5] The chemical has been found to contaminate surface and ground water in Canada and the U.S. The U.S. EPA considers lindane a possible human carcinogen, regulates lindane products under six separate statutes, and has restricted most uses since 1983.[6]

Lindane may be best known to consumers as the active ingredient in many anti-lice shampoos. It continues to be approved for this use by the U.S. Food and Drug Administration (FDA) even though it has been reported to cause seizures and other adverse effects in children treated for head lice.[7] The National Pediculosis Association has submitted hundreds of lindane-related adverse event reports to the FDA, including reports of seizures, behavioral changes, neuromuscular complaints, and skin eruptions.[8] After reviewing adverse event reports, including six deaths, Public Citizen petitioned the FDA to remove lindane shampoos from the market as early as 1995.[9] As of January 1, 2002, lindane was banned for treatment of lice and scabies in the state of California.[10]

According to the U.S. EPA, animal studies have demonstrated that lindane can cause liver cancer when ingested by mice.[11] Moreover, a small 1993 study of children's exposure to pesticides in Missouri found increased rates of brain cancer in children treated with lindane shampoos.[12]

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Lindane has also been linked to breast cancer. In 1990, a Finnish study published in the respected journal *Cancer* found that a type of lindane (beta-HCH) posed a significant risk factor for breast cancer.[13] Widespread use of lindane on sugar beets in Lincolnshire, England came under fire when it was discovered that breast cancer rates were 40 percent higher in that community than the national average.[14] Such studies and anecdotal evidence led to a complete ban on lindane for agricultural uses in the European Union in July of 2000 effective June 2002.[15]

Lindane has been a source of trade tensions between the United States and Canada. In both countries it is used primarily as a seed treatment to prevent seeds from being destroyed by mold or fungus while in storage or early implantation. However, while Lindane was permitted as a seed treatment for canola in Canada, the U.S. allows lindane for seed treatment of 13 other crops, but not canola.[16] American canola growers have complained that the higher cost of lindane substitutes puts them at a disadvantage, and Canadian canola growers were worried that Washington might block their imports.[17]

The governments have worked to reduce tensions by pursing a "harmonized" policy with regard to lindane and seed treatments. Under the harmonization mandates of NAFTA, Canadian and U.S. pesticide agencies are currently undertaking a joint review of lindane.[18] Rather than restricting lindane uses further, the U.S. EPA is actually considering allowing the use of lindane on canola and recently requested public comments on this proposal as part of the joint review.[19]

Crompton, formerly known as Uniroyal Chemical Company, produces a variety of specialty chemical products used in agriculture, housing and automotive products.[20] Crompton reports $2.7 billion in annual sales and employs 7,800 people in its 50 manufacturing plants in 20 countries.[21] Crompton's World Headquarters is located in Greenwich, Connecticut.

Crompton also owns a Canadian company, Crompton C./Cie, which is incorporated in the province of Nova Scotia. It has a manufacturing facility in Elmira, Ontario which produces various products including seed treatment products.[22] The Elmira plant also produced the chemical pesticide lindane under the registered trademark name of Vitavax.[23]

Beginning in 1998, the Canadian Pesticide Management Regulatory Agency (PMRA) and canola growers represented by the Canadian Canola Council[24] organized an effort to get companies who sell products containing lindane to agree voluntarily to remove canola claims from product labels by December 31, 1999.[25] This would mean that it would no longer be legal to produce new lindane products for canola seed treatment or to treat canola seeds for sale. However, old stock that was produced prior to the cut-off date could still be sold and used until July 1, 2001. After that date all sales and uses of lindane for canola/rapeseed must be terminated.[26]

This was a voluntary effort which would only be successful if all four companies selling lindane in Canada agreed. These companies were Zeneca Agro, Rhone-Poulenc, Interprovincial CO-OP and Uniroyal/Crompton. Ironically, it seems that the Canadian canola growers instigated their effort to voluntary eliminate lindane in an attempt to reduce trade tensions, not exacerbate them.

According to PMRA, the agency received a letter from the Canadian Canola Council stating that all registrants had agreed to these terms, followed by letters from the companies to this effect.[27] However, according to Crompton, the company set special conditions for its participation in the removal of lindane from the market in an October 27, 1999 letter to the pesticide agency.[28]

Crompton wrote that it would go along with the December 31 cut off, only if PMRA and EPA concluded the pending risk assessments of lindane. If the agencies proved that lindane was unsafe for

use on canola, then Crompton would not request that lindane be made legal again for use on canola seeds in Canada. However, if the PMRA failed to demonstrate that lindane had adverse health impacts, lindane would again be allowed for use on canola.[29] The company also wrote that it would not accept discontinued use after July 1, 2001, and demanded that it be able to sell its lindane product indefinitely until its stocks were depleted.[30]

As neither the Canadian government nor the company are willing to release the October 1999 letters, it is difficult to know precisely what was agreed to in this exchange. However, in Crompton's own description of the correspondence in its Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter 11, the company seems to contradict itself. The company's notice clearly states that Crompton agreed in its October 27, 1999 letter to the PMRA that "all stocks of Crompton Co's products containing lindane for use on canola/rapeseed are allowed to be used up to and including July 1, 2001."[31]

Per the agreement, Crompton stopped producing new lindane product on December 31, 1999, but continued to sell its old stock. In February 2001, Crompton alleges that PMRA publically announced that the use of lindane-based seed treatment would be prohibited after July 1, 2001, and further, purchasers and users would be subject to criminal charges and fines of up to $200,000.[32] The company claims that after this announcement, sales of lindane plummeted, even though under the voluntary agreement it was still able to sell its remaining lindane product for another six months.[33]

Before filing its Notice of Intent to pursue a NAFTA claim, in April 2001, Crompton sued the government of Canada in Canadian federal court for injunctive relief. While generally NAFTA Chapter 11 forbids companies from pursuing an action in domestic court at the same time as the NAFTA claim, NAFTA Article 1121 also contains an exception for injunctive, declaratory or other extraordinary relief not involving damages. The company demanded that the government issue public notice to inform purchasers of lindane and lindane-treated seeds that the products could be used indefinitely if purchased prior to the July 1, 2001 cutoff date.[34] The judge ruled against lindane, noting that initially Crompton agreed to the July date and finding that the public interest would be served best by supporting the original terms of the voluntary agreement.[35]

Even though they lost the first round, according to PMRA, Crompton is still pursuing its case against the agency in Canadian federal court. While still litigating in domestic court, Crompton now seeks to pursue its claim in a NAFTA tribunal. The company is using NAFTA to make a new array of arguments and is demanding reinstatement of its registration for lindane products and damages of $100 million for loss of sales, profits and good will.

Crompton's Chapter 11 claim is based on four alleged NAFTA violations. First, claiming a breach of NAFTA Article 1102 ("national treatment"), Crompton claims that it is being treated differently than its Canadian competitors, because they produce low-cost, lindane substitutes in Canada and will not be as affected by the change in policy.[36] Claiming a violation of NAFTA Article 1105 ("fair and equitable treatment"), Crompton alleges that Canada unfairly reneged on its deal with the corporation by not undertaking the promised scientific review.[37] Using Article 1106 of NAFTA, Crompton claims that the government of Canada is instituting a NAFTA-illegal "performance requirement" that negatively impacts Crompton, but which helps Canadian companies that produce substitutes.[38] Finally, Crompton charges that the Canadian government, by banning the use of lindane after July 1, 2001, has "expropriated" the company's property in violation of NAFTA Article 1110.[39]

In arguing that the governments must first offer proof that lindane is a public health problem before taking any action, the Crompton Corporation is holding the Canadian government to

a very difficult standard. "Companies are forcing governments to come up with more and more detailed scientific data at the same time that government funds for such activities are being cut back. The only way out of this dilemma is for governments to spend a lot more money on long-term scientific studies or take a more precautionary approach when the potential impact on humans and the environment is so significant," said Gina Solomon, Senior Scientist at the Natural Resources Defense Council. "If we don't take action, human health will suffer over time as more of these chemicals build up in the environment and accumulate in the food chain."[40]

Reaction to the imminent NAFTA case has been swift. Anti-toxic campaigners including PAN, Sierra Club, and the International POPs Elimination Network condemned Crompton's efforts to reverse the product ban in Canada. The groups demanded: 1) that Canada "steadfastly resist Crompton's threats" and continue to restrict lindane;[41] 2) that the NAFTA parties reopen and renegotiate the provisions of Chapter 11 to ensure the ability of national and sub-national governments to protect their citizens and the environment from toxic substances; and, 3) that the governments seek alternatives to the NAFTA model of investment liberalization in future trade agreements, particularly the Free Trade Area of the Americas (FTAA), a proposed NAFTA expansion to 31 additional countries in the Western Hemisphere.[42]

The environmental groups have drawn worrisome parallels to a similar NAFTA case filed in 1998. In that case, the U.S.-based Ethyl Corporation sued Canada for $250 million under NAFTA because Canada banned the gasoline additive MMT due to environmental and health concerns.[43] Ethyl claimed the ban violated NAFTA because it "expropriated" future profits and damaged Ethyl's reputation. After learning that the NAFTA tribunal was likely to rule against its position, the Canadian government revoked the ban, paid Ethyl $13 million, and issued a public statement declaring there was no evidence that MMT posed health or environmental risks.[44]

Ethyl Corporation's claim that restrictions on MMT "expropriated" the company's investment and the NAFTA tribunal's decision to accept the claim and allow it to proceed on the merits constitutes a significant and potentially dangerous loophole that can be used to advert regulatory action.

"Governments must be able to appropriately regulate a product to safeguard the environment or public welfare without having to pay a foreign corporation that makes or imports the substance," said David Waskow, Friends of the Earth.

There are currently four NAFTA cases pending against Canada, four against the United States and four against Mexico.

Topic: *Canadian Hemp Industry Uses Domestic Courts and NAFTA to Attack U.S. Drug Rule*

Contact: Frank Sapienza, U.S. Drug Enforcement Agency, 202-307-7183. Jean Laprise, Kenex President, 519-351-3433.

On January 14, 2002, a Canadian hemp producer notified the U.S. government that it intended to sue for compensation under the investor-to-state provisions of the North American Free Trade Agreement (NAFTA) because of a new regulation promulgated by the U.S. Drug Enforcement Agency (DEA).[45] The October 9, 2001 DEA rule instantly criminalized hemp products for human consumption in the United States. The Canadian company, Kenex Limited, imports a variety of hemp products into the U.S. market and is seeking $20 million in damages from U.S. taxpayers for the business they have lost as a result of the U.S. action.

Hemp is harvested from cannabis sativa plant, varieties of which are used in the production of marijuana. For centuries hemp fibre was an important cash crop used for making rope, sails and other tough fiber products. In the early 20th century, hemp was banned by many countries attempting to control or eliminate the production of marijuana. In recent decades, hemp has made a comeback and a wide range of hemp products are produced internationally including clothing, paper, textiles, auto parts, plastics and food products. Currently, hemp production is legal in 33 countries, including Germany, England, France, Holland, Russia and China.[46] In 1998, hemp production was legalized in Canada.[47]

In the U.S., however, the legal status of hemp has a convoluted history. The 1937 definition of marijuana in the Marihuana Tax Act outlawed marijuana production, but specifically exempted many parts of the cannabis plant used for hemp production.[48] Hemp farms produced fiber for rope and other products for the federal government during World War II, but since the 1950's hemp production has been significantly restricted. Tetrahydrocannabinol (THC) is the chemical substance in marijuana which gives it psychoactive properties. In 1968, synthetic THC was banned. The 1970 Controlled Substances Act (CSA) incorporated the ban on marijuana and synthetic THC, but also listed THC as a controlled substance and required a federal permit for hemp production.[49] Subsequently, U.S. appellate court rulings added to the confusion by finding that the 1970 CSA only applied to synthetic and not natural THC.[50]

In any case, so few federal permits have been issued that legal hemp production is essentially non-existent in the United States. Imports of hemp products, however, have been allowed, and in recent years Americans have seen more and more hemp products, from clothing to soap to waffles, on store shelves. Trace amount of THC can be found in most edible hemp products, but recent studies show that as long as the hemp is produced with low THC content, these trace amounts are unlikely to affect drug tests.[51] Marijuana can have anywhere from 3-20% THC while hemp is bred to have less than 1%.[52]

Relative to wood or other fibers, hemp is favored by environmentalists because it is a hearty and versatile renewable resource which takes little pesticides to cultivate.[53] In addition, more and more farmers in the U.S. are expressing an interest in entering the fast-growing hemp market. Even though hemp is a $100 million industry in the U.S., mainly in textiles and cosmetics which are not effected by the DEA rule, U.S. farmers have had to sit on the side-lines watching Canadian farmers and others reap the benefits of the burgeoning market.[54] U.S. tobacco farmers in particular see hemp as an attractive replacement crop for tobacco.[55]

Kenex Limited of Ontario, Canada is a producer of bulk hemp products including hemp oil, seed and fibre.[56] The company is licensed by Health Canada and the Canadian Food Inspection Agency. Kenex Canada is the owner of Kenex U.S. Ltd. incorporated in Delaware. Kenex products are used in a variety of hemp foods commonly sold in U.S. health-food stores, including energy bars, chips, pretzels, veggie burgers and salad oils. According to some estimates, the hemp food industry is a $5 million a year business, doubling in size in each of the last three years.[57]

At issue in the Kenex NAFTA claim are three rules published simultaneously in the Federal Register on October 9, 2001 by the U.S. DEA. The first "interpretive rule" states that under the Controlled Substance Act any product containing *any* amount of THC is classified as a Schedule I controlled substance.[58] Schedule I, which is one among five schedules for legal and illegal drugs, is reserved for the most dangerous and addictive drugs such as heroin and PCP. The DEA rule was effective immediately upon publication, instantly criminalizing the entire hemp food industry. Since the publication of the rule, no person can manufacture, sell or even eat hemp products made for human consumption in the U.S. The rule does provide for a 120-day grace period for the disposal

of existing inventories of products containing THC.

This rule was accompanied by two others that amended existing DEA regulations to reflect the new policy. The second "proposed rule" would revise the wording of DEA regulations to make clear that the listing of THC in Schedule I refers to both natural as well as synthetic THC.[59] The DEA requested comments on this proposed rule with a deadline of December 10, 2001. The third, is an "interim rule and request for comments" which exempts from the CSA and the new rules certain industrial products, animal feed mixtures and processed plant materials not intended for human consumption.[60] The DEA also has requested comments on this last proposed regulation.

DEA spokesman Will Glaspy argues that the agency is simply applying the law. "A lot of people did not understand the law. The clarification says if a substance contains THC and is intended to enter the body then it is an illegal product," Glaspy said.[61]

To combat the DEA rules, the hemp industry is simultaneously pursuing two parallel strategies. First, on October 19, 2001, the Hemp Industries Association and seven U.S. and Canadian hemp companies including Kenex, asked the U.S. 9th Circuit Court of Appeals to stay the new DEA rule until a full hearing on the merits.[62] The companies argue that the DEA action was not an "interpretation," but a final, substantive and legally binding rule that was promulgated without the public notice and opportunity for comment required by the U.S. Administrative Procedures Act. [63] They also argue that the U.S. failed to conduct the on-the-record rulemaking and opportunity for a hearing required by the CSA.[64] The companies also state that the rule is in violation of NAFTA Article 718 which requires 60 day prior notification to NAFTA trading partners of any new sanitary and phytosanitary measure (food, plant or animal health or safety standard) and an opportunity for interested parties to comment on the measure.

On the merits, the industry argues that Congress made the hemp trade legal and only Congress can make it illegal. The industry cited an interpretive memo sent to the DEA on March 20, 2000, by the U.S. Department of Justice (DOJ). The DOJ examined the statutes and pertinent case law to conclude that not only was hemp explicitly excluded from regulation under the CSA, but that the U.S. was not "able to regulate or prohibit the importation of 'hemp' products based on any residual or trace content of naturally occurring THC."[65] The hemp industry has also focused on why the DEA is cracking down on hemp when it has long tolerated the sale and consumption of poppy seeds. Poppy seeds, which come from the same plant that produces opium, are exempted from the CSA even though they can create a false positive in a urine drug test.[66]

Meanwhile, Kenex is also pursuing a parallel claim under NAFTA's investor-to-state mechanism. Since NAFTA's enactment in 1994, corporate investors in all three NAFTA countries have used unprecedented new rights granted to them in NAFTA's investment chapter (Chapter 11) to challenge a variety of national, state and local environmental and public health policies, and even domestic judicial decisions as NAFTA violations. This investor-to-state mechanism empowers private investors and corporations to sue NAFTA-signatory governments in special arbitration tribunals to obtain cash compensation for government policies or actions that investors believe negatively impact their profitability and violate their new rights under NAFTA. If a corporation wins its case, it can be awarded unlimited amounts of taxpayer dollars from the treasury of the offending nation even though it has gone around the country's domestic court system and domestic laws to obtain such an award.

Generally NAFTA Chapter 11 forbids companies from pursuing an action in domestic court at the same time as a NAFTA complaint. NAFTA Article 1121, however, contains an exception for injunctive, declaratory or other extraordinary relief not involving damages, thus

enabling Kenex to pursue a dual strategy.

In its letter to the U.S. government, Kenex signals the type of arguments it might make if it were to fully pursue a NAFTA Chapter 11 claim. Kenex argues that the Canadian company is being accorded less favorable treatment than their competitors, such as poppy seed producers or producers of flax oil, in violation of NAFTA's anti-discrimination or national treatment provision (Article 1102) and NAFTA's most favored nation standards (Article 1103). Kenex also claims a violation of Article 1104, which requires that NAFTA investors be granted the better of national or most favored nation treatment.[67]

The company also charges that the government's action also violates the international law principles of transparency, good faith, and proportionality required by NAFTA's guarantee to afford investors a "minimum standard" of treatment under international law (Article 1105) and NAFTA's most favored nation provision (Article 1103).[68] Further, the company argues that the fact that the rule was promulgated without opportunity for notice and comment violates the "fair and equitable treatment" standard of NAFTA Article 1105 and most favored nation standard (Article 1103).[69]

Finally, Kenex seeks to import into its NAFTA Chapter 11 claim U.S. obligations under the World Trade Organization's Sanitary and Phytosanitary Agreement (WTO SPS), which governs trade in food, animal and plant life. Kenex charges that the U.S. had an obligation under the WTO SPS to base its measure on "sound science" and to ensure the measure was no more trade restrictive than necessary.[70] Because Article 1105 requires governments to treat investors in accordance with "international law," many NAFTA investors have tried to bring obligations under other trade agreements into their NAFTA claims utilizing this article. In July 2001, the three NAFTA trade ministers issued a clarification attempting to narrow this 1105 loophole to "customary" international law, thereby excluding obligations under more recent trade agreements. However, the issue has not been ruled upon yet by any NAFTA tribunal, leaving the status of the clarification yet to be determined.

The DEA's new zero tolerance policy for food products containing THC stands in puzzling contrast to the global trade rules the U.S. has helped to promulgate in the WTO and NAFTA. These rules require governments to pursue the least trade restrictive policies possible and require scientific proof of harm before a government can take regulatory action, except in rare instances.

The U.S. has been zealous in requiring other nations to meet such conditions in their regulations[71]. Yet in its new regulations, the DEA did not put forward any new studies saying that hemp food products were posing a law enforcement or drug testing problem in the U.S. Nor did the agency present studies saying that levels of THC were higher in these hemp products than the hemp industry was declaring. The DEA also reportedly refused an official request from the Government of Canada to provide the scientific and other relevant material used for the development of the new rules as required under NAFTA and the WTO.[72] In contrast, the hemp industry touts a variety of scientific studies and argues that "the most reliable scientific research currently available indicates that even the extensive use of hemp products [conforming to industry standards] cannot lead to "confirmed positives" in urine tests for marijuana and do not cause psychoactivity or other detrimental health effects in humans."[73]

The Canadian government has taken an interest in the U.S. policy and recently sent a letter to the DEA cautioning that the ban would violate WTO rules requiring that risk-assessment be performed before products are restricted or regulated.[74] The U.S. based it successful WTO suit against the European Union's ban on artificial growth hormones in beef on this rule. Of the new DEA rule, Canadian Department of Foreign Affairs and Trade deputy director of trade Andre Lemay

stated, "We don't feel the ban is legitimate. We say, 'Show us the proof.'"[75]

On March 8, 2002, the U.S. Court of Appeals for the 9th Circuit granted the stay and blocked enforcement of the DEA rules. Oral arguments on the merits of the case are scheduled for April 8, 2002. In the meantime, the DEA has been flooded with over 115, 000 comments from the public on the criminalization of hemp foods according to a hemp industry spokesperson.[76] All but one are in favor of lifting the ban.[77] DEA Director Asa Hutchinson has stated that the DEA will take public comments into consideration as it reviews the new regulations.[78]

Whether this case is resolved in the U.S. court system, by a NAFTA tribunal or ultimately in the dispute settlement body of the WTO, it stands as a significant reminder that all U.S. policies, federal, state and local could be challenged as barriers to trade, even federal drug enforcement policies. The case also raises the specter of the U.S. as a defendant in such a case, versus the U.S. in its traditional role of plaintiff attacking another nation's law. Finally, interested observers will be watching to see if a relatively small company like Kenex, will be able to afford the extremely costly NAFTA Chapter 11 arbitration process. Kenex is among the smallest companies ever to attempt to pursue a NAFTA Chapter 11 complaint.

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Department of Agriculture

Retained Water in Raw Meat and Poultry Products: Suspension of Regulation (FSIS)
67 Fed. Reg. 1277-1281 (January 10, 2002)
Final rule; suspension of regulation. Amendments effective January 9, 2002.

Environmental Impact Statement on Proposed Release of Genetically Engineered Pink Bollworm into the Environment (APHIS)
Fed. Reg. 67 5086-5087 (February 4, 2002)
Notice of intent. Submit written or electronic comments at any time. Draft EIS for public review TBA.

Department of Health and Human Services

International Conference on Harmonization; Availability of Revised Guidance Entitled "Q1A Stability Testing of New Drug Substances and Products" (FDA)
66 Fed. Reg. 56332-56333 (November 7, 2001)
Notice. This guidance is effective November 7, 2001. Submit written or electronic comments at any time. Submit written requests for single copies of draft guidance at any time.

International Conference on Harmonization; Draft Guidance for Industry Entitled "Clinical Studies Section of Labeling for Prescription Drugs and Biologics--Content and Format" (FDA)
66 Fed. Reg. 58150-58151 (November 20, 2001)
Notice and reopening of comment period. Submit written requests for single copies of draft guidance at any time.

International Conference on Harmonization; Availability of Draft Guidance Entitled "Electronic Common Technical Document Specification" (FDA)
66 Fed. Reg. 59431-59432 (November 28, 2001)
Notice. Submit written requests for single copies of draft guidance at any time.

Veterinary International Conference on Harmonization; Availability of Draft Guidance for Industry Entitled "Pharmacovigilance of Veterinary Medicinal Products: Management of Periodic Summary Update Reports (VICH GL29)" (FDA)
66 Fed. Reg. 64450-64451 (December 13, 2001)
Notice and request for comments. Submit written requests for single copies of draft guidance at any time.

Final Rule Establishing the Notification and Recordkeeping Requirements for Exportation of Human and Animal Drugs, Food, Cosmetics, Biological Products and Devices That May Not Be Sold in the United States (FDA)
66 Fed. Reg. 65429-65448 (December 19, 2001)
Final rule. This rule is effective March 19, 2002.

Draft Guidance for Industry Entitled "Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora" (FDA)
66 Fed. Reg. 66910-66912 (December 27, 2001)
Notice and request for comments. Submit written and electronic comments until March 27, 2002. Submit written requests for single copies of draft guidance at any time.

Final Rule and Partial Stay on Sunscreen Drug Products for Over-the-Counter Human Use (FDA)
66 Fed. Reg. 67485-67487 (December, 31, 2001)
Final rule; partial stay. Rule effective January 30, 2002. Submit written and electronic comments until April 1, 2002.

Final Guidance for Industry Entitled "Safety Studies for Veterinary Drug Residues in Human Food: Reproduction Toxicity Testing (VICH GL22)" (FDA)
67 Fed. Reg. 603-605 (January 4, 2002)
Notice. Submit written or electronic comments at any time.

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices; Third-Party Pre-market Submission Review and Quality System Inspections Under United States/European Community Mutual Recognition Agreement (FDA)
67 Fed. Reg. 1770-1771 (January 14, 2002)
Notice. Submit general written or electronic comments at any time.

Draft Guidance for Industry Entitled ``Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms (VICH GL30)" (FDA)
Fed. Reg. 67 5605-5606 (February 6, 2002)
Notice. Submit written requests for single copies of draft guidance at any time.

Department of Transportation

New ARAC Task Assignment: Review the Adequacy of Current Bird Ingestion Requirements and Determine If They Establish a Minimum Standard of Safety for Transport Airplanes (FAA)
66 Fed. Reg. 56367-56368 (November 7, 2001)
Notice of new task assignment for the Aviation Rulemaking Advisory Committee.

New ARAC Task Assignment: Review and Evaluate the Current "Safe Life" Standards for Transport Airplanes and Engines (Sec. 33.14--JAR-E 515) (FAA)
66 Fed. Reg. 56366-56367 (November 7, 2001)
Notice of new task assignment for the Aviation Rulemaking Advisory Committee.

Revised Requirement for Material Strength Properties and Design Values for Transport Airplanes
67 Fed. Reg. 4317-4322 (January 29, 2002) Notice of proposed rule making.
Submit comments until April 1, 2002.

TABLE OF NAFTA CHAPTER 11 CASES

Corporation or Investor	Venue	Damages Sought (U.S. $)	Status of Case	Issue
Cases Against the United States				
Loewen Oct. 30, 1998	ICSID	$725 million	Pending	Canadian funeral conglomerate challenges Mississippi jury damage award
Mondev Sept. 1, 1999	ICSID	$50 million	Pending	Canadian real estate developer challenges Massachusetts Supreme Court ruling on local government sovereign immunity
Methanex Dec. 3, 1999	UNCITRAL	$970 million	Pending	Canadian corporation challenges California phase-out of gasoline additive MTBE, which is contaminating drinking water around the state.
ADF Group Jul. 19, 2000	ICSID	$90 million	Pending	Canadian steel contractor challenges U.S. "Buy America" law
Cases Against Canada				
Ethyl Apr. 14, 1997	UNCITRAL	$201 million	Settled; Ethyl Win, $13 million	U.S. chemical company challenges Canadian environmental regulation of gasoline additive MMT
S.D. Myers Oct. 30, 1998	UNCITRAL	$20 million	S.D. Myers Win award pending	U.S. waste treatment company challenges Canadian ban of PCB exports compliant with multilateral environmental agreement
Pope & Talbot Mar. 25, 1999	UNCITRAL	$381 million	P & T Win, award pending	U.S. timber company challenges Canada's implementation of 1996 U.S.-Canada Softwood Lumber Agreement
UPS Apr. 19, 1999	UNCITRAL	$160 million	Pending	UPS claims Canadian post office parcel delivery service enjoys unfair subsidy because it is a public service
Sun Belt Oct. 12, 1999	UNCITRAL	$10.5 billion	Pending	U.S. water company challenges British Columbia's bulk water export moratorium
Cases Against Mexico				
Metalclad Jan. 13, 1997	ICSID	$90 million	Metalclad Win, $15.6 million	U.S. firm challenges Mexican municipality's refusal to grant construction permit for toxic waste dump and State declaration of ecological zone
Azinian, *et al* Mar. 17, 1997	ICSID	$19 million	Dismissed	U.S. investors challenge Mexican federal court decision revoking waste management contract for suburb of Mexico City
Waste Management Sept. 29, 1998	ICSID	$60 million	Pending	U.S. waste disposal giant challenges City of Acapulco revocation of waste disposal concession
Karpa Apr. 7, 1999	ICSID	$50 million	Pending	U.S. cigarette exporter challenges denial of export tax rebate by Mexican government
Adams, *et al* Feb. 16, 2001	UNCITRAL	$75 million	Pending	U.S. landowners challenge Mexican court ruling that developer who sold them property did not own land
Calmark Jan. 11, 2002	UNCITRAL	$400,000	Pending	U.S. development company challenges Mexican court ruling in development dispute

NOTES:

1. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001.

2. In June 2001 President Bush signed the POPs Treaty which is an international commitment to rid the world of the 12 worst POPs including PCBs and 11 other chemicals. While lindane did not make the initial list, it is currently a candidate for review under the POPs treaty once the agreement is ratified by a sufficient number of nations.

3. Interview with Gina Solomon, Senior Scientist, Natural Resources Defense Council, Feb. 19, 2002.

4. Pesticide Action Network Updates Services (PANUPS), "Canadian Government Sues for Banning Lindane," Jan. 3, 2002.

5. Pesticide Action Network Updates Services (PANUPS), "Canadian Government Sues for Banning Lindane," Jan. 3, 2002.

6. EPA, "National Primary Drinking Water Regulations; Consumer Fact Sheet on Lindane," Office of Groundwater and Drinking Water, on file with Public Citizen.

7. Lindane Preliminary Risk Assessment; Comments submitted on behalf of the Natural Resources Defense Council et. al. by Gina Solomon, MD, MPD, Oct. 29, 2001.

8. National Pediculosis Association, "FDA Action Shows Grave Dangers of Lindane Lice Treatment," Press Release, Apr. 10, 1996.

9. Public Citizen, Citizen's Petition to Immediately Ban Lindane, June 15, 1995 on file with Public Citizen.

10. California Health and Safety Code, Section 111246.

11. U.S. EPA, 1,2,3,4,5,6-HEXACHLOROCYCLYHEXANE (all stereo isomers)(LINDANE) Hazard Summary, May 7, 2001, on file with Public Citizen.

12. Davis JR, Brownson R.C., Garci R., Bentz B.J., Turner A., "Family Pesticide Use and Childhood Brain Cancer," *Archives of Environmental Contamination and Toxicology* 1993; 24: 87-92.

13. Mussalo-Rauhamaa, Hasanen, Pyysalo, Antervo, Kaupila, Pantzar, "Occurrance of Beta-hexachlorocyclohexane in Breast Cancer Patients," *Cancer*, Nov. 15, 1990, 66 (10): 2124-2128.

14. Richard Young and Jayne Diston, "Lindane and Breast Cancer: Why take risks?," Soil Association Policy Paper, 1998.

15. The framework for regulating plant protection products on the EU market is provided in Council Directive 91/414/EEC. After review, an active substance is either added to Annex I of the Council Directive, which means its use is legal, or a decision is taken to not to add it to Annex I, which means the substance is prohibited. As of June 2002 Lindane will be prohibited from the EU market.

16. EPA, Office of Pesticide Programs Announcement, "EPA Releases Preliminary Risk Assessment for Lindane," Aug. 29, 2001, on file with Public Citizen.

17. "Ottawa Faces Suit Over Banned Pesticide," *The Globe and Mail*, Dec. 10, 2001.

18. For more information on this joint review see, www.epa.gov/pesticides/reregistration/lindane. The EPA just closed a public comment period for its lindane risk assessment on October 29, 2001. The docket number is OPP 34239.

19. 66 FR 45677 (Aug.29, 2001).

20. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001 at 2.

21. Crompton, Investor Relations Overview, Crompton Web Page, Feb. 13, 2001, on file with Public Citizen.

22. Notice of Intent to Submit A Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6 2001, at 2.

23. *Id.*

24. Canadian Pest Management Agency, *MRA Points*, Issue 8, Jan. 19, 2000.

25. Letter from C.A. Franklin, Executive Director, Pest Management Regulatory Agency, to Mr. Gene Dextrase, President Canola Growers Association, Feb. 9, 1999 on file with Public Citizen.

26. Letter from C.A. Franklin, Executive Director, Pest Management Regulatory Agency, to Mr. Gene Dextrase, President Canola Growers Association, Feb. 9, 1999 on file with Public Citizen.

27. Conversation with Marc Richard, spokesperson for PMRA Canada, Dec. 20, 2001. Neither PMRA nor Crompton would release the letters in question.

28. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 4.

29., Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 4.

30. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 4.

31. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 5.

32. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 6.

33. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 6.

34. Crompton Co./CIE v. Canada (Minister of Health and Minister of Agriculture and Agri-food) 2001 FCT 435. Date: 20010504, Docket: T-585-01. Reasons for Order and Order.

35. Crompton Co./CIE v. Canada (Minister of Health and Minister of Agriculture and Agri-food) 2001 FCT 435. Date: 20010504, Docket: T-585-01. Reasons for Order and Order.

36. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 7.

37. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 8.

38. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 10.

39. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Crompton Corp. v. Government of Canada, Nov. 6, 2001, at 10.

40. Interview with Gina Solomon, Senior Scientist, Natural Resources Defense Council, Feb. 19, 2002.

41. Letter from Alaska Community Action on Toxics et al. Jan. 22, 2002, on file with Public Citizen.

42. Letter from Alaska Community Action on Toxics et al. Jan. 22, 2002, on file with Public Citizen.

43. Statement of Defense in the Matter of an Arbitration Under Chapter 11 of the North American Free Trade Agreement between Ethyl Corporation and the Government of Canada, United Nations Commission on International Trade, Nov. 27, 1997, at 24.

44. Government of Canada, “Statement on MMT,” Jul. 20, 1998.

45. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Kenex Ltd v. The Government of the United States, Jan. 14, 2002.

46. John Roulac, "Hemp 101: Introduction from Industrial Hemp," 1997, from Nutiva web page Mar. 13, 2002, on file with Public Citizen.

47. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Kenex Ltd v. The Government of the United States, Jan. 14, 2002 at 4.

48. 21 USC § 802 (16) The U.S. definition of marijuana excludes "the mature stalks of such pant, fiber produced from such stalks, oil or cake made from the seed of such plant, any other compound, manufacture, salt derivative, mixture or preparation of such mature stalks (except resin extracted there from), fiber, oil, cake or the sterilized seed of such plant which is incapable of germination."

49. 21 CFR §1308.11 (d) (27).

50. United States v. Wuco, 535 F. 2d 1200 (9th Cir. 1976), United States v.McMahon, 861 F. 2nd (1st Cir. 1988).

51. Gero Lesson and Petras Pless, "Evaluating Interference of THC in Hemp Food Products with Employee Drug Testing," *Journal of Analytical Toxicology*, Nov/Dec 2001.

52. John Cloud, "This Bud is Not for You," *Time Magazine*, Feb. 18, 2002.

53. John Cloud, "This Bud is Not for You," *Time Magazine*, Feb. 18, 2002.

54. Michelle Morgante, "DEA Rule Banning Food Products Containing THC Challenged," *Associated Press*, Feb. 4, 2002.

55. John Cloud, "This Bud is Not for You," *Time Magazine*, Feb. 18, 2002.

56. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Kenex Ltd v. The Government of the United States, Jan. 14, 2002 at 3.

57. Hemp Industries Association, "DEA Does Homework on Hemp Foods After New Rule is Announced," Press Release, Jan 22. 2002.

58. 66 FR 51530, Oct. 9, 2001.

59. 66 FR 51535 Oct. 9, 2001.

60. 66 FR 51539 Oct. 9, 2001.

61. Michelle Morgante, "DEA Rule Banning Food Products Containing THC Challenged," *Associated Press*, Feb. 4, 2002.

62.In the United States Court of Appeals for the 9th Circuit, Hemp Industries Association et. al. vs. Drug Enforcement Administration, Asa Hutchinson as Administrator, Drug Enforcement Administration, Urgent Motion of Petitioners for Stay Pending Review, Oct. 19, 2001.

63. 5 USC § 553.

64. 21 USC § 811 (a).

65. Letter to Donnie Marshall, Acting Head of U.S. Drug Enforcement Agency, from John Roth, Chief of the Narcotics and Dangerous Drug Section, U.S. Department of Justice, Mar. 23, 2000, on file with Public Citizen. Emphasis added.

66. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Kenex Ltd v. The Government of the United States, Jan. 14, 2002, at 9.

67. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Kenex Ltd v. The Government of the United States, Jan. 14, 2002, at 9.

68. *Id.*

69. *Id.*

70. *Id.*

71. See, WTO, European Communities - Measures Affecting Meat and Meat Products (Hormones) (WT/DS26 1996) Complaint by the United States.

72. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Kenex Ltd v. The Government of the United States, Jan. 14, 2002 at 8.

73. Notice of Intent to Submit a Claim to Arbitration Under Section B of Chapter 11 of the North American Free Trade Agreement, Kenex Ltd v. The Government of the United States, Jan. 14, 2002 at 4.

74. Adria Vasil, "Hemp Madness," *Now Magazine*, Jan. 31 2002.

75. Adria Vasil, "Hemp Madness," *Now Magazine*, Jan. 31 2002.

76. Interview with Adam Eidinger, Mintwood Media, Mar. 5, 2002.

77. Interview with Adam Eidinger, Mintwood Media, Mar. 5, 2002.

78. Mintwood Media, "DEA Head Clarifies New Rule on Hemp Foods," Press Release, Jan. 31, 2002.

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