

Lawyer Insights

October 23, 2018

Why Enviros, Agencies Disagree On Safe Glyphosate Levels

By *Lori Elliott Jarvis, Thomas Waskom, Lawrence DeMeo and Elizabeth Reese*

Published in *Law360*



The nonprofit Environmental Working Group has teamed up with several major food companies to petition the U.S. Environmental Protection Agency to reduce the tolerance level for glyphosate residue in oat-based products to a level 300 times lower than EPA's current level. The petition, filed Sept. 27, 2018, also urges EPA to ban preharvest use of glyphosate as a drying agent. Eight food companies joined in the petition: Ben & Jerry's Homemade Inc., Happy Family Organics, MegaFood, MOM's Organic Market, National Co-op Grocers, Nature's Path Foods Inc., One Degree Organic Foods and Stonyfield Farm Inc.



Just days after EWG filed its petition, the U.S. Food and Drug Administration released a report finding that none of the more than 750 samples of corn, soybean, milk and egg products it tested in 2016 contained violative levels of glyphosate. EWG quickly struck back at the FDA, criticizing the agency for failing to test oat- and wheat-based products — staple consumer food products that EWG contends pose a significant risk to consumer health when they contain glyphosate residue.

EWG Petition Asks EPA to Lower Glyphosate Limit to 1993 Rate

Controversy over the alleged carcinogenic effects of glyphosate, the most widely used pesticide in the world, has dominated headlines in recent months, following a California state court jury's award of \$289 million to a former groundskeeper who claimed that glyphosate in Monsanto's popular Roundup product caused his non-Hodgkin's lymphoma.

EWG's petition capitalizes on the increased publicity surrounding glyphosate, and touts EWG's own August study, which found glyphosate present in all but two samples of 45 different oat-based foods and cereals. According to EWG, glyphosate levels were within the current legal limit in each of these samples, but roughly three-fourths of the samples contained levels higher than what EWG considers safe for human consumption.

Citing claimed concerns for human health — particularly children's health — EWG asks the EPA to set the glyphosate tolerance level in oat-based products at 0.1 parts per million. EWG thus asks the EPA to reduce the current tolerance level for oat-based products, 30 ppm, to a level 300 times lower. EWG also points out that a level of 0.1 ppm would return the tolerance level to the original level the EPA set for

HUNTON ANDREWS KURTH

Why Enviro, Agencies Disagree On Safe Glyphosate Levels

By Lori Elliott Jarvis, Thomas Waskom, Lawrence DeMeo and Elizabeth Reese

Law360 | October 23, 2018

glyphosate in oat-based products in 1993, the first year the EPA regulated the concentration of glyphosate in those products.

That level has increased twice since 1993 — once in 1997 to 20 ppm in response to a petition filed by Monsanto, and again in 2008 to 30 ppm. According to EWG, the current level of 30 ppm does not account for any cancer risk of glyphosate, because the EPA classifies the pesticide as “not likely to be carcinogenic to humans.”

EWG’s petition also asks the EPA to ban the use of glyphosate as a preharvest drying agent. EWG claims that farmers have increasingly used glyphosate as a drying agent to accelerate the harvest process by spraying it directly on crops, causing the crops to dry out faster than they naturally would. According to EWG, the use of glyphosate in this way — while generally a minor use of glyphosate — actually increases the concentration of glyphosate residue in oat-based products because of the timing of the pesticide’s application to crops.

EWG asserts there is at least a “likely link” between glyphosate and cancer, and criticizes the EPA for failing to acknowledge the cancer risks of the pesticide. Further, the petition argues an internal inconsistency exists within the EPA in light of a 2016 report by the EPA’s Scientific Advisory Panel, which concluded that in adopting its current stance on glyphosate, the EPA “did not adhere to the EPA Guidelines for Carcinogen Risk Assessment.”

Some SAP members also felt the EPA “appeared to discount statistical findings and overemphasize non-statistical criteria.” However, this alleged internal inconsistency seems to be quelled by the EPA’s 2017 revised report, which notes that it took all of SAP’s criticisms into account, and ultimately affirms its original classification of glyphosate: “not likely to be carcinogenic to humans.”

EWG reached its proposed tolerance rate based on calculations indicating a 0.1 ppm legal limit would achieve a one-in-one-million cancer risk for children who eat roughly one cup of oat-based cereal per day. The petition focuses on claimed health risks to children, and asserts that children are “exposed to more pesticides than adults and are more susceptible to the toxic effects of pesticides, particularly those that cause cancer.”

It also notes the EPA’s legal obligation to consider “food consumption patterns unique to infants and children” in setting the tolerance rate, as well as the “cumulative effects on infants and children of [pesticides] that have a common mechanism of toxicity.”

FDA Releases Annual Pesticide Report for Fiscal Year 2016

On Oct. 1, 2018, just after EWG filed its petition, the FDA released its Annual Pesticide Report for Fiscal Year 2016, reporting the results of its annual sampling program. From Oct. 1, 2015, through Sept. 30, 2016, the FDA analyzed 7,413 samples, including 6,946 foods intended for human consumption and 467 foods intended for animal consumption.

The FDA found that over 99 percent of United States-sourced foods and 90 percent of imported foods complied with federal tolerance levels, and that the majority of those foods (52.9 percent of domestic foods and 50.7 percent of imported foods) contained no pesticide residue at all.

Why Enviro, Agencies Disagree On Safe Glyphosate Levels

By Lori Elliott Jarvis, Thomas Waskom, Lawrence DeMeo and Elizabeth Reese

Law360 | October 23, 2018

The FDA used its new selective residue method developed specifically for glyphosate to test for residue in 274 grain corn, 267 soybean, 113 milk and 106 egg samples. While glyphosate residue was found in 173 of the corn samples and 178 of the soybean samples, none of the samples contained glyphosate residue in excess of the federal tolerance levels for the particular kind of food.

EWG immediately released a statement criticizing the FDA's testing, pointing out that the FDA did not test oat- or wheat-based products — which EWG claims are the two major crops on which glyphosate is used as a drying agent, and which EWG itself tested in August.

National Debate on Alleged Carcinogenic Effect of Glyphosate Continues

Both the EWG petition and the FDA report add to the heated international debate regarding glyphosate's alleged cancer-causing properties. While the EPA has a legal obligation to respond to EWG's petition "within a reasonable time" under the Administrative Procedure Act — meaning the public can expect a response from the EPA in the next few months — it remains to be seen whether the EPA will take any meaningful action.

Likewise, it is unclear whether the FDA will begin testing oat- and wheat-based products for glyphosate residue, in addition to the corn, soybean, milk and egg products it is currently testing. Regulatory agencies both in the United States and abroad have disagreed about whether the chemical can cause cancer, creating a complex regulatory landscape that can be difficult to navigate for companies whose products may contain glyphosate residue.

If the EPA were to take action in response to EWG's petition, companies in the retail industry could find themselves facing manufacturing process changes, labeling changes and associated business disruption. And if the FDA begins testing oat- and wheat-based products, companies may find themselves in the spotlight if any of their products are tested and found to contain violative levels of glyphosate residue.

But even if the EPA and the FDA do not take action, it seems certain that EWG and other consumer advocacy groups will continue to press regulatory agencies to take action on glyphosate. Glyphosate is unlikely to fade from the public eye, given the early successes on the litigation front for the plaintiffs bar, and individual companies may be pulled into the glyphosate debate, as consumer advocacy groups like EWG continue to test popular products and publicize results in their efforts to keep glyphosate in the news.

Lori Elliott Jarvis and Thomas R. Waskom are partners at Hunton Andrews Kurth LLP in the Richmond office. Lori's practice focuses on environmental litigation and toxic torts, mass tort litigation and class actions, product liability, multidistrict litigation, general commercial litigation and appellate advocacy. She can be reached at (804) 788-8630 or lj Jarvis@HuntonAK.com. Tom's practice focuses on class action, mass tort and environmental litigation. He can be reached at (804) 788-8403 or twaskom@HuntonAK.com. Lawrence K. DeMeo is of counsel at Hunton Andrews Kurth LLP in the Boston office. He advises clients in all aspects of intellectual property law, from procurement through trial. He can be reached at (617) 648-2746 or ldemeo@HuntonAK.com. Elizabeth Reese is an associate at Hunton Andrews Kurth in the Richmond office. She can be reached at (804) 787-8060 or ereese@HuntonAK.com.