May 3, 2012

National Organic Standards Board Materials Committee Spring 2012 Meeting Albuquerque, NM

Re. Significant Residues Definition in Classification of Materials Policy

Dear Board Members:

I am a consulting food technologist who is involved in assisting food companies comply with organic regulations (along with a range of other activities). I support the first approach suggested in this review, i.e., to define an insignificant level of a synthetic substance as being below any applicable regulatory limits for the substance and having no technical and functional effect in the final material. Details of my position are provided in this letter.

I have worked with a number of companies over the years and had to deal with issues regarding residues, incidental substances, etc. and would like to share my impressions of reasonable and achievable approaches in setting limits. An example that is perhaps easy to understand concerns gluten free limits. The FDA defines gluten free as <20 ppm gluten. Some countries will allow gluten free labeling but will not specify a limit to meet gluten free requirements. Instead, they might indicate that if gluten is found at any level, an ingredient or food would not be gluten free. I have found it very difficult to deal with claims when a maximum level is not defined. Because gluten detection levels have continued to improve, it is possible to detect 2 ppm of gluten but that level has no health impact on an individual with Celiac Disease. In a country without defined maximum levels, several pieces of wheat gluten in tote of rice can yield rice flour that is not acceptable for use in gluten free products. By setting a limit of none detectable, it significantly impacts a company's ability to manufacture and promote products that are healthy, safe and desired by consumers.

I understand that, even given the best intentions and practices, very low levels of incidental contaminants of no health and/or environmental significance can enter our food supply. While significantly less likely for organic products, the issue is still relevant. While ingredient suppliers and food processors will continue to make improvements to mitigate these instances, it will take some time. I do not believe it is practical to state that any level of a synthetic substance that is known or detectable would render a food unacceptable for use in organic products. Under this scenario, the use of food grade grease on food processing equipment might not be allowed which would eliminate the use of many processing operations for organic foods.

I also do not think it is practical at this time for the NOSB to set guidelines to screen all potential synthetic residues. While this might be a long term goal with efforts initiated now, I do not believe the NOSB would be ready to address these issues on the wide range of chemicals present in our world for quite a period of time.

For these reasons, I think that the first approach suggested in the discussion document makes the most sense. Under this scenario, a significant level of a synthetic substance in a final material would:

- be above an applicable regulatory limits for the substance
- have a technical effect in the final material OR
- have a functional effect in the final material

In a situation where any one of these criteria is met (above regulatory limit, having a technical effect or having a functional effect), the residue would be considered to be present at a significant level. I believe this is sufficient, actionable and supports the intent of OFPA.

Thank you very much for your consideration of my comments.

Sincerely,

Marsha Kopral Consultant