

The National Organic Program Policy on Synthetic Substances used in Food Processing

A Background Paper

The Organic Materials Review Institute

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Purpose

OMRI developed this paper to examine implications of the National Organic Program (NOP) Policy on Synthetic Substances used in Food Processing (December 12, 2002). We are submitting it to the National Organic Standards Board (NOSB) and the NOP for consideration in their respective discussions and policy making. We are also making it available to certifiers, members of the organic industry, and the public in an effort to inform and educate them on the complexities of the issues raised by the NOP Policy. Our intent with this document is to facilitate discussion and to offer possible solutions.

Background

The NOP posted a policy on their website on December 12, 2002 bearing the title, *Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances Are Used as Ingredients in Processed Food Products* (NOP Policy). This policy states that all food additives regulated by FDA in sections of 21 CFR Parts 172, 173, 180, 181, 182, and 184 must be reviewed by NOSB and included on the National List, except those substances in 21 CFR Parts 172, 173, 180, and 181 which are classified as food-contact substances by the FDA. This policy is a significant departure from past practices of organic certification agencies and may go beyond the scope of Organic Foods Production Act of 1990 (OFPA) and the NOP Final Rule (7 CFR Part 205).

What does the FDA classify as a food contact substance?

According to Food and Drug Administration (FDA),

“In November 1997, Congress passed the Food and Drug Administration Modernization Act (FDAMA) of 1997. Section 309 of FDAMA amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a notification process for food contact substances (FCSs). An FCS is defined as *any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food* (21 U.S.C. 348(h)(6)). Congress intended the notification process to be the primary route for authorizing the use of FCSs (21 U.S.C. 348(h)(3)(A)).”¹

This premarket notification process for food contact substances is now the primary method by which the FDA authorizes the use of food additives that are food contact substances. Prior to FDAMA, these types of materials had to be petitioned for status as a food additive. With FDAMA, the more rigorous petition process has been replaced with a streamlined notification process. Accordingly, manufacturers submit the required information as a Food Contact Notification (FCN) and will succeed in having their trade named product “approved” unless FDA objects within 120 days. New products are then added to the FDA website entitled

¹ <http://www.cfsan.fda.gov/~lrd/foodadd.html> (see Food Workshop Sept 18, 2002 notice)

“Inventory of Effective Premarket Notifications” at <http://www.cfsan.fda.gov/~dms/opa-fcn.html>. Currently, there are approximately 300 materials on this list. The list is expected to grow as this process replaces the pre-FDAMA process for approving indirect food additive petitions.

FDA’s premarket notification inventory has the following disclaimer:

“All persons who purchase a food contact substance manufactured or supplied by a manufacturer or supplier identified in an effective notification may rely on that notification to legally market or use the food contact substance for the use that is the subject of the notification, consistent with any limitations in that notification.”

Most of the substances that appear on the list have specific technical limitations on their use as FCS. These limitations often refer in turn to specific conditions contained in sections of 21 CFR.

What about indirect additives?

The NOP Policy refers to FDA-regulated direct food additives and secondary direct additives. However, it does not mention indirect food additives, which are listed in 21 CFR Parts 174-178 and 186. No single, simple definition is given for indirect food additives in 21 CFR Part 170. In general, these regulations cover substances that are used in articles that are in contact with food, such as preparation surfaces, sanitizers, lubricants, adhesives, labeling inks, processing equipment, and packaging that may migrate into food at ‘negligible’ levels. The threshold for ‘negligible’ is also not generally defined, but in certain cases, the regulations establish a numerical limit. Substances used in food-contact articles (e.g. food-packaging or food processing equipment) that migrate into food are exempt from regulation if they meet the threshold criteria established in 21 CFR §170.39.

Sanitizers and equipment lubricants are included in 21 CFR as indirect additives (see Appendices). Among substances that have been historically prohibited or regulated by organic certifiers are sanitizers such as chlorine bleaches and quaternary ammonia compounds (21 CFR §178.1010); lubricants such as mineral oil (21 CFR §178.3620) and petroleum wax (21 CFR §178.3710); and preservatives used in packaging such as pentachlorophenol (21 CFR §178.3800). Under the NOP Policy, it is not clear whether NOP considers these uses to be prohibited or restricted, or whether NOP intends to reclassify them as indirect and permitted. Additionally, there is considerable regulatory conflict within the framework of the NOP Rule created by the unclear nature of the NOP Policy for several so-called indirect additives. For example, most chlorine bleaches, certain quaternary ammonias, and pentachlorophenol packaging preservatives are also considered pesticides by the Environmental Protection Agency (EPA) under 40 CFR Part 180. The use of mineral oil as a releasing agent is also classified as a direct food additive under 21 CFR §172.878.

In response to an OMRI question regarding the indirect additive policy, NOP stated that indirect additives listed in 21 CFR Parts 174-178 and 186 are outside the scope of the NOP Rule, and are permitted even though they do not appear on the National List. OMRI requests that NOP provide a regulatory justification for bypassing the OFPA requirements for NOSB review of substances such as indirect additives and food contact substances.

How will the NOP Policy affect processors and manufacturers?

The greatest direct impact on processors and manufacturers appears to be contained in the last paragraph of the NOP Policy:

“Handlers must include in their organic systems plan a list of all synthetic substances to be used in the production of processed products. Each synthetic substance must be identified as an ingredient or a contact substance. Any substance identified as a contact substance must be accompanied by documentation that substantiates the claim.”

This NOP Policy change requires processors and handlers to document which given substances are considered ‘food contact’ for the specific use in question. OMRI has received a number of questions from processors and certification agencies regarding the acceptability of various cleaners, disinfectants, sanitizers, and other substances that are considered food contact substances only when used under strict limitations. The policy puts the burden on the processor or handler to document compliance as well as on the certifier to review and verify that these restrictions are met.

How can one determine if a substance is a food-contact substance?

Processors who wish to use a food additive will need to know its legal status as listed in 21 CFR for the particular use in question in order to comply with this provision of the NOP Policy. Depending on use, food-contact substances are listed in different categories. For example, mineral oil is listed at 21 CFR §178.3620 as well as §178.3570 for use in lubricants with incidental food contact while also listed as a direct food additive at §172.878. Many, but not all, food-contact uses can be identified using the FDA database, “Everything Allowed in Food in the U.S.” (EAFUS).² According to the NOP Policy, if the use in question falls into one of the categories requiring NOSB review, the food contact substance must be on the National List. According to FDA regulation, many of the food contact substances have specific use limitations. At a minimum, these limitations should also apply to organic handling and processing. Thus, within this NOP Policy framework, some substances are required to be on the National List for some purposes but not for others, causing confusion about the status of the substance.

According to NOP, any item appearing on FDA's list of FCSs need not be reviewed unless it is being used in a way that differs from the FDA conditions established for food-contact use. However, the status of some substances may not be readily discernible using FDA databases. Some substances are considered by FDA to be Generally Recognized as Safe (GRAS) because they are “prior sanctioned,” i.e., in use prior to the 1958 enactment of the Food Drug and Cosmetic Act. For instance, perlite, diatomaceous earth, and cellulose powder are not listed anywhere in 21 CFR for use as filtering aids, but they are considered prior sanctioned by FDA. As filtering aids, they may meet the definition of a food-contact substance. However, manufacturers do not have to file a FCN under FDAMA for their use as a filtering aid, as this is a permitted use for a prior-sanctioned GRAS additive. On this point, FDA states:

² <http://www.cfsan.fda.gov/~dms/eafus.html>

“FDA believes that a substance that is GRAS or prior sanctioned for its intended use in contact with food also may be an FCS, and may be the subject of an FCN, even though authorization under the FCN process is not required for the FCS use.”³

In other words, GRAS or prior-sanctioned materials may be considered food contact substances and regulated as such, even though suppliers are not required to file a formal FCN. By relegating food contact substances to the exclusive authority of FDA, the NOP Policy would have the effect of nullifying the regulation of substances under 7 CFR §205.605, as well as many others considered and/or rejected by the NOSB. To perform their duties under OFPA, certifiers would need to perform a case-by-case review of all additives to determine if their use in each product would meet the FDA definition of a food-contact substance.

Some substances are already defined in 21 CFR as being “food-contact substances.” While the new FDA website is planned to be the method for notification of new uses of food additives as food-contact substances, substances listed in existing 21 CFR regulations that meet the FDAMA definition of food-contact substances are not required to go through the notification process. Thus, for example, molecular sieve resins are secondary direct food additives permitted in the processing of food for human consumption and regulated by 21 CFR §173.40. They can also be used as gel filtration media to remove lactose in whey purification. The molecular sieve resins act purely as an inert filter with no technical effect on the food. However, they are not listed on the FCN website because FDA only requires a FCN for new uses of substances that are food additives, a definition which includes direct and indirect additives used in food manufacture. Also, a FCN may be used to notify FDA of new uses of food-contact substances that are not food additives (i.e. constituents of food additives, GRAS, and prior-sanctioned substances.)⁴

How will this policy change current certification policy?

Current NOP certification policy is based on an approach that requires all ingredients to be certified organic, unless an explicit exception is made. The organic industry has historically considered not only food additives, but also processing aids and other incidental ingredients to be ‘ingredients.’ This US approach is consistent world-wide and is reflected in the *Codex Alimentarius* guidelines, the European Union regulations, the IFOAM Basic Standards, each of these listing processing aids as well as additives in their lists of substances allowed for organic processing. The NOP has received significant numbers of comments from the industry on this point in response to the 1997 and 2000 proposed NOP Rule. We offer several examples of the potential changes that implementation of the NOP Policy will institute in the current operation of the NOP Rule.

Preservatives in Packaging

Fungicides, preservatives, and fumigants used in packaging materials are prohibited under the provisions contained in OFPA, 7 USC §6510(a)(5), and the NOP Rule, 7 CFR §205.272(b)(1).

7 CFR §205.272(b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:

³ <http://www.cfsan.fda.gov/~dms/opa2pmna.html>

⁴ <http://www.cfsan.fda.gov/~dms/fcnwshan/sld024.htm>

- (1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;

The intention and practice has been to prohibit a number of antimicrobials and fungicides that are commonly allowed in conventional food handling from use in organic food handling. These substances include synthetic chemicals (e.g., formaldehyde, morpholine, o-phenylphenol) and ethylenebisdithiocarbamate (EBDC) fungicides such as zineb. Many of these substances are allowed under FDA regulation for conventional food handling and processing and may be considered indirect additives. FDA explicitly defines antimicrobial agents as preservatives as follows:

21 CFR §170.3(o)(2) “Antimicrobial agents”: Substances used to preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under “preservatives.”

A number of food-contact substances listed on the FDA FCN website serve as fungicides and preservatives in packaging materials and their components. By allowing fungicides, preservatives, and antimicrobials listed on the FCN or otherwise treated as food-contact substances by FDA, the NOP Policy directly contradicts OFPA’s and the NOP Rule’s explicit prohibition on these types materials.

Examples

Nisin is an anti-microbial peptide that is considered a GRAS food additive. It was reviewed by the NOSB in 1995 and prohibited from use in organic food handling and processing. Several research groups are developing *Nisin*-coated plastic wrap for retail meat products. Adding an antimicrobial to the packaging does not require labeling to inform the consumer. The peptide must act on the food, however, to kill bacteria. In this respect, *Nisin* will directly affect the food and thereby is technically prohibited by 7 CFR §205.272 (b)(1) yet allowed by the NOP Policy.

The functionality of the *Nisin* requires a direct interaction with food as explained in its patent description (Daeschel and McGuire, US Patent #5,451,369):

“Bacteriocin molecules must become detached from a bacteriocin-treated surface in order to function optimally as bacteriocidal agents. Thus, contact of a bacteriocin-treated surface with a food material, particularly a material having a significant liquid content, will enable bacteriocin molecules to detach from the surface so as to enable the molecules to lethally interact with susceptible bacteria present in the food material and located near the contact surface. Bacteriocin-treated surfaces can also kill susceptible bacteria that become deposited directly on the treated surfaces.”

Piperonyl butoxide and pyrethrins as components of bags are pesticides that are listed as indirect additives in 21 CFR §178.3730 and permitted for insect control on bags used for dried feed or food. In addition to adding a prohibited substance to packaging, their use poses a risk of exposure to children who might accidentally consume part of a bag.

Dimethyl dicarbonate is an antimicrobial that is added to juices and acts on microbes contained in the juice. It is also listed as an approved food-contact substance on the FDA inventory for use in non-carbonated juice beverages. Microbes that it would treat could be present due to

inadequate disinfection of the containers or could have also been present in the juice prior to packaging. Dimethyl dicarbonate appears to be a direct food additive, even if it was added prior to filling.

2-Propenoic acid is listed in 21 CFR §176.170 as a fluid absorbent added to paper or plastic liners in the packaging of fatty and aqueous foods. It is used to draw excess water and blood from refrigerated poultry, meat, or fish. 2-Propenoic acid appears to directly affect the meat by removing fluids and lowering the humidity inside the package. Both effects inhibit the pathogen growth and thus increase the meat's shelf life. Removal of blood from packaged meat appears to be a 'technical effect in or on the food.' Whether packaging chemicals migrate into the food or spoilage substances migrate out of the food, the final result on the meat is the same. In this respect, an additive, packaging chemical does not need to migrate into the food to have a functional effect on it.

All **Sanitizers** now appear to be *de facto* allowed. While this situation was assumed prior to the publication of the December 12, 2002 NOP Policy, some have been routinely restricted by certification agencies due to their propensity to leave persistent residual contamination on food. This issue should be clarified by the NOSB rather than dropped as a consequence of the NOP Policy.

Some—though perhaps not all—**Boiler Water Additives** are listed as Food Contact Substances and would be allowed under the NOP Policy. It is not clear whether all boiler chemicals are considered food-contact substances by the FDA definition, or whether only the new FCN boiler chemicals are permitted.

The NOSB reviewed and prohibited amine-based boiler additives that contact food in such processes as the steam blanching of vegetables or steaming of corn flakes, while recommending limited use of some amine compounds for cleaning the insides of cans and bottles before filling. OMRI considers non-volatile boiler chemicals to be currently permitted, without further regulation needed, provided that the systems are monitored to provide assurance that the boiler chemicals do not affect the organic integrity of the product. However, the well-supported recommendations of the NOSB will not be followed under this NOP Policy.

Waxes and Coatings such as beeswax and wood rosin are considered direct additives approved for use as fruit coatings on citrus by 21 CFR §172.210. Petroleum wax is a direct additive for coating cheese, fruits, and vegetables allowed by 21 CFR §172.886. Shellac may be a prior-sanctioned GRAS but this distinction is not clearly stated in 21 CFR. Shellac is also considered an indirect additive, used as an adhesive in fruit coatings. GRAS waxes are also considered indirect additives when used as "hot melt strippable wax" that can be removed from a product (21 CFR §175.230), e.g., paraffin used as a wax coating for cheeses. These indirect uses as adhesives and strippable waxes would be permitted without review under the NOP Policy. Currently, paraffin is prohibited as a wax on organic products (7 CFR §205.105(c)).

Conclusion

Historically there has been some difficulty distinguishing processing aids from ingredients. However, the NOSB has held that both categories require review and inclusion on the National

List. A carefully crafted policy that identifies food additives by their FDA regulatory categories that require NOSB review will be helpful to processors and certification agencies. NOSB did propose such guidance in October of 2002, but it has not been publicly available for review. Experts who OMRI has consulted on the December 12, 2002 NOP Policy have been unable to agree both on the broad implications and on the specific outcomes of the NOP Policy. Overall, most believe that this policy will be considerably more permissive than the current organic industry norms. Such a move carries the potential of removing historical obstacles to processing food under the USDA organic standards. This approach is problematic for the following reasons:

- It is difficult to identify which materials are considered to be food-contact substances. Legal opinions may provide different interpretations as to the status of various substances, thus forming an obstacle to consistent implementation.
- The FDA process for review and designation as food-contact substances in conventional food processing does not match NOP regulatory criteria for substances permitted for organic processing.
- The NOSB's statutory responsibility to review materials for organic processing will be delegated to FDA without reference to requirements of OFPA or the NOP Rule.
- FDA determination of FCS status may not be consistent for similar substances or for the same substances used differently because FCN is a voluntary system that depends on manufacturer submissions.
- The NOP Policy contradicts OFPA and the NOP Rule by allowing preservatives, fungicides, and pesticides used in packaging.
- The NOP Policy contradicts the NOP Rule at 7 CFR §205.272 (a), which requires handlers to protect organic products from contact with prohibited substances.
- The NOP Policy does not conform to 7 CFR §205.105(c), which states, "the product must be produced and handled without the use of "Nonagricultural substances used in or on processed products, except as otherwise provided in §205.605."
- The NOP Policy effectively adds materials that can be used under the NOP Rule without going through the petition, NOSB review, and public comment process to amend the National List as mandated under OFPA.
- The NOP Policy creates an "open" list that effectively adds many materials not reviewed by the NOSB for use in organic production.
- The NOP Policy may be difficult to reconcile with international trading partners and may not be acceptable to consumers interested in organic products that are produced with a minimum of synthetic additives.

Recommendations

1. Maintain the integrity of the National List for processing substances as it currently stands as a closed positive list. To use a substance in organic food processing, it must either be organic or appear on the National List as an approved non-organic substance.
2. Clarify that materials that do not have food contact and do not impact the organic system will not require review and can be referenced to the appropriate 21 CFR sections

regulating indirect additives. For example, cleaning and sanitizing materials that do not leave residues and are appropriately rinsed, as well as boiler additives that are not carried in steam, should continue to be exempt from consideration. NOSB should continue to review any materials that are in direct contact with organic products to determine potential impact on organic integrity. Guidance can be developed as needed for specific areas such as packaging or lubricants.

3. Clarify that OFPA and the NOP Rule ban on preservative, fungicides, and pesticides applies to all packaging, whether or not these substances are considered indirect additives. Re-affirm the responsibility of certification agents to verify the prevention of contact with prohibited substances.
4. Consider and discuss possible revision of the processing rules to redefine product composition of the “Made With Organic [specified ingredients]” category. Currently the regulation requires that for a 70% organic product, all non-agricultural food additives must be on the National List. Redefining this category or creating another without the National List requirement for non-agricultural food additives may offer a means to lessen the burden on manufacturers who wish to make use of non-approved additives. This option will maintain a clear standard of distinction for products able to achieve ‘organic’ label claims (95% or 100% organic ingredients, and allow the USDA seal) and provide truth in labeling to consumers looking for that assurance.⁵

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⁵ (See the separate OMRI position paper – Proposal for A Basic Change to the USDA Processing List, OMRI comments on USDA proposed rule, June 2000, revised).