GMO Beyond The Science

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

David Zaruk, Founder of GreenFacts, Environmental-Health Risk Governance Analyst, Professor at Odisee University College | July 24, 2018

Highlights:

- ***European regulators that set rules governing exposure to farm chemicals used in tandem with genetically engineered crops (GMOs) confuse 'risk' with 'hazard,' defying basic science and stifling innovation.***
- ***International Agency for Research on Cancer alone among agencies that evaluate risk view the 'dose-response' model as a medieval concept, replacing it with a more "caring" and "protective" concept: "the timing makes the poison".***
- ***Agricultural products are often banned or restricted if they pose theoretical hazards, only to be replaced by less effective alternatives, even though their toxicity profiles are more problematic.***

This is the first 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?

Why is Europe seemingly so confused when it comes to understanding the differences between chemicals and technologies posing manageable hazards versus those that threaten us with unacceptable risks? It's a conundrum that perhaps only a child can fully appreciate.

I was recently discussing the concept of safety, dangers and risks with a seven-year-old boy who wanted to cross the street to join his friends in a playground.

"Cars can be dangerous," I advised him. "Please stay away from the streets when playing."

It seemed like common sense advice. A hazard (like a car) is only a risk if we are involved in a crash or it hits us while moving.

That seven-year-old intuitively understood that a hazard —the car—only becomes a danger—a risk—when it can severely impact us. If he does not expose himself to moving cars in traffic (hazard), there is no risk.

Said in more scientific terms: ***Risk = Hazard x Exposure***.

Said simply, proper risk management is child's play.

Credit: Iida Ruishalme at Thoughtscapism.com, Alison Bernstein SciMoms.com

So why is it that European agricultural policy regulators charged with setting real-life rules governing human and environmental exposure to farm chemicals often used in tandem with genetically engineered crops (GMOs) can't seem to figure this stuff out?

The problem arises when someone interrupts this risk-management model with open-ended, uncertainty-driven and often far-fetched "What ifs". What if a car crashes through a barrier and drives across the playground? Unless impenetrable barriers are constructed, this potential event cannot be completely excluded, the most precautionary-minded adults say. So, they propose a solution that would reduce that risk to zero: lock that boy in the house so that this hazard, highly unlikely to begin with, is now impossible. Yes, he will never be injured by a wayward automobile…but he will also not experience the benefits of playing safely and happily with his friends.

What are the trade-offs to reducing risks to near zero? What benefits are lost in taking this hyper-precautionary approach?

As the boy looks out the window at the playground filled with his friends, he does not intuitively understand the wisdom of the Full Monty hazard-based approach imposed on him by zero-tolerance "What-iffers".

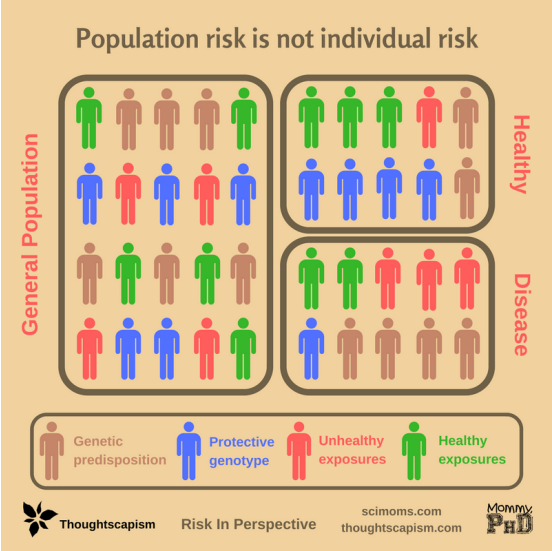
This article focuses on how European Union legislators have locked themselves out of a reasonable risk management process when it comes to farm chemicals and agricultural biotechnology, from GMOs to gene editing; instead they are basing their regulations on extreme "What-if" hazard assessments that have real—and deleterious—consequences.

Hazards of risk management

The difference between a *hazard-based approach* to decisions and a risk-based approach is simple: a hazard-based approach identifies the existence of a potential harm, but only under certain circumstances.

Focusing solely on hazard is the approach of the World Health Organization sub-agency known as IARC—the International Agency for Research on Cancer. Its role is to conduct and coordinate research into the causes of cancer to determine if a substance or situation could cause cancer. It is not empowered to assess whether a substance is likely to cause cancer (that's a "risk" assessment and risk is dependent on exposure.)

Over the last 50 years, this agency has reviewed approximately 1000 agents (from coffee to alcohol to meat to mobile phones) or situations (exposure to



Credit: Iida Ruishalme at Thoughtscapism.com, Alison Bernstein SciMoms.com

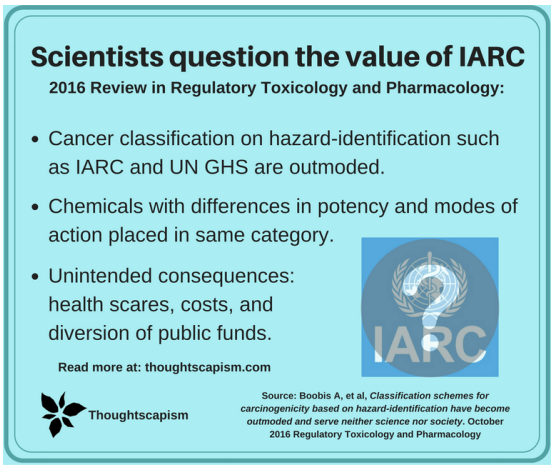
The graphic above illustrates that many factors influence risk for disease. Genetic variations may have a positive, negative, or neutral effects on development of disease. Exposures (including lifestyle factors) can also have positive, negative or neutral effects. By looking at large groups of people, epidemiologists can detect differences in the percent of people in various subgroups (by genetics or exposure) that develop a disease. However, from that population level data, it is not possible to predict an outcome for any specific individual within that population.

sunshine, working the night shift) to determine if something or a situation might cause cancer under certain circumstances.

Over the last 50 years, this agency has reviewed approximately 1000 agents (from coffee to alcohol to meat to mobile phones) or situations (exposure to sunshine, working the night shift) to determine if something or a situation might cause cancer under certain circumstances.

If IARC finds that substance X (say, coffee that contains the chemical acrylamide produced during the roasting process or is very hot) may cause cancer in rats, at whatever the exposure level, then the hazard is identified as cancer-causing, even if the likelihood of extensive exposure is rare. The agency is not empowered to address the likelihood of extensive exposure; that's what's called a "risk analysis," which is what regulatory or advisory agencies around the world, such as the Environmental Protection Agency in the US or the European Food Safety Authority engage in.

IARC makes a simple declaration: substance or situation x is probably or likely to cause cancer. There is no question about the amount of a substance a laboratory research rat would need to consume to develop cancer, or how the substance might affect humans. Substance X —coffee, sunlight, meat or the toxicologically harmless herbicide glyphosate—is therefore automatically labelled a carcinogen—it can cause cancer. Out of nearly 1,000 agents examined over the course of the IARC monograph program's history, only one has been classified as probably not carcinogenic.



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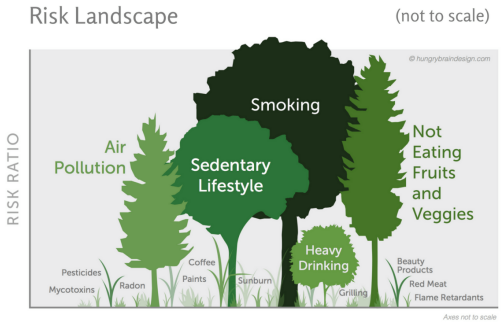
A *risk-based analysis* normally follows after a hazard identification by testing the exposure to Substance X. How much would a person need to consume or be subject to per day and under what conditions before a risk of cancer materialized. Substance X could be a glass of red wine, cleaning product, sunscreen additive, insecticide, or even a stressor, such as working the night shift for extended periods of time. In the case of coffee, researchers have determined it would take a person drinking as many as 2000 cups a day, day-after-day for one year, before it would even approach levels considered risky (yet drinking three cups a day can lower your risk of numerous diseases, including hardening of the arteries). But IARC considers coffee a cancer hazard nonetheless.

'The timing makes the poison'

The "What-iffers", such as IARC, environmental advocacy groups that argue for a hazard-based regulatory process and European legislators that look to a cancer hazard determination for guidance, reject the risk-based approach used by regulatory agencies around the world to measure and evaluate exposures, arguing that we just cannot be certain what level of any substance is harmful. They reject he famous declaration by Paracelsus, the 16th century physician known as the father of toxicology, that "the dose makes the poison." Paracelsus understood that any substance, even water, could pose a potential toxic risk, if we are exposed to it at high doses (e.g. Such as when someone drowns).

Activists groups—and IARC alone among agencies that evaluate risk and hazard—view the 'dose-response' model as a backward, medieval concept. They have replaced the risk-based standard with what they contend is a more "caring" and "protective" concept: "the timing makes the poison". For example, they maintain that if a baby or a fetus might be potentially exposed to a chemical, no matter the amount or for how long, it must be removed (except if it's coffee, a European favorite, which they inexplicably exempt!)

Under this scenario, costs and benefits are often not considered. Products are regularly banned or heavily restricted if they are deemed to pose theoretical hazards, only to be replaced by less effective products, which and often because of political reasons, remain available for use even though their toxicity profile is far more problematic.



Credit: Anne Martin at hungrybraindesign.com, Alison Bernstein at SciMoms.com, Iida Ruishalme at Thoughtscapism.com

A look at the overall landscape of a selection of modifiable risk factors common in the developed world.

Today in Europe, more and more crop protection products—herbicides, insecticides and fungicides, primarily—are being taken out of the farmers' toolkit, not because they pose risks (exposures can be safely managed), but because they are identified as potential hazards, even when they are perfectly safe as used.

Agricultural products are regularly banned or heavily restricted if they are deemed to pose theoretical hazards, only to be replaced by less effective products, which remain available for use (often for political reasons) even though their toxicity profiles are far more problematic.

The hazard-based approach, which is the application of what is known as the "precautionary principle," is a problematic tool for policy and is considered an outdated and even a deceptive tool by the vast majority of the science community. Because every substance is potentially carcinogenic, if exposure levels are not taken into account, everything conceivably could be regulated off the market—if this radical perversion of the Precautionary Principle is consistently applied.

Think of the implications for modern farming. All pesticides, including those approved for and critical to organic farming would be banned. All food additives and stabilizers would be gone. There would be no more packaging, processing or cleaning of food. If what we demand is certainty, we will have no approved foods (and that is certain).

Credit: Iida Ruishalme at Thoughtscapism.com, Alison Bernstein SciMoms.com

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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.

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