GMO Beyond The Science

Precautionary Politics: Europe Moves Backward into a Fear-Based 'Dark Ages' in Regulating Agriculture and Cancer Risks

David Zaruk, Founder of GreenFacts, Environmental-Health Risk Governance Analyst, Professor at Odisee University College | July 25, 2018

Highlights:

- ***The confusion between hazard and risk has led to bungled European regulation of three popular chemicals: glyphosate herbicide, 'endocrine disruptors' and neonicotinoid insecticides***
- ***The EU precautionary principle has evolved into a tool to manage environmental and human dangers that places the burden on manufacturers to remove all potential hazards from a product, even when that's impossible***
- ***EU agricultural technology is stuck with an illogical policy tool that has become a global embarrassment among scientists and policymakers***

This is the second article in a three-part series on risk and hazard:

Part I: Risk, Hazard and the Precautionary Principle: Why Europe Gets Crop Biotechnology and Chemical Regulation So Wrong

Part II: Precautionary Politics: Europe Moves Backward into a Fear-Based 'Dark Ages' in Regulating Agriculture and Cancer Risks

Part III: In the Battle to Regulate GMOS, Gene Editing and Other New Breeding Techniques, Who Has 'Hazard Blood' on Their Hands?

When any technology is held up to a strictly-applied hazard-based regulatory approach, the result is a near certain ban. For environmental activists who are deeply skeptical of technology, that may be the point. In European agricultural policy, certain technologies considered critical to modern farming and deemed safe by regulatory agencies around the world have been limited or eliminated with the application of a hazard-based model; it should come as no surprise that the consequences for farmers have been difficult.

Despite an opportunity to reverse this biotechnology innovation backsliding, on July 25 the European Union again placed itself firmly on the side of politics over science. The Court of Justice of the European Union ruled

that gene-edited crops should be subject to the same stringent 2001 directive as conventional genetically modified (GMO) crops.

Scientists and farmers hoped that seeds created using precise new breeding technologies such as CRISPR–Cas9 would be exempted from existing European law that has limited the planting and sale of GMO crops.

The court also ruled that that any new crops created through mutagenesis—more than 2000 crops, such as Italian durum wheat and sweet grapefruits, have been created since the 1940s by zapping seeds with radiation or soaking them in chemicals—must also be considered under the EU GMO regulation. The decision will have global reverberations because the EU is such a huge market.

The scientific illiteracy behind these decisions show how far into the Dark Ages European authorities have fallen. Despite the fact that neither gene editing nor modern mutagenesis does not introduce any "foreign" genes into seeds, the courts sided with the French activist groups in concluding that if the results of this process could allow for herbicide-tolerant plants (think glyphosate), then it must be treated as a GMO.

Seeing how mutagenesis has been practiced for more than 50 years and has led to plant breeding improvements of most foods consumed by Europeans, the Court then showed its ignorance by trying to differentiate between the crude conventional mutagenesis techniques that have been available for 70 years (grandfathered in as acceptable) and the more precise, modern technologies (which would be restricted).

The only means to determine the difference of the two technologies was the "long safety record" of conventional mutagenesis. The decision by the Court of Justice ensures that plant breeding in Europe will not emerge from the dark for decades.

Here are three additional case studies illuminating the backwardness of EU farm policy:

1. Glyphosate

Glyphosate is the world's most popular, and considered the most toxicologically safe, herbicide. Originally sold under patent by Monsanto as Roundup, it has been available in generic form since 2000 and is sold by more than a dozen companies. It's often paired with genetically-engineered herbicide-resistant crops. Those sold by Monsanto are called 'Roundup Ready'.

Material	What the heck is it?	LD50 (mg/kg)*	toxic category**
water	You know this one.	90000	practically non-toxic
sucrose	...and this one. Refined from sugar cane or sugar beets	30000	practically non-toxic
citric acid	A chemical in citrus fruits (lemons, oranges, etc)	12000	slightly toxic
ethanol (component in many bevvies)	Hic!	7000	slightly toxic
glyphosate	A broad-spectrum systemic herbicide used to kill weeds brought to market under tradename RoundUp	5600	slightly toxic
sodium bicarbonate (baking soda)	One word: Biscuits	4220	moderately toxic
sodium chloride (table salt)	Not too much now...	3000	moderately toxic
acetaminophen	Whoa...I'm getting a headache	1944	moderately toxic
hydrogen peroxide	Common household product often used industrially for drinking water and waste water treatment	1580	moderately toxic
theobromine	Is a bitter alkaloid of the cacao plant in CHOCOLATE (*What the heck is this doing on this list?)*	1265	moderately toxic
Rotenone	A broad-spectrum insecticide and pesticide approved for use in organic production	132-1500	very toxic
copper sulfate	A compound approved for use in organic production as a fungicide	300	very toxic
caffeine	Gasp. See *italicized* comment on chocolate^	192	very toxic
DDT	Tasteless and almost odorless chemical known for its insecticidal properties. Was used in WWII to control malaria and typhus.	113-800	very toxic
Nicotine	A potent alkaloid found in the nightshade family of plants (Solanaceae) and a stimulant drug and a major contributing factor to the dependence-forming properties of tobacco smoking.	50	extremely toxic
cyanide	Cyanides are produced by certain bacteria, fungi, and algae and are found in a number of plants - used in mining, industrial organic chemistry and for pest control.	10	extremely toxic
vitamin D	Vitamin D toxicity can occur when you have excessive amounts of vitamin D in your body by megadoses of of vitamin D supplements (not by diet or exposure to the sun).	10	extremely toxic
Strychnine	Is a highly toxic, colorless, bitter crystalline alkaloid used as a pesticide, particularly for killing small vertebrates such as birds and rodents.	1-2	super toxic
aflatoxin	Naturally occurring mycotoxins produced by species of fungi. 14 different types of aflatoxin are produced in nature. They can colonize and contaminate grain before harvest or during storage.	0.003	super toxic
botulin	A protein and neurotoxin produced by a bacterium. It its pure form, it is the most acutely toxic substance known. Preparations of the toxin can be effectuvely used for therapeutic or cosmetic purposes.	0.00001	super toxic

Sources: 'The Dose Makes the Poison' in *Assessing Toxic Risk* (http://ei.cornell.edu/teacher/pdf/ATR/ATR_Chapter1_X.pdf); various Wikipedia entries; various MSDS sheets found online.
Inspiration: Joni Rose's witty and informative FB post in response to (mis)understanding about chemicals and toxicity.
*Please note: the LD50 levels outlined are based on oral ingestions by rats
**Toxicity rankings are based on the EPA's categorization (I through IV) (Title 40 of the Code of Federal Regulations).

@DocCamiRyan

Glyphosate has been approved and safely used in home gardens for 45 years. It is far less toxic than vinegar (acetic acid), which is used with no controversy by organic farmers to control weeds—and it is far more effective.

The entire "ban glyphosate" movement (now a global propaganda effort directed at modern agriculture) hinges on a hazard assessment conducted by the only agency in the world that evaluates the hazards instead of the risks of substances: the United Nations WHO sub-group IARC. Over more than 50 years of its existence, the IARC has assessed more than 1000 substances, classifying only one as non-carcinogenic. IARC's list of "known" (group 1), "probable" (group 2A), and "possible" (group 2B) carcinogens includes: sunshine, mobile phones, alcoholic beverages, wood dust, outdoor pollution, working as a hairdresser, wood smoke, night shifts, hot yerva mate tea, red meat—as well as coffee and the herbicide glyphosate.

IARC found no evidence that minute glyphosate residues in our food supply were hazardous but did find, in some studies but not others, a weak correlation between glyphosate and a form of cancer, non-Hodgkin's lymphoma, in workers. In practical terms, the risk is negligible and all other (risk-based) scientific institutions, from the US Environmental Protection Agency to Health Canada to the European Chemicals Agency and the European Food Safety Authority, have rejected IARC's hazard-based findings.

Still a global alliance of anti-chemical NGOs and anti-industry advocacy groups have pushed the narrative and fooled a fair number of people into believing the hazard assessment linking glyphosate to the remote possibility of cancer actually means something in real-life terms. The near-hysteria stirred has intimidated the European Commission to the point that it has struggled for years to renew the glyphosate authorization. It is now on what appears to be borrowed time, with a five-year extension.

2. Endocrine Disrupting Agents

Since the early 1990s, chemophobic campaigners have made sweeping claims that many well-tested and approved chemicals, such as Bisphenol-A used as a plasticizer or glyphosate, are making us infertile, androgynous and susceptible to a wide range of diseases because they disrupt endocrine functions, primarily in females and young children.

Overlooking the reality that contraceptives and hormone replacement therapies intentionally disrupt the endocrine system and that natural substances in coffee, soy, hummus and many other foods are known endocrine disrupters, advocacy groups have been successful in generating fears about a potential hazard-based link between pesticides and the endocrine system. While mainstream science contends the link is dubious, under the hazard-based approach if it is hypothetically impossible to disprove this link then the chemicals must be banned.

If the European Commission continues down this path, all crop protection tools (including all organic pesticides) could be taken off of the market.

When researchers fed honeybees a diet based solely on neonicotinoid insecticides, the bees did not react very well. This lab feeding-test data seemed to suggest a major threat not seen in real-world data.

3. Neonicotinoid insecticides

For years, some environmental advocacy groups have been warning of an impending "bee-pocalypse." Their claim, repeated in press releases and media headlines, is that honeybee populations are rapidly declining—honeybees may soon go extinct, some have claimed—and because bees pollinate much of the food we eat, the world could soon be starving. Most entomologists, and the basic facts—the number of honeybee hives are now at an all-time high, with Europe and North America at 20-year highs—do not support these claims of doom.

The prime alleged culprit in this narrative is a relative new class of insecticides known as neonicotinoids, or "neonics," for short. Neonics are a class of systemic pesticides

Most entomologists, and the basic facts—the number of honeybee hives are now at an all-time high, with Europe and North America at 20-year highs—do not support these claims of doom.

introduced in the early 1990s and popular in North America, Europe, Australia and elsewhere to help corn, soy, cotton and canola farmers. They have been embraced as a less toxic replacement of organophosphate pesticides, which are known to kill bees and wildlife (and have been linked to health problems in workers). But they have been mired in controversy since the mid 2000s when reports emerged of a sudden and widespread bee die-off known as Colony Collapse Disorder, prompting scientists to launch dozens of studies.

When researchers fed honeybees a diet based solely on neonicotinoid insecticides, the bees did not react very well. The European Commission then drafted the Bee Guidance Document that systematically excluded research from all normal exposure scenarios from field tests, which had shown that bees were faring well, CCD had abated, and worldwide numbers of beehives were at 25-year highs. That left only the lab feeding-test data, which seemed to suggest a major threat not seen in real-world data.

With no realistic exposure data, the European Commission left itself only one choice: follow the hazard assessment and impose a temporary precautionary ban on neonics. The Commission's Joint Research Centre recently concluded that the ban was devastating to farmers, the environment, consumers and bees, but the Commission felt comfortable enough with their hazard-based findings to ignore the study presented by their own experts. The European Commission recently went one step further down the road of ignorance, banning all outdoor applications of neonic seed treatments, including on sugar beets, which don't flower and are of no interest to pollinators.

The revision of the EU Pesticides Directive set out to create a hazard-based regulatory framework. The previous regime focused on lowering maximum residue levels (risk management by reducing exposures to hazardous substances); the new regime has sought to ban any substance posing a hazard to public health or the environment. It is an irrational policy tool that is forcing regulators to be irresponsible to European citizens.

Two paths to precaution

Today European agricultural policy is largely led by uncertainty managers, taking a hazard-based approach to food safety, with the precautionary principle the tool of choice to eliminate any undesirable hazards. There are different formulations of the "precautionary principle", some more rational than others.

Precaution first started to be widely discussed at the Rio Earth Summit in 1992 in debates on the possibility of climate change. Principle 15 of the Rio Declaration states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. *Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."*

Principle 15 of the Rio Declaration states: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

This is known as the triple negative: Even if the science on potential climate change lacks full certainty, that is not a reason (given the enormous risks to humanity due to global warming) to not act to mitigate potential causes of climate change. It was a proactive form of uncertainty management. (This approach could easily justify the quick adoption of GMOs: Even if the science of GMOs is not fully certain, that is not a reason (given the serious potential stresses on food security from increasing global populations) to not act to improve agricultural output.) This form of precaution is a call for more risk taking in the face of uncertainty.

The version of the precautionary principle widely used in Europe is different and even more extreme. It was developed by the European Environment Agency and commonly referred to as the reversal of the burden of proof. Previously products were put on the market, and then regulators had to prove there were risks by assessing exposure.

With this version of precaution, the burden of proof was reversed. Now, unless an organization can prove a substance, technology or methodology is safe, precaution would be taken (it would not be allowed on the market). While the European Commission did not use this definition of precaution in its 2000 Communication, and it is not defined in any treaty, in practice the reversal of the burden of proof is used in many directives.

When a regulator does not consider exposures in assessing hazards (when there is no risk management process), then precaution is the only readily available policy tool. The seven-year-old boy gets locked in his bedroom; crop protection tools get taken off the market.

The EU precautionary principle version is an uncertainty management tool: "Unless you can prove that an agricultural technology (e.g. pesticide, seed technology, fertilizer) is safe, the precautionary principle must be imposed. Safety though is relative: what may be perceived as safe when exposures are reasonably managed may be deemed unsafe to a "What-iffer".

Why are Europeans hazard-obsessed?

European policymakers willingly forego safe technologies and endanger their ability to produce sufficient quality food. What is behind this rejection of common sense, something a seven-year-old could understand? Why is the hazard-based approach so widely accepted in Europe? Here are some possible answers:

- ong history of precautionary practices in Europe dating to urban wall-building in medieval times
- Biologists tend to differ from chemists on the risks of long-term, low-dose exposures and potential cocktail effects.
- Trust issues, either in the honesty of the regulators in determining acceptable exposure levels or in individuals being able to follow instructions and properly manage risks.
- Risk crises in the 1990s (from mad cow to acrylamide to tainted blood to dioxins).
- Pro-organic food lobby has done an impressive job propagating a hazard-based approach.

There is much irony in how the precautionary mindset is applied in real life. While legislators embrace the precautionary principle, Europeans in general have not in their actual lives. We impose precaution on substances rejected because of cultural prejudices: pesticides, GMOs and most seed breeding technologies, but not high-benefit but arguably hazardous products (according to IARC) like mobile phones, cars and coffee).

The popular narrative does not feel comfortable rejecting organic food, so we tolerate organic-approved pesticides or the outsized percentage of bacterial contamination in the organic food industry even if their toxicity and exposure levels are far higher than well-tested, targeted and safe food using synthetic alternatives. "What iffers" are not looking for rational solutions, so precaution follows seamlessly with this normative (value-based) decision process.

While Europeans understand the limitations of the hazard-based approach and are fully capable of making common-sense decisions when allowed to participate, there is a small minority of opportunistic interest groups in Europe that have used this flawed distinction to their ideological advantage. Because of them, EU agricultural technology is stuck with an illogical policy tool that has become a global embarrassment among scientists and policymakers.

David Zaruk is an environmental-health risk governance analyst and a professor at Odisee University College. He sits on various research ethics panels and frequently serves as a chair, expert, rapporteur, adviser or evaluator for European-funded research projects. Until 2006, David worked twelve years in chemicals issue management for Solvay, Cefic and Burson-Marsteller. In 2001, he was one of the founders of GreenFacts, a science-based risk communications tool for non-specialists. He writes a blog under the pseudonym The Risk-Monger, assessing the European use of evidence in environmental-health policy management.

Global Farmer Network® (GFN) is a non-profit advocacy group led by farmers from around the world who support free trade and farmers' freedom to choose the tools, technologies and strategies they need to maximize productivity and profitability in a sustainable manner. Established in 2000, the Global Farmer Network is committed to inserting the worlds farmers voice in the global dialogue regarding food and nutritional security. The Global Farmer Network identifies, engages and supports strong farmer leaders from around the world who can work with others to innovate, encourage and lead as full stakeholders in the work that is being done to fill the world's food and nutrition security gap in a sustainable manner.

The **Genetic Literacy Project** is a 501(c)(3) non profit dedicated to helping the public, journalists, policy makers and scientists better communicate the advances and the technological, ethical and religious challenges ushered in by the biotechnology and genetics revolution, including CRISPR gene editing, in biomedicine and agriculture.