

Sensible Biosafety

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An editorial, unlike a peer-reviewed paper, offers a unique opportunity to be wrong and yet get published. Editorial writing is thus at once liberating and stressful, since one might get panned (although this is infinitely more welcome than benign neglect). To be controversial, provoke more questions than get answered, and stimulate debate are editorial tenets. The topic here is bias in biosafety and more pointedly, is there an end run around biosafety? Are biosafety concerns overlooked, ignored, and minimized? Or, is biosafety exaggerated, over-emphasized and biosafety concerns overblown? Biosafety covers a large subject area (*vide infra*). Therefore, representative topics will be discussed to illustrate a balance between “the sky is falling” hysteria vis-à-vis a laissez faire attitude towards biosafety.

Since biosafety is frequently invoked by scientific professionals, various non-governmental organizations (NGOs) as well as the general public, it is useful to first define “biosafety.” In the age of the internet, one might imagine that it should be easy to uncover a definitive definition by resorting to scientific and popular search engines. A PubMed-NCBI search of “biosafety” elicited 1394 papers including 279 reviews [1] Google Search yielded approximately 2.8 million results. Based on this, one might further imagine that there will be a universally accepted definition for the term. However, one would be grievously mistaken on both counts. Apparently, biosafety means different things to different individuals, groups, organizations and governments around the world. The narrative immediately below is offered in the hope that others might avoid countless hours of futile search for a universally accepted definition of biosafety. A byproduct of this editorial might indeed be the unexpected (manufactured?) controversy surrounding the definition of “biosafety.”

Biosafety is frequently associated with modern biotechnology such as recombinant DNA (rDNA), transgenes, synthetic life, and genetically/living modified organisms (GMO/LMO), and their intentional, incidental, or accidental release to the environment. Stakeholders also view biosafety in terms of lab practices for protecting the worker from potential harm. Still others include protecting biodiversity and preventing bioterrorism within the realm of biosafety. In other words, protecting the worker from the environment and protecting the environment from the worker! Institutional Biosafety Committees (IBCs) concern themselves with not only research involving rDNA, toxins, pathogens, *et cetera*, but also include rDNA involving human participants within their operating envelope (gene therapy/transfer). Parenthetically, human clinical trials involving rDNA require IBC and Institutional Review Board (IRB) approvals. [The IRB is tasked with review and monitoring of biomedical research involving human subjects]. The American Biological Safety Association (ABSA) lists microbiologists, industrial hygienists, biologists, engineers, veterinarians, occupational health professionals, environmental health professionals, clinical healthcare professionals and biosecurity professionals as biosafety professionals [2]. The Merriam-Webster Medical Dictionary defines biosafety as “safety with respect to the effects of biological research on humans and the environment” [3]. The Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual declares biosafety as “the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials” [4]. Similarly broad definitions are adopted by the World Health Organization

(WHO) and the Biological and Toxin Weapons Convention (BTWC). Various advocacy groups (consumer protection, healthcare, religious, business/industry, environmental, *et cetera*) campaign for the inclusion of their favorite subjects within the biosafety umbrella.

Definition of biosafety becomes delightfully more complicated when such words must be translated from English into languages which may not have equivalent words. For example, the Food and Agricultural Organization (FAO) used the word “biosecurity” without translation and “biosafety” within parenthesis in their 2003 Chinese report on “Biosecurity in Food and Agriculture,” presumably due to a lack of equivalent words in that language [5]. The international (Cartagena) protocol on biosafety promotes the protection of biodiversity from potential risks of LMOs [6]. It is clear that biosafety impacts the diverse fields of ecology, environment, agriculture, medicine, chemistry and space biology with risks and rewards to plant, animal and human health along with ethical, societal, diplomatic and political concerns, collectively perhaps leading to this recent comment: “Despite this attention, a clear understanding of the meanings of biosecurity and biosafety has yet to be achieved” [7]. Such complex cornucopia offers a marvelous outlet for editorializing on “biosafety” without becoming fatally flawed.

It is important to briefly examine some of the legal terms governing international instruments of biosafety before exemplifying “sensible biosafety.” These frameworks fall into two broad categories: binding and non-binding. The various instruments such as, code of conduct, guidelines, best practices, recommendations, position statement, and action program are all non-binding. On the other hand, treaty, convention, protocol and agreement are internationally binding [8]. It follows therefore that the Convention on Biological Diversity and the Cartagena Protocol on Biodiversity are legally binding instruments governing international biosafety work. Obviously, “binding” applies only to signatory nations.

Now that we have muddled the definition of biosafety sufficiently, how might one illustrate “sensible biosafety”? One way is through case studies of GMO/LMO. Jones [9] laid out a compelling case for safety and other undeniable benefits of GM food crops including decreased use of insecticides (*Bacillus thuringiensis* toxin, *Bt*), improvements in yield, texture (tomatoes), nutritional content (β -carotene, “golden” rice) and cost savings. However, these arguments got a bit diluted by focusing on minutiae such as objecting to the word “modification” (as in GM), with the position that a genetically “modified” plant with a

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single “foreign” gene (measured in kilobase) inserted is still 99.999% identical to that plant’s genome (measured in gigabase) without the particular gene insert. By this logic, after ingesting potassium cyanide (lethal dose, 1.5 mg/kg), the human body too, is 99.999% “unmodified.” A balanced treatment of GM plants and biosafety may be found in the article by Neal Stewart and colleagues [10] who highlighted the environmental, health, ecological and food safety issues and exhorted scientists to be “proactive in the public debate” whilst addressing valid concerns regarding biosafety, risks identification and mitigation during the evaluation of actual and potential rewards.

“Biopharming,” the concept of producing biologics (for example, drugs, proteins, and edible vaccines) and chemicals in transgenic plants and animals, also provides exemplars of sensible biosafety. The Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) in coordination with the Environmental Protection Agency (EPA) (monitoring amongst others, compliance with National Environmental Policy Act, NEPA), Food and Drug Administration (FDA) and the National Institutes of Health (NIH) provide oversight for GMO approvals. Production simplicity, higher yield, and lowered costs are amongst the potential benefits of this technology [11]. However, production of pharmaceuticals and industrial chemicals in human food or animal feed crops is problematic due to concerns regarding commingling of food crop with pharmaceutical-producing crop or cross-pollination between the two. For example, ProdiGene’s field trials of GM corn contaminated the harvested soybeans from the same land. In a separate instance, the company’s GM corn was suspected of cross-pollinating corn growing in a neighboring field. Such biosafety violations resulted in destruction of contaminated crops and penalties to the company [12]. These are serious matters and should not be treated with levity or sarcasm, by suggesting that biopharming could result in commingling which “by an *amazing coincidence* (my emphasis), be picked up by random tests conducted by Friends of the Earth” [13]. Residues of StarLink™, a variety of *Bt* corn cultivated as animal feed, turned up in human foods leading to the cancellation of its registration. Similarly, two GE lines of rice (LibertyLink) were found in commercial rice. However, biopharming can be sensibly regulated through an assessment of environmental risks, appropriate documentation and stringent containment measures. The risks can be further mitigated by geographical segregation of biopharm crops or by using plants that are not destined for human food or animal feed [13].

Biosafety debate gets complicated when a prestigious journal such as *Nature* publishes a paper showing the presence of transgenes in wild type maize [14] and then issues a note [15] asserting “..... to allow our readers to judge the science for themselves” thereby diluting the paper’s import or giving the appearance of waffling. This ambivalence resulted in a popular misconception that the journal retracted this paper, which *Nature* denied. However, if the published work was unequivocal, there is no need for an editorial note. If the research was flawed, it should not have been published in the first place. Ironically, transgene contamination in maize was confirmed several years later and the story was covered in the News section of *Nature* [16]. Perversely such examples solidify the self-correcting nature of science-based work rather than taking these findings as articles of faith. Self-correction is also the basis for setting biosafety regulatory frameworks as witnessed by the EPA accepting the conclusions of Sears *et al.* [17] for extending approval to *Bt* corn after an earlier controversy regarding the effects of its pollen on Monarch butterfly larvae’s survival [18]. Regarding the evolving nature of science-based evidence, one need look no further than the initial successes of 1,1,1-trichloro-2,2-bis(*p*-chlorophenyl) ethane (DDT) in eradicating malaria and early motion pictures of

children (and adults) exuberantly frolicking in the smoke from DDT-laden trucks spewing the chemical in neighborhoods, before its toxicity and environmental impact were recognized [19]. However, none of these controversies justify vandalism, violent protests against so called “Frankenstein Foods” and destruction of approved GM field trials, purportedly in the interests of biosafety [20].

To conclude, biosafety is complex, complicated, and must be treated with science-based seriousness. In modern biotechnology there are biosafety risks and economic and societal rewards. Transparency to eliminate distrust on both sides of the issue, individual, societal and environmental benefits are key to shaping biosafety discussions. Biosafety must therefore be vigilantly monitored and sensibly regulated while refraining from exaggerated claims of either rewards or risks from polarized protagonists on the two sides of the biosafety debate. Failure to act differently will result in undesirable outcomes, governmental regulations, class action lawsuits (extreme regulation!) and validate the old saw that the road to an exceedingly hot location may indeed be paved with good intentions.

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