

amount of inositol in milligrams per 100 kilocalories of formula, except when it is not added to milk-based formulas (21 CFR 107.10).

Supplementation is only necessary if the formula does not contain adequate inositol without supplementation. Has the committee determined that the non-milk formulas would be deficient in inositol without supplementation. As stated in the TR for choline (lines 125-127), "Lecithin (a naturally occurring mixture of the phosphatides of choline, ethanolamine, and inositol) is a direct food substance affirmed as GRAS by FDA with no limitation other than good manufacturing practice (21 CFR 184.1400)." Lecithin is available in both organic and nonorganic forms for supplementing foods. Thus, even if the formula does require supplementation, a natural form is available.

There is no explanation in the Handling Committee's recommendation why the FDA's requirement for inositol in non-milk infant formula should also justify its allowance in milk-based infant formulas labeled as "organic" or "made with..." The Handling Committee also recommends without justification allowing it in the "made with organic..." category for use in agricultural products other than infant formula.

## **2. What are the human health and ecological impacts?**

Although the TR does not point out any hazards to human health or the environment from the manufacture of synthetic inositol, the three commercially practical procedures for isolating inositol from corn or rice steep liquor involve hazardous materials including sulfurous acid, hydrochloric acid, sulfuric acid, ammonium salts, and barium. (TR lines 268-311) While there is a yeast-based process that still results in a synthetic inositol, the TR states that there do not appear to be any sources of inositol produced this way.

## **3. Is it consistent with principles of organic production and handling?**

Addition of an unnecessary synthetic ingredient to organic food is not compatible with consumer expectations of organic food.

## **4. Conclusion**

The Handling Committee has not shown a need for synthetic inositol to be added to the National List. Therefore, we urge the board to reject the recommendation to list synthetic inositol for use in infant formulas.

## **C. Gibberellic Acid**

### **1. Is there a need?**

The Technical Evaluation Report (TR) for gibberellic acid (GA) does not establish a need for GA in bananas or any other fruit. In fact, we note that the question, "Is there another practice that would make the substance unnecessary?" was not addressed in the TR, as required for review.

## **2. What are the human health and ecological impacts?**

While human health effects that may be associated with gibberellic acid have not been documented in the TR, we should keep in mind that GA is a plant hormone, and therefore is active in very small concentrations. The impacts of a plant hormone when used in a cropping system would, of course, be significant. How about the impacts of post-harvest application? Egyptian researchers have discovered that GA has an impact on the antioxidant defense system (glutathione peroxidase, superoxide dismutase, and catalase) of mammals, as well as causing liver damage and DNA damage.<sup>4</sup> Other plant hormones have impacts on humans. Abscisic acid (ABA) has shown efficacy in the treatment of diabetes and inflammation.<sup>5</sup> And, of course, we are all well aware of the health effects of synthetic auxins like 2,4-D.

## **3. Is it consistent with principles of organic production and handling?**

The committee has not indicated that it would place any restrictions on the manufacturing methods. The TR does indicate laboratory synthesis of synthetic gibberellic acid is possible, and since the committee has voted that GA is synthetic, we assume that it means to specify GA made by fermentation. However, the TR also says (274-277) that GA (at least that which is made by submerged fermentation techniques) is “purified using methanol, acetone, ammonia/ammonium salts, and/or ethyl acetate (Brueckner et al., 1989). Specific details on the recovery and purification processes are generally not published, but rather kept as confidential business information by each manufacturing company (Brueckner et al., 1989).” This list of solvents includes a number of volatile synthetic solvents, and as we have indicated in our comments on the extractants discussion paper, these should not be used in or on organic food.

Even though the proposed use is on a tropical fruit that has become somewhat of a staple in the diets of Americans living in temperate climates, we question whether the use of a plant growth regulator is compatible with organic practices, even if its use it is used to facilitate long-distance transport.

## **4. Conclusion**

Lacking any data supporting need, and in view of the potential harm, use of volatile synthetic solvents in purification, and long distance transport as a justification, we must take a precautionary approach and oppose the listing of gibberellic acid for use on bananas on §205.605(a).

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<sup>4</sup> Hanan A.E.Soliman, Mona M. Mantawy, and Hany M. Hassan, 2010. Biochemical And Molecular Profiles Of

<sup>5</sup> Bassaganya-Riera J, Guri AJ, Lu P, Climent M, Carbo A, Sobral BW, Horne WT, Lewis SN, Bevan DR, Hontecillas R. **Abscisic acid regulates inflammation via ligand-binding domain-independent activation of PPAR {gamma}**. *J Biol Chem.* 2010, Nov 18, 2010