

**Public Comment:
To the
National Organic Standards Board
Washington, D.C.
June 6, 2000**

Submitted by
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OMRI has prepared extensive comments on the proposed organic rule, and I have copies available for board members. We have also just put these documents on the OMRI website (<http://www.omri.com>) so they are easily available.

This proposed rule is a good framework for implementation of National Organic Standards and our comments are made in context of positive improvements, some technical fixing, and clarification of issues and language.

The major issues we see as important in our rule comments include:

1. Genetic engineering
We are pleased the USDA has explicitly prohibited the use of GMOS in organic agriculture, though we question the change in terminology. OMRI has suggested some principles and definitions and more specific language for crop inputs, livestock and thenational list.
2. Soil Fertility, Manure and Compost
OMRI supports the stringent requirements for raw manure. OMRI also believes that manure should either be composted or processed in an approved way in order to be used without the restrictions applied to raw manure. OMRI does not believe that the Natural Resource Conservation Service's practice standard provides an appropriate guideline for the organic regulations and offers definitions for both compost and organic material as well as improvements in the proposed regulatory text.
3. Inert Ingredients: . OMRI supports allowance for List 4 inerts, but with a provision that NOSB can specifically prohibit any that do not meet organic criteria. OMRI offers several practical suggestions to improve the ability to implement the program. OMRI finds there will be a need for specific materials used as carriers, adjuvants, surfactants, and stabilizers in non-pesticide formulations, and believes they should be reviewed and added to the National List.
4. Structure and content of the processing list: OMRI suggests a category for allowed non-organic ingredients, allowed non-organic processing aids, and prohibited synthetics for the MWO claim. We think that a more flexible MWO category will allow the industry to grow while offerering a truthful labeling option for those products made with synthtetics not on the National List.
5. Need for clear criteria to evaluate materials, including processing and livestock.
6. Livestock – need for priority on health care materials, general review of synthetic vitamins and minerals
7. PDP for residue testing – a promising system, but there are some problems that need to be resolved..
OMRI has a detailed analysis that will be posted on our website.

OMRI has also recently surveyed certification agents and collated a list of materials currently in use for the organic industry that are likely to be petitioned . This contains about 200 items at this point, and probably is the tip of the iceberg. We urge NOSB to think carefully about process and develop a workplan and timetable to move forward on these items once the petition process is opened.

Organic Materials Review Institute (OMRI)
Comments on the USDA Proposed Rule, National Organic Program

7 CFR Part 205, TMD-00-02-PR2

Soil Fertility and Crop Nutrient Management Practice Standard
June 5, 2000

Executive Summary

Manure: OMRI supports the stringent requirements for raw manure application. OMRI also believes that manure should either be composted or processed in an approved way in order to be used without the restrictions applied to raw manure.

Compost: OMRI does not believe that the Natural Resource Conservation Service's practice standard provides an appropriate guideline for the organic regulations and offers definitions for both compost and organic material as well as improvements in the proposed regulatory text.

Mined Minerals of High Solubility: OMRI recommends that the rule include the NOSB recommended limitations on Chilean (sodium) nitrate and potassium chloride.

Sewage Sludge: OMRI proposes a definition change to include the ash from incinerating sewage and the grit and screenings from the preliminary treatment.

205.203(a), (b), (c) General

OMRI supports the requirement of a positive soil building plan. This is consistent with OMRI's previous comment. The requirements for producers to maintain or improve organic matter, carefully supply nutrients, and prevent contamination or erosion are better measures of soil stewardship than the previous rule's concept of preventing measurable degradation.

205.203 (c)(1) Use of raw animal manure

The first proposal invited comments in regard to the minimum time that must pass after raw manure application before a crop may be harvested for human consumption.

The OFPA allows the application of raw manure on a crop for human consumption only if the crop is harvested after a reasonable time determined by the certifying agent to ensure the safety of the crop, but in no event shall this interval be less than 60 days (7 USC 6513(b)(2)(B)(iv)). This proposed rule requires that animal manure must either be composted before applied to crops for human consumption, or it must meet a 90-120 day requirement between soil incorporation and harvest.

Background

OMRI provided a detailed review of scientific data regarding human pathogens and safety considerations in response to the first proposed rule (OMRI, 1998). OMRI recognizes that organic is not a guarantee of food safety and that organic products must meet the same food safety requirements of all other food. The proposal provides a sound precautionary approach to improve the safety in the use of an important source of nutrients for organic producers. Although composting is desirable in most situations to stabilize nutrients and reduce pathogens, due to particular farm circumstances and needs it is not always an option available to farmers.

The NOSB also reviewed literature (Sideman, 1999) and supported this position at the June 1999 meeting in Washington, D.C. Field studies are few on the survival rates of pathogens in soil

incorporated situations, although this topic is currently the subject of active research. In a 1996 review article concerned mostly with conventional methods of manure disposal, the authors noted that *E. coli* 01577:H7 survived when inoculated in a lab study into cow manure for 42-70 days at temperature ranging from 41°F to 96°F. The authors also cite a study on soil survival of pathogenic strains of *E. coli*, finding a range of survival from 2 to 100 days, based on pH and temperature. The average survival time was 45 days (Stehman, 1996). A recent study using liquid dairy manure slurry that was incorporated approximately 120 days before harvest of potatoes found no detectable generic *E. coli*, *Salmonella*, or *Listeria* on harvested tubers although these pathogens were soil detected up to six weeks in the soil (Liao, 2000). Recent communications with researchers developing production guidelines under the auspices of FDA's Food Safety Initiative indicate that a recommended time frame of 99 days from soil incorporation until harvest will be proposed (Rangarajan, 2000).

The OFPA allows for use of raw manure with specific limitations.

6513(b)(2) Manuring

- (B) Application of Manure. Such organic plan may provide for the application of raw manure only to
- (i) any green manure crop;
 - (ii) any perennial crop;
 - (iii) any crop not for human consumptions; and
 - (iv) any crop for human consumption, if such crop is harvested after a reasonable period of time determined by the certifying agent to ensure the safety of such crop, after the most recent application of raw manure, but in no event shall such period be less than 60 days after such application.

Although the proposal limits the use of raw manure more stringently than permitted under OFPA, OMRI agrees that the time limits proposed represent a "reasonable" period of time based on industry knowledge at present. At the time OFPA was written in 1990, Congress deliberated over pesticide residues, heavy metals, and food-borne pathogens in organic food. No other federal agency regulates the field application of raw manure in crop production. OMRI believes this regulation, while it cannot "ensure the safety" of organic crops, does match the intent of the authors of the Act to take extra precautions desired by consumers in the handling of raw manure. The Center for Food Safety and Applied Nutrition (CFSAN) has recommendations for good manure handling practices in its *Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables*, but does not set an absolute standard and relies on diversified tactics, such as could be identified in an organic Farm Plan.

Research on pathogen survival in untreated manure, treatments to reduce pathogen levels in manure, and assessing the risk of cross-contamination of food crops from manure under varying conditions is largely just beginning. Some pathogens tolerate higher temperatures than others. In addition, management practices required to achieve the time and temperature necessary to eliminate or reduce microbial hazards in manure or other organic materials may vary depending on seasonal and regional climatic factors (such as ambient temperature and rainfall) and on the specific management practices of an individual operation.

While the agencies do not have sufficient data to make specific time and temperature recommendations that would apply to all composting or other manure treatment operations, good agricultural practices, as discussed below, may reduce the risk of microbial contamination of fresh produce by manure.
CFSAN, Oct. 1998

Good agricultural practices described by CFSAN include water quality management, worker sanitation, cleanliness of packing equipment, transportation, and storage facilities. These are all items that can be incorporated in the Farm Plan and observed by a trained farm inspector. OMRI believes that these procedures are adequate for ensuring the safety of the crop as required by OFPA.

The statute explicitly vests certifiers with the authority to require a longer period if deemed necessary. Certifiers can make such a determination based on local conditions and requirements. However, the certifiers of handlers cannot discriminate against product certified by another USDA accredited certifier that meets the statutory minimum.

OMRI believes that certifiers should not be bound to set restrictions solely on days to harvest. Certifiers need the authority to not allow raw manure to be applied to frozen ground, on steep slopes, next to waterways, and at excessive rates on permeable soils with shallow water tables. Accredited certifying agents and state programs are the appropriate authorities to establish restrictions on manure application specific to local crops and growing conditions.

Manure management in organic production needs to be considered a work in progress that requires more research and education. OMRI believes that the proposed rule offers a precautionary approach, but recognizes that there is room for improvement, and advises NOSB and NOP to continue to revisit these requirements as new research reports becomes available.

205.203 (c)(2) Uncomposted waste

This section of the proposed rule allows for the use of “other uncomposted plant or animal wastes, such as aged, fully decomposed animal manure.” The proposed rule offers no definition for “fully decomposed” manure, yet in light of the food safety concerns relating to raw manure use, and measurable requirements proposed for compost, this allowance is inadequate. In the words of the Center for Food Safety and Applied Nutrition (CFSAN):

“Composting should not be confused with simpler passive treatments such as aging. In general, passive treatments, such as aging, will require a significantly longer period of time to reduce microbial hazards compared to active treatments which expose pathogens to lethal conditions, such as high temperature or high pH.”

E. coli 0157:H7 has been shown to survive for more than a year in non-aerated manure piles that were kept covered but otherwise exposed to climatic changes (Kuvda, et. al 1998).

OMRI believes that manure should either be composted or processed in an approved way in order to be used without the restrictions applied to raw manure. Pathogens can be reduced in manure by active treatment through a physical process such as pasteurization. If the process used results in a product documented to have a sufficiently reduced pathogen level, then there should be no need to meet the same days-to-harvest restriction as raw manure. OMRI policy for distinguishing between raw and uncomposted product states:

The parameters [for other required laboratory tests] are not, at this point, measured against absolutes, but are instead used to compare finished compost against the claimed feedstocks and composting method. An exception is with the indicators for **food-borne pathogens**. Maximum *E. coli* [laboratory test result levels] cannot exceed three colony forming units per gram (CFU/g); salmonella must test negative. Failure to achieve this level of pathogen reduction will result in categorization as uncomposted (raw).

OMRI Operating Manual for Review of Brand Name Products, Dec. 1999, p. 6.

Application of such a product would not be considered a ‘soil building’ program, but rather a supplement to one. Chemical treatment with a prohibited substance, such as metam-sodium, is not acceptable and is well addressed in the important clause of 205.203(e)(1).

205.203(c)(3) Use of Compost

The proposed rule uses the following definition of compost:

Compost. The product of a carefully managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost used in an organic operation must be produced in a facility in compliance with the Natural Resource Conservation Service's practice standard for a composting facility (Code 317) and must use methods to raise the temperature of the raw materials to the levels needed to stabilize nutrients and kill pathogens.

This definition was amended from the previous rule, based on comments (including OMRI's) that asked for clarification of the term and more restrictions about what types of materials are acceptable for use in compost production (*Fed. Reg.* 13517). The USDA response was to cite the NRCS practice standard to manage a composting facility. OMRI recognizes the usefulness of this practice standard for conservation management.

However, the intent and scope of that practice standard does not address all of the concerns for compost management in an organic farming system. This practice standard is concerned primarily with the "biological stabilization of waste organic material" that is generated on an agricultural production or processing site. As such, it may not provide for the use of off-farm sources of natural organic materials such as leaves, source-separated landscaping material, animal manure, and spoiled hay. The practice standard does not specifically limit synthetic ingredients (such as fertilizers otherwise prohibited) added to the compost. It does include general guidelines for temperature monitoring to favor pathogen reduction, as well as nutrient conserving standards related to moisture content, protection from runoff, and storage.

The NRCS standard provides a very brief summary of some of the many parameters used to measure compost quality. It specifies a carbon:nitrogen ratio range of 25:1 to 40:1. Although an optimum ratio is generally believed to be 30:1, compost is a forgiving process and a wider range of C:N ratios (20:1 to 40:1) will work equally well (Dougherty, 1999).

The NRCS practice standard requires that a water supply is available, though it doesn't mention that too much water is commonly a problem in rainy conditions and covers or roofs may be valuable to prevent leaching and anaerobic conditions (Rynk, 1992). Temperature monitoring is a very important tool to be used to indicate stage of activity and pathogen reduction. Although temperatures above 130°F for several days are recommended to destroy pathogens and weed seeds, a combination of factors are considered to reduce pathogens in compost piles. These include natural competition, predation by living organisms, and antibiotic effects within the pile (Dougherty, 1999). Proper aeration by mixing and enough time to achieve thorough heating will aid pathogen reduction.

Compost maturity can be measured in a number of ways: the achievement of a sustainable drop in temperature, the use of oxygen or carbon dioxide measurement, absence of odor, a growth test using barley, cress or other sprouts, nitrate /ammonia tests, the ability to reheat. Several compost guides suggest putting a sample in a sealed plastic bag and checking for odors and ability to reheat after several days. Mature compost should have a pleasant odor and uniform consistency (Rynk, 1992; NOFA-VT, 1999).

In summary, neither the proposed rule nor the NRCS practice standard reflects the state of the art of composting for organic agriculture. The practice standard does not prevent the use of sludge, unseparated municipal solid waste, and synthetic nutrients; feedstocks that are considered unacceptable in organic production. This practice standard also explicitly excludes some feedstocks and methods that are generally considered acceptable in organic production. The practice standard is not suitable for smaller scale farm produced compost that relies on a longer aging process to achieve nutrient stabilization. Alternative systems of composting that involve fermentation or anaerobic digestion at lower temperatures, or a biological process such as vermiculture would also be precluded by the narrow definition.

OMRI has proposed a revised definition of compost and organic materials (below), as well as regulatory text to limit compost feedstocks.

205.203(d)(2) Mined minerals of high solubility

The proposed rule requires justification of the use of mined minerals of high solubility by soil or crop tissue analysis. This allows sodium nitrate and potassium chloride without the specific use restrictions recommended by the NOSB, as neither is referred to in the proposed rule (since they are considered non-synthetic and not in scope of National List).

The NOSB recommendation from November of 1995, Austin, placed careful restrictions on the use of Chilean (sodium) nitrate. These limited use to a maximum of 20% of the total supplied nitrogen, required the farm plan to provide strategies for reduction over time, and to optimize efficiency of application. The NOSB also called for a shortened sunset period (re-review) of 2 years rather than the 5 years required by OFPA.

OMRI recommends that the rule include the limitations as proposed by the NOSB on these non-synthetic but highly soluble materials. OMRI also requests that the NOSB review the status of these two materials as originally proposed, including the consideration of the salt index that is required by the OFPA criteria 6518(m)(5). Potassium chloride is currently prohibited by most of OMRI's certifier subscribers, yet it can be included in brand name formulations of fertilizer products, which provides a verification problem for certifiers. In addition, IFOAM or European certification agencies do not permit these two materials, which requires further verification on the part of U.S. certifiers.

205.203(e)(2) Sewage Sludge

While the NOP definition includes the solid or semi-solid residue generated by the treatment of sewage, the definition does not specifically excludes either the ash from incinerating sewage, or the grit and screenings from preliminary treatment. OMRI commented extensively on the contaminants found in sewage sludge in previous proposed rule comments, including organic and heavy metals, synthetic additives, and volatile organic compounds and pollutants (OMRI, 1998). Sludge incineration to produce ash serves to concentrate these contaminants and certainly also meets the NOSB definition of synthetic. Grit or screenings are also potential sources of synthetic contaminants, and must be included in the definition as used in this regulation.

OMRI proposes the following changes and additions:

205.2 Terms defined

Compost. The product of a carefully managed process by which organic materials are thermophilically digested. Compost must reach a temperature of at least 130°F for a period of several days and then finish decomposing for approximately six weeks.

Organic material. Substances derived from microorganisms, plants, and animals. For the purposes of this section, organic material does not include sewage sludge, municipal solid waste, or any material that contains levels of prohibited substances above unavoidable residual environmental contamination.

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 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 treatment works.

§ 205.203 Soil fertility and crop nutrient management practice standard.

- (a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.
- (b) The producer must budget plan for and supply appropriate crop nutrients by rotation or interplanting of cover crops and the application of compost or other organic material not restricted by this section. ~~properly utilizing manure or other animal and plant materials, mined mineral substances, and substances approved in §205.601.~~
- (c) The producer must manage ~~animal and plant waste~~ organic materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. ~~Animal and plant waste materials include:~~
 - (1) ~~Raw animal manure, which must be composted unless it is:~~
 - (i) ~~Applied to land used for a crop not intended for human consumption;~~
 - (ii) ~~Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or~~
 - (iii) ~~Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;~~
 - (2) ~~Other uncomposted plant or animal wastes, such as aged, fully decomposed animal manure;~~
 - (3) ~~A composted product produced in a facility in compliance with the Natural Resources Conservation Service's practice standard for a composting facility (Code 317); and~~
 - (4) ~~A composted or uncomposted plant or animal waste material that has been chemically altered by a manufacturing process: Provided, That, the material is included on the National List of synthetic substances allowed for use in organic crop production established in §205.601.~~
- (d) In addition to cover crops, compost, rotations and plant and animal waste and organic materials, a producer may supply apply other non-synthetic soil and crop nutrients without restrictions that

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Organic Materials Review Institute
Comments on Genetic Engineering in the
USDA Proposed Rule, National Organic Program
7 CFR Part 205, TMD-00-02-PR2
June 5, 2000

Executive Summary

OMRI supports the explicit prohibition of genetically modified organisms (GMOs) as stated in this rule, but questions the change in terminology to “excluded methods,” the rule’s deletion of parts of the NOSB GMO definition, and NOP’s rejection that GMOs are synthetic. OMRI suggests basic principles and definitions to clarify what is and is not an excluded method.

OMRI believes that the prohibition on excluded method (genetically engineered) crop inputs should be limited to those that are direct products of GE techniques. “Directly produced” means that products are derived from genetic engineering techniques, cannot be produced otherwise, and have a potential to express the trait that has been added by such techniques.

OMRI supports the proposed rule’s prohibition on excluded method (genetically engineered) organisms for breeding purposes in livestock production. In addition, the rule must prohibit any livestock feed, feed supplements, and feed additives produced using excluded (GE) methods.

OMRI fully supports the requirement that GEOs/GMOs and their products be prohibited in processed foods labeled “organic” and “100% organic,” as well as “made with organic (specified ingredients)”. In the absence of consistent positive labeling of GEO/GMO non-organic ingredients, however, the NOP should work with processors, handlers and certifiers to set a standard for verification of the non-GMO status of such ingredients.

The definition and terminology

The proposed rule states:

“Many commenters suggested that we use the definition for certain methods to be excluded from organic production systems proposed by the NOSB. This proposal essentially adopts that definition. “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 macroencapsulation. Such methods would not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. 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." FR 13521

"This proposal contains a specific prohibition on the use of seeds, annual seedlings and planting stock (section 205.204(b)), pest control substances (section 205.206(f)), organisms (section 205.236 (b)(3)), and ingredients (section 205.270(c)(2)) produced with excluded methods." FR 13534

"This proposal prohibits labeling of whole products or ingredients as "organic" if those products or ingredients are produced using any of the following production or handling practices: (1) Ingredients or processing aids containing or created using excluded methods (genetically modified organisms (GMO)) or the products of excluded methods;...." FR13533

The last National Organic Program (NOP) proposed rule called for comments regarding genetically engineered organisms (GEOs) used in organic production. The Secretary specifically requested comment in the 1997 proposed rule as to whether or not GEOs should be categorically allowed, categorically prohibited, or allowed on a case-by-case basis (62 *Fed. Reg.* 65875, December 17, 1997). More significantly in the minds of many was that the first proposed rule did not explicitly prohibit GEOs. Therefore, the use of rDNA techniques could be interpreted as allowed, particularly if the final rule declared GEOs to be non-synthetic. At the same time, the rule proposed to add two products of GEOs to the National List as allowed synthetics.

The USDA requested such comment in the face of a clear National Organic Standards Board (NOSB) recommendation that the NOP prohibit a broader category defined as genetically modified organisms (GMOs). The NOSB determined GMOs to be synthetic and therefore prohibited by default under OFPA (Indianapolis, 1996). The NOSB defined GMOs as:

"Made with techniques that alter the molecular or cell biology of an organism by means that are not possible under natural conditions or processes. Genetic engineering includes recombinant DNA, 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, or tissue culture."

Codex Alimentarius adopted a very similar definition for "genetically engineered / modified organisms:"

Genetically engineered/modified organisms, and products thereof, are produced through techniques in which the genetic material has been altered in a way that does not occur by mating and/or natural recombination.

Techniques of genetic engineering/modification include, but are not limited to: recombinant DNA, cell fusion, micro and macro injection, encapsulation, gene deletion and doubling. Genetically engineered organisms will not include organisms resulting from techniques such as conjugation, transduction and hybridization. (*Codex Alimentarius* CAC/GL 32-1999)

As noted in the re-proposed rule, the USDA received extensive public comment, with the single greatest response addressing the issue of GEOs and GMOs in organic food. That comment overwhelmingly supported the categorical prohibition of GEOs over the other two options. **OMRI's comments were consistent with this consensus.**

The preamble of the current proposed rule recognizes this consensus. The preamble further states that “[t]his proposal prohibits the use of genetic engineering (included in the broad category of ‘excluded method’ in this proposal, based on the definition recommended by the National Organic Standards Board) in the production of all foods and ingredients that carry the organic label.” (65 Fed. Reg. 13513)

The proposed rule itself does not refer to GEOs or GMOs, except in defining a new term called “excluded methods” (EMs).

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 macroencapsulation. Such methods would not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture. (FR 13611)

This new term raises several questions not addressed in the preamble or the rule itself. OMRI questions why the USDA did not use the term genetically engineered/modified organism in this proposed rule when it specifically requested comments on that term in the previous proposed rule. The terms GEO and GMO are widely and commonly used in existing certification and accreditation programs. The term “Excluded Methods” is confusing and the change in terminology unnecessarily complicates implementation of the policy stated in the preamble.

Why does the proposed rule’s definition delete some examples from the NOSB definition and not others? The USDA stated that their scientists considered these examples redundant. The remaining examples “recombinant DNA, cell fusion, and micro- and macroencapsulation” serve to demonstrate the range of techniques that are “not possible under natural conditions or processes and are not considered compatible with organic production.” The term “recombinant DNA” refers to a DNA molecule containing segments from different sources using various techniques.¹ The deleted terms “gene doubling and deletion, insertion of a foreign gene, and the changing of the position of genes” in OMRI’s opinion only help clarify some of the techniques used in forming recombinant DNA and do not detract from this definition. On the other hand, traditional breeding techniques may rely on induced mutagenesis that results in gene doubling, deletion, or rearrangement through non-rDNA techniques (gene “jumping”). OMRI proposes wording to clarify these distinctions.

OMRI supports the use of the clarifying word ‘traditional’ in the phrase “Such methods would not include the use of *traditional* breeding” as a useful addition to the original NOSB definition. This may provide guidance when a technique is evaluated for compatibility with organic systems.

¹ 1998. New Penguin Dictionary of Science, M.J. Clugston, ed. “Recombinant DNA is a DNA molecule containing segments from different sources. Appropriate restriction enzymes can cut DNA from different organisms or from chemical synthesis to form sticky ends. If DNA from different sources is cut with the same restriction enzyme and mixed, the sticky ends join by complementary base pairing and can be further stabilized by the enzyme DNA ligase. By such means, genes from different organisms can be combined in the same DNA molecule. Genetic engineering makes extensive use of recombinant DNA.”

Recommendation: rewrite the proposed rule as follows:

205.2 Excluded methods, (genetically modified/engineered organisms) 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 macroencapsulation, and the following results when achieved by recombinant techniques: gene deletion and doubling, introducing a foreign gene, and changing the positions of genes. Such methods would not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

§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:

(d) Excluded methods: including genetically modified/engineered organisms, sewage sludge, or ionizing radiation.

GMOs are synthetic

The proposed rule's preamble states that the distinction between synthetic and non-synthetic is not relevant as they are all excluded [65 *Fed. Reg.* 13519-13520]. The preamble also states that the proposed rule prohibits the use of genetic engineering in organic production [65 *Fed. Reg.* 13513] but does not offer any basis in OFPA for the prohibition, other than response to the public comment.

OMRI commented extensively in the previous rule that GMOs are synthetic. Such an interpretation of OFPA would prohibit GMOs by default unless they are added to the National List. The NOP acknowledged the comments of a “Technical Institute” that made the case that GMOs needed to be defined as synthetic and therefore prohibited under OFPA, but rejected that line of thinking.

If the NOP rule clearly considered GMOs synthetic, then NOSB and TAP would need to review and recommend any such organism or product petitioned as an exception to this rule. Instead, the re-proposed NOP rule appears to give the Secretary and the Administrator the discretion to determine what is and is not an excluded method. If this assumption is true, the USDA could therefore determine that a GMO, as defined under Codex/NOSB is not an EM. OMRI is concerned that this could take place without National Organic Standards Board (NOSB) recommendation, Technical Advisory Panel (TAP) review, or public comment. OMRI supports the on-going role of the NOSB in reviewing techniques that could be considered excluded methods and prohibited.

OMRI believes that decisions made with respect to what methods are considered “excluded” should be open and transparent. It is OMRI's experience that given the ubiquitous nature of the

technology and lack of access to information on its release, such decisions are not always easy or obvious. OMRI supports the categorization of excluded methods/genetic engineering as prohibited, and believes that in addition, the definition identifies these techniques or their products as synthetic according to the OFPA. If there is a question about a genetic technique or process, it will be the job of the NOSB to evaluate it first as excluded, and then as synthetic.

Verification of GMOs in non-organic ingredients

The NOP also seeks comments regarding verification of EMs in non-organic ingredients [65 *Fed. Reg.* 13535]. Some processors think that meeting such a requirement will not be possible unless the FDA requires mandatory positive labeling of food containing GMOs. This may also be necessary for livestock feed, animal drugs, pesticides, plant foods, and any other place where GMOs are likely to enter the organic food and farming system.

OMRI fully supports the requirement that GEOs/GMOs and their products be prohibited in foods labeled 'organic' and '100% organic.' The organic industry has not yet developed a method to verify the GMO status of non-organic ingredients in a 95%+ 'organic food' claim. Of particular concern in this instance are non-organic agricultural ingredients allowed under 205.606.

The origin of the non-organic portion of those processed products that fall within the "Made With Organic [specified ingredients]" (MWO or 50%+) category will be more difficult to determine and enforce. OMRI is aware that commenters on the previous proposed rule and at NOSB meetings have expressed a desire for non-organic ingredients in such products to be to be non-GMO. While such a standard is desirable for a number of reasons, this could be the most difficult of the excluded methods to verify. To comply with such a standard, processors and handlers would benefit from consistent positive labeling of GEO/GMO non-organic ingredients.

In the absence of such required labeling, certifiers will need to develop a system to ensure that non-organic ingredients in a processed product that makes an MWO claim are non-GMO. Lack of ability to enforce these claims will be a liability for certifiers and will undermine the credibility of other organic labels. The organic industry will need time and resources to develop the capacity to enforce such a standard. The NOP will need to work with certification agents and the industry to develop an acceptable protocol for verification of non-GMO status of these non-organic ingredients.

Towards a Workable Policy

In the terms used in the current *OMRI Generic Materials List*, OMRI prohibits the use of genetically engineered organisms or their products "in any form or at any stage in organic production, processing, or handling." The organic industry faces the complex and controversial task of responding to the immediate concerns of its constituents regarding the acceptability of GEOs. Because GEOs have become so widespread in such a short period, too broad an interpretation would eliminate a large number of inputs and minor ingredients currently used by organic farmers. However, an interpretation that was too narrow would subvert the demands of consumers that organic provide food products that have not been genetically engineered.

Beyond a few specific examples, the rule is not clear what products are and are not considered produced by excluded methods. At a minimum, OMRI suggests that the National Organic Program adhere to the following basic principles:

1. Prohibit the intentional release of any live genetically modified organism into an organic farming system.
2. Consider any production input produced exclusively by rDNA techniques to be prohibited.
3. Farm inputs produced from sources that may or may not rely on rDNA techniques and are practically indistinguishable as being from one or the other source (e.g., corn oil used as adjuvant) are not considered GMOs. As long as they are non-synthetic, such products are allowed by default.
4. Ensure that ingredients used in organic processed products are not from genetically modified sources.

Other specific language and suggested changes

a) Crops

The proposed rule states for crop production that:

205.204(b) Seeds and planting stock must not be produced with excluded methods.

205.206(f) Producer must not use a pest, weed, or disease control substance produced through excluded methods.

Discussion: OMRI strongly supports 205.204(b). OMRI has faced questions regarding a number of crop inputs that may contain the products of GEOs. Organic standards prohibit crops grown from genetically engineered seeds or transplants, pesticides derived from GEOs, such as *Bacillus thuringiensis* encapsulated in *Pseudomonas fluorescens*. The line is clear: Unless corn or *P. fluorescens* are genetically modified, they do not express the Bt toxin. Certifiers will need access to the information needed to determine whether a given seed, biorational agent, or other crop production material is genetically engineered. The clearest and most efficient approach is by labeling. Farmers and their certifiers would benefit by having seed companies label GMO seed as such. A requirement for organic seed will also help consumers identify non-GE seed varieties. A similar approach might be needed for EPA registered biological pesticides.

More difficult to determine are the by-products of GEO crops and livestock used for soil fertility, crop protection, and as production aids. OMRI considers that a "pest, weed, or disease control substance produced through excluded methods" should refer to direct products of excluded methods/GMO techniques. However, OMRI does not consider by-products or incidental ingredients derived indirectly from commodities that might possibly contain some genetically altered material to be GMOs. The proposed rule does not and, in OMRI's opinion, should not exclude from use such products in organic crop production. Decomposed crop residues or composted manure would not be able to express GM traits and represent a positive recycling of nutrients. Refined oils from corn, cottonseed, and soybean are unlikely to express their genetically engineered traits. Vegetable oils are generally more compatible with organic

principles than petroleum distillates used in spray materials. Other examples of indirect products used in GMOs include:

- Cottonseed meal used as feeding stimulant for insects;
- Manure from animals exposed to GEOs or their products;
- Citric acid derived from a natural fungus that converts a potentially GM substrate corn used to adjust the pH of a foliar fertilizer;
- Lecithin used as a non-active (inert) ingredient in an EPA registered pesticide.

This last point appears to require some clarification because of the inconsistency between the text of the rule, allowing all List 4 inert ingredients, and the preamble's reference to excluded methods in the discussion of inert ingredients [65 *Fed. Reg.* 13589]. OMRI finds this an unreasonable extension of the prohibition on GMOs for the time being. This is not consistent with the statement of policy also found in the preamble:

“ As with other prohibited substances, a positive detection of a product of excluded methods would trigger an investigation by the certifying agent ... and would not necessarily represent a violation on its own. The presence of a detectable residue alone does not necessarily indicate use of a product of excluded methods that would constitute a violation to the standards.” FR 13535

Following that statement, OMRI would appreciate if the NOP could offer further guidance on this matter. In particular, if such products *are* considered 'excluded methods' under the proposed regulatory scheme:

- What is the threshold of contamination allowed for non-EM sources of such inputs?
- What is considered due diligence in making the determination?
- What are the labeling obligations for the suppliers of such products?

Much more difficult to address are those applications where rDNA methods enhance an existing trait and the products are not readily distinguishable from their non-modified counterparts. These may require some form of public review process and oversight to make such a determination. This is not a call for case-by-case review of GMOs on their merits to be classified as allowed synthetics. Instead, it is a request for classification of individual materials in or out of a category that is prohibited. OMRI believes that the prohibition on GE derived crop inputs should be limited to those that are direct products of GE techniques. “Directly produced” means that products are derived from genetic engineering techniques, cannot be produced otherwise, and have a potential to express the trait that has been added by such techniques.

Proposed rewrite

205.206 (f) Producer must not use a pest, weed, or disease control substance directly produced through excluded methods (genetically modified/engineered organisms).

b) Livestock

The rule clearly states that:

205.236(b)(3) No organism produced by excluded methods may be used for breeding purposes or for the production of livestock products intended to be sold, labeled, or represented as organic.

OMRI supports this position. However, no mention of excluded methods is made in the section on feed or feed supplements in either subpart C or subpart G.

Recommended addition:

205.237 (b) The producer of an organic operation must not:
(7) Use feed, feed supplements, and feed additives produced by excluded methods (GM/GE techniques).

The preamble (65 *Fed. Reg.* 13535) appears to seek comment on issue of GM vaccines; they are not prohibited in either the livestock health care practice standard section or the National List.

Currently it seems that a number of genetically engineered vaccines are approved that affect livestock production, including one for avian flu and one for Mareks disease in poultry as well as several commonly used in dairy production.

The standard for GMOs in livestock is parallel to that for crops. Feed must not only be non-GEO; it must also be produced organically. A different standard may need to be applied to animal health care products in the overarching interest of providing for animal welfare.

The EU organic regulation (209291) states:

Article 6 (1)(d) "Genetically modified organisms and/or any product derived from such organisms must not be used, with the exception of veterinary medicinal products."

Probiotics are combinations of microbial products (such as enzymes and bacteria) used as preventive health and digestion aids. Because these are biologically derived and have elements of both health and nutrition applications, probiotics illustrate many of the GMO issues faced in livestock production. They may contain non-organic agricultural products, but are not generally considered a feed when used in preventative health care. However they are fed in a routine matter, "in the absence of illness." OMRI believes that non-synthetic probiotics should be considered as supplements and generally subject to the requirement for organic sources and a prohibition on GM derived microbes.

OMRI agrees at this time with the proposed rule's silence on the issue of genetically engineered medications. This area needs more research and development as well as international consensus that is lacking at the present time.

c) Processing

OMRI has faced questions regarding the sources of minor ingredients that are allowed non-organic ingredients in processed foods labeled as 'organic.' Because consumers purchase and eat such products, these are likely to be the most controversial and to undergo the greatest scrutiny.

The rule proposes to prohibit EMs as ingredients in “100 percent organic,” “organic,” and “made with organic (specified ingredients)” foods [205.270(c)(2)]. This includes the non-organic as well as the organic portion of the product.

OMRI considers positive labeling of GEO/GMO seeds, agricultural inputs, and ingredients a necessity in order to fairly and practically implement this requirement.

The proposed National List states that dairy cultures [205.605(a)(9)] and yeast [205.605(a)(24)] cannot be produced by EMs, but not enzymes [205.605(a)(11)]. Therefore, it is unclear whether or not the proposed rule would prohibit enzymes produced by gene doubling or the insertion of a gene from another organism. A reasonable case could be made for them being excluded methods, but the argument that they are not considered excluded might be equally compelling. OMRI considers such enzymes to be prohibited under existing organic standards and asks that the final rule makes this more clear.

Among the other GMO products that may or may not be EM under the proposed rule are cornstarch, citric acid, enzymes, lecithin, tocopherols, and mono- and di-glycerides. As rDNA technology becomes more widely adopted, new genetically engineered sources of other existing products will be coming to the market.

OMRI supports a general prohibition on GM sources of all National List allowed items. This is accomplished by the modification to 205.600 proposed above. Individual annotations as ‘non-EM sources’ are then not needed on each item.