

## Draft 4-28-O2

### **Guidelines for determining what processing technologies require a petition to be reviewed by the NOSB:**

OFPA's definition of processing appears to allow most, if not all, mechanical, and biological processes. However, the intent of OFPA, although broadly inclusive, was not necessarily meant to allow in organic processing all of the novel processing methods currently being used in the production of foodstuffs.

The following guidelines have been developed to assist processors, certifiers and others in determining whether a process that does not appear to fit into the category of allowed processes described in the definition for processing and in 7 CFR 205.270(a) needs to be petitioned and reviewed by the NOSB to determine compatibility with organic processing. Upon review NOSB will make a recommendation to the National Organic Program regarding the compatibility of the reviewed processing technology in the handling of organic ingredients and foodstuffs.

1) Processes that are strictly mechanical, physical, or biological are allowed for processing of organic food products. Any process that does not cause a change in the food, other than by mechanical, physical, or biological means, and does not introduce nonagricultural substances, other than those already listed in §205.605, would not need to be reviewed.

[Examples include: centrifuging, grinding, rolling, filtration, gravimetric separation, drying, churning, pressing, vacuum extraction, heating, cooking, distilling, natural fermentation, and UV light treatment.]

2) Processes that involve the use of non-organic ingredients, processing aids, primary additives, or secondary additives as defined by FDA are subject to the requirements established in 7 CFR 205.270, 7 CFR 205.301 (1), 7 CFR 205.600, 7 CFR 205.605, and 7 CFR 205.606. Any substance used would need to be petitioned, reviewed, recommended, and added to the National List to be allowed for using in processing food or ingredients labeled as organic, even when such processing results only in incidental amounts of a given substance in the food.

[Examples of non-organic, nonagricultural substances that must appear on the National List to be used in organic processing include: acids and bases used in hydrolysis; fermentation organisms and cultures; use of secondary additives such as ion-exchange resins and membranes; metals used as charged catalysts (e.g., nickel or platinum used to hydrogenate oils); gases that are added to food (e.g., hydrogen for hydrogenation or carbon dioxide for supercritical extraction); antifoaming agents; and volatile boiler water additives that carry over in steam.]

3) The NOSB will not consider petitions to use ingredients or processing aids made by the use of excluded methods [7 CFR 205.105(e)], prepared with ionizing radiation [7 CFR 205.105(1)], or grown with sewage sludge [7 CFR 205.105(g)].

### **Commentary**

While the NOSB is not clearly delegated in OFPA with authority to review processes as such, Nose clearly has authority to review and consider any processes that involve chemical alteration or contact of organic food with substances not included on the National List. These guidelines help clarify the types of processes that provide an opportunity for such contact. In addition, NOSB should be called upon to review novel or specialized processes to make a determination whether they do involve chemical modification.

Mechanical processes, such as those mentioned in 7 CFR 205.270(a), that do not introduce nonagricultural substances, other than those already listed in §205.605, into the organic food would not need to be reviewed. In addition, physical methods, such as ultraviolet; light. that also meet the criteria listed above, would not need to be reviewed.

Biological processing is allowed under the 7 CFR 205.270(a). However, NOP rule requires that individual organisms used in biological processing must be either organically produced or appear on the National List. Dairy cultures and yeasts are examples of fermentation organisms that currently appear on the National List.

A number of other processes, however, would be considered chemical processing and would require a petition for the specific materials used in the process. Examples of some of these processes are included below and include ion exchange resins, catalytic metals and inert gas used for hydrogenation, some carbohydrate conversion processes.

### **Ion Exchange**

The NOP Final Rule allows for the limited use of Ion exchange. Secondary additives that are in direct contact with food are considered processing aids under 7 CFR 205.301 (1).(4). The Food and Drug Administration considers ion exchange resins (21 CFR 173.25), ion exchange membranes (21 CFR 173.20), and molecular sieve resins (21 CFR 173.40), to be secondary direct food additives.

Resins used in Ion exchange meet the definition of 'processing aid' under the NOP final rule (205.2). The preamble clarifies that the term 'ingredients' as used under the NOP Final Rule includes processing aids and incidental ingredients as well as declared ingredients (65 Fed. Reg. 80587). Therefore, the resins, membranes, or other substances that are in direct food contact and function as processing aids would need to be organically produced or appear on the National List:

### **Hydrogenation**

Similarly, the hydrogenation of oils would also be considered chemical processing. Hydrogen and the catalysts used to generate hydrogen, such as nickel, are not currently on the National List. These are also considered food additives (see 21 CFR 184.1537 for nickel). For hydrogenation to be acceptable, both hydrogen and the catalyst would need to appear on the National List.

### **Carbohydrate conversion**

Carbohydrate conversion refers to a number of different techniques for modifying, reducing, or transforming carbohydrates into proteins, fats, or other carbohydrates. Some of these are chemical in nature, some biochemical, some physical, and others biological. Those that are physical are allowed without consideration of additives. Chemical and biochemical modification obviously requires that all of the reactants be either organically produced agricultural ingredients or be on the National List. Biological modification also requires that the organisms used either be organically produced or appear on the National List.

Modified starch would be an example. The acids and bases used for hydrolysis would need to be on the National List. Another example of chemical conversion is carbohydrate reduction involving the use of various charged metal catalysts. If these catalysts are considered food additives, then they must appear on the National List. Yeast fermentation and the conversion of sugar to alcohol are not prohibited because yeast appears on the National List. Enzymatic conversion, such as the use of maltase or amylase to malt grains, is also allowed by the NOP Final Rule without further NOSB review, provided that the enzymes are not prepared by excluded methods.