MONTANA STATE UNIVERSITY
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MONTANA AGRICULTURAL EXPERIMENT STATION
EXTENSION

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Docket No. APHIS-2008-0023
Regulatory Analysis and Development, PPD, APHIS
Station 3A-03.8
4700 River Road, Unit 118
Riverdale, MD 20737-1238

Submitted via the Federal eRulemaking Portal

RESPONSE TO DOCKET NUMBER APHIS-2008-0023

The Animal and Plant Health Inspection Service of the USDA has requested comments relative to a proposed rule for aligning regulations for the import, interstate transportation, and environmental release of certain genetically engineered organisms with provisions of the Plant Protection Act. This correspondence represents my public comments on APHIS-2008-0023. Please note that the comments contained in this letter are mine and not necessarily those of my employer, Montana State University. I am an expert in environmental and biological risk assessment and have been working on assessments of chemical and biological toxins for more than eleven years. I currently am the leader of the Biological Risk Assessment program at Montana State University, a research, teaching, and outreach program dedicated to assessing and communicating risks from agricultural and other technologies, including biotechnology.

In general, I agree that "the mere act of genetic engineering does not trigger regulatory oversight," (p. 60012, 2nd column, line 11). Regulating organisms produced through recombinant DNA technology while at the same time not regulating organisms produced through other genetic means is nonsensical from a scientific standpoint. Despite this, however, I also recognize that relatively new technologies often require regulations in excess of their technical risks. Still, it is encouraging that APHIS recognizes that it should be the products that are regulated rather than the process used to produce them, and that it is committed to a flexible approach to regulation of genetically engineered organisms. I encourage APHIS to use the risk assessment paradigm—and its associated science-based objective and transparent processes—to assist our democratic society in making decisions about how to manage agricultural biotechnology. We must consider public perceptions carefully and implement appropriate regulatory policy.

My primary concern with the proposed rule is that the matrix used for assignments to permit categories (Table 3, p. 60019) seems to be fundamentally unsound and inflexible. Perhaps more disconcerting is the fact that nowhere in the proposed rule is there a discussion of known limitations associated with qualitative risk ranking and matrix schemes. This could reflect either a total dismissal of the importance of these limitations or, worse, a lack of understanding of these issues within the discipline of risk analysis. Risk analysis as a discipline has advanced tremendously in the past 20 years. To bolster public trust in APHIS

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regulatory decision making, APHIS should actively engage itself in and thoroughly understand risk analysis, especially risk assessment. Additionally, there are now a handful of academic research programs in the US focusing on environmental risk assessment. These programs should be utilized by APHIS for their experience, expertise, and research capabilities.

Risk assessment experts have clearly demonstrated the limitations of risk matrices. These limitations are not restricted to the realm of esoteric mathematics, but rather can lead to erroneous decision making. In particular, the recent work of Cox and colleagues should be evaluated carefully by APHIS staff and used where appropriate (Cox et al., *Risk Analysis* 25:651-662, 2005 and Cox, *Risk Analysis* 28:497-512, 2008).

A potential rebuttal to this argument could be the statement on page 44 of the proposed rule, "it should be emphasized that the categories are intended only for initial sorting, and other factors are taken into account in the APHIS evaluation when determining specific permit conditions". Therefore, it could be argued that APHIS will deal with these limitations by considering other factors. However, this argument is not acceptable because it ignores the fundamental mathematical limitations of the qualitative matrix itself.

The variety of recombinant proteins that can be expressed by numerous receiving organisms demands that the risks associated with them be assessed on a case-by-case basis. A case-by-case analysis fits well within the stepwise nature of risk assessment, yet seems to be obscured by the proposed rule's reliance on the matrix, which does not lend itself readily to a case-by-case analysis approach.

Although the widespread adoption of risk matrices by federal government agencies makes their use an attractive option for setting permit categories, APHIS needs to be aware of the limitations, address those limitations in the proposed rule, and address how it intends to deal with those limitations.

Two other aspects of risk assessment and the proposed rule bear mentioning. The proposed rule mentions (p. 60017, 2nd column) using tiers to designate lowest to highest risks. Although later in the paragraph, it is mentioned that "…APHIS found that it was challenging to pre-assign all conceivable releases into tiers representing discrete levels of risk", and therefore "tiers" will not be used, I find it highly disconcerting that APHIS would even consider using a term associated with its risk assessment and permitting scheme that has a completely different and well established meaning in risk assessment. In the proposed rule, there does not seem to be any recognition of this, which is troubling given that APHIS has been charged with implementing risk assessment approaches within its areas of responsibility.

APHIS has equated several factors with exposure and hazard, but these are not sufficiently defined. Because risk is a function of exposure and hazard, it is unfortunate that APHIS has confused this issue by naming certain exposure and hazard factors as "risks" (e.g., persistence risk). I recommend reducing or eliminating the use of the term "hazard" because it does not fit well for genetically engineered organisms. Rather, the term "effect" is more appropriate. Finally, neither the persistence nor the potential harm groupings appear to fully consider aspects of environmental risks that may be relevant to release conditions.

Persistence groupings do not consider residues of the expressed plant product as a potential route of exposure and, additionally, harm groupings do not address potential environmental harms such as non-target exposure (for other than vertebrates or sexually compatible plants) or for adverse effects on ecological services. Are these assumed to be NEPA considerations? If so, this should be explicitly stated.

Risk assessment is amenable to both quantitative and qualitative approaches. The ability to describe risk qualitatively will be important for genetically engineered organisms because of difficulties in establishing an effect with the highly specific proteins that could be expressed and the variety of receiving organisms. However, the ability to describe these risks quantitatively is probably more important for comprehensive societal decision making and communication. Indeed, the public is more receptive to information presented within an objective, statistical context. Although the complexity of quantitative risk assessment often will exceed lay understandings, the implementation and communication of these powerful techniques for assessing environmental risks from genetically engineered organisms will help enhance public trust in the decision making processes surrounding the technology. Given this and the other issues mentioned above, I strongly recommend that APHIS re-analyze its reliance on the qualitative risk matrix process.

Sincerely,

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