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November 13, 2013

Food and Drug Administration  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20852  
Attention: Docket No. FDA-2011-N-0921

Re: Proposed Rule 21 CFR Parts 1, 16, 106, Et al.

Dear FDA Administrator:

Thank you for the opportunity to provide comments on FDA's Proposed Produce Safety Rule. As the representative of the compost manufacturing industry, our comments focus on biological soil amendments.

The US Composting Council (USCC), a 501(c)6 Trade and Professional Association, is the only national organization in the United States dedicated to the development, expansion and promotion of the composting industry. The USCC has over 800 member companies, including private and municipal compost manufacturers, equipment companies, product suppliers, academic institutions, public agencies, nonprofit groups and consulting/engineering firms.

First and foremost, the USCC takes compost safety very seriously. We believe that composts manufactured to current standards for pathogen reduction are safe for general use<sup>1</sup>. In fact, to our knowledge, there have been no known documented cases where commercially manufactured compost was the cause of an illness. However, we fully support the FDA's efforts to improve the safety of our food supply and understand that "the absence of evidence is not the evidence of absence". Commercial food growers using composts on agricultural crops that will be consumed raw carry risks not associated with other users, and so those composts need special attention. This is particularly true when the composts are derived from feedstocks of animal origin, such as manures, or that have been potentially exposed to human pathogens, such as restaurant table scraps. To address these risks, we recommend a two-tier approach, whereby a grower would have a zero application-to-harvest interval if the compost meets stringent criteria, but would have a 45 day interval for compost meeting general safety standards and being used on certain covered crops.

The following is a summary of the issues that need additional consideration. Our more detailed comments follow.

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<sup>1</sup> Includes meeting time and temperature parameters for the composting method and microbial limits of less than three MPN *Salmonella* species per four grams of total solids (dry weight basis) and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis)

- Composting, when properly practiced with regards to time, temperature and handling procedures, produces soil amendments as safe as those produced by chemical or physical treatment methods. Therefore, if the compost meets the same microbial standards as the physical and chemical methods, it should be subject to the same restrictions as far as application-to-harvest intervals.
- We disagree with characterizing composting as either “static” or “turned” and present an alternative that more accurately reflects the state of the industry.
- The proposed produce safety requirements will conflict with organic fertility practices required under the USDA National Organic Program. Without clear scientific evidence to the contrary, these new regulations should conform to the NOP standards and not place undue burden on organic growers, who constitute the majority of compost users that will be affected by these regulations.
- The USCC agrees with and supports the comments of the Organic Trade Association in the use of guidance documents versus incorporating metrics in the rule itself. If the science behind a specific standard or testing metric is inconclusive, yet offers a target range of usefulness, the provision should be added to guidance. Guidance documents are easier to update as research proceeds, and can be adapted more easily to different growing regions and crops, than incorporating the metrics in the rules.

Pg	issue	comment
3630	composting definition	<p>FSMA: Composting means a process to produce humus in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131°F (55 °C)), followed by a curing</p> <p>Comment: Composting does not produce “humus” (see next comment). Specific time and temperature conditions can be required for manufacturing compost destined for crops covered by this Act, but should be included in the broad definition of composting.</p> <p>USCC Proposes: Composting means the controlled biological decomposition and stabilization of organic material to a point that it is beneficial to plant growth.</p>
3631	Humus definition	<p>FSMA: Humus means a stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.</p> <p>Comment: This is a definition of compost, not humus. Compost, the product of composting, contains many constituents, including humus. The term humus is most commonly used to refer to very stable organo-mineral complexes, part of the long term organic matter of soil and a common chemical constituent of compost. It is neither commonly used nor appropriate as a general term for</p>

		<p>compost.</p> <p>To avoid confusion, we recommend using “composting” when referring to the verb, the act of making compost, and “compost” to refer to the soil amendment.</p> <p>Proposed: Compost means the product of the controlled biologic decomposition of organic material stabilized to a point that it is beneficial to plant growth.</p>
	Pre-consumer vegetative waste	<p>“Yard trash” should be changed to “yard trimmings” to be consistent with the definitions.</p> <p>“or any waste generated by restaurants” should be deleted, as restaurants may choose to keep their pre-consumer vegetative waste separate, so should not be categorically excluded.</p>
3632	Static composting	<p>Issue: Static composting includes passively aerated systems, which are likely to have cold spots due to uneven aeration.</p> <p>Recommend changing to “Actively Aerated Static Composting”.</p> <p>Actively Aerated Static Composting means a process in which decomposing organic material is placed in piles or a vessel with an air supply system that can be used to provide oxygen and control temperature for the purpose of producing compost. Piles or vessel must be insulated to ensure that all parts of the decomposing material reach and maintain temperatures at or above 55°C for a minimum of 3 days. Insulating material may not include biological materials of animal origin unless they have been treated per the requirements of these regulations.</p>
	Turned composting	<p>FSMA: Turned composting means a process to produce humus in which air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.</p> <p>USCC Recommends deleting. For the purposes of these regulations, Actively Aerated Static Composting is the only recognized subset of composting. Moreover, the definition is incorrect because the turning does not significantly supply air.</p>
3636 §112.54 (c)1 and 2	Acceptable practices	<p>FSMA: (1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for consecutive 3 days and is followed by adequate curing, or which includes proper insulation;</p> <p>USCC Recommends: (1) Actively aerated static composting that</p>

		<p>maintains a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing.</p> <p>FSMA: (2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation;</p> <p>USCC Recommends: (2) Composting that maintains a minimum average temperature of 131 °F (55 °C) or higher for 15 days or longer and is followed by adequate curing. During the period when the compost is maintained at 131 °F (55 °C) or higher, the pile of composting materials shall be mixed a minimum of five times with a minimum of 3 days between mixings. The 15 or more days at or above 131 °F (55 °C) do not have to be continuous.</p> <p>“Adequate curing” is defined as reaching a state of “stable” or “very stable” as described in Table 05.08-1 (attached)</p> <p>Note that the proposed requirement for insulating curing piles of compost is completely impractical physically and economically and unfounded biologically.</p> <p>USCC recommends development of a guidance document for manufacturing compost for use on “covered crops” that details proper monitoring and sampling procedures, training requirements and other Best Management Practices to be considered a “scientifically valid controlled composting process”</p>
<p>3637 §112.56 (4)(i)</p>	<p>Application requirements and intervals</p>	<p>FDA acknowledges that controlled composting suitably destroys pathogens to a minimal risk factor, and, therefore, the 45-day application interval is incongruous with FDA’s assessment. Inconsistency in any pathogen mitigation process can lead to the use of soil amendments that pose a public health risk. It is unclear why FDA determined that the potential inconsistencies in the compost process warrant a unilateral application interval, yet those inconsistencies inherent to physical or chemical treatment processes (equipment malfunction, inadequate cleaning, etc.) do not warrant the same level of precautionary measures. Furthermore, it is unclear how the 45-day interval was determined. Application-to-harvest intervals should be determined using science-based knowledge about pathogen levels in and transfer from compost, and that if a monitored and validated composting process reliably meets pathogen standards of §112.55(a), there should be no minimum time limit between application and harvest.</p> <p>However, given the uncertainty in the scientific literature, the liabilities to compost manufactures and food producers, and the mandate for public safety, we acknowledge that a 45 day application-to-harvest interval is prudent in specific circumstances</p>

		<p>until further research better defines what, if any, the proper interval should be.</p> <p>The USCC recommends that:</p> <p>For a biological soil amendment of animal origin treated by a composting process as per §112.54(c), that has been demonstrated to satisfy the microbial standard in §112.55(a), and is used in a manner that minimizes the potential for contact with the harvestable or harvested part of the crop during or after application, the minimum interval between application and harvest should be zero, the same as with physical and chemical treatment processes (§ 112.54(a) and (b)). The combination of meeting processing, handling and microbial standards ensures the risk of transmitting viable pathogenic organism is sufficiently minimized.</p> <p>Likewise, the minimum application-to-harvest interval should be zero when using a biological soil amendment of animal origin that</p> <ul style="list-style-type: none"> <li>a) is treated by a composting process as per §112.54(c),</li> <li>b) has been demonstrated to satisfy the microbial standard in §112.55(b),</li> <li>c) is used on covered produce whose edible portion does not have direct contact with the soil surface or soil particles, and</li> <li>d) is applied in a manner that prevents contact with the harvestable or harvested part of the crop during and after application.</li> </ul> <p>A 45 day minimum application-to-harvest interval shall be required when using a biological soil amendment of animal origin that</p> <ul style="list-style-type: none"> <li>a) is treated by a composting process as per §112.54(c),</li> <li>b) has been demonstrated to satisfy the microbial standard in §112.55(b),</li> <li>c) is used on covered produce whose edible portion has direct contact with the soil surface or soil particles, and</li> <li>d) is applied in a manner that minimizes the potential for contact with the harvestable or harvested part of the crop during and after application.</li> </ul>
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Considering the number of questions asked in the preamble of the proposed rule and the number of tentative conclusions, USCC requests that FDA consider and respond to the extensive comments received and move from the current proposed rule to either an interim rule or to a second proposed rule. We expect there will be many substantive changes made to the proposed rule that will require an additional public comment opportunity.

We appreciate the efforts that have gone in to the proposed rule, and would be happy to discuss our recommendations.

Regards,  
Lori Scozzafava  
Executive Director

Table 05.08-1 Compost Stability Index—Ranges indicate relative compost stability for respiration methods described in TMECC. The level of microbial activity in a sample is based primarily upon results of respiration monitoring. The index assumes optimized moisture, temperature, pH, and nutrient status that favor microbial activity, and insignificant concentrations compounds that inhibit microbial respiration. Test Methods for the Examination of Composting and Compost, 2001, USDA

<i>SOUR (OM)</i> 05.08-A	<i>CO<sub>2</sub>-C</i> 05.08-B	<i>DEWAR</i> 05.08-D	<i>SOLVITA®</i> 05.08-E	<i>BAC OC</i> 05.08-F	<i>STABILITY RATING</i>	<i>GENERAL CHARACTERISTICS</i>
< 3	1		8	< 2	very stable	<ul style="list-style-type: none"> <li>▪ well cured, finished compost</li> <li>▪ no continued decomposition</li> <li>▪ no odors</li> <li>▪ no potential for VFA phytotoxicity and odor</li> </ul>
3 – 10	2 – 4	V	7	2 – 4	stable	<ul style="list-style-type: none"> <li>▪ moderately well cured compost</li> <li>▪ odor production not likely</li> <li>▪ limited potential for VFA phytotoxicity and odor</li> <li>▪ minimal to no impact on soil carbon and nitrogen dynamics</li> </ul>
11 – 20	5 – 7	IV	5 – 6	5 – 8	moderately unstable, curing compost	<ul style="list-style-type: none"> <li>▪ curing compost</li> <li>▪ odor production not likely</li> <li>▪ aeration requirement reduced</li> <li>▪ limited potential for VFA phytotoxicity and odor</li> <li>▪ minor impact on soil carbon and nitrogen dynamics</li> </ul>
21 – 26	8 – 9	III	4	9 – 12	unstable raw compost	<ul style="list-style-type: none"> <li>▪ active, uncured compost</li> <li>▪ minimal odor production</li> <li>▪ high aeration requirement</li> <li>▪ moderate to high potential for VFA phytotoxicity</li> <li>▪ moderate potential for negative impact on soil carbon and nitrogen dynamics</li> </ul>
27 – 31	10 – 11	II	3	13 – 20	raw compost, raw organic products	<ul style="list-style-type: none"> <li>▪ highly active, uncured compost</li> <li>▪ odor production likely</li> <li>▪ high aeration requirement</li> <li>▪ high potential for VFA phytotoxicity and odor</li> <li>▪ high potential for negative impact on soil carbon and nitrogen dynamics</li> </ul>
> 32	> 11	I	1 – 2	> 20	raw feedstock, unstabilized material	<ul style="list-style-type: none"> <li>▪ raw, extremely unstable material</li> <li>▪ odor production expected</li> <li>▪ high aeration requirement</li> <li>▪ probable VFA phytotoxicity with most materials</li> <li>▪ negative impact on soil carbon and nitrogen dynamics expected</li> <li>▪ generally not recommended for use as compost</li> </ul>

REPORTING UNITS:

*SOUR OM* : mg O<sub>2</sub> g<sup>-1</sup> OM d<sup>-1</sup>; *CO<sub>2</sub>-C* : mg CO<sub>2</sub>-C g<sup>-1</sup> OM d<sup>-1</sup>; *Dewar and Solvita®* : refer to respective indices; *BAC OM* : mg CO<sub>2</sub>-C g<sup>-1</sup> OC d<sup>-1</sup>. It is not recommended to report a respirometry test result as the sole measure of compost stability.

NOTE—Anticipate refinement of the compost stability index with advances in compost stability research.

