Overview: Regulatory Review of Glyphosate

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On Thursday, November 12, the European Food Safety Authority (EFSA) will announce a decision on whether glyphosate should remain on the market. It is expected to recommend to the European Commission that Europe continue to approve glyphosate, and it will probably raise the acceptable daily intake level. The European Commission is expected to then propose that glyphosate be re-approved for use in pesticides sold in Europe. Individual nations in Europe authorize the pesticides themselves.

The European Commission will likely approve glyphosate for at least 10 more years , if member states on the Standing Committee on Phytopharmaceuticals do not reject the proposal. The Commission is expected to vote in the first half of 2016.

The U.S. Environmental Protection Agency (EPA) began its own review of glyphosate in 2009. It was expected to complete a risk assessment late this year. Before doing so, EPA went ahead in October 2014 and approved a new product, Enlist Duo, which contains glyphosate, for use in six states. Enlist Duo combines glyphosate with another powerful weed killer called "2,4-D." This past April, EPA approved the use of Enlist Duo in nine more states.

Glyphosate was introduced in 1974 as the active ingredient in the weed-killer Roundup.® Glyphosate is now the most widely used weed-killer in the world. It is applied to more than 150 food and non-food crops, and yields almost $5 billion a year in revenue for Monsanto. Glyphosate is popular largely because it is sold for use with "Roundup Ready®" crop seeds that have been genetically modified to be glyphosate-tolerant. This allows farmers to broadly apply the chemical without killing their cash crop. In the United States, its use in agriculture has exploded, from under 50 million pounds a year in the mid-1990s to almost 300 million pounds today. It is used on farm crops like soy, corn, and cotton, in public parks, and by homeowners throughout the U.S. and Europe.

This past March, the World Health Organization's (WHO) cancer research arm, the International Agency for Research on Cancer (IARC), classified glyphosate as a "probable" (Group 2A) human carcinogen. 17 expert scientists from around the world reached this unanimous conclusion for IARC after reviewing all relevant published studies.

Monsanto responded with a statement that it was "outraged" at IARC's "agenda-driven bias" and "irresponsible" decision-making.

This past May, WHO asked an ad hoc task force to review the information available to IARC and decide whether, the Joint Meeting on Pesticides Residue (JMPR), a committee of the WHO and Food and Agriculture Organization (FAO), should re-evaluate its 2011 recommendations for the amount of residue of glyphosate allowed in food. The task force was comprised of the WHO's Core Assessment Group on Pesticide Residues, along with a representative of the IARC working group. NRDC and other environmental groups sent a letter to WHO voicing concerns about a conflict of interest, as several

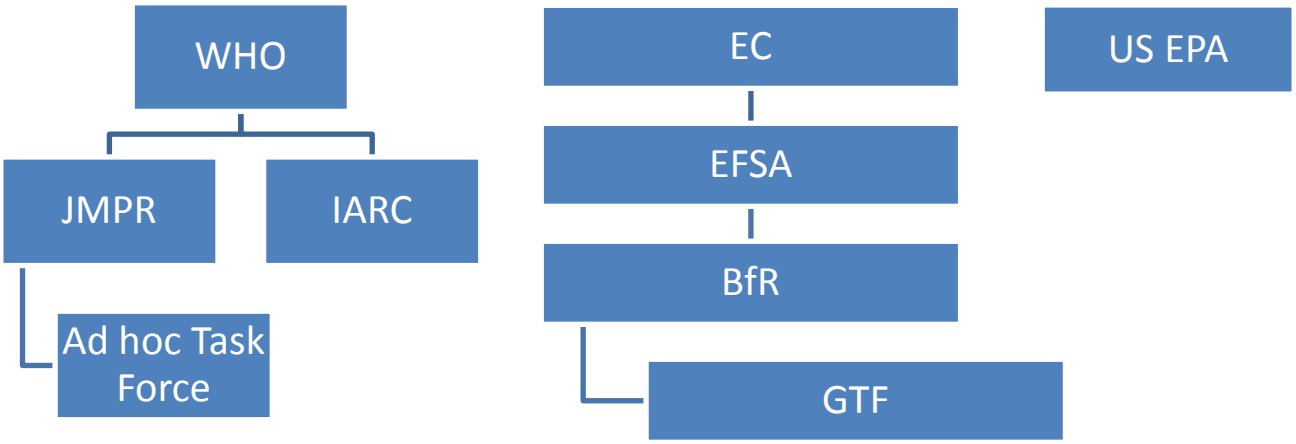
members of the task force had financial ties to the agrochemical industry. WHO acknowledged receipt of the letter, but has made no changes to the panel, to our knowledge.

In September, the task force recommended that JMPR re-evaluate its recommendations and review its internal guidelines on using both publicly available and non-public data sources.

JMPR is expected to make its recommendations in 2016 to set the Maximum Residue Level on food, or MRL (also known as the CODEX Alimentarius levels). These recommendations are not legally binding, but most countries tend to adopt them.

Players:

- **WHO - World Health Organization**: the United Nations agency on international public health
- **JMPR - Joint Meeting on Pesticide Residues**: an ad hoc body of experts, administered jointly by FAO and WHO, that reviews pesticide residues
- **IARC - International Agency for Research on Cancer:** WHO's cancer assessment arm
- **EC - European Commission:** the executive and legislative arm of the European Union. The EC is is represented in the Standing Committee on Phytopharmaceuticals
- **EFSA - European Food and Safety Authority: a European body that** guides the EC on food safety risks and provides scientific support for EC decision-making, and
- **BfR - Germany Federal Institute for Risk Assessment:** Germany's scientific body that advises on food, substance and product safety
- **GTF - Glyphosate Task Force:** an industry consortium, including Monsanto, Dow and other agrichemical companies, that advocates for approval of the use of glyphosate on the market in the EU, and provides scientific data to both BfR and EFSA
- **EPA - U.S. Environmental Protection Agency:** the US federal environmental agency responsible for regulating pesticides



Timeline of Action on Glyphosate:

1974: EPA's initial approval of glyphosate.

1985: EPA classified glyphosate as a possible carcinogen, based on experiments showing tumors in glyphosate-treated rodents, based in part on the same studies IARC reviewed in 2014/15.

1991: Upon input from Monsanto and EPA's Science Advisory Panel, EPA reinterpreted these studies and re-classified glyphosate as non-carcinogenic. [CFW report- EPA link now redirects to EPA's pesticide page]

1993: EPA makes final decision on whether glyphosate is eligible to be re-registered. It concludes pesticides must be reviewed every 15 years.

2002: The EC approves glyphosate for a maximum of 10 years. The renewal process requires a few steps: (1) a draft risk assessment by a designated member state—in this case, Germany (note that *industry* selects the country it wants to conduct the review); (2) EFSA peer reviews the report and sends its conclusion to the EC, which decides whether to include it on a list of approved active substances.

2010: Monsanto applied for a renewal, and the EC extended glyphosate's approval until 2015 to "enable the applicants to prepare their applications." (FOE)

2011: JMPR evaluated glyphosate and deemed the Acceptable Daily Intake for glyphosate (in combination with N-acetyl-glyphosate, AMPA and N-acetyl-AMPA) to be: 0-1 mg/kg bw

March 2015: IARC classified glyphosate as "probably carcinogenic to humans (Group 2A)," based on "convincing " evidence from animal tests, "limited" evidence in humans for non-Hodgkin lymphoma, and "strong" evidence that glyphosate exhibits two characteristics associated with carcinogens, namely genotoxicity and the ability to induce oxidative stress.

April 2015: Germany, through its risk-assessment body, BfR, submitted a draft report to EFSA, concluding that glyphosate is "not carcinogenic." BfR did not report on the original studies in detail, but based its evaluation partly on descriptions provided by the Glyphosate Task Force (GTF), an industry consortium of agrochemical firms such as Dow, Monsanto and Syngenta. (Guardian) (GTF Website)

May 2015: WHO assembled an *ad hoc* task force to review the information IARC used and determine whether to update JMPR's earlier assessment.

June 2015: NRDC and a coalition of environmental groups sent a letter to the WHO, citing potential conflicts of interest among JMPR's task force members. Our concerns went unheeded.

July 2015: Monsanto announced that it was conducting its own review, and hired Intertek Scientific & Regulatory Consultancy to convene a panel of scientists to review IARC's work. Previously,

Intertek had jointly published a paper with Monsanto, defending the safety of glyphosate in the industry-sponsored journal *Regulatory Toxicology and Pharmacology.*

August 2015: WHO responded to NRDC's letter, acknowledging receipt, but declining to take any action to address our concerns.

August 2015: Germany, through BfR, submitted a revised report on carcinogenicity to EFSA, acknowledging the evidence and conclusion by IARC, but finding that glyphosate is not carcinogenic.

September 2015: WHO's task force recommended that JMPR do a full re-evaluation of glyphosate. It reasoned that IARC had analyzed more peer-reviewed scientific literature than JMPR, and so another JMPR review was warranted.

September 4, 2015: California's Office of Environmental Health Hazard Assessment announced it will list glyphosate as a risk for cancer under Proposition 65. This is a routine step when IARC lists a carcinogen as either Group 1 (known) or Group 2 (probable or possible) to cause cancer in humans.

September 22, 2015: Agricultural workers file suit against Monsanto in federal courts in CA and NY for cancers in farm workers. Plaintiffs include:

- Enrique Rubio (58), former farm worker in CA, TX, and OR; diagnosed with bone cancer in 1995
- Judi Fitzgerald (64), horticultural worker in VA, diagnosed with leukemia in 2012

October 14, 2015: More plaintiffs sue Monsanto in Delaware state court:

- Joselin Barrera (24): child of migrant farm workers from Texas; diagnosed with non-Hodgkin lymphoma.
- Elias de la Garza (74): former migrant farm worker and landscaper from Texas; also diagnosed with non-Hodgkin lymphoma.
- Judi Fitzgerald (64): joined Delaware suit after seeking dismissal of her suit in NY

October 20, 2015: Monsanto claims California's Office of Environmental Health Hazard Assessment acted illegally by not considering all valid information when it characterized glyphosate as a carcinogen.

November 3, 2015: An investigative report reveals that EPA relied on industry-funded (Glyphosate Task Force) research in its determination that glyphosate is not an endocrine disruptor.

November 12, 2015: EFSA is expected to publish its risk assessment of glyphosate. Its draft was underway when IARC made its announcement in March, and EFSA had requested an extension until November. NRDC does not expect EFSA to change its earlier position that glyphosate is "non-genotoxic" and "non-carcinogenic."

Late 2015: EPA is expected to issue preliminary risk assessment of glyphosate. While EPA is scheduled to complete its registration review for glyphosate, the agency is not expected to meet that deadline. In its Glyphosate Final Work Plan in 2009, EPA projected that it would issue a Preliminary Risk Assessment to the public between January and March 2014.

May 2016: JMPR is expected to complete its re-assessment.

By late June 2016: The European Union's Standing Committee on Phytopharmaceuticals is expected to vote on whether to approve glyphosate.