Trails and Trials in Biotechnology Policy

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A Natural Scientist

It was the mid-1980s when my career in biotechnology began at a smallish, Catholic liberal arts college in the Upper Midwest. I knew that I had to major in natural science, as those were the terms of my full-tuition scholarship for 4 years. I had an affinity for chemistry and math; however, during my freshman biology class, I learned about how the natural world operated at the molecular level, and my interest was piqued. Soon thereafter, I joined the laboratory of a young, cell and molecular biology professor who had just joined the college and was brave enough to start a research program with only undergraduates. Our college did not have many other research labs, as we were an institution with just budding strengths in the natural sciences. However, in this environment, I was able to get excellent training in many facets of research, unguided by a cadre of graduate students and postdocs. For example, there were four students in my molecular biology class, and I remember reading the peer-reviewed technical literature about PCR (which had just arrived on the scene) and debating the molecular methods with my classmates. Overall, it was a stellar education.

Our lab, under the direction of Professor Jennifer Cruise (my first, fabulous female mentor) at the College (now University) of St. Thomas in St. Paul, MN, I worked on molecular, cellular, and biochemical mechanisms of liver regeneration, and the lab subjects were usually rats. My adviser knew and respected that I would not be killing any rats (not that I am or was against it, but I just simply couldn't stomach it); however I was asked to grow up viruses for our work to deliver molecules into cells in order to study biochemical pathways. I still remember the day when I tried to harvest the virus from eggs and the needle got stuck (or was grabbed?) by a chicken fetus. I ran out of the lab, practically screaming. I continued

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to work in the lab, but I didn't have to harvest viruses from eggs again, and at that point, I was pretty sure that I should look for graduate work that would focus on plants or microbes.

During this time, between courses and lab work, I was politically active. In the 1980s, key issues were apartheid in South Africa and the proliferation of nuclear weapons for deterrence in the Cold War with the Soviet Union. I was also a part of a social justice group at the college, as movements to help the impoverished and oppressed and work for peace were prominent in liberal Catholicism at the time. I had many interests in areas outside of the natural sciences, and I was able to take several courses to nurture these interests. I had a passion for philosophy and ethics, music, and social science. However, because natural science and math came easy to me and I was also interested in them, my advisers encouraged me to continue this path in graduate school given the need for more women in these male-dominated areas.

The decision to go to graduate school was somewhat capricious. I came from a family with 6 kids, and my father was the first to go to college in his 12-sibling family. He was a veteran of World War II and went to the University of Minnesota on the GI bill, graduating in chemical engineering. Although he didn't have a generous salary working as an engineer in the iron ore mines in Northern Minnesota, he and my mom made sure all of their 6 kids went to college. But they also made sure that my siblings chose sensible, practical careers in fields like dentistry or health care. We were not dirt poor, but we didn't have much money either, so when my college adviser suggested that I should go to graduate school and get my Ph.D., my first question was whether I would have to pay for it. I didn't really know what graduate school or a Ph.D. was about at the time. He said I'd make enough money as a graduate research assistant to live on and go out to a movie once in a while. That was enough for me. So as a junior in college, I started thinking about graduate work in biochemistry to blend my interests in both organic chemistry and biology. I majored in both chemistry and biology, as my college didn't have a major in biochemistry at the time. Biochemistry was considered interdisciplinary.

Around the same time, I started reading and thinking more about the philosophical, ethical, and social questions surrounding genetic engineering. It was during the time of the first proposed field-trials of genetically-engineered organisms (GEOs) in the mid-1980s, the ice minus bacterium. I found a lab at the University of Colorado Boulder working on ice minus bacteria. The lab also worked on the isoprene bio-synthetic pathway in plants and called itself an "environmental biochemistry" group. The focus on plants and bacteria ensured that no rats or chicken fetuses would be in my future. UC Boulder also had a strong program in biochemistry with several prominent faculty pioneering RNA catalysis, DNA synthesis, and other work. Finally, Boulder was a good cultural fit for my social justice leanings.

Graduate school proved to be a trying time with most of my experiments destined to fail. The lab was a pleasant place to be people-wise, but our work on big questions at the nexus of the environment and biochemical pathways and exploration of previously undiscovered proteins meant that there were no easy experiments. I did manage to make progress, however, and one of my contributions was the discovery that bacteria produce the volatile compound isoprene. Isoprene is a

precursor to natural rubber and is usually obtained by cracking petroleum. With bacteria producing quite a bit of relatively pure isoprene gas, we envisioned a more sustainable future source. I obtained a patent on that discovery with my thesis adviser Prof. Ray Fall and the lab technician Michele Nemecek-Marshall. Unfortunately, we were about 15 years ahead of our time with our interest in more sustainable bioproducts, and the patent sat for many years. It was not licensed until over a decade later, in 2007. However, it was satisfying to know I was working on something with broader societal and environmental implications, and today, Goodyear and DuPont Industrial Biosciences are making BioIsoprene™ for the production of rubber to help reduce the tire industry's dependence on oil-based products. During my thesis work, I also purified an enzyme for isoprene synthesis and tried to clone the gene, but that was proving to be difficult given that genomic science was not really a part of the early 1990s. Thankfully, I eventually had enough work for a thesis, so I moved on.

My second contribution in natural science was the discovery of abscisic acid in a signaling pathway for plant responses to stress (drought, salinity) as a postdoc at Rockefeller University in New York City. The move from Boulder to the Upper East Side of NYC was quite a cultural shift, and this was a hard time for me in more ways than one. Lab work was becoming more tedious and less interesting to me, and I would escape the lab and "concrete jungle" of Manhattan many weekends to play in beach volleyball tournaments on the Jersey Shore or Long Island, where I eventually met my spouse at a charity tournament. Despite the growing disdain for lab work, I did feel proud of the bigger picture of my work, as the ultimate goal would eventually be to engineer plants tolerant to stress, so that the hungry and suffering would have more food. The results of my work were my first (and only technical) publication in the journal *Science*. I wrote the first draft and most the article, but because the professional technician did most of the hours on the wet-lab work, I relinquished first authorship to her. At that point, my passion for a career in biochemistry and molecular biology was waning and it didn't really matter to me. So with a patent and high profile publication in hand, I finally allowed myself to acknowledge just how unhappy I was with the day-to-day work of laboratory science. It was just not for me. The focus on one enzyme, biochemical pathway, or gene was too detailed for me, yet I retained a deep and strong passion for the broader societal context and implications of biotechnology, so looked for ways to move on using my Ph.D. and postdoctoral experience. At this time, I had no idea how I could blend my interests in biotechnology with social science, politics, and ethics.

A Risk Analyst

Thankfully, I soon thereafter found an advertisement for a science policy fellows program and applied on a whim. On crutches, suffering from a volleyball tournament injury, and with my ACL ligament freshly repaired, I hobbled to Washington DC in early 1997 for an interview for the American Association of the

Advancement of Science (AAAS) Science Policy Fellows program. I remember that I had written my policy brief for the interview on a subject I knew little about, the mining of methane from the ocean floor as a more sustainable fuel source. It was of interest to me because this technology potentially posed both significant environmental risks and benefits. I remember that the interview panel asked why I would write on something that I didn't know much about, as opposed to something I knew more about like biochemistry or molecular biology. My answer must have been OK, or they took pity on me because of the crutches and full-leg brace, as I landed the AAAS fellowship. It is true that in the world of policy-practice in Washington DC, you have to get up to speed on diverse issues in a fairly short time. This was a perfect fit for someone like me with broad interests at the nexus of science and society, but also deep analytical skills.

For the AAAS fellowship, I was placed into a topical area that I knew little about too, risk analysis for food-borne pathogens and hazards. So the first few months in Washington DC at the US Department of Agriculture, I mainly (and smartly) kept my mouth shut and soaked in the technical information and nuances of the politics. I observed where natural science and decision making intersect—where the rubber hits the road so to speak–in risk analysis, decision making, and regulatory policy. I owe a great deal to another fabulous female mentor, Dr. Nell Ahl, for giving me the chance to learn risk analysis methods, regulatory policy, public policy, and politics of decision making during my fellowship. She was patient with me, as a novice to these worlds, and in time, I do think I contributed to the office she directed. But mainly, I learned.

One of the highlights at the USDA was writing and helping to negotiate the interagency politics over the scope of a risk assessment for mad cow disease in the United States, a big concern in the late 1990s. Different agencies within USDA had distinct priorities and missions. One unit wanted the risk assessment to stop at the quantification of the risk of animal disease, and yet another wanted it to go all the way to estimating human health outcomes. Diplomacy was needed to see both sides and reflect compromises in writing. Another big project for me was helping with a farm-to-table risk assessment for *E. coli* 0157:H7 in ground beef (Ebel et al. 2004). I worked on the slaughter module, helping to model contamination in animal processing plants. The same person who couldn't kill rats was now being asked to visit slaughterhouses. It wasn't pleasant, but it was interesting, and in addition to learning about potential sources of contamination with the bacterium, I developed an appreciation for the hard labor that workers in these plants do.

Foodborne contamination with *E. coli* 0157:H7 was a big issue at the time. I remember my first regulatory policy meeting on this topic in DC. For most of the day, natural scientists risk assessors, and regulatory policy experts talked about how very low the risk of death or severe illness was from eating ground beef. Stakeholders from cattle or beef industry associations argued against a stringent standard for the pathogen in ground beef. Then, in the closing panel, a parent whose child died because of the Jack in the Box *E. coli* 0157:H7 outbreak in hamburger stood up and made it clear that even one death was too much. This event wasn't too many years after my 1 year old nephew died in a drowning accident in the presence

of a baby sitter, so needless to say, her plea really touched me, as well as others in that room. So much for "sound science" in telling us what is probable or right.

The fellowship year was transformative, and many lessons were learned from my observations and work. One was that natural scientists, especially those with a stake in the issue or technology, often display hubris by claiming to have the answer and know what is safe or right for all people, when in fact there is a great deal of uncertainty and interpretation of evidence that comes into play. For example, the agricultural minister in the UK fed his child a burger on TV during the height of the mad cow disease crisis and made claims that there was no risk to humans, or no link between the animal form of the disease (BSE) and the human illness (nvCJD) (Leiss and Powell 1997). He turned out to be wrong, causing considerable loss of trust in the UK for regulatory policy officials. It didn't help the situation that nvCJD is always fatal and a horrifying neurological disease.

I learned how assumptions and values color even the best of the risk analyses used for decision making. Not only was there intentional bias in the political sphere, but also unintentional bias or world views that cause even the best and brightest natural scientists to make strong claims about uncertain situations. Mainly, I came to understand how I, as a natural scientist and technologist, did not have the answers to saving the world from hunger or petroleum dependency. For example, sometimes producing a bio-product takes *more* oil than it replaces, and sometimes a GE crop will pose risks, however small, that are not acceptable to people in light of the fact that they do not receive the benefits. I learned that technologies, which come with their own risks, are not always (or even usually) the best way to address global problems, which are caused by a confluence of natural, social, economic, and political factors. More often, social and political systems are the main causes of hunger and petroleum dependency.

A Science and Technology Policy Practitioner

Approaching 30-years old now and married, it was time to find a "permanent" job. So after the fellowship in late 1998, I applied for and received a position at the National Academy of Sciences (NAS) (now National Academies of Science, Engineering, and Medicine NASEM) as a study director in the area of biotechnology for the Board of Biology (now Board on Life Sciences). I didn't really have a boss when I first arrived, as the board was in transition. So, I got to know the President of the NAS, Professor Bruce Alberts, quite well in the first year, as he was most interested in NAS studies related to biotechnology as a pioneer in molecular biology. I was excited to be back in the area of biotechnology after my foray into microbial food safety. It was a time during which the Coordinated Framework for the Regulation of Biotechnology had been formalized through proposed or enacted regulatory rules (OSTP 1986; USDA 1993, 1997); GE crops were proliferating in field trials, and they had recently entered the open market (Kuzma 2013).

My first big assignment at NAS was as study director for a committee report examining the science and regulation of GE plants designed for pest-protection. Instead of spraying pesticide on a field, these crops had pesticide-like proteins within them, mostly from the bacterium *Bacillus thuringiensis*. The study was called for by the NAS membership itself, as the Environmental Protection Agency (EPA) had proposed to regulate GE plants with Bt proteins and other plant pesticides (EPA 1994, 2001), and several NAS members (prominent molecular biologists, biochemists, plant pathologists, or agronomists) were not too happy about this situation.

The USDA already regulated GE plants under the Federal Plant Pest Act (FPPA) (USDA 1993, 1997). USDA's mission as an agency is to protect U.S. agriculture, and through the FPPA, it looks at risks to agriculture from plant pests. In the case of GE crops, the plant pest sequences used for genetic engineering, like *Agrobacterium* and Cauliflower Mosaic Virus, were used as the regulatory hook for USDA. In contrast, the EPA has the mission to more broadly protect the environment. EPA proposed to exercise authority under the Federal Insectcide, Rodenticide, and Fungicide Act (FIFRA) for GE plants with pesticidal proteins or molecules (EPA 1994, 2001). Under FIFRA, EPA takes a rigorous look at safety to non-target organisms and requires significant data prior to approval for marketing a pesticide. It also has post market re-registration and monitoring authority. Under the FPPA (now the Plant Protection Act, PPA), USDA's assessment focuses on "plant pest" risks to agriculture, and once a crop is deregulated, no post-market monitoring authority exists. EPA's proposed role under the CFRB would include assessments for impacts on non-target insects, birds, fish, and mammals from GE crops, as well as the human safety of ingesting residues of plant pesticides like Bt in food.

The NAS molecular biologists did not want any additional regulation of GE crops, and therefore asked the NAS to commission a study in the hopes that the committee would come out against EPA regulation (and perhaps even question USDA's regulation). Many of them felt that GE crops should not be singled out for regulation at all, as conventionally bred crops can pose similar risks. A 1987 NAS committee on which several of those same NAS members served "Introduction to rDNA Organisms in the Environment" stated that the risks of GE crops and conventional crops are "the same in kind" and that there are "no new categories of risk" (NAS 1987). The "science-based" conclusion to them was that therefore, there should be no formal regulation of GE crops, just like conventional crops.

It was a contentious study and we were criticized by both the pro-GE and anti-GE groups—we had a few committee members from private consulting groups for biotechnology industries, so we were criticized by NGOs for being biased towards industry from the start of the study. The pro-GE groups criticized us for including scientists with ties to environmental NGO groups and for not including some of those NAS members that called for the study on the committee. On the morning of the report's release, protestors surrounded the building dressed in lab coats or as Monarch butterflies, as a recent study had just showed that Bt pollen was toxic to Monarch larvae in laboratory feeding studies (Losey et al. 1999). Former Presidential candidate, then Representative Dennis Kucinich, was outside the

building with the protestors, some who were holding signs with slogans like "Just Say No to GMOs". It was an intriguing experience for my first report at the NRC as study director.

In the report, the committee extensively discussed a strict "scientific basis" for a regulatory system and decided it was not feasible. For such a foundation, two logical policy options existed—if GE crops were equivalent to conventional crops, we should regulate both conventional and GE crops or regulate neither. These two extreme options were not respectively practical or protective of ecological or human health. Furthermore, choosing between one or the other option is not a decision solely based on "sound science", as one's values must guide whether everything (GE and conventional) should be assessed and regulated prior to or whether nothing should be regulated. The decision between those two "science based" options involves world views about the role of government in protecting ecosystems compared to the role of technological and economic development. The committee also disappointed the NAS members calling for the study by supporting a role for the EPA in regulating GE crops, given that USDA's scope was limited to agricultural protection and that EPA focused more broadly on ecosystem harm. The committee also suggested that given the lack of experience, uncertainties, and public concern associated with GE plants, it made sense to regulate them and not conventionally bred crops for the time being (NRC 2000).

Through these discussions, I learned that it is impossible to design a completely "science-based" regulatory system. Regulatory capture can be informed by natural science, but judgements come into play depending on levels of uncertainty, novelty, potential harms or risks, and other societal concerns (Kuzma 2016a). Regulation should also be informed by social science, values people hold, and ethical criteria. Science can help to tell you what is, but cannot dictate what to do.

I observed the different communities associated with genetic engineering during my time at the NAS. Although I do not want to rearticulate and support all my arguments on the subject of GEOs governance (see Kuzma et al. 2009; Kuzma 2013, 2016a as overviews), I have learned that natural scientists (more specifically, those natural scientists on the technology development side) call for "evidence-based" and "science-based" regulation, but still come with just as many value-based arguments and biases as those who prefer more precaution (consumer and environmental groups, many toxicologists and ecologists, several social scientists) before releasing GE crops in the field.

One indication of the biases was in the world of peer-reviewed publication on risk science associated with GE foods. In this domain, I also observed how those who published studies that showed any potential harm from GE crops in the peer-reviewed literature were discredited, pressured to retract the papers, and their findings dismissed by the mainstream plant biotechnology community (e.g. the Puzstai, Chapela, and Seralini cases as discussed in Bardocz et al. 2012; Loening 2015). When studies do not find risks with GEOs, protocols and designs of them are not of concern to industry and academic product developers or GEO advocates; however, studies that use similar or the same designs that show potential harms are harshly critiqued and met with vile (Meyer and Hilbeck 2013; Hilbeck et al. 2015).

Concerning the critics of studies that suggest potential risks or harms, Loening (2015) states that "The vehemence of the(se) critics is not matched by their evidence; it is often based on entrenched assumptions and on mis-representing published material. The arguments have challenged normal healthy scientific dialogue, and appear to be driven by other motives." I agree, even though I personally do not think GE foods currently on the market pose significant danger to human health (and many a GE food can be found in my kitchen and is eaten by my kids in a given day). However, I am dismayed by the unscientific approach taken by critics on both sides of the safety debate. As someone with risk assessment, biochemistry, and policy backgrounds, I believe that we, as "technological elites" are not communicating honestly. No one should be claiming categorically that "GE foods are safe"; just as no one should be claiming that "GE foods are dangerous". Safety involves verifying an absence of an effect, which under logic rules does not constitute "proof". In other words, just because you see "no effect", it doesn't mean that there *is* no effect in a given study. *All* studies come with uncertainty, and the short term 90-d toxicity studies done on rodents for regulatory review, which are of insufficient time scales and unrealistic contexts, are no better categorically than the imperfect lifetime, whole-food feeding studies that may be imperfect. Some studies in the peer-reviewed literature do report biochemical and morphological changes that may indicate negative effects on test animals from consumption of GE foods (e.g. Dona and Arvanitoyannis 2009; Vecchio et al. 2009; Domingo and Bordonaba 2011; Carman et al. 2013; Bøhn et al. 2014; Gu et al. 2014; Glöckner and Séralini 2016; Lurquin 2016); but the balance of studies show no such effects (e.g. reviewed recently in Domingo 2016). The fact remains that we do not currently have a sound, scientific way to look for the long-term effects of a life-time consumption of GE foods in humans, especially if those effects are of the more subtle kind like food allergenicity, intolerances, or sensitivities. Let's be honest about this, and from a policy perspective, think more about the tradeoffs in potential risks and benefits of GE foods compared to alternatives. For tradeoff analysis, values must come into play and therefore in a democratic society, these conversations require societal dialogue and input. In fact, values come into play in risk assessment too (Kuzma and Besley 2008). Even with good data, although you can estimate a dose response curve, there is always uncertainty about where you draw the line for a regulatory standard, and therefore, of what is "safe" always comes with a value judgement (Kuzma 2016a, b).

I am a scientific and logical thinker, and am continually dismayed by the mainstream molecular biology community thinking that those who have objections to GE crops "just don't understand the science", "need to be educated", and don't get it or are "luddites". There is a lot of misinformation about GE out there, but not all those who are critical or questioning of GE crop-safety are doing so out of an agenda or ignorance. Also, most regular people I converse with can indeed understand the science with a little background and ask insightful questions. Let's give the critics some credit and have an honest exchange about tradeoffs and multiple types of criteria for making a decision about whether to use GEOs in a given situation or to address a particular societal problem.

Recently, at a national meeting, I questioned whether GE crops were needed to feed the world. In my opinion, this is a valid question given that we produce more calories per capita than needed (FAO 2016) and that GE crops have not consistently increased yields (NASEM 2016). I don't disagree that they may have a role under some conditions, but claims of needing them to feed the world are not scientific. They might be desirable, but they are not necessary.

For questioning the necessity of GE foods for food security, I was accused of wanting to let people starve by a developer of GE products at this meeting. Given my social justice background and political leanings, this comment infuriated me. No moral and sane person wants anyone else to starve. However, if we do have enough calories to feed the world, why doesn't it make more sense to focus on the socio-political distribution of food? Why are we not putting billions of dollars into those issues instead of GE crop research? This is a societal judgement based on values. It was questions like this in the practical science and technology policy world that led me to what will likely be the final phase of my career—a professor in policy and social sciences focusing on emerging technologies, governance, and decision making. In 2003, it was time to move back to academe, so I could study and write freely about these issues from the interdisciplinary perspectives that I accumulated.

A Professor in Policy and Social Sciences

My time as a professor for the past 13 years at two different universities, the University of Minnesota and North Carolina State University, has been spent on looking at questions of governance for emerging technologies, particularly nanotechnology, biotechnology, and synthetic biology. I am now a distinguished professor and endowed chair in a field in which I did not get my Ph.D. Sometimes that is a bit unsettling to me, as I do not have full legitimacy around hard core disciplinary social scientists. But at other times, it is a great asset to have a good foundation in both the natural and social sciences. It has well positioned me to try to cross barriers of understanding, different theories, and diverse methodologies. In the past decade, with colleagues and students, I have developed methodologies to help integrate diverse types of metrics (criteria) that can assist with decision making for emerging biotechnological products, to deal with uncertainty in risk governance, and to anticipate new products and their risk and benefit potentials well in advance of product development and regulation. I have also studied the intersection of values with evidence for genetic engineering and argued for middle-ground approaches to risk governance that blend precautionary and promotional perspectives (Kuzma 2016a, b) These are currently my main areas of contribution to the agricultural biotechnology debates.

It was a great honor in 2016 to be asked to serve on a National Academy of Sciences, Engineering and Medicine (NASEM) study committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory Systems, as it is a subject about which I've written

extensively. That committee's work is underway at the time of the writing of this chapter, and I find myself now on the other side of the table at the National Academies. As a society, we are at a crucial time in biotechnology policy. New genetic engineering technologies like gene editing, gene drive systems, synthetic biology, and de-extinction are challenging our abilities to keep pace from a governance perspective. On top of biotechnologies are emerging capabilities in nanotechnology, robotics, neuroscience and neurotechnology, information technology, data sciences, and geo-technology that are converging with genetic engineering.

I truly hope that we can come together in a democratic society to open up the decision making processes to a wider range of social science, cultural, ethical, and demographic perspectives. We are in need of science-informed, value attentive governance systems to envision and guide technology down paths that most benefit society and lead to human happiness and health and ecological sustainability. We need to hear from many voices, including youth, to envision the society we would like our children and grandchildren to inherit. In the context of GEOs, will it be the market, technological elites, or many publics who will decide whether and which GEOs are deployed into products and the environment? I personally hope for the latter.

Most recently, I have become very interested in the gender, intergenerational (Kuzma and Rawls 2016), and cultural equity issues surrounding technological decision making. For example, In the social science literature (under the rubric of cultural theory), it has been found across multiple studies and science and technology areas that women and under-represented racial or ethnic groups have higher concern about technological risks and the environment, while white males have a lower level of concern, even when education, income, and other demographic factors are accounted for (Kahan 2012). Females and minorities are also more likely to have egalitarian and communitarian political leanings, as opposed to hierarchical and individualistic ones held by white or Caucasian males (Kahan et al. 2007). Yet, leaders and decision-makers (e.g. division directors in government or company executives whom interact with them) are disproportionately Caucasian males. As a woman relatively advanced in her career, I am often the only or one of very few females at higher-level meetings, panel discussions, or workshops. The current decision making system seems to me to be unjust. An opening up of regulatory processes to a greater diversity of people and perspectives might remedy this inequity and increase procedural justice. So now, I am returning to that social justice interest I had as an undergraduate again. The beauty of policy sciences is the ability to learn and return to different, but related topical areas.

I come with my own biases to the agricultural biotechnology debates, as I've freely expressed in this chapter. We all have these biases and must be cognizant of them. We also must respect alternative perspectives and biases that do not match our own. As I traveled on my career path, these biases were shaped by my background in ethics and philosophy, biochemistry and molecular biology, risk analysis, science and technology policy, and the social sciences. I hope to see the current biotechnology revolution shaped by many different viewpoints so it is done in the best interest of all of society, not just a few groups (like technology-elites or

white-males in the United States). Only then will we be able to move past the inflamed and divisive rhetoric and enable safe, responsible, socially desirable and appropriate use of genetic engineering.

References

Bardocz S, Clark A, Ewen S, Hansen M et al (2012) Seralini and science: an open letter.' Independent Science News [Online], 2 October. http://independentsciencenews.org/health/seralini-and-science-nk603-rat-studyroundup/

Bøhn T, Cuhra M, Traavik T, Sanden M, Fagan J, Primicerio R (2014) Compositional differences in soybeans on the market: Glyphosate accumulates in Roundup Ready GM soybeans. Food Chem 153:207–215

Carman JA, Vlieger HR, Ver Steeg LJ, Sneller VE, Robinson GW, Clinch-Jones CA, Edwards JW et al (2013) A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. J Org Syst 8(1):38–54

Domingo JL (2016) Safety assessment of GM plants: an updated review of the scientific literature. Food Chem Toxicol 95:12–18

Domingo JL, Bordonaba JG (2011) A literature review on the safety assessment of genetically modified plants. Environ Int 37(4):734–742

Dona A, Arvanitoyannis IS (2009) Health risks of genetically modified foods. Crit Rev Food Sci Nutr 49(2):164–175

Ebel E, Schlosser W, Kause J, Orloski K, Roberts T, Narrod C, Powell M et al (2004) Draft risk assessment of the public health impact of Escherichia coli O157: H7 in ground beef. J Food Prot 67(9):1991–1999

EPA (1994, 2001) Environmental Protection Agency. Regulations under the Federal Fungicide, Insecticide, and Rodenticide Act for plant-incorporated protectants. Fed Reg 66:37855–37869

FAO (2016) United Nations Food and Agricultural Organization. Agriculture and Food Security. http://www.fao.org/docrep/x0262e/x0262e05.htm. Accessed 14 July 2016

Glöckner G, Séralini GE (2016) Pathology reports on the first cows fed with Bt176 maize (1997–2002). Sch J Agric Sci 6:1–8

Gu J, Bakke AM, Valen EC, Lein I, Krogdahl Å (2014) Bt-maize (MON810) and non-GM soybean meal in diets for Atlantic Salmon (Salmo salar L.) juveniles-impact on survival, growth performance, development, digestive function, and transcriptional expression of intestinal immune and stress responses. PLoS ONE 9(6):e99932

Hilbeck A, Binimelis R, Defarge N, Steinbrecher R, Székács A, Wickson F, Novotny E et al (2015) No scientific consensus on GMO safety. Environ Sci Eur 27(1):1

Kahan DM (2012) Cultural cognition as a conception of the cultural theory of risk. Handbook of risk theory. Springer, New York, pp 725–759

Kahan DM, Braman D, Gastil J, Slovic P, Mertz C (2007) Culture and identity-protective cognition: explaining the white-male effect in risk perception. J Empirical Legal Stud 4 (3):465–505

Kuzma J (2013) Properly paced? Examining the past and present governance of GMOs in the United States. In: Marchant GE, Abbott KW, Allenby B (eds), Innovative governance models for emerging technologies, Edward Elgar, Cheltenham, UK, pp 176–197

Kuzma J (2016a) Reboot the debate on genetic engineering. Nature 531:165–167

Kuzma J (2016b) Risk, Environmental governance, and emerging biotechnology. In: Durant R, Fiorino DJ, O'Leary R (eds) Environmental governance reconsidered: challenges, choices, and opportunities, 2nd edn. MIT Press, Cambridge

Kuzma J, Besley JC (2008) Ethics of risk analysis and regulatory review: from bio- to nanotechnology. Nanoethics 2(2):149–162

Kuzma J, Rawls L (2016) Engineering the wild: gene drives and intergenerational equity. Jurimetrics J Law Sci Technol 56(3):279–296

Kuzma J, Najmaie P, Larson J (2009) Evaluating oversight systems for emerging technologies: a case study of genetically engineered organisms. J Law Med Ethics 37(4):546–586

Leiss W, Powell D (1997) Mad cows and mothers milk. McGill–Queen's Press, Montreal

Loening UE (2015) A challenge to scientific integrity: a critique of the critics of the GMO rat study conducted by Gilles-Eric Séralini et al. (2012). Environ Sci Eur 27(1):1

Losey J, Raynor L, Carter M (1999) Transgenic pollen harm monarch larvae. Nature 399:214

Lurquin PF (2016) Production of a toxic metabolite in 2, 4-D-resistant GM crop plants. 3 Biotech 6(1):1–4

Meyer H, Hilbeck A (2013) Rat feeding studies with genetically modified maize—a comparative evaluation of applied methods and risk assessment standards. Environ Sci Europe 25:1–33

NAS (1987) National Academy of Science. introduction of recombinant DNA-engineered organisms into the environment: key issues. National Academy Press, Washington

NASEM (2016) National Academies of Science, Engineering and Medicine. Genetically engineered crops: experiences and prospects. National Academy Press, Washington

NRC (2000) National Research Council, *genetically modified pest-protected plants: science and regulation*. National Academy Press, Washington

Office of Science and Technology Policy (1986) Coordinated framework for the regulation of biotechnology. Fed Reg 51(123):23302–23350

USDA (1993) US Department of Agriculture, genetically engineered organisms and products: notification procedures for the introduction of certain regulated articles and petition for nonregulated status. Fed Reg 58(60):17044–17059

USDA (1997) Introduction of organisms and products altered or produced through genetic engineering which are plant pests or which there is reason to believe are plant pests, 7 C.F.R. § 340

Vecchio L, Cisterna B, Malatesta M, Martin TE, Biggiogera M (2009) Ultrastructural analysis of testes from mice fed on genetically modified soybean. Eur J Histochem 48(4):449–454