

McKenna Long & Aldridge LLP and Technology Sciences Group, Inc. are pleased to share with you our *Pesticide Law and Regulatory Bulletin*. The Bulletin reports on significant pesticide regulatory developments in the U.S., Europe and Canada and the regulation of GMOs worldwide.

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In This Issue:

- [NRDC and Four State AG's Sue EPA Over FOQA](#)
- [Another ESA Lawsuit](#)
- [2nd Circuit Hears Argument on the NPDES Issue](#)
- [EPA Scientists Report That Bt Crops Are Safe](#)
- [Expediting EUP Permits](#)
- [EPA Program, Enforcement and Meetings](#)
- [New Methyl Bromide Regulations in California](#)
- [Canada Requires Emergency Plans](#)
- [EU Harmonizes MRLs](#)
- [EU Committee Opines on Antifouling Products](#)
- [European Court Defends Italy's Ban on GM Foods](#)
- [Cartagena Protocol on Biosafety Now Effective](#)

Contact Us

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EPA

► NRDC and Four State Attorneys General Allege EPA Violated FOQA

John Conner, Jr., McKenna Long & Aldridge, Washington, DC

Two separate but coordinated actions filed on September 15, 2003, in the United States District Court for the Southern District of New York by NRDC, eleven interest groups, and the attorneys general of New York, New Jersey, Connecticut and Massachusetts claim that EPA failed to apply the additional tenfold margin of safety

factor of the FQPA to account for infants and children when assessing pesticide tolerances for nine pesticides. Natural Resources Defense Council et al. v. Horinko, (S.D.N.Y.); New York et al. v. EPA, (S.D.N.Y.)

The National Resources Defense Council ("NRDC") contends that EPA lacked reliable data to justify departing from the additional tenfold safety factor of the Food Quality Protection Act of 1996 ("FQPA") when the Agency reassessed the tolerances of alachlor, captan, diazinon, disulfoton and oxydemeton methyl. NRDC alleges the Agency failed to consider non-dietary exposure routes for infants and children. As well, the suit alleges that EPA failed to protect farm children as a major identifiable subgroup of consumers and relied on a "confidential, proprietary" computer model to assess human pesticide exposure.

The four states allege that EPA violated FQPA when the Agency reassessed tolerances for alachlor, chlorothalonil, methomyl, metibuzin, and thiodicarb. The attorneys general allege that EPA failed to consider whether these pesticides have a common mechanism of toxicity with other pesticides and, as with the NRDC action, the Agency lacked reliable data on which to base a deviation from the additional tenfold FQPA factor. The FQPA provides that EPA may use a different safety factor, if there are reliable data to show that a different level is safe for infants and children.

▶ **NRDC Sues EPA over Threat of Atrazine to Endangered Species**

Michael Boucher, McKenna Long & Aldridge, Washington, DC

On August 20, 2003, NRDC sued EPA for failing to consult with two other federal agencies on the potential impact of the herbicide atrazine to various endangered species. NRDC v. EPA, (D. Md.). NRDC alleges that EPA failed to consult with the U.S. Fish and Wildlife Service ("FWS") and the National Marine Fisheries Service ("NMFS"), as required by section 7(a)(2) of the Endangered Species Act ("ESA"), to determine whether atrazine's registration endangers the survival and recovery of endangered amphibians, reptiles, fish, and aquatic vertebrates in the Chesapeake Bay and its watershed, in Midwestern rivers and their tributaries, and in rivers and streams in the South.

On January 4, 2003, EPA published an advanced notice of proposed rulemaking ("ANPR") in the Federal Register, describing the Agency's plans to develop new regulations governing its required consultations on pesticides with FWS and NMFS under the ESA. EPA issued the ANPR after being sued on several occasions by environmental groups for allegedly failing to consider how pesticide registration actions under FIFRA would affect endangered species. On August 1, 2003, in partial response to lawsuits alleging harm to endangered salmon species from a variety of pesticides, including atrazine, EPA issued a formal determination that atrazine poses no significant risks to salmon or their habitats in California and the Pacific Northwest. See "Effects Determination for Atrazine" at <http://www.epa.gov/oppfead1/endanger/effects/>. EPA found that use of atrazine in California is low (63,000 lbs. used in 2001) and that concentrations of atrazine from known Christmas tree use in the Northwest did not reach levels of concern for direct and indirect effects to salmon, using the Agency's standard modeling.

On September 12, 2003, growers and agricultural groups, including CropLife America, wrote to the Chairman of the President's Council on Environmental Quality, urging action on EPA's proposed rulemaking. They contend that the recent ESA lawsuits unnecessarily threatens critical pest control products, trade, agricultural production, and small growers.

▶ Second Circuit Hears Argument on Need for NPDES Permit When Applying Mosquito Adulticides

John Conner, Jr., McKenna Long & Aldridge, Washington, DC

On September 17, 2003, the United States Court of Appeals for the Second Circuit received oral argument on whether New York City must obtain a Clean Water Act ("CWA") National Pollution Discharge & Elimination System ("NPDES") permit when spraying mosquito adulticides. No Spray Coalition v. The City of New York, (2d. Cir. N.Y.). Plaintiffs appealed the United States District Court of the Southern District of New York's dismissal of plaintiffs' claim that a NPDES permit is required as consequence of the discharge of adulticides over waters of the United States. The District Court ruled that pesticides are adequately regulated under FIFRA and are not pollutants unless and until they are discharged to water as chemical wastes.

On July 11, 2003, in response to the decision of the Ninth Circuit in Headwaters v. Talent Irrigation District, and comments of the Second Circuit in Altman v. Town of Amherst, EPA issued interim draft guidance that an applicator of an aquatic pesticide or a pesticide applied to control pests over waters does not need a NPDES permit, as long as they are applied consistent with FIFRA. The Agency's draft guidance advises that aquatic pesticides are not "chemical wastes" but "EPA-evaluated products designed, purchased and applied to perform their intended purpose of controlling target organisms in the environment." The Agency has invited comment on its draft guidance. The Agency's interim guidance is available at http://www.epa.gov/npdes/pubs/pesticide_interim_guidance.pdf

Similarly, the Agency issued guidance on September 3, 2003, in response to the Ninth Circuit's decision in League of Wilderness Defenders v. Forsgren, holding that the U.S. Forest Service must obtain a NPDES permit for the aerial spraying of silvicultural pesticides to control moths directly over and into navigable waters. The Ninth Circuit concluded that the aerial pesticide spraying did not qualify as a non-point source silvicultural activity under Clean Water Act regulations. EPA's September 3 guidance states that outside the Ninth Circuit EPA intends to follow its interpretation of the NPDES silviculture regulation that a NPDES is not required for silviculture pest and fire control activities.

On October 6, 2003, the United States Supreme Court denied a forestry coalition's efforts to intervene in the Forsgren case in order to request the Court to issue a writ of certiorari and review the Ninth Circuit's decision.

▶ EPA Scientists Publish Journal Article On Safety of Bt Crops

Dr. Gary Burin, Technology Sciences Group, Washington, DC

A recent publication by EPA scientists and regulators described the approach that has been taken by federal agencies in the evaluation of crops that have been genetically engineered to express genes from *Bacillus thuringiensis* ("BT"). The article, published in *Nature Biotechnology* in September by Mike Mendelsohn and others, noted that crops genetically engineered to have pesticidal traits are overseen by three federal agencies: the EPA, the U.S. Food and Drug Administration ("FDA"), and the U.S. Department of Agriculture ("USDA"). EPA's oversight focuses on the safety and potential environmental impacts of the pesticidal substance, the delta-endotoxin in the case of BT plants. FDA may be consulted to determine whether the crop itself is equivalent to conventional counterparts and USDA determines whether the crop

will be regulated as a plant pest.

EPA prepares a comprehensive scientific assessment to assess potential impacts of the genetically modified crop on human health and the environment. The health assessment of the engineered plant evaluates the fate of the protein after ingestion and the potential for allergenicity or other forms of the toxicity. The environmental assessment includes evaluation of the potential gene transfer to other plants, toxicity to non-target organisms such as butterflies, and the fate of the protein in the environment.

The authors of the *Nature Biotechnology* article concluded that none of the plants genetically engineered to express the BT gene shows characteristics of food allergens or other toxic substances. The EPA review also noted that, for the most part, the engineered plants “do not have a reasonable possibility of passing their traits to native plants” and that the proteins, once released into the environment, do not have effects on biota. BT crops are not expected to cause widespread or irreversible harm to insect populations. While extending the time-limited registrations, EPA requested additional confirmatory data to show protection of non-target insects, breakdown of the protein in soil and that measures are being taken to limit gene flow from BT cotton to weedy relatives.

▶ **EPA Issues New Guidance on Expedited Reviews for Certain Experimental Use Permits**

Dr. Robert Stewart, Technology Sciences Group, Washington, DC

Pesticide Registration Notice (“PR Notice”) 2003-2 provides guidance to applicants for Experimental Use Permits (“EUPs”) for products that may replace methyl bromide or organophosphates or which otherwise qualify as reduced-risk pesticides. Dietary risk assessments required by the FQPA and ecological risk assessments required by the ESA have caused the review times for EUP applications to approach the time required for approval of a full registration under FIFRA § 3. As a result, fewer EUP applications have been filed in recent years. EPA has determined that it can review the foregoing types of EUP applications on an expedited schedule, without impacting its review priorities for other pesticide actions, in the following circumstances:

- The EUP application is not for a food use, a tolerance or tolerance exemption for the active ingredient exists, or the application provides for the destruction of the treated crop.
- The proposed use rates, application methods and exposure levels are similar to already approved products having the same active ingredient.
- The proposed use does not result in increase in residential, worker or bystander exposure.
- The proposed use would not result in aggregate or cumulative exposure exceeding the acute or chronic population adjusted dose.
- The application proposed use on less than 2,000 total acres for a major use or less than 100 total acres for an aquatic or a minor use.
- The proposed use includes no more than 100 acres for watershed.
- The use will occur where no endangered species exist or the Level of Concern for species that are present will not be exceeded.

Expedited EUP applications must meet all of the FIFRA § 5 and 40 C.F.R. part 172 requirements and include a justification as to why the application poses a minimal

burden on the Agency. PR Notice 2003-2 is found at http://www.epa.gov/opppmsd1/PR_Notices/pr2003-2.pdf.

▶ **EPA Enforcement, Personnel and Registration**

OPP Personnel Changes

On October 8, 2003, the Director of OPP announced the following personnel changes in OPP: Anne Lindsay will become OPP's Deputy Office Director for Programs. Upon her return from Brussels in December, Lois Rossi will become Director of the Registration Division. Lois has been on a six-month detail to the Plant Directorate, European Commission ("EC") where she is serving as a National Expert to further cooperation and work sharing on chemicals that are under review in Europe and the United States. Debbie Edwards will become the Director of the Special Review and Reregistration Division upon Lois's return from Brussels.

Failure to Report Pesticide Production

EPA on September 18, 2003, announced settlements with four companies to pay fines totaling \$18,700 for failing to submit their 2002 pesticide production reports on time. Pesticide producing establishments must annually report by March 1 the quantities of pesticides produced and distributed during the prior calendar year. The annual reports and instructions are available online.

Other recent enforcement initiatives include fining a registrant for distributing products with missing or torn labels, fining an aerial applicator for allowing a pesticide to drift onto residential property and a device producer filing an incorrect production address.

Meetings

October 27-28, 2003: AAPCO/State FIFRA Issues Research and Evaluation Group Working Committees on Water Quality and Pesticide Disposal and Pesticide Operations & Management Working Committee. Days Inn Crystal City, 2000, Jefferson Davis Highway, Arlington, VA 22202. Information and agenda at <http://www.epa.gov/fedrgstr/EPA-MEETINGS/2003/September/Day-26/m24369.htm>.

October 28, 2003: EPA's Pesticide Program Dialogue Committee's ("PPDC's") Registration Review Work Group. Hyatt Regency Crystal City; 2799 Jefferson Davis Highway, Arlington, VA. Information at <http://www.epa.gov/oppead1/cb/ppdc/>.

October 28-29, 2003: FIFRA Scientific Advisory Panel ("SAP") will review data quality for in vitro tests used as alternatives to animal studies for regulatory purposes. Holiday Inn Hotel, 1900 North Fort Myer Drive, Arlington, VA. The telephone number for the Holiday Inn Hotel is (703) 807-2000. Information at agenda at <http://www.epa.gov/EPA-PEST/2003/September/Day-22/p24124.htm>.

October 29-30, 2003: EPA's PPDC will hold a public meeting to discuss a report from the PPDC's Registration Review Work Group, endangered species, non-governmental stewardship activities, pesticide budget/fees and output efficiencies, certification and training, and follow-up to issues discussed at the April 2003 PPDC meeting. National Rural Electric Cooperative Association, Conference Center, 4301 Wilson Blvd, Arlington, VA. Information at <http://www.epa.gov/oppead1/cb/ppdc/>.

December 3-5, 2003: FIFRA SAP to review probabilistic exposure and risk assessment for children who contact chromated copper arsenate ("CCA")-treated wood on play sets and decks and CCA-containing soil around these structures. Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA 22202. Information and agenda at <http://www.epa.gov/fedrgstr/EPA-MEETINGS/2003/September/Day-26/m24402.htm>.

[↗ Back to top](#)

California

▶ Proposed New Methyl Bromide Regulations

Greg Gorder, Technology Sciences Group, Davis, CA

The California Department of Pesticide Regulation ("DPR") has proposed new methyl bromide regulations aimed at enhancing protection for workers and others who face potential exposures from multiple fumigations over the course of several weeks ("seasonal" exposures). The new rules will mandate more protective gear and work-time restrictions for laborers to achieve a 16 ppb seasonal standard established for adults. Agricultural workers often work five to seven days per week over the "season"; a period of four to five weeks during August to October. The regulations would also limit any single township to total applications of less than 270,000 pounds a month. In recent years, this would represent an unusual level of use: in 2001, the highest monthly application in a township was 202,000 pounds of methyl bromide.

The proposed regulations on seasonal exposures will add to the existing emergency regulations for short-term exposures and make the emergency regulations permanent. DPR's action levels include a 100-fold margin of safety to allow for sensitivity differences between individuals and differences between humans and experimental animals. The assessments and other scientific documents that DPR relied on in establishing proposed regulatory action levels are found at http://www.cdpr.ca.gov/docs/dprdocs/methbrom/riskasses_fum.htm.

DPR's actions are separate from federal regulations under the Clean Air Act and the Montreal Protocol. The United States has agreed to end production of the fumigant by 2005. Federal and international authorities, however, are now considering "critical exemptions" to allow continued use when no feasible alternatives exist.

The proposed regulations are posted at <http://www.cdpr.ca.gov/docs/legbills/03-004text.pdf>. DPR is accepting written comments until November 18, 2003; public hearings are scheduled for November 14, 15, and 17. For details, see <http://www.cdpr.ca.gov/docs/legbills/03-004notice.pdf>.

[↗ Back to top](#)

Canada

▶ Canada Requires Environmental Emergency Plans

Heather Bjornson, Technology Sciences Group, Washington, DC

On September 10, 2003, Environment Canada issued final regulations in the Canada

Gazette requiring Canadian commercial and industrial facilities owning or controlling amounts of 174 listed substances to prepare and implement environmental emergency plans. Some of the substances serve as active ingredients in pesticides. The new regulations become effective on December 9, 2003. Environmental Emergency Regulations target small and medium-sized chemical plants, which are not likely to have emergency plans in place. The regulations are intended to better protect the environment and Canadians' safety against uncontrolled, unplanned, or accidental release of a toxic or hazardous substance into the environment.

Initially, facilities have 90-days from the above enforcement date to submit information to Environment Canada on quantities of these substances they are storing. After the 90-day period, facilities have six months to submit a Notice of Preparation, or E2 plan, and up to one year to implement the plan. E2 plans must be tested and updated annually. The Environmental Emergency Regulations are similar to the Risk Management Planning Regulations in the United States under the Clean Air Act.

Under the E2 regulations, any facility storing or using a listed substance above specified thresholds, or that has a container with a capacity for the substance in excess of the specified quantity will have to notify Environment Canada of the place where the substance is held, along with the maximum expected quantity and size of the largest container for that substance. If both the above criteria are exceeded the facility is required to prepare and implement an environmental emergency plan and notify Environment Canada. Exemptions from the reporting requirements include:

- Short-term storage of these substances (less than 72 hours);
- Storage of 30 kilograms or less of the listed substance;
- Gaseous or liquid substances at low pressure; and
- Subdivision of the schedule of designated substances into flammable and other hazardous substances.

Environment Canada will provide limited public access to the E2 plans though it intends to keep confidential any information that might be the target of terrorist activity. Environment Canada estimates that 1,500 facilities will be affected by the new regulations. The complete list of the substances and notice are available at <http://canadagazette.gc.ca/partII/2003/20030910/html/sor307-e.html>.

[↗ Back to top](#)

Europe

▶ Harmonization of MRLs

Claudio Mereu, McKenna Long & Aldridge, Brussels

The European Union ("EU") Commission's proposal for a Regulation harmonizing the maximum residue limits ("MRLs") of pesticides (Ref: COM(2003)117) is currently under First Reading in the European Parliament and Council. The Parliament plans to adopt its position in January 2004; the Irish Presidency could then reach a Political Agreement in early 2004.

The future Regulation will replace and simplify the four existing Council Directives on MRLs (Ref: Directive 76/895 on MRLs in and on fruits and vegetables; Directive

86/362 on MRLs in and on cereals; Directive 86/363 on MRLs in and on food of animal origin; Directive 90/642 on MRLs in and on certain products of plant origin, including fruits and vegetables). This Regulation should remove the inconsistencies of the current schemes under which Member States can set their own national MRLs in the absence of specific EU MRLs. The Commission believes there is an urgent need for this Regulation, because some countries could wish to ban on their national markets products containing some of the 388 active substances not regulated at EU level.

Under the proposed Regulation, all MRLs will be harmonized after a transitional "phase in" period and set exclusively at the EU level on the basis of risk assessments conducted by EFSA (the recently created European agency; European Food Safety Authority). During the phase-in period, the Commission will establish temporary MRLs based on existing national MRLs. The proposal sets a default limit of 0.01 mg/kg in cases where there is no data available to determine whether a residue constitutes a risk to human health.

▶ **Scientific Committee Issues Opinion on Antifouling Product Restrictions**

Koen Van Maldegem, McKenna Long & Aldridge, Brussels

On September 19, 2003, the Scientific Committee on Toxicity, Ecotoxicity and the Environment ("CSTEE") adopted an opinion on the Dutch proposal to forbid the application of copper-based antifouling preparations on pleasure crafts in the Netherlands. These copper-based preparations are biocidal products classified under product type 21 (antifouling products) under Directive 98/8/EC. The Commission is concerned that the Dutch authorities use appropriate risk assessment procedures under Directive 98/8/EC, especially since DG ENV is developing procedures for conducting these risk assessments.

The CSTEE was "not convinced that the Netherlands has provided sufficient scientific justification to show that copper-based antifouling products present environmental risks." It recommended that "the conclusions be revisited in the light of more up-to-date data and modern methodology currently being developed as part of a voluntary programme for the risk assessment of copper in the context of the Existing Substances Regulation."

Because the use of copper-based antifouling products is not presently harmonized at the Community level, the restrictions on these products must first be examined in the light of Articles 28 and 30 of the EC Treaty, which provides that measures equivalent to quantitative restrictions on imports by Member States shall be prohibited unless they are justified to protect humans, animals or plants. Following the CSTEE opinion (which is not binding), the Commission is likely to request the Netherlands to withdraw this measure.

▶ **European Court Defends Italy's Action Against Genetically Modified Food**

Claudio Mereu, McKenna Long & Aldridge, Brussels

The EU's highest court, The European Court of Justice (Luxembourg), has ruled that the Italian government has the right to temporarily stop sales of genetically modified ("GM") foods if it is concerned that they could have adverse effects on human health and the environment. The court's ruling stands for all EU member countries, industry watchers say. The court said last week that any EU country "can, as a preventative

measure, temporarily restrict or suspend the marketing of [GM] foods in its territory. There should be no relaxation of the safety requirements that must be met by novel foods." The court, however, warned that Italy must still provide detailed evidence of the risks posed by GM products before they can be banned.

The EU recently issued labeling and tracking laws that lift its five-year GM crop moratorium. The United States recently launched an investigation by the World Trade Organization (WTO; Geneva) to determine whether the moratorium violates WTO trade rules. WTO is also investigating whether the EU's GM labeling law is legal, following complaints from Argentina, Canada, and U.S. governments. The law becomes effective this fall. The European Commission had moved against GM restrictions earlier this month when it rejected proposals by the Austrian government to introduce GM crop exclusion zones. Austria's proposal, however, was not based on human health concerns.

[↗Back to top](#)

Biotechnology

▶ **Cartagena Protocol on Biosafety's Entry Into Force Will Affect Non-Parties**

Sarah Lukie, McKenna Long & Aldridge, Washington, DC

On September 11, 2003, the Cartagena Protocol on Biosafety entered into force. The Protocol is the first legally binding international agreement governing the movement of living modified organisms ("LMOs") across national borders. Those countries that ratified the Protocol ("Parties to the Protocol") must now comply with and implement all its provisions. Party countries, however, are not the only countries that are affected by its requirements. Article 24 of the Protocol provides that transboundary movements of LMOs between Parties and non-Parties must be consistent with the Protocol's objectives. Countries such as the United States and Canada that have not ratified the Protocol but export LMOs to Parties must also comply with the Protocol's provisions implemented in the importing country. To date, 62 countries have ratified the Protocol; none of which export LMOs.

Although the Protocol is now effective, many Party countries have not yet developed and implemented national biosafety legislation. Further, what is actually required by the Protocol is ill defined. Party countries will convene in February, 2003 to address topics related to the operation and implementation of the Protocol. Meanwhile, non-Party countries often are without any legislation, regulations or directives outlining how they will abide by the Protocol's provisions in many countries to which they export LMOs.

For a list of countries that have ratified the protocol, see <http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt>.

[↗Back to top](#)

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