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U.S. Should Stop Funding the International Agency for Research on Cancer Misleading Classifications Promote Counterproductive Bans and Adverse Market Impacts By Angela Logomasini, Ph.D.*

Numerous scientific bodies around the world, both public and private, attempt to assess the cancer-causing potential of various industrial chemicals. Ideally, those research programs should inform everyone, from policy makers to manufacturers to consumers, enabling people to make better decisions to minimize risks. However, too often classification programs rely on outdated and faulty methodologies and are influenced by political considerations that lead to inappropriate cancer classifications. Their faulty conclusions can create serious problems, including bans on useful products, market deselection of such products, and public confusion about cancer risks. Unfortunately, such problems are becoming commonplace.

Among some of the most flawed programs is the Lyon, France-based International Agency for Research on Cancer (IARC), which is partly funded by U.S. government grants. IARC classifications are highly influential and often generate headlines that can be alarming to consumers and can trigger regulatory actions around the world. But as this paper details, IARC's process for designating chemicals as carcinogenic is flawed and increasingly susceptible to political influences.

IARC's misguided 2015 classification of the weed killer glyphosate as "probably carcinogenic" exemplifies the far-reaching, adverse impacts associated with faulty classifications. Although the overwhelming body of science indicates that glyphosate, which is the active ingredient of Monsanto's Roundup, is not a carcinogen, a California jury used it as a basis for a \$289 million award to a plaintiff who claimed it caused or contributed to his non-Hodgkin's lymphoma. About 8,000 other lawsuits are pending. Governments around the world may follow up with bans, which may eventually force Monsanto to abandon one of its most popular and beneficial products. Farmers will suffer as they lose access to a useful tool while few alternatives exist. For consumers, it will mean higher food prices.

IARC Mission and Funding. Launched in 1965, IARC is a division of the World Health Organization, which is part of the United Nations. IARC's mission, as described on its website, is to "promote international collaboration in cancer research." It focuses on assessing environmental cancer risks, which includes any non-genetic cause of cancer. IARC notes that its classifications are supposed to inform lawmakers and regulators, promoting policies that will reduce cancer risks.

* Angela Logomasini is a senior fellow at the Competitive Enterprise Institute.

The IARC receives funding from member states and has a two-year budget of €44.1 million (\$51.2 million), of which the United States was assessed to pay more than €3.3 million (almost \$4 million) for 2018-2019. U.S. funding comes in the form of grants issued by the National Institutes of Environmental Health Sciences, which is part of the U.S. National Institutes of Health.

IARC Classification Process. IARC began publication of a series of monographs in the 1970s, titled, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans*, which sought to address specific potential cancer risk factors or "agents," most of which focus on chemicals. These monographs are written by working groups of IARC's scientific members and advisory consultants. For each agent, a working group is supposed to review the science, produce a monograph describing the research, and then place the agent within one of several categories related to its cancer-causing potential. The categories are detailed below.

The monograph series includes a preamble, which is updated periodically. The most recent iteration, from 2006, notes that it "is primarily a statement of scientific principles, rather than a specification of working procedures." In other words, the standards set in the preamble are non-binding on working groups. The organization's working groups write the monographs using their own operating procedures, often relying on precedents from earlier meetings, rather than adhering to any firm operating procedures or scientific standards outlined elsewhere.

Among the principles noted in the preamble is IARC's focus on assessing chemicals based mostly on "hazard." The preamble explains that IARC'S classifications are not based on a complete assessment of risks:

A cancer "hazard" is an agent that is capable of causing cancer under some circumstances, while a cancer "risk" is an estimate of the carcinogenic effects expected from exposure to a cancer hazard. The *Monographs* are an exercise in evaluating cancer hazards, despite the historical presence of the word "risks" in the title. The distinction between hazard and risk is important, and the *Monographs* identify cancer hazards even when risks are very low at current exposure levels, because new uses or unforeseen exposures could engender risks that are significantly higher.⁴

However, classifying substances or activities as "hazardous" is not particularly helpful. It is only the first step in a full chemical risk assessment, which involves a number of steps. The U.S. Environmental Protection Agency (EPA) identifies four:⁵

- 1. **Hazard Identification.** Researchers consider whether a chemical has the *potential* to cause harm at some exposure level.
- 2. **Dose-Response Assessment.** This step determines if there is any relationship between exposure to the chemical and health conditions.

- 3. **Exposure Assessment.** If the dose-response assessment finds a relationship, researchers assess at what exposure levels it occurs (considering such things as a chemical's potency, estimated public exposure levels, and frequency or duration of exposures).
- 4. **Risk Characterization.** Using information collected in the other three steps, researchers assess actual risk levels.

Many times, chemicals that pose hazards carry little actual risks because either they are too weak to impact public health, public exposure is too low or too infrequent, or all of the above. But IARC working groups do not need to proceed past step one before placing chemicals in one of its cancer categories. This process occurs behind closed doors among the working group members without any binding scientific guidelines. Monographs discuss exposure levels and other research, but they are not required to determine whether exposure is sufficient to pose actual risks.

In addition, working groups have only weak and non-binding guidelines to use when deciding how to classify a chemical. According to the preamble, based on hazard alone, IARC working group members place agents under one of the following five classifications:

Group 1: *carcinogenic to humans*

Group 2A: probably carcinogenic to humans

Group 2B: possibly carcinogenic to humans

Group 3: not classifiable as to its carcinogenicity to humans

Group 4: probably not carcinogenic to humans

If IARC's "possibly" and "probably" guidelines sound unscientific, it is because they are unscientific. In fact, the guidelines for all these categories are murky, allowing ample room for interpretation.

For instance, chemicals are placed in what would seem to be the most dangerous category, "Group 1: carcinogenic to humans," if there is "sufficient evidence of carcinogenicity." The "sufficient evidence" criteria are vague and allow for exceptions. The preamble states that a chemical can be dubbed as "known to cause cancer" even if there is not sufficient evidence from human studies when there is "strong evidence in exposed humans that the agent acts through a relevant mechanism of carcinogenicity" *and* there is "sufficient evidence" from rodent studies.

There is some mention about weighing the evidence, indicating that working group members should place emphasis on the best available science. But since the preamble is largely descriptive of the process rather than advisory, working groups need not focus on the best quality studies, such as those with large sample sizes, sound methodologies, and strong

associations that are biologically plausible. Nor are they directed to focus on research that has accessible data and results that have been replicated elsewhere. Instead, IARC working groups are free to focus on myriad small-scale studies with weak associations and implausible results, if they so choose. Basically, they are free to cherry-pick studies that serve predetermined biases of working group members.

There are apparent problems with bias, arising from the fact that working group members are selected from those researchers who are most published in the field, and supposedly most knowledgeable on the topic. This presents a selection bias, whereby researchers are able to validate their own studies and reputations by advancing IARC decisions based on their own research. These factors can make IARC decisions little more than the researchers' self-fulfilling prophesies. Some have suggested reforms such as balancing working groups by requiring that 50 percent of the members be researchers who lack any vested interest in the process.⁷

In fact, the preamble states: "Inclusion of a study does not imply acceptance of the adequacy of the study design or of the analysis and interpretation of the results, and limitations are clearly outlined in square brackets at the end of each study description." In other words, working groups may base decisions on any study they want, as long as they note any potential weakness in brackets.

Results of Hazard-Only Classifications. Dr. Timothy Pastoor, CEO of Pastoor Science Communications, pointed out the absurdities of IARC's hazard-focused approach at recent congressional hearings. He explained that the organization's refusal to consider the potency and exposure levels of the agents examined explains why IARC's classification system absurdly places plutonium and salty fish in the same "known carcinogen" category. Other "known carcinogens include serious risks such as "smoking tobacco," alongside more innocuous things such as wood dust, painting houses for a living, and processed meat. Pastoor further pointed out how exposure is crucial to understanding risk, using aspirin as an example, which is a valuable pain reliever at low exposures but deadly at high ones. Accordingly, IARC's hazard-based classifications are misleading and unhelpful. He rightly concluded that IARC "needs to be significantly reformed or abolished."

IARC's classification system creates confusion rather than informs, particularly as it generates news headlines. IARC's classification of red meat in 2016, for example, garnered misleading headlines like: "Processed Meats Rank Alongside Smoking as Cancer Causes—WHO." IARC based this classification on a meta-analysis, a study that combines data from various other studies to see if the combined dataset could find statistical associations between two factors, in this case red meat and cancer. This meta-analysis found a weak association, one that many researchers would dismiss as not useful for drawing conclusions. Still, IARC scientists used the meta-analysis to suggest that people who eat 100 grams (a serving is about 85 grams) of red meat daily may expect a 17 percent increased risk of colon cancer, while people who eat 50 grams (a serving is about 28 grams) of processed meat daily can expect an 18 percent increased cancer risk.

That may seem scary, but it is not as substantial as it sounds. According to the National Cancer Institute, the average person's risk of getting colon cancer is 5 percent. ¹⁴ So an 18 percent increased risk associated with processed meat consumption would increase the cancer risk to 5.9 percent. If true, this is not to be dismissed, but it is a risk that can be managed, ¹⁵ and it certainly should not be placed in the same category as smoking. ¹⁶ The IARC admits further in a summary of its decision in *The Lancet Oncology*: "Red meat contains high biological-value proteins and important micronutrients such as B vitamins, iron (both free iron and haem iron), and zinc." ¹⁷

Clearly, IARC's classification system is unhelpful and confusing. After all, it is absurd to compare the theoretical risks associated with eating bologna sandwiches or working as a painter with *actual* smoking-related deaths that total nearly half a million people annually in the United States alone.¹⁸

Glyphosate Controversy. IARC's hazard-based approach and lack of enforceable scientific standards have opened the door to sloppy and politically influenced decisions, resulting in nonsensical cancer classifications. The 2015 classification of the weed killer glyphosate as "probably carcinogenic to humans" offers an egregious example of a classification that appears politically driven.

Glyphosate is used in both residential and agricultural settings. Homeowners can use it in their gardens. Farmers use it to protect various crops, including to kill weeds near corn that has been genetically modified to withstand exposure to the herbicide. While such innovative "Roundup ready" corn is an amazing innovation that makes corn farming easier and more affordable, it has led anti-GMO activists to oppose glyphosate as well, adding to the politically charged nature of this issue.

Not surprisingly, IARC's hazard-based approach lumps glyphosate into a category of agents that have little in common in terms of risk. Among other "probable carcinogens" are a wide range of industrial chemicals as well as diseases such as malaria and the human papillomavirus type 68, and more mundane things like red meat, being a hairdresser, or shift work that leads to irregular sleep patterns.

IARC's hazard-based designation of glyphosate shows how agency decisions can be tainted by the ideologies of working group members and advisors. Known by the brand name Roundup, glyphosate was originally produced by Monsanto, a chemical company that has long been a major target of environmental activist groups. Unfortunately, IARC's decision to dub it a probable carcinogen has not been immune to anti-pesticide and anti-Monsanto politics.

IARC dubbed the chemical as "probably carcinogenic" based on flimsy science. The only supposed "evidence" comes from a handful of rodent studies. Data related to human exposures did not demonstrate any significant cancer risk to humans, particularly at plausible real-life exposure levels. A 2016 joint evaluation by the United Nations' Food and Agricultural Organization (FAO) and the World Health Organization explains: "[T]he only

large cohort study of high quality found no evidence of an association at any exposure level."¹⁹

In fact, a collaborative effort between academic and government agencies in the United States, known as the Agricultural Health Study, has been monitoring the health of licensed pesticide applicators (primarily farmers) since 1993 to see if there are connections between pesticide use and cancer rates. With more than 89,000 participants and more than 30 years of data, it has never found an association between glyphosate and cancer.²⁰

The FAO/WHO report further point out that rat studies found no association with cancer; it found only that mice that were administered *very high doses* formed tumors. Such studies reveal little if anything about risks to humans exposed to very low amounts of the chemical. Indeed, many chemicals found in a healthy diet—including those that naturally form in fruits and vegetables such as carrots, celery, and lettuce—cause tumors in rodents when administered in massive doses.²¹ These tests remind us of a well-known toxicological principle: it is the dose that makes the poison.

Considering all the evidence, the FAO/WHO report concluded that "glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet." Other governmental scientific reviews came to the same conclusion, including those by the EPA (in its 2017 draft risk assessment), ²³ the European Food Safety Authority in 2015, ²⁴ Health Canada, ²⁵ and others.

The IARC's faulty process is compounded by the fact that its decisions appear tainted by anti-chemical ideologically motivated activism and conflicts of interest. Geoffrey Kabat provides an excellent overview of the issue in *Forbes*, making three key points: 1) IARC cherry picked studies to support a "probable carcinogen" label and ignored any contrary data; 2) the IARC relied on an advisor with serious conflicts of interest; and 3) IARC doctored its report at the last minute to essentially change its conclusion, as revealed by a Reuters investigative reporter.²⁶

One piece of evidence on the first point, Kabat points out, is an article by Robert Tarone in the *European Journal on Cancer*.²⁷ Tarone points out that the data IARC used for both human and animal studies was seriously flawed. He said: "It is shown that the classification of glyphosate as a probable human carcinogen was the result of a flawed and incomplete summary of the experimental evidence evaluated by the Working Group."²⁸

Moreover, the IARC working group appears to have no problem including environmental activists in its proceedings. For instance, it enlisted Environmental Defense Fund (EDF) senior contributing scientist Christopher Portier to help as an "advisor" on the decision. Given EDF's strident anti-chemical agenda, it should have no influence over what is supposed to be a purely scientific evaluation.

Moreover, an exposé by blogger David Zaruk revealed the fact that Portier had a serious financial conflict of interest. Within a week of the IARC classification, attorneys that had been developing lawsuits against Monsanto retained Portier as an expert witness. After

signing with the law firm, Portier collected more than \$160,000 for his services while trotting the globe lobbying for government bans on glyphosate, all without disclosing who compensated him.²⁹

Finally, Reuters investigative reporter Kate Kelland discovered that the IARC monograph was essentially doctored at the last minute to change the final conclusion. Kelland reported: "Reuters found 10 significant changes that were made between the draft chapter on animal studies and the published version of IARC's glyphosate assessment. In each case, a negative conclusion about glyphosate leading to tumors was either deleted or replaced with a neutral or positive one. Reuters was unable to determine who made the changes." ³⁰

The timing of the glyphosate classification coincided with governmental decisions and has helped advance legal cases against the product. That may not have been coincidental. IARC began to review glyphosate around the same time that the European Union (EU) was considering reauthorizing its use, which it does every 10 to 15 years. Although the European Food Safety Authority deemed glyphosate as unlikely to be carcinogenic, IARC's classification influenced member states and advanced efforts to ban the chemical.³¹ Fortunately, reason prevailed and the EU approved its use, but only for five years rather than 10, which means this debate about its use will continue in Europe.

The glyphosate decision also had policy implications as far away as California, where chemicals are added to the state's carcinogen list automatically once IARC issues classifications. The State of California provided notice³² that it would list glyphosate as a carcinogen under the state's "right-to-know" law, originally passed by voters in 1986 as Proposition 65 shortly after the IARC issued the monograph. Monsanto appealed this listing because it is based only on the IARC classification and California's Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) found it was not carcinogenic. Monsanto lost its appeal and OEHHA's listing became effective in July 2017.³³

The IARC's classification also coincides with interest among trial lawyers seeking to develop class action lawsuits against chemical manufacturers. If they can convince juries that the world's most common weed killer causes cancer, they can cash in by charging massive legal fees on behalf of alleged victims, most of whom are likely to get very little benefit themselves.

The IARC classification and the Proposition 65 listing has already helped bolster legal cases claiming that glyphosate causes cancer. The first case to reach trial involved DeWayne Johnson, a former school groundskeeper who applied Roundup to control weeds during his employment from 2012 to 2015. Johnson was diagnosed with non-Hodgkins lymphoma in August 2014, which his case claims is a "direct and proximate result" of his exposure to Roundup.³⁴ Johnson's cancer is tragic, but it is highly unlikely to have anything to do with glyphosate, yet a jury awarded him \$289 million.

The jury did not have to determine if science proved that glyphosate caused the plaintiff's cancer. Rather, they were just asked to consider if Monsanto failed to adequately warn the

plaintiff of *possible* risks. As *Business Insider* explains: "For neglecting to alert Johnson (and the rest of the public) about the potential links between Roundup and cancer, the jury ordered Monsanto to pay Johnson \$39 million to cover his medical bills, pain, and suffering, plus an additional \$250 million for punitive damages (or punishment)." ³⁵

This court case has set the stage for more cases and potentially huge payouts to trial lawyers. According to news reports, there are now about 8,000 anti-glyphosate cases pending in courts around the nation.³⁶ DeWayne Johnson's case was the first, which sets a precedent for the others, and trial lawyers are trolling for more clients.³⁷ All this negative publicity will undermine the market for Roundup, if not destroy it, and governments will likely start banning it as France is preparing to do.³⁸

Impacts of Misleading Classifications. IARC's misleading classifications clearly have political impacts, but more importantly, they can impact humans in material ways, as the case with glyphosate makes clear. Glyphosate, for example, may have avoided an EU ban for now, but French President Emmanuel Macron announced last November plans to ban it in France within three years, ³⁹ many governments around the world at various levels have imposed bans or restrictions, ⁴⁰ and some retailers have decided to stop selling Roundup. ⁴¹

The IARC's misclassification can also lead consumers to avoid the product, undermining its value and even harming consumers in the long run. The minute traces of glyphosate that might end up on vegetables have no measurable public health consequences, but this misguided classification can generate fear about conventional fruits and vegetables. As a result, people may consume less of such healthy produce or end up spending more money for "organic" produce, which is not any healthier. This is unfortunate, since a diet filled with healthy fruits and vegetables is one of the best defenses against cancer.

These bans and market changes also threaten to undermine food production and raise prices. Herbicides have direct benefits to farm workers because they replace the hard labor associated with manually pulling weeds or mechanical tilling of the soil. Manual and mechanical weed removal raises farming costs, thus increasing food prices. Also, it is often less effective in controlling weeds, thereby reducing yield. Research confirms that elimination of glyphosate will raise costs for farming substantially, impacting food prices.⁴²

Herbicide use also produces environmental benefits that will be lost if these products are banned. For example, herbicides have made it possible to avoid tilling the soil for weed control. Before the 1960s, farmers relied on tilling, which leads to sediment runoff into nearby waters. Such sediment blocked sunlight out of streams and waterways, killed vegetation, and harmed wildlife.

"Many environmental scientists agree," Washington State University professor Allan Felsot explains in his book, *Pesticides & Health: Myths vs. Realities*, that "eutrophication and sedimentation of aquatic resources due to runoff and erosion from agricultural land is the most important cause of water quality impairment, not to mention being responsible for transportation problems as rivers backfill with sediment." The answer to this problem

came from no-till and conservation tillage (reduced tilling) for farming, a practice made possible by chemical herbicides. Using herbicides to control weeds decreases the need for tilling soil, which, reduces soil erosion by 50 to 98 percent, according to Dennis Avery of the Heartland Institute.⁴⁴

Conclusion. The International Agency for Research on Cancer's classification scheme is fatally flawed and incapable of providing meaningful information for policy makers or consumers. Worse, its increasingly political nature indicates that reform is unlikely to solve these problems. Whether it is related to processed meats, smoking, salty fish, pesticides, or other products or activities, IARC's classifications are out of line with actual risk assessments, yet they attract considerable attention from media and policy makers, and thus have proven highly influential. The fallout is that consumers are needlessly alarmed, policy makers respond with counterproductive policies, and useful products can be removed from the marketplace. It makes no sense for the U.S. government to fund the IARC. Pulling funding would be a helpful message to the world that IARC's nonsensical classifications should be disregarded.

Notes

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weighted. Therefore, the analysis is performed as if the data were derived from a single sample. ... In meta-analysis, data from subgroups or individual studies are weighted first, then combined, thereby avoiding some of the problems of simple pooling." Dena M Bravata and Ingram Olkin, "Simple Pooling Versus Combining in Meta-Analysis," *Evaluation & the Health Professions*, Vol. 24, No. 2 (June 2001), pp. 218-230, https://www.ncbi.nlm.nih.gov/pubmed/11523387.

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