



BEYOND PESTICIDES

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November 22, 2013

ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

Re: *Comments on the proposed rules for "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (Produce Rule) - Docket Nos. FDA-2011-N-0921; RIN 0910-AG35 and "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" (Hazard Analysis Rule) - FDA-2011-N-0920; RIN 0910-AG36*

Dear Sir/Madam:

Beyond Pesticides would like to thank the U.S. Food and Drug Administration (FDA) for the opportunity to submit these comments concerning the above-noted proposed implementing regulations of the Food Safety Modernization Act (FSMA). While FDA demonstrates its hard work in crafting detailed and thoughtful rules, we do not believe that the rules in their current form align with the intent or specific criteria of FSMA in many critical respects.

As a member of the National Organics Coalition (NOC), we are party to the comments submitted on behalf of the coalition members. The majority of our concerns are outlined and discussed in detail within their comments. Of particular concern is FDA's direct contradiction of the National Organic Program (NOP) standards in several aspects of the regulations, which is expressly prohibited by FSMA.¹ Beyond Pesticides fully supports NOC's identified issues and recommendations for correcting these and the other identified issues and we urge you to adopt the changes proposed within NOC's comments.

Outside of the conflicts with the NOP standards and other issues raised within the NOC comments, however, we believe a few overarching issues warrant separate discussion and correction on the part of FDA. These issues include a need for more expansive chemical and

¹ Food Safety Modernization Act (FSMA), 21 U.S.C. § 350h(a)(3)(E) ("[I]n the case of production that is certified organic, not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990, while providing the same level of public health protection as the requirements under guidance documents, including guidance documents regarding action levels, and regulations under the FDA Food Safety Modernization Act . . .").

biological hazard and protections and the inclusion of efficacious least-toxic alternative in the procedural framework and standards. .

I. FSMA Mandates Prevention of Reasonably Foreseeable Chemical Hazards

FSMA sets forth specific criteria that FDA must include in its FSMA-implementing regulations. Included in those criteria is a requirement that regulations set forth “procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards,”²

Indeed, FDA recognizes in its introductory discussion of the Produce Rule, that prevention of serious adverse health consequences and death arising from chemical hazards is an important aspect of risk prevention measures required under FSMA. Rather than embrace this opportunity to establish a new level of security and protection for our nation’s food supply and the adults and children that consume it, however, FDA defers to current monitoring, regulations, and industry practice.

FDA provides inadequate and inaccurate excuses, such as the following, as to why the agency did not include revised chemical hazard preventions in its Produce Rule:

Illnesses attributable to chemical hazards are rare (Ref. 7). In fact, between 1997 and 2011, there have been no Class I recalls of produce associated with a chemical hazard for which there is a reasonable probability of causing serious health problems or death (Ref. 8) *Current monitoring, regulations, and industry practice have been sufficient to keep these hazards under control.*³

We beg to differ. While we do not dispute FDA’s claims and data that support its statement that “between 1997 and 2011 there have been no Class I recalls of produce associated with a chemical hazard,”⁴ we do take issue with FDA’s incongruent definition of “serious adverse health consequences and death” as applied to chemical hazards.

A. Serious Adverse Health Consequences Need Not Be Acute

The minimum science-based standards required under FSMA⁵ are not limited to acute effects of pathogen-related illness. If Congress had wanted FDA to consider only acute illness and effects,

² FSMA, 21 U.S.C. § 350h(c)(1)(A).

³ Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Rule), U.S. Dept. of Health and Human Services, Food and Drug Admin., 21 CFR Parts 16 and 112, Docket No. FDA-2011-N-0921, RIN 0910-AG35, at 21-22.

⁴ *Id.*

⁵ FSMA, 21 U.S.C. § 350h(a)(1)(A).

it would not have used the broad language of “serious adverse health consequences” and would not have included chemical hazards. There is no timeline attached, directly or implied, in this language.

Yet, FDA’s affirmative decision to ignore consideration of serious adverse health consequences of chemical hazards and focus exclusively on acute, pathogen-related illness, flies in the face of not only modern science and the requirements of FSMA but common sense.

Scientific studies and evidence mount each day concerning the serious adverse health consequences, especially in children and pregnant women, from exposure to chemicals commonly used on and in agricultural and food production. Often these chemicals, the ones that pose the most serious adverse health consequences, are used to control the pests and contamination that the proposed FSMA rules seek so stringently to limit. To name just a couple of the commonly used pest-control agricultural and food product chemicals:

- **Chlorpyrifos:** Chlorpyrifos is a cholinesterase inhibitor which binds irreversibly to the active site of an essential enzyme for normal nerve impulse transmission, acetylcholine esterase (AChE), inactivating the enzyme. Chlorpyrifos is registered for the control of cut-worms, corn rootworms, cockroaches, grubs, flea, beetles, flies, termites, fire ants, mosquitoes, and lice. It is used as an insecticide on grain, cotton, fruit, nut, and vegetable crops, as well as on lawns and ornamental plants. It is also registered for direct use on sheep and turkeys, farmbuildings, storage bins, and commercial establishments. Studies have documented that exposure to low levels of chlorpyrifos during pregnancy can impair learning, change brain function and alter thyroid levels of offspring into adulthood, especially females.^{6,7,8,9} Research also finds that children exposed to high levels of chlorpyrifos had mental development delays, attention problems, attention-deficit/hyperactivity disorder problems, and pervasive developmental disorder problems at 3 years of age.^{10,11}

⁶ Haviland et al. 2009. Long-term sex selective hormonal and behavior alterations in mice exposed to low doses of chlorpyrifos in utero. *Reproduc. Tox.* 29(1):74-9

⁷ Abou-Donia MB, et al. 2006. In utero exposure to nicotine and chlorpyrifos alone, and in combination produces persistent sensorimotor deficits and Purkinje neuron loss in the cerebellum of adult offspring rats. *Arch Toxicol.*;80(9):620-31.

⁸ Abdel-Rahman A, et al. 2003. Increased expression of glial fibrillary acidic protein in cerebellum and hippocampus: differential effects on neonatal brain regional acetylcholinesterase following maternal exposure to combined chlorpyrifos and nicotine. *J Toxicol Environ Health A.*;66(21):2047-66.

⁹ Icenogle LM, et al. 2004. Behavioral alterations in adolescent and adult rats caused by a brief subtoxic exposure to chlorpyrifos during neurulation. *Neurotoxicol Teratol*;26(1):95-101.

¹⁰ Rauh VA. 2006. Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first 3 years of life among inner-city children. *Pediatrics*;118(6):e1845-59.

¹¹ Rauh V, Arunajadai S, Horton M, Perera F, Hoepner L, Barr DB, et al. 2011. Seven-Year Neurodevelopmental Scores and Prenatal Exposure to Chlorpyrifos, a Common Agricultural Pesticide. *Environ Health Perspect* 119:1196-1201.

- **Pyrethroids:** Commonly used on food/feed crops, livestock and livestock housing, modes of transportation, structures, and buildings (including food handling establishments). Several studies have determined that dietary ingestion is a main source of children’s exposure to pyrethroid pesticides.^{12,13} Effects include disturbed dopaminergic and cholinergic pathways which are more pronounced during the "growth spurt" period in the young and may lead to a functional delay in brain maturation.¹⁴

The list goes on. And the serious adverse health consequences connected to the chemicals on that list through science-based research does as well. These studies and the multitude of other science-based research demonstrate that the broad range of serious adverse health consequences are directly linked to agricultural and food production chemicals and that these hazards cannot be assessed in a myopic acute-effects bubble.

More importantly these and other studies demonstrate that the chemical hazard effects can be acute, but are more often delayed and show more dangerous impacts at lower doses that do not lead to acute reactions or symptoms and are not prevented by existing pesticide residue tolerances. Lastly, these and other studies show that the evaluation of what serious adverse health consequences befall a population must not only consider adults, but the most sensitive of populations, like children, infants, and fetuses.

Current chemical hazard protections do not go far enough. FDA’s assertion that it “monitors chemical and pesticide residues in foods through its regulatory monitoring programs with emphasis on raw agricultural commodities (RACs) and foods consumed by infants and children”¹⁵ is insufficient and does not address the fact that the drafters of FSMA envisioned stronger and more clearly defined safeguards.

B. Short-Term Death Should Not Be the Only Consideration

Not only does FDA take too narrow an approach in identifying “serious adverse health consequences” associated with chemical hazards and food, but it also fails to acknowledge potential long-term fatalities associated with chemical hazards. Recognizing that some scientific data linking chemical hazards to fatal effects and diseases can defy traditional risk assessment standards and be difficult to track, it can be challenging and sometimes tenuous to link a specific person’s disease, let alone death, to a specific chemical.

¹² Schettgen T, Heudorf U, Drexler H, Angerer J. 2002. Pyrethroid exposure of the general population-is this due to diet. *Toxicol Lett* 134:141–145.

¹³ Heudorf U, Angerer J, Drexler H. 2004. Current internal exposure to pesticides in children and adolescents in Germany: urinary levels of metabolites of pyrethroid and organophosphorous insecticides. *Int Arch Occup Environ Health* 77:67–72.

¹⁴ Malaviya M, Husain R, Seth PK, Husain R. 1993. Perinatal effects of two pyrethroid insecticides on brain neurotransmitter function in the neonatal rat. *Vet Hum Toxicol*, 35:119-122.

¹⁵ Produce Rule, U.S. Dept. of Health and Human Services, Food and Drug Admin., 21 CFR Parts 16 and 112, Docket No. FDA-2011-N-0921, RIN 0910-AG35, at 21-22.

But this hurdle does not mean that FDA should ignore its obligation to establish procedures and practices that guard against potentially fatal consequences linked to chemical hazards. If enough science-based evidence exists that certain chemicals used in and around food increase a person's chance of developing a fatal disease, such as cancer, no matter how long down the road, then FDA should address this in its regulatory framework and takes steps to protect the public from this reasonably foreseeable danger.

II. FSMA Mandates Prevention of Reasonably Foreseeable Biological Hazards and This Should Include the Hazards of Over-Sterilization and Antibiotic Resistant Pathogens

As discussed in the above section, FDA has to a fault limited the scope of its regulations to address reasonably foreseeable biological hazards. But again, FDA's efforts in this category ignore and, in many ways, exacerbate one of the most pressing and science-based biological hazards of our time: over-sterilization and superbugs.

A. Excess Use of Antimicrobials Can Lead to Reasonably Foreseeable Serious Adverse Health Consequences

We return to the issue of FDA's choice to define "serious adverse health effects" as narrowly as possible and in doing so make the affirmative choice to increase a known biological hazard that falls outside of this narrow definition.

"Antimicrobial resistance is recognized as one of the greatest threats to human health worldwide."¹⁶ "Just one organism, *methicillin-resistant Staphylococcus aureus* (MRSA), kills more Americans every year than emphysema, HIV/AIDS, Parkinson's disease, and homicide combined."¹⁷ According the Centers for Disease Control (CDC), MRSA is now endemic, and even epidemic, in many US hospitals, long-term care facilities (6), and communities (7,8).¹⁸

While many scientific studies of late have focused on the overuse of antibiotics and antimicrobials in livestock,¹⁹ the conclusion and warning is the same: antimicrobial and antibiotic use must be significantly reduced.

Yet, FDA, within its proposed rules, seems intent on ignoring these warnings and making sterile what simply cannot nor needs to be. FDA fails to identify alternative practices and provides a

¹⁶ Infectious Disease Society of America (IDSA), "Facts About Antibiotic Resistance"

¹⁷ IDSA, "Facts About Antibiotic Resistance"

http://www.idsociety.org/IDSA/Site_Map/Topics_of_Interest/Antimicrobial_Resistance/Public_Policy/Facts_about_Antibiotic_Resistance.aspx accessed 2/14/2013.

¹⁸ Eili Klein*, David L. Smith†, and Ramanan Laxminarayan, Hospitalizations and Deaths Caused by Methicillin-Resistant *Staphylococcus aureus*, United States, 1999–2005, Volume 13, Number 12—December 2007, at http://wwwnc.cdc.gov/eid/article/13/12/07-0629_article.htm.

¹⁹ *Industrial Food Animal Production in America: Examining the Impact of the Pew Commission's Priority Recommendations*, Johns Hopkins Center for a Livable Future, Fall 2013, http://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-center-for-a-livable-future/_pdf/research/clf_reports/CLF-PEW-for%20Web.pdf.

blank check for yet another unnecessary and dangerous encouragement of prescriptive antimicrobial pesticide use.

B. Clean Does Not Have to Mean Sterile and Not all Bugs Are Bad

The U.S. Environmental Protection Agency (EPA) acknowledges that even in environments where infectious disease outbreaks occur in the most sensitive of populations (e.g., schools), infectious disease prevention plans should not impose a blanket standard of disinfection and sterility.²⁰ Instead, balanced plans should be adopted that take into consideration the toxic health and environmental effects of many disinfecting agents on sensitive populations and the environment and dictate their use only in specific circumstances.

FDA's regulations ignore these expanded biological hazards and impose rigid standards that associate sterile with clean and provide little room for "clean but not sterile" alternative methodologies. While we understand that the pathogens of concern in the U.S. food supply are nothing to ignore, the procedures and methodologies proposed by FDA do not attempt to distinguish between the good and the bad.

Sterilization and "[a]ntibiotics kill off both good and bad bacteria. This can leave people susceptible to weedy microbes such as antibiotic resistant *Clostridium difficile*, which can cause relentless diarrhea that can be fatal, particularly in older individuals."²¹ Additionally, killing off bad microbes kills the good microbes in the environment, often leading to increased pathogens and pests.²² Challenging though it may be, FSMA requires FDA to examine the bigger picture and consider the full spectrum of biological hazards.

III. FDA Must Establish and Encourage Efficacious Least-Toxic Alternatives

Because the proposed rules fail to broaden chemical hazard standards and protections and also fail to advise on alternative pest control, sanitization, and cleaning methods that are not chemically reliant, the proposed rules may reduce some risks while increasing others. Moreover, FDA does not carry out FSMA's intent by relying on existing regulatory frameworks and standards.

²⁰ *Cleaning, Sanitizing, and Targeted Disinfecting in the Classroom*, U.S. Env't Prot. Agency, http://www.epa.gov/SC3/downloads/Cleaning_Classroom.pdf. ("Schools across the country are adopting comprehensive cleaning programs that address the various demands of cleaning in a school environment. These programs include protocols that help prevent the spread of infectious diseases as well as protocols that help reduce asthma triggers and improve indoor environmental quality.")

²¹ Margaret Munro, *Modern life versus microbes: Our obsession with clean living is harming us*, Edmonton Journal, Nov. 14, 2013, <http://www.edmontonjournal.com/health/Modern+life+versus+microbes+obsession+with+clean+living+harming/9155675/story.html>

²² *Study Sheds Light On Soil Microbes as Key to Ecosystem Health*, Beyond Pesticides Daily News Blog, Nov, 8, 2013, <http://www.beyondpesticides.org/dailynewsblog/?p=12219>.

This can be avoided by establishing within the Produce Rule clearly defined and outlined least-toxic alternatives to achieving new standards and by requiring within the Hazard Analysis Rule least-toxic alternative preventive controls.

IV. Recommendations

Beyond Pesticides raises these issues as overarching problems within both the Produce Rule and Hazard Analysis Rule. On the whole, FDA must adjust its overall approach to both of these rules if our concerns raised within these comments are to be adequately addressed and these deficiencies are to be remedied. Specific examples of amendments that should occur, however, must include the following:

A. Revise the Produce Rule and Hazard Analysis Rule to Go Beyond Existing Chemical Hazard Analysis Standards and Definitions

FDA cannot under FSMA ignore or focus on only a small range of serious adverse effects linked to chemical hazards. It must promulgate rules that include criteria for minimizing the broad range of chemical hazard risks that include not only acute effects, but also long-term and chronic effects. From the agricultural water treatment provisions to the biological soil amendments, to hazard analysis and preventive controls, FDA must revise its orientation that relies on existing and inadequate chemical hazard tolerances and protections as the standard of safety. New rules must not only acknowledge the full range of serious adverse health consequences of many of the chemical hazards, but must also take every step possible to avoid the increased use and introduction of hazardous chemicals into the food supply.

B. Incorporate Procedures, Processes, and Practices that Minimize Serious Adverse Health Consequences from Chemical and Biological Hazards and Establish Cost-Effective Least-Toxic Alternatives.

FDA must also take the additional step of outlining approved practices and procedures that do not require the use of chemicals that pose serious adverse health consequences. This is not achieved with the current rules and cannot be achieved by placing the burden on agricultural and food producers to come up with their own alternatives. Explicit and defined least-toxic alternatives should form the backbone of FSMA's new framework.

V. Conclusion

Again, we appreciate the efforts of FDA and urge that our concerns and recommendations be incorporated into the final rules, thereby assisting the agency in achieving its mission to provide a safer food supply for all. By taking actions to remedy the issues raised in both NOC's comments and ours, we believe that FDA can achieve this mission in the manner envisioned by drafters of FSMA and the American public.

Sincerely,

A handwritten signature in black ink, appearing to read "Aimee Simpson", with a long horizontal flourish extending to the right.

Aimee Simpson

Policy Director and Staff Attorney