May 10, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD. 20852

Submitted via Regulations.gov

Re: Use of the Term "Natural" in the Labeling of Human Food Products; Request for Information and Comments; Docket ID No. FDA-2014-N-1207, 80 Fed. Reg. 69905 (November 12, 2015).

To whom it may concern:

CropLife America (CLA) appreciates the opportunity to provide comment on the recent request by the Food and Drug Administration (FDA or the Agency) for information and comment on the use of the term "natural" in the labeling of human food products. *See* FDA-2014-N-1207. Established in 1933, CLA represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all of the vital and necessary crop protection and biotechnology products used by American farmers, ranchers and landowners.

On November 12, 2015, the FDA requested comment on the term 'natural' in the labeling of human food products. 80 Fed. Reg. 69905. The Agency summarized its 1993 decision not to then engage in rulemaking to define "natural," but to "maintain our policy not to restrict the use of the term 'natural' [in food labeling] except for added color, synthetic substances, and flavors." *Id.* at 69906 (citing 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993)). FDA further referenced its 1993 policy "to interpret 'natural' as meaning that nothing artificial or synthetic (including color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food." *Id.*

Currently, FDA's "natural" policy focuses on ingredients in the food (not the process used to manufacture or process the food), and presence of any artificial or synthetic ingredients (or any color additives, regardless of source (whether synthetic or *natural*) in the finished food. FDA policy provides for discretion to consider whether consumers would expect an ingredient, regardless of its source, to be in food labeled as "natural." FDA's decided not to address food production methods, such as the use of pesticides.

FDA specifically asks, "… should certain production practices used in agriculture, for example … the use of pesticides … be a factor in defining 'natural'?" 80 Fed. Reg. at 69908. CLA maintains that agricultural practices, and specifically pesticide use, should not be incorporated into any FDA rulemaking or policy change regarding the term "natural." The use of pesticides to

protect crops from pests dates back at least as far as the ancient Romans, who killed insect pests by burning sulfur and controlled weeds with salt.[1] Today, the vast majority of agricultural production, including organic production, involves the use of pesticides. *See* 7 C.F.R. Part 205.

It is important to note that all pesticides sold and distributed in the United States are regulated by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and are registered (licensed) for use according to a safety standard that precludes any "… unreasonable adverse effect on the environment." FIFRA §§3(a), 2(x), and 2(bb). For pesticides that will be used on food or feed crops, the Federal Food Drug and Cosmetic Act (FFDCA) establishes a standard of "… reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information …" FFDCA §408(b)(2)(A).

The EPA conducts science-based risk assessments to make the safety determinations required by FIFRA and the FFDCA. Prior to registration of a pesticide active ingredient, EPA requires over 120 tests that examine the toxicity and environmental impacts of the pesticide. EPA then subjects these data to environmental, human health, and dietary risk assessments. Prior to commercialization of the product, EPA approves the label for the crop protection product, which provides directions for use of the product to achieve effective pest control and to minimize environmental and human exposures. Once registered, a pesticide may be used only according to the label directions.

As mentioned above, for pesticides intended for use on growing crops or harvested food, the EPA conducts a dietary risk assessment and sets a tolerance, which is the maximum level of a pesticide residue that may be permitted in or on the food product. FFDCA §408(a). The Food and Drug Administration's (FDA's) Pesticide Residue Monitoring Program (http://www.fda.gov/Food/FoodborneIllnessContaminants/Pesticides/UCM2006797.htm) has been monitoring and reporting on pesticide residues in food since 1987 and has direct enforcement responsibilities. The Pesticide Data Program of the U.S. Department of Agriculture (USDA/PDP; http://www.ams.usda.gov/pdp) also has monitored pesticide residues in food since 1992, and its results inform both the FDA program, as well as the EPA safety assessments. In addition, USDA's Food Safety Inspection Service monitors pesticide residues in meat, milk, poultry, and eggs (http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/chemistry/residue-chemistry), and the Alcohol and Tobacco Tax and Trade Bureau (U.S. Department of Treasury) monitors residues in wine (http://www.ttb.gov/industry_circulars/archives/2010/10-02.html). In combination, these programs help ensure the quality of the nation's food supply and adherence to those established tolerances. These programs indicate that foods grown and sold in the United States, including fruits and vegetables, is overwhelmingly safe. For example, in 2011 PDP found only 0.27% of samples had residues exceeding tolerances set by EPA, and only 3.4% of samples had small amounts of residues for which no tolerances had been established. Based on the rigor and

[1] "Pesticide Usage in the United States: History, Benefits, Risks, and Trends," Delaplane, K.S., Asst. Prof. of Entomology, Cooperative Ext. Service, Univ. of Ga. (1996).

massive volume of testing required by FIFRA, pesticides are among the most heavily regulated industry sectors.

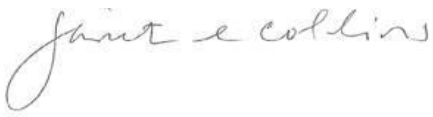
Through technological advances, as well as a strong regulatory program, crop protection in the United States is far safer and more effective than in centuries and decades past. Modern pest control, which includes the use of synthetic pesticides, allows for the reliable and consistent production of abundant, affordable and safe food grown across this country and around the world. These same technologies allow for the development of new crop protection products with better environmental and toxicological properties, thus affording greater human health and environmental protection.

In summary, CLA supports the May 10, 2016 comments of the Biotechnology Innovation Organization (BIO) and of the Grocery Manufacturers Association (GMA) in support of FDA's longstanding policy to not consider agricultural production methods in its consideration of the term "natural." As GMA stated in its comments, "Consideration of farming or agricultural methods, including pesticide and herbicide use, use of biotech seeds, and animal husbandry practices, should be outside the scope of the 'natural' definition. We believe that this is a key distinction between an organic claim, which is based on the use of organic farming and production methods, and natural claims, which should be based on the natural/synthetic status (with certain exceptions, such as for added vitamins and minerals) and post-harvest processing of the ingredients."

Should you have any questions or wish to discuss any of the statements specifically, please contact me directly by email (jcollins@croplifeamerica.org) or telephone (202) 833-4474.

Thank you for your consideration of these comments.

Respectfully,



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