Is Glyphosate Legal?

By Donald Sutherland

It is springtime and millions of pounds of the world's most common herbicide are being applied to the agricultural land in the United States.

This year the United States Department of Environmental Protection (EPA), who license and regulate glyphosate and its 750 products, must decide if the herbicide is safe for prenatal, infant, child, and adult consumption in food crops and products- and the agency is stalling.

The EPA's sister European Food Safety Authority (EFSA) and European Commission are also stalling a reauthorization of glyphosate under a peer review re-evaluation of EU's list of approved active substances. Currently, France, Italy, Sweden, and the Netherland's are opposed to the relicensing of glyphosate and Germany is abstaining.

In the United States the EPA is under a federal mandate requiring the agency to re-evaluate all pesticides on a 15-year cycle. The federal regulatory agencies (EPA, USDA, FDA) that establish food safety regulations claim the world's most commonly used herbicide is as safe as table salt if used under directions.

So, why doesn't the EPA reregister the license for glyphosate use in agriculture?

In 2015 the World Health Organization's International Agency for Research on Cancer (IARC) assessed glyphosate and its products as a probable human carcinogenic health risk, and this year the California state government intends to list the herbicide as a carcinogen. The California Office of Environmental Health Assessment (OEHHA) intends to list glyphosate as a carcinogen under the mandates of state law Proposition 65 (The Safe Drinking Water and Toxic Enforcement Act of 1986).

http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/intent_to_list/090415LCset27.html

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So far, the EPA hasn't agreed with the California OEHHA and World Health Organization's IARC assessment of glyphosate and its products is a human carcinogenic health risk.

Clinical, peer reviewed studies by science, industry, and government bodies show glyphosate kills plants and bacteria by interfering with an enzyme producing aromatic amino acids which are essential for life in plants, bacteria and humans.

The EPA and glyphosate manufacturers admit consumers absorb glyphosate in

minute amounts from food and drinking water, but assure us decades of clinical studies show it only harms plant life and passes harmlessly through the body in urination.

"All labeled uses of glyphosate are safe for human health and supported by one of the most extensive worldwide human health databases ever compiled on an agricultural product," states Dr. Philip Miller, Vice President Global Regulatory Affairs, Monsanto.

Not so, says an international contingent of scientists.

These scientists, using peer reviewed clinical data, defend the IARC assessment glyphosate poses a human health risk. They argue the US EPA and EFSA have cited biased industry sponsored clinical data to make their case glyphosate is safe, and didn't consider the low dose effects in prenatal, infants and children. "The science consisted solely of toxicological studies commissioned by the herbicide manufacturers in the 1980s and 1990s and never published, not an uncommon practice in U.S. pesticide regulation," says Philip J. Landrigan, M.D., and Charles Benbrook, Ph.D. in their New England Journal of Medicine report GMOs, Herbicides, and Public Health. "These studies predated current knowledge of low-dose, endocrine-mediated, and epigenetic effects and were not designed to detect them. The risk assessment gave little consideration to potential health effects in infants and children, thus contravening federal pesticide law," Landrigan and Benbrook say.

The exponential increase in the agricultural use of glyphosate over the past two decades and its' correlation with human health issues involving neurological, intestinal, and cancer disorders, is hotly contested by both sides of the glyphosate safety debate. “I personally believe that glyphosate is the main reason why we have an epidemic in autism. I think it's also responsible for the rise in Non-Hodgkin's lymphoma, pancreatic cancer, thyroid cancer, inflammatory bowel disease, ADHD, COPD, Alzheimer’s, diabetes, obesity, and probably several other chronic conditions that we face today," says Stephanie Seneff, a senior research scientist at the Massachusetts Institute of Technology (MIT). I don't agree with the WHO's designation as "probably carcinogenic," she says. "I think it is definitely carcinogenic."

The stakes are huge in this political scientific schism.

The future of the global proprietary owned agro-industry glyphosate ready genetically modified organism (GMO) crops lies in the resolution of the split between the World Health Organization's IARC and the US EPA & EFSA. Food manufacturers using GMO crops also have a huge stake at risk if glyphosate is banned or restricted. Over 90% of US corn, soy, and sugar beet crops are grown with glyphosate, and these GMO crops and their products constitute over 80% of processed food products.

Glyphosate is also used in wheat production. Kellogg's, a Fortune 500 food manufacturer, acknowledges grains purchased on the open market contain agricultural herbicide residues

and herbicides including glyphosate are consumed by customers in their processed products. "Nearly all crops in the US are treated with herbicides and pesticides, and may leave behind very low residue levels on some foods," says a customer service Kellogg Company spokesman. "In the US, the acceptable level of pesticide and herbicide use in crops is set by the Environmental Protection Agency (EPA) based on, a standard of reasonable certainty that the use would cause no harm to human health or the environment," says the company spokesman.

US federal agencies in charge of protecting the public's health with a "standard of reasonable certainty", (EPA, USDA, and FDA), state they have never tested glyphosate residue in federal aggregate food crop tests (outside of a USDA Soy 2011 test), because manufacturer and EPA cited laboratory tests claim there is no human health risk. They also insist glyphosate herbicides are safe if used under direction. These same federal agencies also authorized the safety of " Roundup ready" transgenic genetically modified organisms (GMOs) crops as "substantially equivalent to nature", and give GMO glyphosate ready crops a pass from federal food testing requirements.

This year the California OEHHA intends to list glyphosate as a carcinogen under the mandates of state law Proposition 65 (The Safe Drinking Water and Toxic Enforcement Act of 1986)."The law requires that certain substances identified by the International Agency for Research on Cancer (IARC) be listed as known to cause cancer under Proposition 65. Labor Code section 6382(b)(1) refers to substances identified as human or animal carcinogens by IARC." It's a complicated byzantine federal process proving glyphosate isn't a health risk to humans.

But, when it is unraveled a secret is found - the licensing of glyphosate and its products is in violation of the federal laws governing pesticides.

Under the Federal Food Drug and Cosmetic Act (FFDCA) and the Food Quality Protection Act (FQPA) aggregate testing of food crops and products is mandated for all pesticide residue tolerances to account for the accumulated exposures of the herbicide's chemical residue in commonly consumed food.

US federal agencies (EPA, USDA, FDA) claim there is no government aggregate food testing of glyphosate residues, so the EPA uses "available information".

The EPA also admits to waiving the FQPA Safety Factor additional tenfold risk margin for safety for pesticide maximum residue levels (MRLs) protecting the safety of the most vulnerable population group - prenatal, infants, and children.

Clinical laboratory glyphosate health risk testing data cited by the EPA Hazard Identification Assessment Review Committee (HIARC) is used in the federal agencies Office of Pesticide Programs (OPP) and Health Effects Division(HED) ruling the safety of infants and children is adequately protected if the FQPA Safety Factor were reduced to 1X

instead of 10X. For now, the EPA insists glyphosate and its MRLs, established before the herbicide was declared a probable carcinogenic health risk by the World Health Organization, is safe for humans.

"If you are asking if glyphosate is safe, then yes, we have said that glyphosate does not cause unreasonable adverse effects to human health and the environment so long as it is used according to the pesticide labels," says Khue Nguyen, Chemical Review Manager, Risk Management and Implementation Branch 1 Pesticide Re-evaluation Division, Office of Pesticide Programs, EPA. "EPA regulates pesticides, which means we deal primarily with pesticide policy and we determine what appears on the pesticide labels. We do not do food safety inspections or testing on food/feed commodities. To be clear, we set tolerances for all pesticides that are used on food/feed commodities. A pesticide having a tolerance or multiple tolerances does not mean that it is unsafe," says Nguyen.

Section408 (b)(2)(A)(i) of the Federal Food Drug and Cosmetics Act states that EPA can establish a tolerance for a pesticide chemical residue in or on food only if EPA determines that the tolerance is safe. “Safe” is then defined as a “reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures.

Consumer advocates claim without the government providing a transparent aggregate testing of glyphosate chemical residue in food there is no total accounting for the public’s cumulative exposure to the herbicide in a daily diet, and no safety MRL can be established. “The legal process for tolerance setting must be based on human health effects from dietary exposures. However, without data on actual residues on these crops, this cannot be verified. We have challenged EPA’s tolerance setting before and will continue to do so," says Nichelle Harriott, Science and Regulatory Director, Beyond Pesticides.

In a little publicized federal government sponsored program called the IR-4 Project the USDA, EPA, and glyphosate manufacturers do test glyphosate tolerance residue on crops, but without transparency to the public. The United States Department of Agriculture funded IR-4 Project partnering with the EPA; state government agencies, glyphosate manufacturers, and universities have been testing glyphosate residues in food crops and feed to facilitate the herbicide's use in agriculture. IR-4 sounds like a federal secret, but when it petitioned the Environmental Protection Agency (EPA) in the federal register to increase food crop MRL residue tolerance levels of the world's most popular herbicide it gave away its cover.

The IR-4 petition went unnoticed in the shadow of Monsanto's (an IR-4 member) EPA petition, and was approved by the EPA (also an IR-4 member). Headquartered in Princeton, N.J., the IR-4 operates as a "unique" partnership between the USDA, EPA, the National Institute of Food and Agriculture (NIFA), the Agricultural Research Service (ARS), the State Agricultural Experiment Stations (SAES), agrochemical industry, universities, commodity groups, and

growers. Monsanto, Syngenta, DuPont, Dow, Bayer, and BASF are listed in the IR-4 directory. With a staff of over 125 full time members the mission statement for the IR-4 Project is to "facilitate registration of sustainable pest management technology for specialty crops and minor uses." Specialty crops tested by IR-4 include commonly consumed food crops (i.e. fruits, vegetables, nuts, herbs, spices,) and non-food plants and flowers used in landscape. "As some background, for more than 50 years, the USDA funded IR-4 Project is the only resource for facilitating registrations of conventional chemical pesticides, biopesticides, and organic products for growers of specialty crops and other minor uses (specialty uses) in the United States. These are uses not supported by registrants. IR-4 is a partnership with government, industry and growers," says Jerry J. Baron, PhD, Executive Director, IR-4 Project. "We typically develop residue exposure data to assist EPA with their risk assessment. Basically we apply the test product the way the farmer would potentially use the pesticide or biopesticide. When the crop is mature, we harvest the raw agriculture commodity and analyze for the presences of the chemical, biochemical and/or metabolites, " says Baron.

What was the IR-4's urgent need to exponentially increase the herbicide residue levels on such foods as carrots, sweet potatoes, fruits, grains, and berries? "The IR-4 Project received multiple request for assistance to facilitate modifications to the registration of glyphosate from public sector scientists with USDA and the State Agricultural Experiment Stations. These requests were reviewed during IR-4 Project Food Use Workshops and classified as high priority," says Baron.

The IR-4 insists there is no conflict of interest with government regulatory bodies and glyphosate industry manufacturers collectively using their testing data to petition the EPA in the federal register to increase glyphosate MRL levels for crops. "Though IR-4's data development is independent of the companies, IR-4 submissions are coordinated with the companies. Due to provisions of the Pesticide Registration Improvement Act, IR-4 submissions are often classified as part of a company submission," says the IR-4 Executive Director. The IR-4 also insists their hidden glyphosate residue data developed under USDA and EPA testing standards is "different" from the USDA MRL monitoring data used in national USDA food survey's to protect the health of the public. "The data IR-4 develops is much different than glyphosate monitoring data by EPA and USDA; we are fully removed from that activity. USDA just released a report within the last couple of weeks from their Pesticide Data Program out of the Agriculture Marketing Service. You may find some glyphosate monitoring data in that sample set," says Baron.

The USDA Pesticide Data Program (PDP) Annual Summary report is conducted by the USDA Agricultural Marketing Service (AMS) to collect data on pesticide/herbicide residues in over 10,000 samples of fruit, vegetables, fresh and processed products, and infant formulas throughout the US using the MRL tolerances set by the EPA. This PDP data is presented to the public to assure consumers the food they feed their families is safe. "Ultimately, if the EPA determines a pesticide is not safe for our families it is removed from the market," states the USDA in their 2014 PDP report. The USDA admits they don't test in the PDP for the mostly

commonly used herbicide in the US (glyphosate) in food crops and food products - except for a USDA soy test in 2011. "The PDP tests a wide variety of domestic and imported foods using a sound statistical program and the most current laboratory methods. Glyphosate is not detectable using the multi-residue methods (MRM) the PDP testing laboratories use and would require a specialized method. Glyphosate requires the single analyte method to test for residues," says Peter Wood, spokesman for the Public Affairs Office of the USDA AMS.

When asked, why didn't the USDA PDP use USDA funded IR-4 glyphosate residue MRL data for those foods listed in the annual survey the USDA spokesman said, "The report does not include data from other sources." Why then doesn't the USDA use the single analyte method used in the 2011, PDP testing of 300 soybean samples for glyphosate and its metabolite AMPA (aminomethylphosphonic acid)?
"USDA and EPA specialists discuss the selection of commodities and pesticides for testing. With USDA's scientific input and EPA's data needs, EPA makes the determination which commodities and pesticides are tested," says Wood. "Currently, the U.S. Food and Drug Administration (FDA) are testing corn and soybean grains for glyphosate residues. EPA is waiting on the results from FDA testing before making the determination if additional data is needed for its ongoing evaluation of glyphosate tolerances to ensure that the levels set by EPA meet the safety standards prescribed by the law," he says.

The FDA is responsible for enforcing EPA pesticide tolerances, but admits it is the first time they have ever tested for glyphosate MRLs in any food commodity. "FDA has not routinely looked for glyphosate in its pesticide monitoring regulatory program for several reasons, including that available methods for detecting glyphosate were selective residue methods that would have been very expensive and labor intensive to implement in FDA field labs," says Charlotte Lian, Ph.D., Plant Products Branch, Division of Plant Products and Beverages, Office of Food Safety Center for Food Safety and Applied Nutrition, Food and Drug Administration. "FDA is aware of the 2015 IARC World Health Organization's assessment of glyphosate. In the U.S., risk assessments of pesticides are conducted by EPA," says Lian.

How was glyphosate and 750 products licensed without abiding by the aggregate tolerance residue testing data mandates for risk assessments under the Food Quality Protection Act? The EPA dodges the question.

Anne Overstreet, Chief Communication Services Branch, Field and External Affairs Division Office of Pesticide Programs, Environmental Protection Agency says, "the Federal Food, Drug, and Cosmetic Act states: To make the safety finding, EPA *considers*, among other things: the toxicity of the pesticide and its break-down products, aggregate exposure to the pesticide in foods and from other sources of exposure and any special risks posed to infants and children."

"While testing for aggregate exposure is nearly impossible – people eat different foods, combinations of foods, and amounts of foods – EPA uses *models* to assess

likely aggregate exposure and adds an additional safety factor to further protect consumers, especially children, as required by the Food Quality Protection Act," she continues. "In setting tolerances, EPA must make a finding that the tolerance is "safe," with safe being defined as meaning that there is a "reasonable certainty that no harm will result from aggregate exposure to the pesticide residue," she says. Anne Overstreet then refers to the USDA PDP aggregate exposure testing as proof consumers shouldn't worry about pesticides residues on their food - even though the 2014 PDP didn't test for glyphosate. "The PDP data demonstrate that overall pesticide residues found on foods tested are at levels below the tolerances established by EPA and pose no safety concern. Based on the PDP data, consumers can feel confident about eating a diet that is rich in fresh fruits and vegetables," says Overstreet. "Glyphosate residue data are not part of 2014 PDP sampled pesticides. To find out whether FDA has plans to test for glyphosate residues, please contact FDA directly," she says.

This type of circular non-answer on glyphosate's safety is how the EPA has been stalling their decision to reregister the herbicide and its products - permitting its' continued use. The EPA also hasn't responded on whether the herbicide's current MRL tolerance residue levels are in violation of the FQPA Safety Factor protecting prenatal, infants, and children. "The real question is whether the EPA was in violation of the law when glyphosate was approved then and now," says Jonathan Evans, Environmental Health Legal Director and Senior Attorney for the Center for Biological Diversity.

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