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Comments to Docket No. TMD-00-02-PR2 USDA National Organic Program; Proposed Rule

Introduction.

The following material is being submitted by the Center for Food Safety as comment to the United States Department of Agriculture ("USDA"), Agricultural Marketing Service's, "National Organic Program; Proposed Rule" found at 65 *Federal Register* 13512 (March 13, 2000).

I. Excluded Methods Prohibition.

Throughout the new proposed National Organic Program, the USDA continually stresses that it has instituted a strict prohibition upon the use of genetic engineering (defined in the rule as "excluded methods"). The proposal does prohibit "excluded methods" in a comprehensive manner including prohibiting use of "excluded methods" in pest control (conceivably covering genetically engineered insects) and livestock production and treatment (covering genetically engineered animals and vaccines). However, a thorough reading of the proposal raises some significant concerns about the universe of genetic engineering techniques prohibited and the manner in which the USDA will define "excluded methods" in the future. The Center for Food Safety's has concerns on the issue and provides the following comments and recommendations.

(A). USDA's Premise for the GMO "Prohibition."

In addressing the issue of "excluded methods" (i.e. genetic engineering), the USDA's proposal states:

Products created with modern biotechnology techniques have been tested, approved by the appropriate regulatory agencies, and can be used safely in general agricultural production. At the same time, consumers have made clear their opposition to use of these techniques in organic food production. This rule is a marketing standard, not a safety standard. Since use of genetic engineering in the production of organic foods runs counter to consumer expectations, foods produced through excluded methods will not be permitted to carry the organic label. 65 Fed. Reg. 13534-35 (March 13, 2000) (emphasis added).

The Center for Food Safety believes that there are many potential human health and environmental risks. The U.S.D.A.'s pronouncement of the safety of genetically engineered foods is negligent and ignores the very real potential of a public health threats posed by these foods.. A significant body of scientific evidence, including findings of FDA's own scientists, shows that the genetic engineering of foods can transform safe foods into dangerous products.

In 1992 the FDA ruled, without any scientific basis, that genetically engineered foods present no different risks than traditional foods.⁽¹⁾ FDA's own scientists ridiculed the agency's policy. "What happened to the scientific elements in [the] document?" one asked.⁽²⁾ FDA scientists consistently stated that "[t]here is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering. . . . [T]his difference should be and is not addressed."⁽³⁾ The USDA should recognize that the "unexpected effects" and health risks posed by genetic engineering are the reasons consumers do not want genetically engineered foods coming on to the market, especially under an organic label. These risks include increases in food toxicity, the presence of new allergens, the creation of antibiotic resistance, immuno-suppression, and the nutritional degradation of foods.

Genetically engineered foods are inherently unstable. Each insertion of a novel gene, and the accompanying "cassette" of promoters, antibiotic marker systems, and vectors, is random. GE food producers simply do not know where their genetic "cassette" is being inserted in the food, nor do they know enough about the genetic/chemical makeup of foods to establish a "safe" place for such insertions.⁽⁴⁾ As a result, each gene insertion into a food amounts to playing food safety "roulette," with the companies hoping that the new genetic material does not destabilize a safe food and make it hazardous. Each genetic insertion creates the added possibility that formerly nontoxic elements in the food could become toxic.⁽⁵⁾

The FDA was well aware of the "genetic instability" problem prior to establishing their no-testing policy. FDA scientists warned that this problem could create dangerous toxins in food and was a significant health risk. The scientists specifically warned that the genetic engineering of foods could result in "increased levels of known naturally occurring toxicants, appearance of new, not previously identified toxicants, increased capability of concentrating toxic substances from the environment (e.g., pesticides or heavy metals). . . ." These same FDA scientists recommended that long term toxicological tests be required prior to the marketing of GE foods.⁽⁶⁾ FDA's response to the potential toxicity problem with genetically engineered foods was to ignore it. The agency refused to require pre-market toxicological testing for GE foods or any toxicity monitoring, whatsoever. The NOP's pronouncement of safety continues the US government's refusal to address the safety issues inherent in genetically engineered foods.

Additionally, in the United States, about a quarter of the population reports some adverse reaction to food.⁽⁷⁾ At least 8% of children have physically identifiable allergic reactions to food.⁽⁸⁾ The genetic engineering of food creates two separate and serious health risks involving allergenicity. The first is that genetic engineering can transfer allergens from foods to which people know they are allergic, to foods that they think are safe. This risk is not

simply hypothetical. A recent study by the *New England Journal of Medicine* showed that when a gene from a Brazil nut was engineered into soybeans, people allergic to nuts had serious reactions to the engineered product.⁽⁹⁾ At least one food, a Pioneer Hi-Bred International soybean, was abandoned because of this problem.⁽¹⁰⁾

There is yet another allergy risk associated with GE foods. These foods could be creating thousands of different and new allergic responses. Each genetic "cassette" being engineered into foods contains numbers of novel proteins (in the form of altered genes, bacteria, viruses, promoters, marker systems, and vectors) which have never been part of the human diet. Each of these numerous novel proteins could create an allergic response in some consumers.⁽¹¹⁾ The FDA was also well aware of this new and potentially massive allergenicity problem. The agency's scientists repeatedly warned that genetic engineering could "produce a new protein allergen." Once again the agency's own scientists urged long-term testing.⁽¹²⁾ However, the FDA again ignored its own scientists. Because these foods were allowed to be marketed without mandatory testing for this kind of allergenicity, millions of unsuspecting consumers have continuously been exposed to a potentially serious health risk

Another hidden risk of GE foods is that they could make disease-causing bacteria resistant to current antibiotics, resulting in a significant increase in the spread of infections and diseases in the human population. Virtually all genetically engineered foods contain "antibiotic resistance markers" which help the producers identify whether the new genetic material has actually been transferred into the host food. FDA's large-scale introduction of these antibiotic marker genes into the food supply could render important antibiotics useless in fighting human diseases.⁽¹³⁾ For example, a genetically engineered maize plant from Novartis includes an ampicillin-resistance gene. Ampicillin is a valuable antibiotic used to treat a variety of infections in people and animals. A number of European countries, including Britain, have refused to permit the Novartis Bt corn to be grown, due to health concerns that the ampicillin resistance gene could move from the corn into bacteria in the food chain, making ampicillin far less effective in fighting a wide range of bacterial infections.⁽¹⁴⁾

For the past seven years, FDA officials have ignored their own scientists' concerns over the antibiotic resistance who warned, "IT WOULD BE A SERIOUS HEALTH HAZARD TO INTRODUCE A GENE THAT CODES FOR ANTIBIOTIC RESISTANCE INTO THE NORMAL FLORA OF THE GENERAL POPULATION."⁽¹⁵⁾ During the same time, medical professionals around the world have become increasingly alarmed at how GE foods are leading to a massive infusion of antibiotic genes into the human diet. Just this year, for example, the British Medical Association (BMA) addressed this problem in its study of GE foods. The BMA's conclusion was unequivocal: "There should be a ban on the use of antibiotic resistance maker genes in GM food, as the risk to human health from antibiotic resistance developing in microorganisms is one of the major public health threats that will be faced in the 21st century."⁽¹⁶⁾

Furthermore, during the last year the well-respected British medical journal, *The Lancet*, published an important study conducted by Drs. Arpad Pusztai and Stanley W.B. Ewen under a grant from the Scottish government.⁽¹⁷⁾ The study examined the effect on rats of the consumption of potatoes genetically engineered to contain the biopesticide *Bacillus thuringiensis* (B.t.). The scientists found that the rats consuming genetically altered potatoes showed significant detrimental effects on organ development, body metabolism, and immune function.⁽¹⁸⁾ Moreover, twenty-two leading scientists recently declared that animal test results linking genetically engineered foods to immuno-suppression are valid.⁽¹⁹⁾

Finally, genetic engineering can also alter the nutritional value of food. The genetic instability of these foods (described above) can be a major culprit in reducing their nutrients. In 1992, the FDA's Divisions of Food Chemistry & Technology and Food Contaminants Chemistry examined the problem of nutrient loss in GE foods. The scientists involved specifically warned the agency that the genetic engineering of foods could result in "undesirable alteration in the level of nutrients" of such foods. They further noted that these nutritional changes "may escape breeders' attention unless genetically engineered plants are evaluated specifically for these changes."⁽²⁰⁾ Once again, the FDA ignored findings by their own scientists and never subjected the foods to mandatory government testing of any sort.

Therefore, CFS recommends that the USDA recognize that the prohibition of "excluded methods" is based upon consumers' reasonable concerns of safety of such foods for both human health and environment. Furthermore, the current government regulatory process for genetically engineered foods is based upon voluntary consultations, and the FDA does NOT in any legal sense approved genetically engineered food for use. Given the government's refusal to require mandatory pre market safety testing of genetically engineered foods, consumers oppose the use of GMOs in organic agriculture precisely because of the unknown health effects and environmental impacts.

(B). Definition of Excluded Methods.

In addressing the new proposed definition of "excluded methods" the USDA states, "This proposal essentially adopts that definition [of the NOSB]." 65 Fed. Reg. 13521. However, the USDA definition eliminates several examples of the "excluded methods" originally recommended by the NOSB for prohibition. The USDA eliminations include gene deletion and doubling, introducing a foreign gene and changing the positions of gene. Because of the proposed definition's flexibility (i.e. "such methods would include . . ."), the elimination of genetic engineering techniques from the definition does not inherently make the new proposed definition of "excluded methods" lesser in scope than the proposed NOSB definition. Nonetheless, it is unclear why the USDA eliminated some key examples such as "introducing a foreign gene." The Center for Food Safety believes these changes may have significant implications down the road and could indicate the USDA's intent to narrow the scope of the genetic engineering prohibition.

USDA/AMS Proposed Definition.

Proposed §§ 205.2 Terms defined.

Excluded methods. Refers to a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods would include recombinant DNA, cell fusion, and micro- and macro-encapsulation. Such methods would not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. 65 Fed. Reg. 13611.

NOSB Definition

(November 1, 1995) (Austin, TX)

Genetically Engineered. (After Food Processing's Biotechnology Glossary, January 1993) Made with techniques that alter molecular or cell biology of an organism by means that are not possible under natural conditions or processes. Genetic

engineering includes recombinant DNA and RNA techniques, cell fusion, micro- and macro-encapsulation, gene deletion and doubling, introducing a foreign gene, and changing the positions of genes. It shall not include breeding, conjugation, fermentation, hybridization, in-vitro fertilization

and tissue culture.

Therefore, CFS recommends that the USDA not to water down the NOSB definition of genetic engineering with its new definition of "excluded methods". See Proposed § 205.2. CFS further recommends that the NOSB recommended definition be amended to read as follows:

Proposed §205.2 Excluded Methods. Made with [or derived from] techniques that alter molecular or cell biology of an organism by means that are not possible under natural conditions or processes. Genetic engineering [includes but is not limited to] recombinant DNA and RNA techniques, cell fusion, micro- and macro-encapsulation, [animal cloning and] gene deletion and doubling, introducing a foreign gene, and changing the positions of genes [accomplished through recombinant techniques]. It shall not include breeding, conjugation, fermentation, hybridization, in-vitro fertilization and tissue culture.

(C). Future Changes to the "Excluded Methods" Prohibition.

In discussing the definition of "excluded methods" the USDA states:

We recognize that the phrases, "natural conditions or processes" and "not considered compatible with organic production," may be subject to interpretation. We have proposed to use these phrases for two reasons. First, "natural conditions or processes" is used in the NOSB and American Organic Standards definitions, both of which were the result of consultation with organic industry and consumer stakeholders and, thus, accurately reflect current industry practices as well as consumer preferences. Second, we recognize that industry and consumer expectations regarding the products of these techniques in organic production systems may evolve. We believe that, taken together, these phrases allow for a degree of flexibility to ensure that our regulations continue to accurately reflect industry practices and consumer preferences. In cases where questions may arise regarding a specific technique, we anticipate that such questions would be resolved by the Administrator based on recommendations from the NOSB. 65 Fed. Reg. 13521 (emphasis added).

This language clearly suggests that the proposed rule does not necessarily prohibit genetic engineering in the future and the USDA will review the issue as consumer expectations "evolve." This presents several areas of concern. First, by what criteria will the USDA measure consumer "evolution" on the issue? The proposed rule is silent as to this issue.

Second, what procedural safeguards will be in place to ensure public involvement in debates over whether a technique fits under the definition of "excluded methods"? While the USDA suggests using the National Organic Standards Board (NOSB), the proposed rule does not provide any procedural avenue for public involvement.

Significantly, the USDA states in a later section of the preamble:

We also do not consider it necessary to classify genetically engineered organisms as either synthetic or nonsynthetic for the purposes of this regulation, since these organisms and their products are prohibited for use in organic production or handling regardless of whether or not they are synthetic. 65 Fed. Reg. 13520 (emphasis added).

This determination is of important legal significance. This means that future questions concerning what is or is not an "excluded method" falls outside of the National List's public petitioning process concerning allowed or prohibited substances. Therefore, there is no legal requirement that the NOSB (and by extension the public) be involved in the decision making. As a result, there are at least two hypothetical scenarios in which the prohibition to "excluded methods" could be reversed or diluted.

Example One. Direct Contact With USDA To Allow A GE Technique. A producer of a genetically engineered product makes a direct request to the Administrator of AMS or the Secretary for a determination that the new product is not an "excluded method." The public and NOSB are unaware that such a request is made. The USDA without any public notice via the NOSB or *Federal Register* makes such a determination and simply places the decision in the latest revised program manual. Because "excluded methods" are not subject to the National List petition procedures, there is no manner for the public to challenge this new determination except a letter to the very agency that just made the unfavorable determination.

Example Two. On The Ground Challenge. A grower attempts to use a genetically engineered crop (for example New Leaf potatoes). After an inspection, a certifier identifies the apparent violation and pulls the grower's certification. The grower appeals the certifier's decision. As a result, the new appeals process is used and an USDA Administrative Law Judge (ALJ) is set to make the decision on whether or not a New Leaf potato is an excluded method. Assuming the ALJ upholds the revocation of certification, the grower now can proceed to United States District Court. As a result, there is a direct legal challenge by the grower to the USDA's entire prohibition of "excluded methods" as something outside the statutory authority of OFPA.

Both scenarios suggest that the USDA's proposal may create a new case-by-case review of genetic engineering techniques in which there is no NOSB or public oversight. The Center for Food Safety strongly believes that there any future decision concerning the use of genetic engineering in organic standards must involve an open public debate and an established decision making process. To address this issue, CFS makes the following recommendation that recognizes that in order to make an alteration to the prohibition to excluded methods the NOSB would (1) have to vote to overturn its general prohibition and (2) have to approve a particular "excluded method" as an allowed synthetic through the National List petition procedures. Accordingly, CFS recommends the following amendments and additions to USDA's proposed § 205.600:

Proposed § 205.600 Allowed and prohibited substances and ingredients in organic production and handling.

To be sold or labeled as "organic," or "made with organic (specified ingredients)," the product must be produced and handled without the use of:

- (a) Synthetic substances and ingredients, except as provided in §205.601 and § 205.603.
- (b) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;
- (c) Nonsynthetic substances prohibited in § 205.602 or § 205.604; and
- (d) Materials, processes, ~~or~~ techniques, [excluded methods, ionizing radiation or sewage sludge] prohibited in § 205.301.

[(1) Any change in the categorical prohibition of excluded methods must be reviewed and approved by the NOSB in accordance with the process provided in § 205.607; and

(2) In the case that categorical prohibition for excluded methods is abolished or modified by review and approval by the NOSB specified in (1), the specific techniques and products defined as excluded methods are synthetic as defined in 205.2 and are subject to case by case review by the NOSB in accordance with the process provided in §205.607.]

(D). USDA Needs to Protect Organic Farmers from "Genetic Pollution"

The commercial introduction of genetically engineered plants has raised a host of new environmental, ethical and human health questions. Of particular concern is the threat of biological or "genetic pollution." Unlike our conventional view of chemical pollution (such as oil slicks and chemical spills), genetically engineered organisms represent living matter that can reproduce without our ability to mitigate and control its impact. As a result, "genetic pollution" creates the novel circumstance that pollution expands in a manner similar to a disease. In ecological terms, this genetic pollution threatens our ecosystems with devastating impacts comparable to the introduction of exotic species such as kudzu vine, the gypsy moth, and the zebra mussel.

With millions of acres of genetically engineered corn, cotton, potatoes, soybeans and canola now planted throughout North America, this new "genetic pollution" is having a fundamental impact on the agricultural sector of North America. Numerous field tests have shown that transgenic genetic material have a high frequency of transferring to non-genetically engineered crops. As a result, organic farmers across North America face a direct threat to their economic well-being as their non-genetically engineered crops become contaminate with the DNA from new, genetically engineered varieties.

The new proposed organic rule is silent as to this issue of "Genetically Modified Organism (GMO) Drift" or "genetic pollution." The Center for Food Safety believes that the USDA must hold manufacturers and/or patent holders of genetically engineered seed responsible for genetic pollution and its impacts on all non-genetic engineering using producers, especially organic farmers. To that end, the USDA should establish a mandatory notification system at the county level for all users of genetically engineered crops and genetically engineered seed dealers. This would ensure that organic farmers are able to identify possible avenues of "GMO drift" and/or GMO seed contamination. Additionally, the USDA should ensure that organic farmers will be adequately compensated should they lose their certification or crop premium because of GMO pollution or seed contamination..

II. Ionizing Radiation Prohibition

Throughout the new proposed National Organic Program, the USDA continually stresses that it has instituted a strict prohibition upon the use of ionizing irradiation. However, a thorough reading of the proposal raises a significant concern about the scope of the prohibition. The following comments stresses the Center for Food Safety's concerns on the issue and provides recommendations.

(A.) USDA's Premise for the Irradiation Prohibition.

In addressing the prohibition on irradiation, the USDA's proposal states:

Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods even though there is no current scientific evidence that use of irradiation presents unacceptable risks to the environment or human health and may, in fact, offer certain benefits. Because this rule is a marketing standard and consumers have expressed a clear expectation that irradiation should not be used in the production of organic foods, foods produced with this technology will not be permitted to carry the organic label. 65 Fed. Reg. 13514 (emphasis added).

The Center for Food Safety (CFS) does not believe irradiation is an appropriate technology to be used in our food production system. CFS believes that the technology poses severe drawbacks and limitations that make the use of irradiation inappropriate. In addition, CFS believes that irradiation creates legitimate health and environmental concerns which are unacceptable to the public.

In particular, irradiation has a number of effects on food (including meat products). Among the major concerns is the ambiguity of its long-term effects on human health. Molecules that absorb irradiation become reactive and form ions and free radicals, which react to form chemically stable radiolytic products.⁽²¹⁾ The number of radiolytic free radicals are believed to be unique, or at least more prevalent in, irradiated foods.⁽²²⁾ Free radicals are highly reactive compounds and some have been associated with oncogenicity, mutagenicity and carcinogenicity. While none of these radiolytic free radicals have been conclusively determined to be carcinogenic, it is not known whether there are long-term health effects associated with these irradiation byproducts.⁽²³⁾

(B.) New Rule Does Not Define Ionizing Radiation.

The USDA's new proposal does not provide a definition for ionizing radiation (irradiation). Therefore, the USDA's prohibition on irradiation use remains open to debate. The USDA has provided no reasoning for this failure and the Center for Food Safety believes this potential loophole must be closed immediately.

Any definition of irradiation must be designed to cover all irradiation techniques, including any attempt to recharacterize food irradiation through terms such as "cold pasteurization." Only by enacting such a definition will the prohibition on irradiation have any teeth. The Center for Food Safety recommends the USDA adopt the following definition:

Proposed § 205.2. [Ionizing Radiation. High energy emissions from radionuclides, (including but not limited to cobalt-60 or cesium-137), capable of altering a food's molecular structure for the purpose of controlling microbial contaminants, pathogens, parasites and pests in food, preserving a food, or inhibiting physiological processes such as sprouting or ripening.]

Similar to CFS' comments concerning the excluded methods prohibition, CFS recommends that USDA clarify that any alteration in the prohibition of ionizing radiation must go through the NOSB procedures for the National List as outlined above in the Center for Food Safety's comments on the "excluded methods" prohibition.

III. Sewage Sludge Prohibition.

Throughout the new proposed National Organic Program, the USDA continually stresses that it has instituted a strict prohibition upon the use of sewage sludge. However, a thorough reading of the proposal raises a significant concern about

the scope of the prohibition. The following memo delineates the Center for Food Safety's concerns on the issue and provides recommended comments at the end.

(A.) USDA's Premise for the Sewage Sludge Prohibition.

In addressing the prohibition on sewage sludge (also known as biosolids), the USDA's proposal states:

Based on this overwhelming public opposition, this proposal prohibits its use in the production of all organic foods, even though there is no current scientific evidence that use of sewage sludge in the production of foods presents unacceptable risks to the environment or human health. We believe consumers have expressed a clear expectation that sewage sludge should not be used in the production of any ingredients contained in mostly organic products. 65 Fed. Reg. 13514 (emphasis added).

The Center for Food Safety believes that use of sludge does pose significant human and environmental impacts. Sewage sludge can contain residue levels of heavy metals, pesticides and contaminants such as Dioxins, PCBs and furans.⁽²⁴⁾ These toxins present potential risks of cancer, hormone disruption and IQ depression. Hospital sludge can include antibiotics, poisons and irradiated material. In fact, consumers oppose the use of sewage sludge in organic agriculture precisely because of these health effects and environmental impacts.

(B.) Proposed Definition Allows Use of Burned Sewage Sludge.

The USDA's new proposal defines sewage sludge as:

A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works. 65 Fed. Reg. 13612 (emphasis added).

Therefore, the USDA's prohibition on sludge use does not cover burned sludge ash and some sewage waste generated early in the treatment process. The USDA has provided no reasoning for these allowances. The Center for Food Safety believes this loophole allows for some unhealthy and potentially dangerous practices.

Therefore, CFS recommended the following new definition for sewage sludge

Proposed § 205.2 Sewage sludge - A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes, but is not limited to: [domestic sewage, industrial sewage, municipal non-point source runoff], domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge [includes] ash generated during the firing of sewage sludge in a sewage sludge incinerator and grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Similar to CFS' comments concerning the excluded methods prohibition, CFS recommends that USDA clarify that any alteration in the prohibition of sewage sludge must go through the NOSB procedures for the National List as outlined above in excluded methods comments.

IV. Proposed Soil Fertility and Crop Nutrient Management Practice Standard

As written, the proposed soil fertility practice standard is unclear as to whether it would allow use of genetically engineered microorganisms for purposes of soil fertility or nutrient management. Such a practice would be contrary to organic principle and consumer expectation. Therefore, CFS recommends the following amendment:

Proposed § 205.203 Soil fertility and crop nutrient management practice standard. (e) The producer must not use [~~(4)any soil input or crop nutrient produced with excluded methods.~~]

V. Proposed Livestock Standards

As written, the proposed rule actually allows for practices that will allow animal factories. Contrary to its stated goals and international norms, there are exemptions from the outdoor access and pasture requirements that would allow for animals to be kept without outdoor access for most of their lives. These exemptions would also allow for lactating dairy cows to be kept on dry lots (dirt enclosures void of any grass and without access to pasture). The Center for Food Safety believes that there are several provisions that must be amended and clarified.

(A). Proposed § 205.236(a)(2). Origin of Livestock. Dairy Animals.

As written, the proposed rule seriously inhibits the ability of small dairy farms to convert to organic production. To that end, the Center for Food Safety supports the adoption of a small farm new herd dairy clause as recommended by the NOSB at its June 6-7, 2000, Washington, DC meeting, with one amendment. The Center for Food Safety believes that the 20% non-organic feed allowed during the first nine months of the final twelve month dairy herd conversion must be feed produced without excluded methods:

Proposed § 205.236(a)(2). Origin of Livestock. (2) *Dairy Animals*. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic.

[Except That, when an entire, distinct herd is converted to organic production the following exemption may apply:

(i) for the first nine months of the final twelve month dairy herd conversion period, animals must be fed at least 80% organic and/or self-raised transitional feed;

(a). For the 20% allowance for non-organic, non-self-raised transitional feed provided for in (i), animals must be fed with feed not produced by or derived from excluded methods.

(ii) for the final three months animals must be fed 100% organic feed; and

(iii) once a dairy operation has been converted to organic production all dairy animals shall be under organic management from the last third of gestation; Except that transitional feed raised on the farm may be fed to young stock up to twelve months prior to production.]

(B). Proposed § 205.237. Livestock Feed.

Section 205.237(b) does not prohibit the use of genetically engineered feeds. Consumers expect that organic livestock do not come in contact with genetically engineered feeds. Accordingly, CFS recommends that this be amended by adding the following:

Proposed § 205.237(b). [(7) Livestock feed. Use feed, feed additives, and feed supplements produced with excluded methods.]

(C). Proposed § 205.238. Livestock Health Care Practice Standard.

(1). Physical alterations.

Under the current proposed § 205.238(a)(5) physical alterations to livestock are broadly allowed. This issue has not been discussed by the NOSB and is below international norms such as the IFOAM standard practices. USDA should seek advice from the NOSB through its public consultation process to establish appropriate guidance to determine the specific kinds of alterations that are to be allowed in organic livestock production. The proposed rule language is too vague and does not provide enough discrimination, such as the differences between "debeaking and beak tipping" in chickens. Special priority should be paid to the behavioral and physiological needs of the species involved. The use of these practices must also be justified and documented. The animals needs should take precedence over the needs of herd management (mutilation) practices that are needed due to confinement, use of breeds unsuited to organic production, or improper stocking densities.

Until the NOSB addresses this issue, CFS recommends the following:

Proposed § 205.238(a)(5). Livestock health care practice standard. (5) Performance of [the least intrusive] physical alterations only when necessary to [maintain] the [individual] animal's welfare in a manner that minimizes pain and stress.

CFS does not believe that this proposed amendment should be permanently adopted. It is proposed to tighten the standard and could used only until the NOSB has completed recommendations on this subject and the USDA engages in rulemaking to implement the NOSB's recommendations.

(2) Medical Treatment.

Proposed § 205.238(c)(7) should be amended so that for treatment of animals that do not respond to permitted organic treatments 'methods acceptable to organic production' include the producer being able to choose humane slaughter, especially for animals where treatment is cost prohibitive. Therefore, CFS recommends the following:

Proposed § 205.238 (c)(7). Livestock health care practice standard. (7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health [or slaughter

consistent with the requirement of the Humane Slaughter Act, 7 U.S.C. §1901, et seq.] when methods acceptable to organic production fail. . . .

(C). Proposed § 205.239. Livestock Living Conditions.

The proposed livestock living conditions under § 205.239 contain several loopholes that may allow large, intensive confinement livestock operations to label their products as organic. Animal stress is directly linked to the organic principles of prevention just as with plants. Reducing stress is the key determining practice that should be clearly included in this section. Providing an environment where animals are able to meet their behavioral and physiological needs, and they have true access to the outdoors, appropriate stocking densities and nutritious foods provide the cornerstones for reducing stress and for disease prevention in organic production system. Thus, CFS opposes any loophole that will allow "animal factories" to be certified as organic and recommends the following amendments.

(1). Outdoor Access Requirement for All Livestock.

As written, the language of proposed § 205.239(a)(1) raises a number of questions. What does the phrase "suitable to the species" mean? If an animal can "tolerate" the conditions, it should not be interpreted as "suitable to the species". Are cages suitable for laying hens? Stanchions for lactating dairy cattle? The phrase "suitable to the species" and "stage of production" should be more clearly defined to reflect the earlier statement that living conditions "accommodate the health and natural behaviors of animals" and to incorporate the NOSB's recommendations that all livestock systems be based on outdoor access and ruminant systems be pasture-based. This would also be consistent with consumer expectations.

Therefore, CFS proposes the following amendment:

Proposed § 205.239(a)(1). Livestock living conditions. Access to shade, shelter, exercise, fresh air, [direct sunlight, and the outdoors to accommodate the health and natural behavior of the animal species, the climate, and the environment.]

(2). Access to Pasture.

CFS strongly supports the requirement that all ruminants must have access to pasture. This could be further strengthened to ensure that ruminants not only have "access," but are primarily raised on pasture.

Proposed § 205.239(a)(2). Livestock living conditions. (2) Access to pasture [and be pastured-based] for ruminants.

Additionally, CFS believes that pasture should be defined in the rule and proposes the following recommended definition:

Proposed § 205.2. [Pasture. Land used for grazing of livestock that is under management designed to maximize soil fertility, provide feed value, protect the environment from degradation, and support such range land health, as approved by the certifying agent in the organic system plan.]

(3). Temporary Confinement.

CFS believes that the proposed allowance for temporary confinement based upon an animals "stage of production" at proposed § 205.239(b)(2) is over broad and will allow confinement for certain animals for a significant period of their life. This could be interpreted to allow confinement operations for beef and hogs during finishing, dairy cows during lactation or hens during egg production. Therefore, the loophole should be tightened and a very clear and firm requirement put in place for ruminant systems to be pasture-based and a requirement for outdoor access for all animals. Stage of production should be changed to a verifiable exemption only for final fattening or 20% of final marketing weight to prevent loss of consumer confidence and organic integrity.

CFS also believes that proposed § 205.239(b)(4) allows for significant confinement of livestock in a manner not consistent with organic principle. Large concentrations of livestock always result in a risk to soil and water quality, so this could be used as a loophole to allow confinement when large numbers of animals are gathered in one place. Proper density and stocking rates and soil and water quality must be directly linked, in order, to prevent abuse of this temporary exemption.

In sum, we hope these recommendations will ensure that the USDA recognizes the NOSB's intent that provisions for temporary confinement must not allow large livestock concentration operation to in anyway undermine animals direct access to sunlight and the outdoors.

VI. Proposed § 205.271 Facility Pest Control

In the new proposed National Organic Program, the USDA has outlined standards pest control in facilities handling organic food. A thorough reading of the proposal raises a significant concern about the possible use of pesticides in organic food facilities for pest control.

(A). USDA's Must Close The Loophole Allowing for Methyl Bromide Use.

In addressing facility pest control, the USDA's proposal states:

If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control facility pests, a nonsynthetic biological or botanical substance or a synthetic substance may be applied to prevent, suppress, or control pests: Provided, That, the substance is applied in the manner consistent with its label as approved by the Federal, State, and local regulatory authorities.65 Fed. Reg. 13617, Proposed § 205.271(c) (emphasis added).

This proposed regulation grants food processors the broad discretion to determine that organic pest controls are "not effective" and turn immediately to synthetic pesticide usage. The Center for Food Safety believes that this loophole will allow food processors and facility handlers to violate organic principles by consistently using synthetic pesticides. One such pesticide of concern is the fumigant methyl bromide. Methyl bromide is a powerful destroyer of the Earth's protective stratospheric ozone layer. It is regulated under the US Clean Air Act, classified as a Class Ozone Depleter and is scheduled to be banned by January 1, 2005. It is also classified by the Environmental Protection Agency (EPA) as a Category I Acute Toxin, the most deadly category of substances. The acute effects of methyl bromide exposure include headaches, drowsiness, lethargy, nausea, vomiting, dizziness, blurred vision, twitching and convulsions, seizures, psychosis and death. The Center for Food Safety believes there should be no broad loophole for methyl bromide or other synthetic pesticides usage in pest control.

The USDA needs to revamp this proposal to ensure that processors and facility handlers are not allowed to use synthetic pesticides for pest control. The NOSB proposed that prohibited pest control substances should not be used during the handling or processing of organically produced food. Processors and handlers should not be allowed to use synthetic substances in pest control that have not been approved by the NOSB. Therefore, CFS recommends the following amendment:

Proposed § 205.271(c). Facility pest management practice standard. If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control facility pests, a nonsynthetic biological or botanical substance or a synthetic substance may be applied to prevent, suppress, or control pests: Provided, That, the substance [appears as an approved synthetic substance on the National List, does not appear as a prohibited natural substance and] is applied in the manner consistent with its label as approved by the Federal, State, and local regulatory authorities.

VII. Proposed § 205.301. Product Composition. Labeling.

As allowed by proposed § 205.301(d), products with less than 50 percent organic ingredients foods with organic ingredients could come on the market despite the use of genetic engineering ("excluded method"), irradiation and/or sewage sludge in the production of the entire food. The Center for Safety believes this is contrary to consumer expectation and a severe watering down of organic principles. When the public notes the word "organic" on either the principle display panel or the ingredient statement they have an expectation that such products will in no way be subject to genetic engineering, ionizing radiation or sewage sludge. The USDA itself has created this expectation when the Secretary of Agriculture recognized the sentiments in the over 275,000 public comments received by the agency during the last proposed rule and announced a strict prohibition on the "Big Three" in the repropoed organic rule. Accordingly, CFS recommends the following new language:

Proposed § 205.301 (d) Products with less than 50 percent organic ingredients.

[(1) All ingredients identified in the ingredient statement must not contain or be created using excluded methods or be produced using sewage sludge or ionizing radiation.]

Recognizing that products under to this provision are not subject to certification, the Center for Food Safety also suggests that the USDA consider ways in which to enforce this requirement through a registration system for any product using less than 50% organic ingredients which requires the food producer to confirm their adherence to such regulation. Such a system would allow both the USDA and/or members of the public enforce this requirement through legal action for misrepresentation and/or fraud.

VIII. Accreditation of Certifying Agents

(A). Proposed §205.501(b)(2) USDA Must Allow Higher Standards.

As proposed, this section prohibits private certifying agents from requiring "compliance with any production or handling requirements other than those provided for in the Act and the regulations in this part as a condition of use of its identifying mark." This limiting language constitutes a violation of commercial free speech and the Organic Foods Production Act does not authorize this provision. The only justification given in the preamble is that "a stated purpose of the Act is to assure

consumers that organically produced products meet a consistent national standard." The Center for Food Safety believes there is no contradiction between allowing certifying agents to control their own seals and maintenance of the USDA's stated purpose of a consistent national standard. All certifying agents will be accredited to a consistent national standard and will not be allowed to have lower standards.

The seals of certifying agents have been used for many years and, in many cases, have established market identities. The right of private certifying agents to control their own seals was recognized by the NOSB, which stated:

It is recognized that some private certifying agents have established programs to address specific philosophies and/or regional considerations, and may wish to include requirements for the awarding of the certifying agent's seal that are supplemental to the standards promulgated in the OFPA. Such requirements shall not be in conflict with the National Organic Standards. Supplemental requirements shall not preclude the certification to OFPA standards of producers and handlers who do not seek to utilize the private agent's seal.[\(25\)](#)

The USDA must amend proposed § 205.501 to restore the rights of farmers to develop and meet additional specific production or handling practices other than those provided in the Act. The final rule should clarify the ways the national "floor" on standards can be raised by farmers, handlers, certifiers, consumers and processors, both through the marketplace and through regulatory process. Section 205.501(b)(2) must be amended to allow certifying agents to issue licensing agreements or certification contracts with "contract specifications" that allow for additional standards (such as labor standards) above the national "floor" and for use of the certifying agent's seal to identify those contract specifications. This would allow certifying agents to maintain control over their licensed trademarks, prevent a violation of commercial free speech, and create an incentive for farmers and certifiers to continually improve upon existing organic practices. Accordingly, the Center for Food Safety recommends that the language of § 205.501(b)(2) be removed. We further ask that the USDA respond to comments submitted by numerous organizations during the last proposed rule comment period asking for the inclusion of a labor standard.

(B). Proposed § 205.500(c) USDA Must Recognize Foreign NGO Certification

Under proposed § 205.500(c) the USDA allows for the approval of a foreign certifying agent's accreditation only if the certifying agent is accredited by a foreign government whose standards and accreditation meet the Act, or have been deemed to be equivalent to the Act. No provisions are made for recognition of a foreign certifying agent accredited by a private sector accreditation body, but not under a government program or accredited by the USDA. Unless amended, the proposed rule would discriminate against producers and certifying agents located in developing countries which do not have government regulations, since the certifying agents would have to be accredited by the USDA, when well established private sector accreditation systems already exist. The USDA should adopt the recommendations of the NOSB which allows for recognition of private sector accreditation by an "International Organic Standards Organization."[\(26\)](#)

IX. The Proposed National List

(A). National Organic Standards Board Legal Role

Under the OFPA, the NOSB performs functions of a unique nature which require powers beyond those of a typical federal advisory committee. This is particularly true of its role in developing the National List.[\(27\)](#) Premised on the fundamental

principle that synthetic chemicals should not be used in the production or handling of organic food product, the OFPA prohibits the use of synthetic chemicals that are dangerous to human health or the environment in organic products. The National List is a procedural mechanism for establishing exceptions to this general principal. The OFPA specifically enumerates the NOSB's expanded role in establishing the National List:

(D) Procedure for establishing National List. (1) In general - The National List established by the Secretary *shall* be based on a proposed national list or proposed amendments to the National List that is developed by NOSB. (2) No additions. The Secretary *may not* include exemptions for synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List.[\(28\)](#)

Specifically, Congress delegated responsibility to the NOSB to develop the proposed National List.[\(29\)](#) Accordingly, the NOSB through its committee structure has developed a proposed National List of prohibited natural substances whose use is not allowed under the OFPA and synthetic substances allowed to be used pursuant to the OFPA.[\(30\)](#) In addition to creating this list, the NOSB may allow the proposed approved synthetics and prohibited natural substances to be listed only after the NOSB consults a technical advisory panel and the Secretary consults with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency.[\(31\)](#) Thus, the OFPA places specific duties upon the NOSB when developing its Proposed National List that go well beyond the traditional role of an advisory committee. The Center for Food Safety strongly supports the NOSB's legal authority over the National List process so long as it is consistent with OFPA.

(B) Specific Comments on the Proposed National Lists

(1). Proposed § 205.600. Excluded Methods, Ionizing Radiation and Sewage Sludge.

previously stated, the Center for Food Safety recommends that the proposed prohibitions to the use of excluded method, ionizing radiation and sewage sludge be linked with the NOSB authority to create the National List. Accordingly, the CFS reiterates its recommendation for amendments to proposed § 205.600 as outlined above.

(2) Proposed § 205.601. Inerts.

Proposed § 205.601(m) allows the use of all synthetic inert ingredients classified by the EPA as List 4 - Inerts of Minimal Concern, without the inert being subjected to NOSB evaluation as is consistent with the recommendation of the NOSB. The NOSB recommendation which states "inerts on the EPA List 4 are considered to be generally recognized as safe and will be accepted for organic production, unless an NOSB evaluation finds a specific List 4 inert to be unacceptable."[\(32\)](#)

However, at the time the NOSB made the recommendation EPA List 4 contained the substances which are now found on EPA List 4A. Since the NOSB recommendation on inerts a new List 4B was created (1995) with 146 substances transferred from EPA List 3 to List 4B. Thus, the entire EPA List 4 now includes many substances which are potentially toxic, and should not be allowed for use in organic production. List 4 contains numerous substances which are otherwise prohibited for use in organic production, such as ammonium nitrate, ammonium sulfate, ethoxyquin, urea, and urea-formaldehyde resins. There are also numerous substances of toxicological and ecological concern on List 4, including: acetophenone; acrylamide; attapulgite (List 4A - recently listed by California as a substance "known to cause cancer"); naphthalenesulfonic

acid; polypropylene glycol; polyvinyl chloride resin; and sodium fluoride (known to cause brain and nervous system damage).

If enacted as proposed, all substances on List 4 will be allowed for use in organic production as "inert" ingredients in pesticide formulations, and as "active ingredients in accordance with any limitations on the use of such synthetic substances." The National List should not include inerts which have not been evaluated by the NOSB and CFS recommends that § 205.601(m) to be amended to read:

Proposed § 205.601(m). Synthetic substances allowed for use in organic crop production. (m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with a synthetic substance listed in this section, for use with a non-synthetic substance, and used as an active ingredient in accordance with any limitations on the use of such synthetic substances - [EPA List 4A - Inerts of Minimal Concern, Provided, That, the synthetic inert ingredient has been evaluated and recommended for use by the National Organic Standards Board.]

(3) Proposed § 205.605. Synthetics in Processing

Consumers expect that in purchasing foods labeled as organic that such foods do not contain synthetic materials. This expectation was clearly embodied in § 6510(a) of the OFPA which explicitly states that handling operations "shall not . . . (1) add any synthetic ingredient during the processing or any post harvest handling of the product" (emphasis added). As proposed the current regulations do not adhere to this legal requirement. The Center for Food Safety believes that: (1) § 6510 (a)(1) must be followed; (2) consumer expectation is that § 6510(a)(1) be followed; and (3) that processors using synthetic materials can use the labeling provisions "made with organic [specified ingredients]" (as established in proposed §§ 205.301(c), 205.304, 205.306, 205.308) without substantial economic hardship. Therefore, CFS recommends that the USDA delete § 205.605 in its entirety. As written, proposed §205.605(b) containing synthetics allowed in processing is a violation of § 6510(a)(1). Additionally, the listing of approved non-synthetics in processed products contained at § 205.605(a) is unnecessary because non-synthetics are allowed for use unless they are listed as prohibited non-synthetic substances by the NOSB and Secretary.

X. Proposed Fee Structure

(A). Proposed 205.640 - 205.642. Fees and other charges for accreditation

The USDA fee structure must fully ensure that small family farms can afford to participate in the National Organic Program. While we strongly support USDA in its request to offset the initial round costs, as proposed the rule disproportionately harms small farmers, businesses, and certifiers. USDA must recognize that the most recent Organic Farming Research Foundation survey of certified organic farms revealed that 57% of current farmers are under \$30,000 in annual sales. This rule's primary focus should be to support and enhance this core constituency.

The proposed rule has also failed to fully provide all fees or estimates of fees. Therefore, it is impossible to sufficiently evaluate the real costs of the proposed fees impact. As written, there appears to be five (5) sets of fees for the certifier: (1). Application fees - \$500 deposit on fees for service; (2). Annual accreditation fees (uncertain as to ultimate cost); (3) Travel charges. (USDA should require inspectors/evaluators be required to be local. This would help greatly to reduce this set of fees on local certifiers); Per Diem fees. (At \$95/hr. this figure is ten times the hourly wages for most of the core farmers

that would be certified by the USDA program! These rates are also clearly prohibitive for developing country certifiers, as well. USDA must reduce this fee to reflect the program's core constituency or create with the NOSB through its public consultation process, a sliding fee scale to not penalize the small stakeholders in this process.) and (5). Other costs such as copying, faxing, etc. (again uncertain as to ultimate costs). Additionally, private certifiers must pay a reasonable security (again uncertain as to ultimate costs).

The Center for Food Safety strongly recommend that the NOP adopt the following process for developing the final AMS fee structure:

- (a). After the first 18 months (or completion of the initial round of accreditation), NOP should conduct and publish a full cost analysis of this initial round;
- (b). NOP should then seek advice regarding this from the NOSB through its public consultation process;
- (c). NOP should then submit a separate *Federal Register* notice outlining all fees including how a sliding scale would help offset overburden to small stakeholders;
- (d). NOP should then implement the final fee structure and costs in a manner to ensure that the burden is not onerous to the small-scale stakeholders; and
- (e). USDA initiates and adopts the Small Farmer Organic Cost-Share Program, (SFOCP) to coincide with this above timeline..

XI. Adverse Action Appeals Process:

A fair and effective appeals system is essential to the success and integrity of the NOP and to the accreditation process. Independence and objectivity being of prime importance, the Center for Food Safety makes the following recommendations for language replacement to the following sections:

Proposed § 205.680 General.

Persons subject to the Act who believe they are adversely affected by a noncompliance proceeding decision of the National Organic Program's Manager or a certifying agent may appeal such decision under the provisions of this chapter in accordance with 7 C.F.R. part 11.

Proposed § 205.681 Appeals.

(a) Certification appeals. An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the National Appeals Division (NAD).

(1) If NAD sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The

act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent. Thus to ensure an "expedited" appeal process 7 C.F.R. sections 11.9(a)(2) and 11.9(d)(2)(I) shall not apply under this chapter.

(2) If NAD denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the Department's Uniform Rules of Practice.

(b) Accreditation appeals. An applicant for accreditation and an accredited certifying agent may appeal a Program Manager's denial of accreditation or proposed suspension or revocation of accreditation to NAD.

(1) If NAD sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation.

(2) If NAD denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the Department's Uniform Rules of Practice.

(c) Appeals of compliance decisions. To obtain a hearing under 7 C.F.R. section 11.8, a participant personally request such hearing not later than 30 days after the date on which the participant first received notice of the adverse decision and other provisions in accordance with 7 C.F.R. section 11.6. A decision to deny, suspend, or revoke a certification or accreditation will become final and non-appealable unless the decision is appealed in a timely manner.

(d) All appeals to NAD must be filed in writing under provisions of 7 C.F.R. section 11.]

XII. Proposed § 205.671 Exclusions from Organic Sale

(A). Estimated National Mean.

Proposed § 205.671(a) provides that agricultural products must not be sold if residue testing detects above "estimated national mean" (ENM) demonstrated by the USDA's Pesticide Data Program.. Adoption of this program has not been analyzed by the NOSB for its appropriateness. Though the data collected by the Pesticide Data Program (PDP) appears to be extensive, the number of commodities tested is limited compared to the number of organic products produced. Also, the commodities are paired with certain pesticides to establish an ENM. Such a system does not address pesticides which are not licensed for use on a particular crop, or that may be present on an organic crop due to drift or misapplication. The PDP does not cover many processed products, and no multi-ingredient products are tested. The data collected may be accurate to establish estimated national means of pesticide-commodity pairs, but it is not yet supported that the levels established are appropriate to serve as tolerance limits for pesticide residues in organic products.

Consumers expect the lowest possible pesticide residue on products sold, labeled or represented as organically produced. Therefore, to ensure that gaps in the PDP data do not limit the effectiveness of the ENM, and to meet consumers' expectation of the lowest possible residue levels, CFS recommends that the USDA residue level excluding organic sale be the lowest of the residue levels established by the ENM , the FDA action level and 5% of the EPA tolerance level. Therefore, CFS recommends the following amendment:

Proposed § 205.671. Exclusion from organic sale. (A) When residue testing detects prohibited substances at levels that are [(1) greater than FDA action levels; (2) greater than 5% of EPA tolerance levels; or (3) greater than the estimated national mean]

(B). Unavoidable Residual Environmental Contamination

Additionally, as proposed this section states that unavoidable residual environmental contamination (UREC) levels will be "determined by the Administrator" and no further guidance is given. This creates significant uncertainty for both organic producers and consumers because UREC levels are not specified, even though products will not be able to be sold as organic if they exceed the UREC levels. This is a critical issue that must be resolved in consultation with the NOSB, as required by OFPA §6518(k)(5), before the final rule is implemented.

(C). Liability for Chemical and Genetic Trespass

The section also fails to provide protection of organic producers from chemical and genetic trespass and liability for damages is not addressed. If a certified organic producer is meeting all requirements of the Act, yet the operation is contaminated by chemical drift, and the products cannot be sold as "organic," as mandated by OFPA 6511(c)(2), organic producers should not be penalized. The manufacturers and applicators of prohibited and excluded materials must be held liable for losses suffered by organic producers when the prohibited and excluded materials they sell and apply contaminate neighboring organic crops and/or livestock. Section 205.671 should be amended to include:

Proposed § 205.671 Exclusion from organic sale. [(c) If the investigation of a certified operation determines that the presence of residues of prohibited materials, in excess of the FDA action level, 5% of the EPA tolerance, the estimated national mean or unavoidable residual environmental contamination, is due to drift from a neighboring operation, the applicator and manufacturer of the prohibited substance shall be liable for damages incurred by the organic producer.]

Conclusion.

The Center for Food Safety submits these comments in the hope that USDA will support the small family farms that are the leaders and heart of organic agriculture and will honor the public/private partnership that was established by passage of the OFPA. We believe that adoption of the recommendations contained herein will help achieve these aims.

In providing these comments, CFS also applauds USDA for a number of provisions in the proposed rule including but not limited to: (1) the establishment of the 100% organic label (proposed § 205.301); (2) the requirement of 100% organic feed without antibiotics or mammalian or poultry slaughter by products (proposed § 205.237);and (3) the creation of a flexible organic system plan (proposed § 205.201).

Respectfully submitted,

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Legal Director

Endnotes:

1. See Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992).
2. Document from Dr. Louis J. Pribyl, "Comments on Biotechnology Draft Document," dated March 6, 1992.
3. *Id.*
4. See Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22984 (May 29, 1992). See also, Transcript of Meeting of the Food Advisory Committee, U.S. FDA, Vol. II, April 6-8, 1994.
5. See, e.g., Millstone, Erik, *et al.*, "Beyond Substantial Equivalence." *Nature*, Vol 401. October 7, 1999.
6. Memo from FDA Division of Food Chemistry & Technology and FDA Division of Food Contaminants Chemistry to James Maryanski, Biotechnology Coordinator, "Points to Consider for Safety Evaluation of Genetically Modified Foods." November 1, 1991.
7. Nestle, Marion, Ph.D., M.P.H.. "Allergies to Transgenic Foods - Questions of Policy." *The New England Journal of Medicine*; Vol. 334, No. 11. March 14, 1996.
8. Hansen, Dr. Michael & Jean Halloran, "Why We Need Labeling of Genetically Engineered Food." *Consumers International*, Consumer Policy Institute, April 1998.
9. Nordlee, Julie A., MS; *et al.* "Identification Of A Brazil-Nut Allergen in Transgenic Soybeans." *The New England Journal of Medicine*; Vol. 334, No. 11. March 14, 1996.
10. See *supra* at note 18.
11. Hansen, Michael, Ph.D. and Jean Halloran, "Jeopardizing the Future? Genetic Engineering, Food and the Environment." *PAN AP Safe Food Campaign*; Ch. 1. 1998.
12. Memo from FDA Division of Food Chemistry & Technology and FDA Division of Food Contaminants Chemistry to James Maryanski, Biotechnology Coordinator, "Points to Consider for Safety Evaluation of Genetically Modified Foods." November 1, 1991.
13. Ho, Dr. Mae-Wan. "Genetically Engineered Foods: The hazards are inherent in the technology." *Third World Resurgence*. No. 79. Ho, Dr. Mae-Wan. "The Hazards of Genetically Engineered Foods." Ho, Mae-Wan. *Genetic Engineering: Dream or Nightmare*. Bath: Gateway Books, 143 (1998).
14. See *supra* at note 18.
15. Memo from Murray M. Lumpkin, M.D., Director of FDA Division of Anti-Infective Drug Products to Bruce Burlington, M.D. December 17, 1992. (Emphasis in original).
16. British Medical Association, "The Impact of Genetic Modification on Agriculture, Food and Health--Interim Statement." May 1999.
17. Ewen, Stanley W.B. & Pusztai, Arpad, "Effect of diets containing genetically modified potatoes expressing *Galanthus nivalis* lectin on rat small intestine." *The Lancet*, Vol. 354, No. 9187, October 16, 1999.
18. Pusztai, Arpad. "Report of Project Coordinator on data produced at the Rowett Research Institute", <http://www.rri.sari.ac.uk/gmo/ajp.htm>, October 22, 1998.

19. Van Driessche & Bog-Hansen, "Memorandum" on Dr. Pusztai's report. http://www.greenpeace.org/%7Eegeneng/mem_pusz.html. May 25, 1999.
20. Memo from FDA Division of Food Chemistry & Technology and FDA Division of Food Contaminants Chemistry to James Maryanski, Biotechnology Coordinator, "Points to Consider for Safety Evaluation of Genetically Modified Foods." November 1, 1991.
21. Woods and Pikaev, 1994.
22. Elias, P.S. and A.J. Cohen. 1977. *Radiation Chemistry of Major Food Components*. New York: Elsevier Biomedical Press.
23. Murray, D.R. 1990. *Biology of Irradiated Food*. New York: John Wiley & Sons.
24. Harrison, Ellen Z., McBride, M.B. & Bouldin, D.R., "The Case for Caution: Recommendation fro Land Application of Sewage Sludges and an Appraisal of US EPA's Part 503 Sludge Rules," Cornell Waste Management Institute Working Paper. August 1997.
25. NOSB Final Recommendation, Standards and Procedures Governing the Accreditation of Organic Certification Organizations, June 4, 1994, Santa Fe, NM.
26. NOSB Final Recommendation, Proposed Rule Regarding Importation of Organic Agricultural Products, June 3, 1994, Santa Fe, NM.
27. 7 U.S.C. § 6517(b). The National List shall contain an itemization, by specific use or application, of each synthetic substance permitted and each natural substance prohibited.
28. 7 U.S.C. § 6517(d) (1998)
29. 7 U.S.C. § 6517(k)(2) (1998)
30. See e.g., NOSB "Processing Material Review Results" (May 1995)
31. 7 U.S.C. §§ 6517(c), 6518(m) (1998)
32. Michael Sligh, "Toward Organic Integrity: A Guide to the Development of US Organic Standards," July 1997 at 179-180.