Chapter 15
Glyphosate Toxicology:
What We Can Learn From the Current Controversy

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ABSTRACT

This chapter explores the glaring scientific differences in the human health assessment of the popular herbicide glyphosate between European and American institutions. The International Agency for Research on Cancer (IARC) classified glyphosate as a probable human carcinogen, while the U.S. Environmental Protection Agency (EPA) concluded that glyphosate is not likely to be carcinogenic to humans. Both IARC's and the EPA's carcinogenic risk assessment processes are discussed. This work reveals uncertainties in the sciences of toxicology and epidemiology, as well as assumptions made in their applications for evaluating glyphosate. These uncertainties, along with the political context of chemical risk assessment, are at the root of the divergent findings on the carcinogenic risks of glyphosate.

INTRODUCTION

By now it is widely understood that determining the safety of a chemical has become a heavily politicized activity. Notwithstanding the claims of regulatory bodies, that science-based evidence guides their health and environmental assessments of a chemical, we continue to see a significant divergence in the toxicological profiles among different sectors of the scientific community and between the agencies of different countries.

The battlegrounds over the safety of chemicals occur between non-profit groups and government regulatory agencies as well as between groups of scientists who position themselves on one side or the other on whether a chemical is safe enough or too dangerous to keep in commercial use.

What can explain the differences in the assessment of chemical safety? The published science behind any chemical assessment is available to all. The science of toxicology is not, at least overtly, embedded in an ideology. It is taught throughout the world utilizing principles and textbooks that are widely shared.

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Since the Enlightenment empiricism has been the cornerstone of the physical and social sciences. We perform experiments and allow the data to determine whether a hypothesis has been confirmed or falsified. Sometimes it takes one elegant, well executed experiment to bring consensus to a community of scientists. That was the case when evidence from an eclipse confirmed Einstein's General Theory of Relativity that the path of light can be altered by a massive body.

In the science of chemical toxicology there are not *experimentum crucis* [crucial experiments] capable of bringing consensus to a problem. Every experimental result in toxicology can be dissected for the gaps in reaching a definitive conclusion that the chemical is hazardous. There are always more experiments to perform to reduce the uncertainties. Commercial interests exploit the uncertainties to derail any regulations by demanding more studies.

Of course, even if there were a consensus on how a substance affects the human body, there remains the normative question, "what is acceptable risk?" These decisions are made every time a new drug is introduced for approval by the U.S. Food and Drug Administration. (FDA). When there is a consensus on the drug's efficacy against a disease, there must be a decision on whether its benefits are worth the risks of the side effects that will accrue to some patients. And even when a drug is licensed by the regulatory body, individuals can decide for themselves whether the risk of side effects are worth the benefits claimed for the drug.

Industrial and agricultural chemicals once approved expose countless people who cannot easily protect themselves or opt out of being exposed to the chemical. As an example, the law regulating industrial chemicals in the United States, first passed in 1976 as the Toxic Substances Control Act (TSCA) had a forty-year run before it was amended in 2016. Within those forty years about 85,000 chemicals were introduced into consumer products, yet only five chemicals were highly regulated or banned (Krimsky, 2017). I will leave to the final section why it has been so difficult for regulatory agencies in the United States to fully evaluate, regulate and ban toxic chemicals.

In this chapter I shall focus on the agricultural herbicide glyphosate. After a brief discussion of its path to commercial use and its special role in genetically engineered crops, I shall examine the cancer hazard assessment carried out by the International Agency for Research on Cancer (IARC) and compare that with the similar assessment by the U.S. Environmental Protection Agency (EPA). While they had access to the same published science, their conclusions were vastly different. IARC found that glyphosate is a probable human carcinogen, while the EPA concluded that it was not a human carcinogen. I will be exploring the reasons for this divergence of views on glyphosate toxicology. Did they use different criteria for determining human carcinogenicity? Did they employ different models of carcinogenesis? Did they select the relevant studies differently? Were there political and economic forces affecting the decision? I shall also discuss the efforts by one of the leading manufacturers of glyphosate, Monsanto, through its product Roundup, to influence a finding that it was safe to use as labeled. My analysis is based largely on two documents, IARC's *Monograph on the Evaluation of Carcinogenic Risks to Humans* and EPA's *Revised Glyphosate Issue Paper* both released in 2017.

DISCOVERY OF GLYPHOSATE

In 1950 a Swiss chemist, Henri Martin, while working for a small pharmaceutical company, developed a new (phosphonomethyl) derivative of an amino acid glycine. Failing to find any pharmaceutical applications, it was left in storage and in the log books. After the company (Cilag) was sold, the research