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# Cricket Soup: A Critical Examination of the Regulation of Insects as Food

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*Entomophagy—the practice of eating insects—has the potential to help meet the demand for human food and address food insecurities in an environmentally sustainable manner. The realization of the potential of insects as food, however, is not without its challenges. These challenges include the lack of regulation specifically addressing insects as food and the stigma towards the use of insects as food.*

*While the United States Food and Drug Administration (FDA) has devoted significant attention to insects as defects in human food, it has given comparatively little attention to insects as human food. The insect food industry in the United States, while still limited, is growing, as is the number of packaged foods offered for sale that intentionally incorporate insects. This Article critically examines FDA's regulation of insects in the context of food, including its regulation of insects as defects, insect-derived products, and insects as food or a component of food. To date, FDA's regulation of insects as food has been largely characterized by inaction. This Article argues that in light of the substantial law categorizing insects as "filth" under the Federal Food, Drug, and Cosmetic Act (FDCA) and FDA's extensive regulation of insects as filth, this inaction is not neutral and FDA should affirmatively and unambiguously recognize that insects used as food are "food" under the FDCA. FDA should also develop a test to distinguish between insects as food and insects as filth and should consider using intent to distinguish between insects as food and insects as filth. This Article suggests that culturally, insects are not commonly considered food in the United States, in part because FDA has generally regulated insects as filth. By recognizing insects as food, FDA may help to facilitate greater cultural acceptance of the use of insects as food.*

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## INTRODUCTION

The United Nations projects that by 2050 the world's population will increase to 9.7 billion people.[1] This growth will be accompanied by an increased demand for food.[2] Incomes are also rising,[3] and with them the demand for meat

1. Dep't of Econ. & Soc. Affairs, *World Population Prospects: The 2015 Revision*, UNITED NATIONS 1–2 (2015), http://esa.un.org/unpd/wpp/Publications/Files/Key_Findings_WPP_2015.pdf [http://perma.cc/7ZGL-2D7D]. The estimated population at the time this Article was written was approximately 7.3 billion people. *Id.*

2. *See, e.g.*, H. Charles J. Godfray et al., *Food Security: The Challenge of Feeding 9 Billion People*, 327 SCI. 812 (2010).

3. *See, e.g.*, Godfray et al., *supra* note 2; Ronald Trostle & Ralph Seely, *Developing Countries Dominate World Demand for Agricultural Products*, U.S. DEP'T OF AGRIC. ECON. RES. SERV. (Aug. 5, 2013), http://www.ers.usda.gov/amber-waves/2013/august/developing-countries-dominate-world-demand-for-agricultural-products/ [http://perma.cc/UBR5-5DA7].

protein.[4] Current food production contributes to serious environmental problems—including climate change. In particular, meat production has significant environmental repercussions. Furthermore, by midcentury, environmental changes are expected to negatively affect crop and livestock production. There is a critical need to consider how to feed the projected future population in a way that is sustainable and advances human and environmental health.[5] Insects, which can be a good source of nutrients, have the potential to help address some of the challenges that increased demands for food and meat are likely to pose, and should be further explored as a food source.[6]

A 2013 report by the Food and Agriculture Organization of the United Nations (FAO) on the "potential of insects as food," argues that entomophagy—the practice of eating insects—may enhance food security and offer a variety of health, environmental, economic, and social benefits.[7] It describes edible insects as "a promising alternative for the conventional production of meat," including for "direct human consumption."[8] Harnessing the potential of insects as human food, however, is not without its challenges. The FAO identifies "the absence of clear legislation and norms guiding the use of insects as food" in developed countries as a "major" factor limiting the potential of insects as human food.[9] The report notes that there is an "absence of *specific* legislation on the use of insects as food and feed" and states that there is a need for "clear and comprehensive" legal frameworks, including on the national level, for the use of insects as

4. *See, e.g.*, Godfray et al., *supra* note 2; David Tilman & Michael Clark, *Global Diets Link Environmental Sustainability and Human Health*, 515 NATURE 518 (2014); Todd Reubold, *Global Meat Consumption Will Soar by 2024. But What Meat Is Eaten Makes a Big Difference in the Impact.*, PUB. RADIO INT'L (Dec. 1, 2015), http://www.pri.org/stories/2015-12-01/global-meat-consumption-will-soar-2024-what-meat-eaten-makes-big-difference [http://perma.cc/J4RY-TMJV].

5. *See, e.g.*, R. Quentin Grafton et al., *Towards Food Security by 2050*, 7 FOOD SEC. 179 (2015); Tilman & Clark, *supra* note 4.

6. *See, e.g.*, Arnold van Huis et al., *Edible Insects: Future Prospects for Food and Feed Security*, FOOD & AGRIC. ORG. UNITED NATIONS (2013), http://www.fao.org/docrep/018/i3253e/i3253e.pdf [http://perma.cc/LZ56-2GX7] [hereinafter FAO REPORT]; Juliet Ramos-Elorduy, *Insects: A Sustainable Source of Food*, 36 ECOLOGY FOOD & NUTRITION 247, 267-68 (1997).

7. FAO REPORT, *supra* note 6. While the report also discusses the use of insects as feed, the use of insects as food for non-human animals is beyond the scope of this Article.

8. *Id.* at 161.

9. *Id.* at xvi; *see also* Ben Klayman, *Edible Bug Industry Hopes Crickets and Kin Are the Next Sushi*, REUTERS (May 27, 2016), http://www.reuters.com/article/us-usa-ediblebugs/edible-bug-industry-hopes-crickets-and-kin-are-the-next-sushi-idUSKCN0YI1B4 [http://perma.cc/42T4-3UXM] (stating that the head of "a nonprofit founded to educate the public on the nutritional and environmental benefits of edible insects" indicated that "regulatory uncertainty" was hindering investment in "edible bugs").

food.[10] In the United States, the Food and Drug Administration (FDA) has devoted significant attention to insects in human food as defects, but has given little public attention to insects as human food or as an intentional component of human food.

While worldwide an estimated 2 billion people practice insect eating,[11] in the United States the predominate cultural conceptions of food do not generally encompass insects. The very idea of eating insects elicits disgust for many. This negative attitude towards entomophagy—which is largely shared by people in other Western countries—may serve as a barrier to consumer acceptance of insects as food and an alternative to conventional meat and meat products.[12] It may also hamper the development of insects for these uses by hindering investment in and research on their use and production.[13] Despite the negative

10. FAO REPORT, *supra* note 6, 154 (emphasis added).

11. P.J. GULLAN & P.S. CRANSTON, THE INSECTS: AN OUTLINE OF ENTOMOLOGY 20 (2014); *see also* FAO REPORT, *supra* note 6, at 1. This number would be much higher if insects as food defects were also included because we all consume insects as natural and unavoidable defects in food. *See Defect Levels Handbook,* U.S. FOOD & DRUG ADMIN., (Dec. 6, 2016) [hereinafter *FDA Defect Levels Handbook*], http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm056174.htm [http://perma.cc/E5VK-URME].

12. *See* FAO REPORT, *supra* note 6, 161-62.

13. FAO REPORT, *supra* note 6, at xiii, xvi, 154, 161; *see also* Gene R. DeFoliart, *Insects as Food: Why the Western Attitude Is Important*, 44 ANN. REV. ENTOMOLOGY 21, 44 (1999) (stating that "[t]he primary need is to eliminate or greatly reduce the Western-driven stigma that has been cast over the use of insects as food, thus providing opportunities for more research").

The FAO notes that, with a few exceptions, "farming insects for food is . . . relatively new" and "[a] few industrial scale enterprises are . . . in various stages of start-up for rearing mass quantities of insects." FAO REPORT, *supra* note 6, at xiv; *see also* Allen Carson Cohen, *Formalizing Insect Rearing and Artificial Diet Technology*, 47 AM. ENTOMOLOGIST 198, 198 (2001) (arguing that there is a need to "formaliz[e] . . . insect rearing" more generally "to advance it as a science and technology"). In addition, there is a need to make insect production "more competitive with regard to meat." Birgit A. Rumpold & Oliver K. Schluter, *Potential and Challenges of Insects as an Innovative Source for Food and Feed Production*, 17 INNOVATIVE FOOD SCI. & EMERGING TECH. 3 (2013). In the United States, in May 2017, several websites were selling one pound bags of roasted crickets for approximately $40, *see, e.g.*, *Crickets: Whole Roasted*, ENTOMO FARMS, http://entomofarms.com/product/crickets-whole-roasted/ [http://perma.cc/33W5-QYD8] ($40); *Edible Roasted Crickets*, EDIBLE INSECTS, http://www.edibleinsects.com/entomophagy/roasted-crickets/ [http://perma.cc/QJ5W-DJKS] ($39.99); *Aketta Whole Roasted Crickets*, AKETTA, http://shop.aketta.com/products/crispy-aketta-whole-crickets [http://perma.cc/W8MD-LRSM] ($37.99), a price far exceeding that of many commonly consumed meats and poultry, *see, e.g.*, Bureau of Labor Statistics, *Average Retail Food and Energy Prices, U.S. City Averages and Northeast Region*, U.S. DEP'T OF LAB., http://www.bls.gov/regions/midatlantic/data/averageretailfoodandenergyprices_usandnortheast_table.htm [http://perma.cc/96LJ-RRVK]. The high cost of crickets

view that many consumers in the United States have of entomophagy, some have accepted insects as food and there is a small but growing insect food industry in the United States.[14] Indeed, several companies selling insects as food specifically promote insects as a "sustainable" alternative to other animal proteins.[15]

This Article is the first to critically examine FDA's regulation of insects as human food or an intentional component of food and to explore how FDA might regulate these foods using its existing authority and regulatory processes. It argues that as an initial matter, FDA should specifically affirm that insects used as food are "food" under the Federal Food, Drug and Cosmetic Act's (FDCA) broad definition of that term.[16] In addition, FDA should distinguish between insects as "food" and insects as "filth." In light of its substantial regula-

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and other insects for human consumption is likely due, at least in part, to the current state of knowledge regarding insect rearing and the current production processes used. *See, e.g.,* Rumpold & Schluter, *supra*, at 3-5, 9 (discussing the production and processing of edible insects and arguing technological developments in these areas are needed). Scientific and technologic developments coupled with economies of scale may help bring down the cost of production of insects as food. *See* Frank Asche & Trond Bjørndal, *Aquaculture: Production and Markets* 60-61, *in* HANDBOOK OF MARINE FISHERIES CONSERVATION AND MANAGEMENT (R. Quentin Grafton et al. eds., 2010) (discussing the growth of aquaculture and its importance in producing seafood for human consumption and stating that "[c]ontrol of the production process allowed technological innovation that reduced production costs[, and] . . . made the product more competitive and the industry more profitable, which led to increased production and lower prices for consumers"); *see also id.* at 63 (discussing the "significant reductions in price" of salmon and shrimp that have accompanied "increased production from aquaculture"). FDA appears to have rejected the sale of "wildcrafted" insects—insects that are "collected in the wild"—for human food because of concerns regarding potential diseases or pesticides. Dr. George Ziobro, FDA Ctr. for Food Safety & Applied Nutrition, Presentation at the Institute of Food Technologists (IFT) 2015, Regulatory Issues, Concerns, and Status of Insect Based Foods and Ingredients, slide 4 (Chicago, Ill., July 13, 2015) (FDA's Standard Entomophagy Response) (on file with author). And even if FDA were to permit wildcrafted insects, wild stocks may be unable to sustain widespread commercialization. *See, e.g.*, FAO REPORT, *supra* note 6, at 45 (discussing potential problems with collecting insects from the wild).

14. *See* Laurie Tarkan, *Why these Startups Want You to Eat Bugs*, FORTUNE (Aug. 25, 2015), http://fortune.com/2015/08/25/edible-insects-bug-startups/ [http://perma.cc/LR7W-MPU3] (noting that one entomologist indicated in 2015 that "[i]n the past three or four years, more than 25 startups that sell insects as food have been launched in the U.S. and Canada").

15. *See, e.g.*, *12 Reasons Why You Should Consider Insect Protein*, ENTOMO FARMS, http://entomofarms.com/future-of-food/#12reasons [http://perma.cc/KF8L-GQ5H]; *Why Crickets?*, EXO PROTEIN, http://exoprotein.com/pages/why-crickets [http://perma.cc/G49L-4WNB]; *Why Eat Crickets*, CHAPUL, http://chapul.com/pages/why-eat-crickets [http://perma.cc/24B8-2CGH].

16. *See* Food, Drug, and Cosmetic Act § 201(f), 21 U.S.C. § 321(f) (2012); Ziobro, *supra* note 13.

tion of insects as "filth,"[17] FDA's regulatory inaction with respect to insects as food is not neutral and it may reflect and reinforce predominate cultural conceptions of food, which do not include insects.[18] Culturally, insects may not be commonly regarded as food, in part, because they have been generally regulated as defects and not as food.[19] By recognizing insects as food and regulating them as such, FDA may help to erode the stigma surrounding these products and may help to advance the study and development of insects as food and as an alternative to conventional animal proteins.[20] This would be consistent with FDA's mission to protect and promote the public health.[21]

This Article proceeds as follows: Part I provides a brief introduction to entomophagy, highlights some of the potential benefits of using insects as food, and explains this Article's focus on FDA. Part II examines how FDA has regulated insects as defects or contaminants in foods. It then considers FDA's regulation of predacious insects added to food to control pest insects and FDA's regulation of two insect-derived color additives. Part III examines FDA's limited statements regarding insects as food and considers how FDA may regulate insects using the general regulatory processes for food. This examination highlights several uncertainties and challenges. Part IV then argues that there is a need for FDA to officially recognize that insects can be "food" under the FDCA and suggests using the concept of intent to distinguish between insects as food and insects as filth. Part IV concludes by explaining how the legal recognition of

17. FDCA § 402(a)(3)-(4), 21 U.S.C. § 342(a) (2012) (providing that a food is adulterated if it consists of any "filthy" substance or if it has been produced "under insanitary conditions whereby it may have become contaminated with filth"); *see infra* Section II.A (discussing the regulation of insects as filth).

18. J. Richard Gorham, *The Significance for Human Health of Insects in Food*, 24 ANN. REV. ENTOMOLOGY, 209, 213 (1979) (noting that one review of entomophobia notes that the public's revulsion and fear of insects "[is] not at all helped by government regulations that refer to insect parts as filth, lumping them together with rodent droppings, the inference being that any insect part is evil whether from beneficial or pest species")(internal citation and quotation marks omitted).

19. This is not to say that the converse may also be true: Insects may be generally regulated as defects and not as food, in part because they are not commonly regarded as food. *See* Naomi Mezey, *Law as Culture*, 13 YALE J. L. & HUMAN. 35, 55 (2001) (discussing law as culture as law).

20. Rachel Feltman, *What Does the Insect Industry Want? A Cricket in Every Pot*, WASH. POST. (Dec. 1, 2016), http://www.washingtonpost.com/lifestyle/magazine/what-does-the-insect-industry-want-a-cricket-in-every-pot/2016/11/30/e1fd11fc-9f94-11e6-8832-23a007c77bb4_story.html [http://perma.cc/KBT5-VXPF] (stating that "[b]ecause food suppliers and consumers are less familiar with crickets than with beef, [the industry] will likely have to push for more-explicit farming and production guidelines to protect and reassure the public—essentially putting [it] in the odd position of seeking more oversight").

21. FDCA § 903(b), 21 U.S.C. § 393(b) (2012); *About FDA*, U.S. FOOD & DRUG ADMIN. (Apr. 4, 2017), http://www.fda.gov/aboutfda/whatwedo/#mission [http://perma.cc/L8J7-728W] (describing FDA's mission).

insects as food may help to erode some of the cultural barriers surrounding the use of insects as food.

## I. Background

### *A. "Insect" and "Bug" Defined*

Insects are invertebrate animals in the class Insecta and phylum Arthropoda.[22] Insects have a head, a thorax, and an abdomen; three pairs of legs;[23] and "typically one or two pairs of wings."[24] Neither spiders, which are in the class Arachnida, nor centipedes, which are in the class Chilopoda, are insects.[25] Informally, however, "most people tend to regard anything with an excess of legs as an insect,"[26] and several dictionaries define insects to include spiders and centipedes.[27] Consistent with the popular usage of the term "insect" as well as much of the literature discussing the human consumption of insects, this Article uses the term "insect" to refer to both insects as well as arthropod species that taxonomically are not insects, such as spiders.[28]

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22. Gordon Gordh & David Headrick, A Dictionary of Entomology 735-36 (2d ed. 2011).

23. *See, e.g.*, Mary R. Berenbaum, Bugs in the System: Insects and Their Impact on Human Affairs 10 (1995).

24. *Insect*, Merriam-Webster (2017), http://www.merriam-webster.com/dictionary/insect [http://perma.cc/RKD4-8NZ7]; Tom Turpin, *Insect Wings Aren't Just for Flying, On Six Legs*, Purdue Extension (Apr. 26, 2007), http://www.agriculture.purdue.edu/agcomm/newscolumns/archives/OSL/2007/April/070426OSL.htm [http://perma.cc/26ZW-7T8C] (stating that "most but not all insects have wings in the adult form").

25. Jan Beccaloni, Arachnids 5 (2009); J.G.E. Lewis, The Biology of Centipedes 1 (2007).

26. Berenbaum, *supra* note 23, at 8.

27. *See, e.g.*, *Insect*, *supra* note 24 (defining insect to include "any of numerous small invertebrate animals (as spiders or centipedes) that are more or less obviously segmented" and noting that this definition is "not used technically"); *Insect*, The American Heritage Dictionary of the English Language 907 (5th ed. 2011) (defining insect to include true insects as well as "[a]ny of various other small, chiefly arthropod animals, such as spiders, centipedes, or ticks, usually having many legs" and noting that this later definition is "[n]ot in scientific use").

    Similarly, the term "bug" is used to refer both to insects as well as to "other creeping or crawling invertebrate (as a spider or centipede)." *See, e.g.*, *Bug*, Merriam-Webster's Collegiate Dictionary (2012). Taxonomically, however, "only Species of Hemiptera [are] correctly called 'bugs.'" Gordon Gordh & David Headrick, A Dictionary of Entomology 147 (1st ed. 2003).

28. *See, e.g.*, FAO Report, *supra* note 6, at 2 (stating that the report "covers other arthropod species eaten by humans, such as spiders and scorpions, which, taxonomically speaking, are not insects"); Ziobro, *supra* note 13 (referring to "bugs/insects").

Even using the narrower taxonomic meaning of the term insects, insects represent a substantial portion of the world's species.[29] Estimates of the number of insect species vary substantially, and are as high as 80 million,[30] although one entomology textbook notes that "[a] figure of between two and six million species . . . appears realistic."[31] There are substantial differences among different species of insects as well as among the same species at different metamorphic stages.[32] Insects are thought to represent "at least half of global species diversity" and "an even greater proportion of extant [terrestrial] species."[33] Insects are pervasive; they occupy our homes,[34] our offices, and yes, even our food.[35]

### *B. Entomophagy*

#### 1. History and Practice

The term entomophagy comes from the Greek words "entomon" (insects) and "phagein" (to devour).[36] The practice of eating insects has deep roots, with the earliest known records of this practice dating from approximately 700 B.C.[37] Numerous writers have penned observations of or arguments for its practice.[38]

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29. *Numbers of Insects (Species and Individuals)*, ENCYCLOPEDIA SMITHSONIAN, http://www.si.edu/encyclopedia_si/nmnh/buginfo/bugnos.htm [http://perma.cc/D7DG-GDMM].

30. *See* P.J. GULLAN & P.S. CRANSTON, THE INSECTS: AN OUTLINE OF ENTOMOLOGY 6 (2014); *Numbers of Insects*, *supra* note 29.

31. GULLAN & CRANSTON, *supra* note 30.

32. *See* EFSA Sci. Comm., *Risk Profile Related to Production and Consumption of Insects as Food and Feed*, 13 EFSA J. 4257 (2015).

33. GULLAN & CRANSTON, *supra* note 30, at 7; *Numbers of Insects*, *supra* note 29.

34. *See* Matthew A. Bertone et al., *Arthropods of the Great Indoors: Characterizing Diversity Inside Urban and Suburban Homes*, 4 PEER J. e1582 (2016), http://peerj.com/articles/1582/ [http://perma.cc/E8FM-KPRF] (noting that "humans and arthropods have been living and evolving together for all of our history" and identifying a "rich arthropod diversity" in the sampled houses).

35. *See FDA Defect Levels Handbook*, *supra* note 11.

36. GORDH & HEADRICK, *supra* note 27, at 511.

37. For a fuller examination of the history and practice of entomophagy, see BERENBAUM, *supra* note 23, at 180; *see also* FAO REPORT, *supra* note 6, at 40-44 (discussing the history of entomophagy); Gene R. DeFolirat, *Foreword*, *in* JULIETA RAMOS-ELORDUY, CREEPY CRAWLY CUISINE: THE GOURMET GUIDE TO EDIBLE INSECTS viii (1998) ("prehistorically[,] . . . insects have played an important role in global nutrition.").

38. *See, e.g.*, MARVIN HARRIS, GOOD TO EAT: RIDDLES OF FOOD AND CULTURE 160-61 (1998) (discussing writers advocating for insect eating); FAO REPORT, *supra* note 6, at 41.

There are also a number of religious references to entomophagy.[39] For example, the tradition of eating some insects has been recognized in Christian,[40] Islamic,[41] and Jewish faiths.[42] Although, the practice has at times generated debate as to its permissibility. For example, in the Jewish faith, there has been debate over whether insects are kosher.[43]

Although precise estimates are difficult,[44] almost "2,000 species of insects . . . are, or have been, used for food."[45] Beetles, grasshoppers and crickets; butterflies and moths; bees, wasps and ants; true bugs; and dragonflies are most

39. *See, e.g.*, BERENBAUM, *supra* note 23, at 180-81 (discussing the treatment of entomophagy in the Old Testament, the Mishnah Torah, and the Koran).

40. *Leviticus* 11:22 (King James) (referring to the consumption of locusts, beetles, and grasshoppers).

41. *See Is Eating Insects Lawful?*, ISLAMIC INFO. PORTAL (Oct. 3, 2013), http://islam.ru/en/content/story/eating-insects-lawful [http://perma.cc/6HWJ-SULT] (noting that "[s]cholars debated and had different opinions regarding the permissibility of eating insects" and providing examples); *see also What Is the Ruling for Eating Insects?*, DAR AL-IFTA AL-MISSRIYYAH, http://www.dar-alifta.org/Foreign/ViewFatwa.aspx?ID=6872 [http://perma.cc/M2H2-WCF4] (stating that "[i]t is permissible to use the insects and consume the substances manufactured from them for medicinal reasons [if it is proven that] they treat diseases or malnutrition without producing any harmful side effects," "[o]therwise, they are forbidden").

42. *See* Zohar Amar, *The Eating of Locusts in Jewish Tradition After the Talmudic Period*, 11 TORAH U-MADDA J. 186 (2002) (discussing texts addressing the consumption of insects and whether an insect is kosher as well as written documentation of entomophagy in Jewish tradition); *see also* Yair Ettinger, *Rabbi Warns Locust-eaters: Insects May Not Be Kosher*, HAARETZ (Mar. 7, 2013), http://www.haaretz.com/jewish/news/rabbi-warns-locust-eaters-insects-may-not-be-kosher.premium-1.507815 [http://perma.cc/Q66X-YTDQ] (noting that "eating locusts has been controversial according to Jewish law for generations" and that "a prominent rabbi banned it").

    The presence of small traces of insects on strawberries that are invisible to the naked eye has led some orthodox Jewish rabbis to wrestle with the question of whether strawberries with such insects are considered kosher. *See, e.g.*, *Rabbis Say Strawberries Not Kosher*, VOS IZ NEIAS? (June 12, 2007), http://www.vosizneias.com/9757/2007/06/12/new-york-rabbis-say-strawberries-not/ [http://perma.cc/HF2W-FZGY]; *Rav Amar: Strawberries Kosher and May Be Eaten*, VOS IZ NEIAS? (May 17, 2009 12:58 PM), http://www.vosizneias.com/31892/2009/05/17/jerusalem-rav-amar-strawberries-kosher-and-may-be-eaten/ [http://perma.cc/DBD6-GNZN].

43. *See generally supra* note 42.

44. *See* FAO REPORT, *supra* note 6, at 9 (identifying challenges in determining the number of edible insect species).

45. GULLAN & CRANSTON, *supra* note 30, at 20. *But see* FAO REPORT, *supra* note 6, at xii, 9 (noting that "1,417 species of edible insects have been recorded in the world").

commonly consumed.[46] Insects are eaten both by necessity and by choice. Insects can serve as a valuable source of calories and nutrients in diets that may otherwise be lacking.[47] For example, there is a "long cultural history of eating insects" in Thailand, where "[h]istorically, insects generally were eaten only by poor people . . . [and] still serve as food for the poor today."[48] Insects, however, can also be a luxury food whose cost exceeds that of meat on a pound per pound basis.[49] For example, "the Oriental Hotel in Bangkok, [Thailand,] one of the world's finest and most expensive hotels and home to an internationally highly regarded culinary academy," featured "Larvae of Honey Bee Queens" as a menu item.[50] Many eat insects because of their "palatability" and "their established place in local food cultures,[51] "as people in many societies make insects an integral part of their diet,"[52] and consider them a delicious delicacy.[53]

46. *See, e.g.*, RAMOS-ELORDUY, *supra* note 37, at 5-6, tbl.1; *see also* GULLAN & CRANSTON, *supra* note 30, at 20 ("Termites, crickets, grasshoppers, locusts, beetles, ants, bee brood and moth larvae are frequently consumed insects."); HARRIS, *supra* note 38, at 156 ("People around the globe seem to be especially fond of locusts, grasshoppers, crickets, ants, termites, and the larvae and pupae of large moths, butterflies, and beetles."); FAO REPORT, *supra* note 6, at xiii, 1 (listing the most commonly consumed insects as beetles, caterpillars, and bees, wasps and ants).

47. *See, e.g.*, FAO REPORT, *supra* note 6, at xi; Wulf Schiefenhövel & Paul Blum, *Insects: Forgotten and Rediscovered as Food: Entomophagy Among the Eipo Highlands of West New Guinea, and in other Traditional Societies*, *in* CONSUMING THE INEDIBLE: NEGLECTED DIMENSIONS OF FOOD CHOICE (ANTHROPOLOGY OF FOOD & NUTRITION) 173 (Jeremy M. MacClancy et al. eds., 2009) (describing how the Eipo people in the highlands of Indonesian West New Guinea gathered insects to "provide[] a 'protein niche' for [the women and children] who need this precious food most").

48. P.P. Chen, et al., *Honey Bees and Other Edible Insects Used as Human Food in Thailand*, 44 AM. ENTOMOLOGIST 24, 25 (1998).

49. *See, e.g.*, RAMOS-ELORDUY, *supra* note 37, at 17.

50. P.P. Chen, *supra* note 48, at 25.

51. FAO REPORT, *supra* note 6, at xi.

52. Jeremy MacClancy et al., *Introduction: Considering the Inedible, Consuming the Ineffable*, *in* CONSUMING THE INEDIBLE, *supra* note 47, at 10; *see also* FAO REPORT, *supra* note 6, at 36 (noting that while "insect consumption is commonplace in the tropics," "insects are also consumed in countries partially or fully in temperate zones, such as China, Japan, and Mexico") (internal citations omitted).

53. *See, e.g.*, FAO REPORT, *supra* note 6, at xi ("[M]any people around the world eat insects out of choice."); GULLAN & CRANSTON, *supra* note 30, at 24; ENCYCLOPEDIA OF INSECTS (Vincent H. Resh & Ring T. Cardé eds., 2003); RAMOS-ELORDUY, *supra* note 37; Dana Goodyear, *Grub*, NEW YORKER (Aug. 15, 2011), http://www.newyorker.com/magazine/2011/08/15/grub [http://perma.cc/UH4P-R54W] ("Insects were among the original specialty foods in the American gourmet marketplace.").

While the nutritional value of insects varies depending on the species, metamorphic stage, habitat, and diet,[54] one review of the nutritional composition of edible insects generally found them "to be highly nutritious and to represent good sources of proteins, fat, minerals, vitamins, and energy."[55] For example, one study found that "insects and meat did not show significant divergence in nutritional composition suggest[ing] that there is no health-related trade-off in promoting insect foods over meat."[56] In fact, the study found that "several insects are potentially superior to meat in situations of undernutrition."[57]

In the United States, however, entomophagy has long been considered outside of the norm, and the idea of eating insects is often met with disgust. This view of entomophagy is shared by many in other western countries.[58] It is most Westerners—Europeans and Americans—however, "who are out on a limb" with their reaction to entomophagy,[59] as "eighty per cent of the world eats insects with pleasure."[60]

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54. *See* FAO REPORT, *supra* note 6, at 83; Birgit A. Rumpold & Oliver K. Schlüter, *Nutritional Composition and Safety Aspects of Edible Insects*, 57 MOLECULAR NUTRITION & FOOD RES. 802, 807, 811, 820 (2013); *see also* Mark E. Lundy & Michael P. Parrella, *Crickets Are Not a Free Lunch: Protein Capture from Scalable Organic Side-Streams via High-Density Populations of Acheta domesticus*, 10(4) PLOS ONE E0118785 (2015) (discussing limitations of insects as food).

55. Rumpold & Schlüter, *supra* note 54, at 802, 806 tbl.1 (reviewing literature on the nutrient content of various insects and providing nutritional information for various insects); *see, also FAO/INFOODS Food Composition Database for Biodiversity*, FOOD & AGRIC. ORG. UNITED NATIONS (Apr. 12, 2016), http://www.fao.org/infoods/infoods/tables-and-databases/faoinfoods-databases/en/ [http://perma.cc/8VDU-CULY] (compiling nutrition information for a variety of insects).

56. C.L.R. Rayne, et al., *Are Edible Insects More or Less 'Healthy' Than Commonly Consumed Meats? A Comparison Using Two Nutrient Profiling Models Developed to Combat Over- and Undernutrition*, 70 EUR. J. CLINICAL NUTRITION 285, 289 (2015).

57. *Id.* at 290.

58. *See, e.g.*, *Arthropods: Insects, Arachnids, and Crustaceans*, 1 ENCYCLOPEDIA FOOD & CULTURE 127, 128 (Solomon H. Katz ed., 2003) (stating that "European populations and European-derived populations in North America historically have placed taboos on entomophagous eating practices . . . and continue to do so"); BERENBAUM, *supra* note 23, at 177, 184 (stating that "[t]he reaction of most Americans to eating insects is a mixture of distaste and disbelief"); FAO REPORT, *supra* note 6, at 39 (stating that "by and large, negative perceptions surrounding insects are fully entrenched in Western societies").

59. MacClancy et al., *supra* note 52, at 10. Despite this reaction, in 2015, the European Commission (EC) addressed insects as human food in its novel food regulation. *See* Press Release, European Commission MEMO/15/5875, Questions and Answers: New Regulation on Novel Food (Nov. 16, 2015), http://europa.eu/rapid/press-release_MEMO-15-5875_en.htm [http://perma.cc/B8Q9-Y585]. In addition, the European Food Safety Authority (EFSA) upon the EC's request prepared a scientific risk assessment on the hazards of using farmed

The aversion to and rejection of insects as food is culture-specific.[61] This aversion, however, is not limited to the West and it may influence the perception and practice of entomophagy elsewhere.[62] But cultural taboos, such as the

insects as food. EFSA Sci. Comm., *supra* note 32.

60. Goodyear, *supra* note 53.

61. Schiefenhövel & Blum, *supra* note 47, at 163; *see also* FAO REPORT, *supra* note 6, at 36; Heather Looy et al., *How Then Shall We Eat? Insect-eating Attitudes and Sustainable Foodways*, 31 AGRIC. HUM. VALUES 131, 136 (2014) (noting that "what we find disgusting is primarily learned"). For example, while insects are often "'associated with filth,'" lobsters—which are also arthropods, but which "instead of eating fresh lettuces and flowers, as many insects do, . . . scavenge debris from the ocean floor"—are a delicacy. Goodyear, *supra* note 53 (internal citation omitted).

This is not to say that an aversion to insects as food may not also serve as "a protective mechanism." *See Acceptance and Rejection: Fear of the New*, 1 ENCYCLOPEDIA OF FOOD & CULTURE, *supra* note 58, at 2 (noting that food neophobia "is especially strong for foods of animal origin . . . , the same foods that elicit reactions of disgust, also thought to be a protective mechanism"). As discussed in Part III, insects in or as food may pose significant health hazards. *See generally* Gorham, *supra* note 18, at 209-24.

For additional examples of the acceptance or rejection of specific animals as food in different cultures, see HARRIS, *supra* note 38, at 14 ("If you are born and raised in the United States, you tend to acquire certain American food habits. You learn to enjoy beef and pork, but not goat or horse, or grubs or grasshoppers. . . . Yet horseflesh appeals to the French and Belgians; most Mediterranean people are fond of goat meat; [and] grubs and grasshoppers are widely esteemed as delicacies."); *id.* at 15-16 (stating that he does "not wish to deny that foods convey messages and have symbolic meanings," but arguing that "major differences in world cuisines can be traced to ecological restraints and opportunities which differ from one region to another"); Adel P. Den Hartog, *Taboos*, 3 ENCYCLOPEDIA OF FOOD & CULTURE 384, 385 (Solomon H. Katz ed., 2003) ("In the United States and other countries with Anglo-Saxon traditions horsemeat is not part of the food culture. This is in contrast to continental Europe, in particular France, where horsemeat is a well-known and appreciated food. The history of horsemeat gives insight into how attitudes toward food avoidance change over the course of time."); Carmen Strungaru, *Consuming the Inedible: PICA Behaviour*, *in* CONSUMING THE INEDIBLE, *supra* note 47, at 34 ("Vast differences in defining what is edible are found. Horse meat is considered perfectly edible in France and much less so in other parts of Europe; dog meat is eaten by members of some Asian societies. Insects, worms, algae, parasites, are delicacies or common food sources on other meridians.").

62. *See, e.g.*, *Arthropods*, *supra* note 58, at 130 (stating that the "worldwide general trend towards the reduction of entomophagous eating practices" may be a result of "the trend toward the adoption of westernized diets"); HARRIS, *supra* note 38, at 160 (noting that "the loathing in which insectivory is held by Europeans and Americans has been communicated to the food experts of less developed countries and this has made them reluctant to study the contribution of insects to national diet, or even admit that their compatriots eat any insects at all"); Looy, et al., *supra* note 61, at 133-34 (discussing the impact of Western culture on insect eating).

aversion to insects as food can be "dynamic."[63] Among at least some consumers in the United States, the perception of entomophagy may be changing.[64]

While the availability of and market for insects is still limited,[65] insects are increasingly showing up in packaged food—and on restaurant menus—as food.[66] For example, after appearing on the television show Shark Tank in

63. J. Richard Gorham, *A Rational Look at Insects as Food*, 5 FDA BY-LINES 231 (Mar. 1976); *see also* M.B. Ruby et al., *Determinants of Willingness To Eat Insects in the USA and India*, 1 J. INSECTS AS FOOD & FEED 215, 216 (2015) ("Insects are generally considered disgusting, but people come to enjoy disgusting things."); Eric J. Hamerman, *Cooking and Disgust Sensitivity Influence Preference for Attending Insect-Based Food Events*, 96 APPETITE 319, 319 (2016) (investigating "the factors that influence willingness to attend an event at which foods that contain insect-based ingredients are served"); Jonas House, *Consumer Acceptance of Insect-Based Foods in the Netherlands: Academic and Commercial Implications*, 107 APPETITE 47, 47-49 (2016) (discussing research on consumer acceptance of insects as food in the West); Wim Verbeke, *Profiling Consumers Who Are Ready to Adopt Insects as a Meat Substitute in a Western Society*, 39 FOOD QUALITY & PREFERENCE 149, 149 (2015) (reporting on a study "profil[ing] consumers [in Belgium] who claim to be ready or willing to eat insects"). Some consumers—e.g., members of certain religious faiths—however, may have permanent food taboos that prevent them from intentionally consuming insects as food. *See supra* notes 41-42.

64. *See* M.B. Ruby et al., *supra* note 63; *see also* House, *supra* note 63.

65. *See* Brian Patrick Eha, *The Whole 'Eating Bugs' Thing Actually Has Legs*, FORTUNE (Apr. 18, 2016), http://fortune.com/2016/04/18/eating-bugs-insect-protein/ [http://perma.cc/7448-4BZP]; Tarkan, *supra* note 14.

66. MacClancy et al., *supra* note 52, at 10; Kyle Ligman, *Weak Oversight Is Holding Back Edible Insects*, NEWSWEEK (Mar. 28, 2015), http://www.newsweek.com/2015/04/10/weak-oversight-holding-back-edible-insects-317518.html [http://perma.cc/93ZZ-3Y4K]; Tarkan, *supra* note 14; *see also 5 Restaurants That Make Bugs Taste Delicious*, HUFFINGTON POST (Nov. 4, 2013), http://www.huffingtonpost.com/the-daily-meal/5-restaurants-that-make-b_b_4192483.html [http://perma.cc/EH8U-J83R]; *Aztec Dark Chocolate & Coffee Protein Bar 12 Pack*, CHAPUL, http://chapul.com/products/aztec-bar-12-pack [http://perma.cc/TQQ9-WYXG] (selling protein bars made with cricket flour); *Chirps Are Chips Made with Cricket Flour*, CHIRPS, http://www.sixfoods.com/#products [http://perma.cc/W68J-W29R] (offering for sale three flavors of "Chirps" (cricket chips)); *Menu*, THE BLACK ANT, http://theblackantnyc.com/dinner/ [http://perma.cc/BD5W-KVLU] (offering dishes including black ants and grasshoppers); *Real Scorpion Suckers,* HOTLIX, http://www.hotlix.com/candy/ [http://perma.cc/53YD-V2L4] (selling a variety of insect candies and snacks); *Starters*, SUSHI MAZI RESTAURANT, http://www.sushimazi.com/menu [http://perma.cc/Z87S-RA94] (offering grasshopper sushi); *The Planet's Most Sustainable Super-Food,* ENTOMO FARMS, http://entomofarms.com/ [http://perma.cc/LG46-QXUX] (selling cricket baking flour, whole roasted crickets, whole roasted mealworms, superworms whole roasted among other items). In 1979, J. Richard Gorham noted in an article in the Annual Review of Entomology that "[s]mall quantities of canned insects [were] already on the market," but that they were "mainly novelties." Gorham, *The Significance for Human Health of Insects in Food*, *supra* note 18, at 211.

March 2014, one company that sells insects as food, Chapul, reportedly "sold more in one month than it did the entire prior year"[67] and "more than quadrupled its annual revenue" (from about seventy-thousand dollars in 2014 to three-hundred thousand in 2015).[68] As another example, in spring 2017, the Seattle Mariners sold 901 orders of toasted chili-lime grasshoppers (about 18,000 grasshoppers) during the first three home games following the snack's introduction, leading the team to impose a per a game limit on orders of the snack.[69] Insect-based foods include those prepared with whole insects and those in which the insects are "processed into granular or paste forms."[70] Consumers in the United States can purchase whole roasted insects;[71] protein bars, chips, and other foods made with insects;[72] as well as insect protein powder and flour.[73]

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In addition, "bug banquets" have been organized to introduce consumers to insects as food. *See, e.g.*, Heather Looy & John R. Wood, *Attitudes Towards Invertebrates: Are Educational "Bug Banquets" Effective*, 37 J. ENVTL. EDUC. 37 (2006); *Buggin' Out at Linger's Bug Banquet & Benefit,* WESTWORD (Jan. 12, 2017), http://www.westword.com/restaurants/photos-buggin-out-at-lingers-bug-banquet-and-benefit-8684678 [http://perma.cc/Z2UJ-25DV]; Rob Williams, *Extension Bug Banquet Makes a Unique Culinary Experience*, TEXAS A&M UNIV. (Nov. 19, 2015), http://entomology.tamu.edu/2015/11/19/bug-banquet-makes-a-unique-culinary-experience/ [http://perma.cc/595Y-6E6R].

67. Ky Trang Ho, *15 of the Best Shark Tank Products Saving the World*, FORBES (July 16, 2016), http://www.forbes.com/sites/trangho/2016/07/16/15-of-the-best-shark-tank-products-saving-the-world/ [http://perma.cc/UPQ8-LRAG]; *see also Chapul Cricket Protein Powder*, CHAPUL, http://chapul.com/products/cricket-flour-high-protein-powder?variant=20358237509 [http://perma.cc/29E7-B94X].

68. Eha, *supra* note 65.

69. *See, e.g.*, *Mariners Imposing Order Limit on Popular Toasted Grasshoppers*, ESPN (Apr. 14, 2017), http://www.espn.com/mlb/story/_/id/19156119/seattle-mariners-selling-toasted-grasshoppers-concession-stand [http://perma.cc/SZZ9-7NQ8].

70. FAO REPORT, *supra* note 6, at xv; *see, e.g.*, *The Planet's Most Sustainable Super-Food,* ENTOMO FARMS, http://entomofarms.com/ [http://perma.cc/K8R8-QTYV]. Proteins can also be extracted from insects for food use, although at the time that this Article was written, the cost of extraction was "prohibitive." FAO REPORT, *supra* note 6, 107-08.

71. *See, e.g.*, *Oven Roasted*, ENTO FARMS, http://entomofarms.com/product-category/oven-roasted/ [http://perma.cc/VM4K-V3ZN].

72. *See, e.g.*, CHIRPS CHIPS, http://chirpschips.com/collections/all [http://perma.cc/7574-333X]; EXO PROTEIN, http://exoprotein.com/pages/shop [http://perma.cc/3W3U-PL26]; HOTLIX, http://www.hotlix.com/candy/ [http://perma.cc/CWP5-F6JN].

73. *See, e.g.*, CHAPUL, http://chapul.com/ [http://perma.cc/FW5T-8LGG]; CRICKET FLOURS, http://www.cricketflours.com/product-category/cricket-flour/ [http://perma.cc/N5KV-L2NW]; *Powder*, ENTO FARMS, http://entomofarms.com/product-category/powder/ [http://perma.cc/N5D3-EF53].

2. Potential Benefits

While the use of insects as human food is not without its challenges and risks,[74] using insects as human food has the potential to help address existing food insecurities for the approximately 795 million people worldwide who are undernourished,[75] and meet future demands for food and animal proteins.[76] Demand for human food, driven by increases in population and incomes, is growing,[77] and by 2050, may increase by sixty percent.[78] In addition, rising incomes have been linked to increased demand for meat protein.[79] The effects of climate change, including increased temperature and changed precipitation patterns, may further exacerbate the challenges of feeding the population.[80]

Food production, in turn, has substantial environmental costs. For example, "the agricultural sector is the leading cause of human-induced climate change . . . [and r]oughly one-third of all greenhouse gas emissions are due

74. *See, e.g.*, *infra* notes 185–186, 189, 190, 193, 196-199, 282, 287 and accompanying text.

75. FAO REPORT, *supra* note 6; Food & Agric. Org., *The State of Food Insecurity in the World: Meeting the 2015 International Hunger Targets: Taking Stock of Uneven Progress*, UNITED NATIONS (2015), http://www.fao.org/3/a-i4646e.pdf [http://perma.cc/7B8L-M5Q4].

76. FAO REPORT, *supra* note 6; *see also* Alan L. Yen, *Edible Insects: Traditional Knowledge or Western Phobia?*, 39 ENTOMOLOGICAL RES. 289, 290 (2009) (stating that "[i]n the debate on how to feed the increasing world population, few would disagree with the view that entomophagy has the potential to supply a significant proportion of the nutritional requirements of humans, either as a direct food source or indirectly as food for livestock").

77. *See, e.g.*, Xavier Cirera & Edoardo Masset, *Income Distribution Trends and Future Food Demand*, 365 PHIL. TRANSACTIONS ROYAL SOC'Y B BIOLOGICAL SCI. 2821 (2010); Godfray et al., *supra* note 2; M. Premalatha et al., *Energy-Efficient Food Production to Reduce Global Warming and Ecodegradation: The Use of Edible Insects*, 15 RENEWABLE & SUSTAINABLE ENERGY REVS. 4357–58 (2011).

78. Food & Agric. Org., *The State of Food Insecurity in the World: Economic Growth Is Necessary but not Sufficient To Accelerate Reduction of Hunger and Malnutrition*, UNITED NATIONS 30 (2012), www.fao.org/docrep/016/i3027e/i3027e.pdf [http://perma.cc/99T6-2NNX].

79. Tilman & Clark, *supra* note 4, at 519.

80. *See, e.g.*, J.R. Porter et al., *Food Security and Food Production Systems*, *in* CLIMATE CHANGE 2014: IMPACTS, ADAPTATION, AND VULNERABILITY 488 (2014) (noting with "high confidence" that "[a]ll aspects of food security are potentially affected by climate change, including food access, utilization, and price stability"); C.L. Walthall et al., *Climate Change and Agriculture in the United States: Effects and Adaptation*, U.S. DEP'T OF AGRICULTURE 1 (2013), http://www.usda.gov/oce/climate_change/effects_2012/CC%20and%20Agriculture%20Report%20(02-04-2013)b.pdf [http://perma.cc/9GY7-3AA4].

to agriculture."[81] Agriculture also "is by far the largest water-consuming sector,"[82] accounting for seventy percent of water use.[83]

Furthermore, the FAO has identified "[t]he livestock sector . . . as one of the top two or three most significant contributors to the most serious environmental problems, at every scale from local to global."[84] The livestock sector is a major factor in land degradation, threats to biodiversity, and atmosphere and climate changes.[85] Livestock production—including grazing and feedcrop production—"accounts for 70 percent of all agricultural land and 30 percent of the land surface of the planet."[86] The greenhouse gas emissions for the livestock sector measured in $CO_2$ equivalent exceed that for transport at 18 percent of emissions.[87] The livestock sector is a major factor in increased water use,[88] and accounts for more than eight percent of human water use worldwide.[89] The United Nations projects that water scarcity will increase and that "[b]y 2025, 1.8 billion people will be living in countries or regions with absolute water scarcity,

81. *See, e.g.*, Jeffrey Sachs, *Rethinking Macroeconomics: Knitting Together Global Society*, BROKER (Feb. 3, 2010), http://www.thebrokeronline.eu/Special-Reports/Special-report-Greening-the-global-economy/Rethinking-macroeconomics [http://perma.cc/Q5W9-87AL]. The agricultural sector, of course, includes agriculture for non-food purposes. *See, e.g.*, *North American Industry Classification System, 2017 NAICS Definition*, U.S. CENSUS BUREAU, http://www.census.gov/cgi-bin/sssd/naics/naicsrch?chart_code=11&search=2017%20NAICS%20Search [http://perma.cc/ETE5-YPLK] (searched 11) (listing, among other things, tobacco farming and cotton farming); *North American Industry Classification System, 2017 NAICS Definition, Sector 11 – Agriculture, Forestry, Fishing and Hunting*, U.S. CENSUS BUREAU, http://www.census.gov/cgi-bin/sssd/naics/naicsrch?code=11&search=2017%20NAICS%20Search [http://perma.cc/ELJ9-XQ5R] (searched 11); *see also* Paul Westcott, *U.S. Ethanol Expansion Driving Changes Throughout the Agricultural Sector*, U.S. DEP'T AGRIC. (Sept. 3, 2007), http://www.ers.usda.gov/amber-waves/2007/september/us-ethanol-expansion-driving-changes-throughout-the-agricultural-sector/ [http://perma.cc/4PU3-W3XZ].

82. Food & Agric. Org., *Coping with Water Scarcity Challenge of the Twenty-First Century*, UNITED NATIONS 9 (Mar. 22, 2007), http://www.fao.org/3/a-aq444e.pdf [http://perma.cc/688E-FLBX] [hereinafter FAO WATER SCARCITY].

83. Walter V. Reid et al., *Ecosystems and Human Well-being*, MILLENNIUM ECOSYSTEM ASSESSMENT BD. 33 (2005), http://www.millenniumassessment.org/documents/document.356.aspx.pdf [http://perma.cc/AN3U-523D].

84. Food & Agric. Org., *Livestock's Long Shadow: Environmental Issues and Options*, UNITED NATIONS xx (2006) [hereinafter FAO LIVESTOCK'S LONG SHADOW].

85. *Id.* at xx-xxiv.

86. *Id.* at xxi. Agriculture uses approximately 37.7% of land. *Data, Agricultural Land*, WORLD BANK, http://data.worldbank.org/indicator/AG.LND.AGRI.ZS/countries/1W?display=graph [http://perma.cc/F2KG-VBYP].

87. FAO LIVESTOCK'S LONG SHADOW, *supra* note 84, at xxi.

88. *Id.*

89. *Id.*

and two-thirds of the world population could live under water stress conditions."[90] The population growth and changing consumption patterns discussed above are likely to put further pressure on environmental resources.[91]

Insects used as food may be well-suited to helping address these challenges.[92] As discussed earlier, using insects as food may have nutritional benefits.[93] Insects, as compared to traditional livestock, are more efficient at converting feed mass into body mass;[94] for example, "crickets are twice as efficient in converting feed to meat as chicken, at least four times more efficient than pigs, and 12 times more efficient than cattle" when the portion of each animal that is edible and digestible is considered.[95] Insects "emit considerably fewer greenhouse gases . . . than most livestock" and "require significantly less water than cattle rearing."[96] In addition, with the exception of feed production, rearing insects "is

90. Dep't of Econ. and Soc. Affairs, *Water Scarcity*, UNITED NATIONS (May 17, 2013), http://www.un.org/waterforlifedecade/scarcity.shtml [http://perma.cc/7LL7-KVFX]; *see also* FAO LIVESTOCK'S LONG SHADOW, *supra* note 84, at xxii.

91. *See, e.g.*, Stefan Wirsenius et al., *How Much Land Is Needed for Global Food Production Under Scenarios of Dietary Changes and Livestock Productivity Increases in 2030?*, 103 AGRIC. SYS. 621, 636–37 (2010) (concluding "that if food and agriculture develop according to projections made by the FAO, global agricultural area is likely to expand substantially . . . [and] would imply increased deforestation pressure, with further loss of biodiversity and increased $CO_2$ emissions" but that "there is substantial scope for land-minimizing growth of world food supply by efficiency improvements in the food-chain, particularly in animal food production, and dietary changes toward less land-demanding food"); FAO WATER SCARCITY, *supra* note 82, at 9 ("With rising incomes and continuing urbanization, food habits change towards richer and more varied diets—not only towards increasing consumption of staple cereals, but also leading to a shift in consumption patterns among cereal crops and away from cereals towards livestock and fish products and high-value crops that consume more water."); *see also supra* notes 77–79 and accompanying text (discussing changing consumption patterns).

92. *See, e.g.*, FAO REPORT, *supra* note 6; *see also* Rene Cerritos, *Insects as Food: An Ecological, Social, and Economical Approach*, 4 CAB REVS.: PERSP. AGRIC., VETERINARY SCI., NUTRITION & NAT. RESOURCES 1 (2009). *But see* Ramos-Elorduy, *supra* note 6; EFSA Sci. Comm., *supra* note 32, at 3, 35, 39 (concluding that the environmental risks are "expected to be comparable to other animal production systems," but "a risk profile on environmental impacts and mitigation" is needed).

93. *See supra* notes 55-57 and accompanying text.

94. *See* FAO REPORT, *supra* note 6, at 60; Ramos-Elorduy, *supra* note 6. Insects are sometimes referred to as "mini-livestock." *See, e.g.*, Goodyear, *supra* note 53.

95. FAO REPORT, *supra* note 6, at 60; *see also* Ramos-Elorduy, *supra* note 6. *But see* Lundy & Parrella, *supra* note 54 (finding that the diet of insects impacts their feed conversion ratios and ability to reach harvestable size and that the feed conversion ratio was less efficient and closer to chickens than had been reported).

96. FAO REPORT, *supra* note 6, at 2, 75.

not necessarily a land-based activity."[97] As a result of these characteristics, using insects as human food may help to meet the growing global demand for food in a way that is more sustainable than conventional livestock.[98]

While these are likely benefits of using insects as food, there is still much uncertainty surrounding the use of insects as food. Further research on the nutritional values of insects and the sustainability and environmental impacts of insect production is needed, as is "significant technological innovation" regarding the rearing, processing, and use of insects for human food.[99] FDA recognition and regulation of insects as "food" may help to further spur research on and development of insects as food.[100]

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97. *Id.* at 2. Indeed, one startup hopes to launch a "desktop hive for edible insects" to enable users to rear mealworms in their homes. *LIVIN Farms Hive*, KICKSTARTER, http://www.kickstarter.com/projects/1468268424/l-i-v-i-n-hive/description [http://perma.cc/5Q55-ULNL]; *see also* LIVIN FARMS, http://www.livinfarms.com [http://perma.cc/5DN4-4NUB].

98. The benefits discussed in the text are not the only potential environmental benefits of using insects as food. For example, the FAO notes that "[m]any edible insects are considered pests and threats to agricultural crops" and collecting these insects could reduce the need for pesticides while protecting crops and providing a source of food. FAO REPORT, *supra* note 6, at 55; Schiefenhövel & Blum, *supra* note 47, at 174; Goodyear, *supra* note 53 (quoting entomologist Tom Turpin as saying "[a]ttitudes in [the United States] result in more pesticide use, because we're scared about an aphid wing in our spinach"). *But see supra* note 13 and accompanying text (discussing FDA's Standard Entomophagy Response, which appears to have rejected the sale of "wildcrafted" insects). Other potential benefits of entomophagy include the economic and social opportunities for improved livelihoods, employment, and cash income that gathering and rearing insects may offer. FAO REPORT, *supra* note 6.

99. *See, e.g.*, FAO REPORT, *supra* note 6; *see also* Allen Carson Cohen, *Formalizing Insect Rearing and Artificial Diet Technology*, 47 AM. ENTOMOLOGIST 198, 198 (2001) (observing that "insect rearing has minimal formal standing as a legitimate discipline," and suggesting changes to improve its standing and development); Birgit A. Rumpold & Oliver K. Schlüter, *Potential and Challenges of Insects as an Innovative Source for Food and Feed Production*, 17 INNOVATIVE FOOD & EMERGING TECHS. 1, 3 (2013) (discussing the production and processing of edible insects and noting that "it is . . . necessary to develop rearing and harvest as well as post-harvest processing technologies including safety and quality monitoring for the automation of insect (protein) production to decrease its production costs and ensure food and feed safety").

100. *See* Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 175, 179–80 (2014) ("[S]omewhat counterintuitively new technologies can benefit from decisive, well-timed regulation. Some early regulatory interventions, might even become, in Daniel Carpenter's words, 'market-constituting,' by enabling a robust market that otherwise might not exist, especially for credence goods that are difficult for consumers to evaluate."); *see also* J. A. Caswell & E. M. Modjduszka, *Using Informational Labeling to Influence the Market for Quality in Food Products*, 78 AM. J. AGRIC. ECON. 1249, 1249-51 (1996) (discussing search,

### 3. The Role of United States and the Food and Drug Administration

The FDA is viewed as "a gold standard whose lead other countries often follow."[101] FDA's failure to specifically recognize that insects used as food are "food" under the FDCA may prevent investment in research and the development of insects as food, and reinforce cultural conceptions of food that do not include insects.[102] This failure may in turn hinder the realization of the potential of insects as food. The exclusion of insects from Western understandings of food has arguably impacted their use as food elsewhere.[103] The "westernization of diets"—shifts in dietary preferences toward, for example, meat and dairy—poses an additional challenge to realizing insects' potential as human food.[104]

American food policy has and has had global consequences.[105] For example, the United States exports a tremendous amount of food.[106] Over the past two decades, U.S. exports of beef, pork, and poultry and their corresponding prod-

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experience, and credence attributes of food and stating that "the food safety and nutritional attributes of food are largely credence attributes").

101. Katie Thomas, *Trump's F.D.A. Pick Could Undo Decades of Drug Safeguards*, N.Y. TIMES (Feb. 5, 2017), http://www.nytimes.com/2017/02/05/health/with-fda-vacancy-trump-sees-chance-to-speed-drugs-to-the-market.html [http://perma.cc/Y435-AERT].

102. *See infra* Sections IV.A & C.

103. FAO REPORT, *supra* note 6, at 141–42; *see also Current Issues in Non-timber Forest Products Research*, CTR. INT'L FORESTRY RES. 47 (1996), http://www.cifor.org/ntfpcd/pdf/ntfp-current.pdf [http://perma.cc/K52P-8YWR] (noting that "researcher disgust and bias against entomophagy as a 'primitive' practice may cause informants to hide certain food resources").

104. *See* FAO REPORT, *supra* note 6; Colin K. Khoury et al., *Increasing Homogeneity in Global Food Supplies and the Implications for Food Security*, 111 PROC. NAT'L ACAD. SCI. U.S. 4001, 4003-04 (2014) (discussing the increasing homogeneity of the global food supply).

105. *See, e.g.*, Corinna Hawkes, *Uneven Dietary Development: Linking the Policies and Processes of Globalization with the Nutrition Transition, Obesity, and Diet-Related Chronic Diseases*, 2 GLOBALIZATION & HEALTH 4 (2006); Emma Rothschild, *Food Politics*, 54 FOREIGN AFF. 285 (1976) (discussing U.S. food policy); *U.S. Government Global Food Security Strategy FY 2017-2021*, U.S. AGENCY FOR INT'L DEV. (2016), http://www.usaid.gov/sites/default/files/documents/1867/USG-Global-Food-Security-Strategy-2016.pdf [http://perma.cc/UN2B-XDZ5]; *U.S. International Food Assistance Report FY 2015*, U.S. AGENCY FOR INT'L DEV. (2016), http://pdf.usaid.gov/pdf_docs/PA00MHDH.pdf [http://perma.cc/YW5G-76YT].

For an historical examination of American "food power," with a focus on the period of 1945 to 1975, see BRYAN MCDONALD, FOOD POWER: THE RISE AND FALL OF THE POSTWAR AMERICAN FOOD SYSTEM (2017).

106. *See* Econ. Research Serv., *U.S. Agricultural Trade*, U.S. DEP'T AGRIC., http://www.ers.usda.gov/topics/international-markets-trade/us-agricultural-trade/ [http://perma.cc/PZU2-YT8L].

ucts have increased.[107] For fiscal year 2017, exports are projected to increase further, "driven by rising exports of livestock, poultry, and dairy."[108]

In addition, U.S. firms export U.S. conceptions of food and food production systems.[109] U.S. food and beverage, and restaurant companies—e.g., Coca-Cola Company, PepsiCo, McDonald's, and Starbucks—are among the largest and most powerful public companies in the world.[110] Many U.S. food and beverage companies advertise and market extensively outside of the United States,[111]

107. *See* Econ. Research Serv., *Interactive Chart: The Evolution of U.S. Agricultural Exports Over the Last Two Decades*, U.S. DEP'T AGRIC., http://www.ers.usda.gov/topics/international-markets-trade/us-agricultural-trade/interactive-chart-the-evolution-of-us-agricultural-exports-over-the-last-two-decades/ [http://perma.cc/ET5P-83XA] (showing the value of exports each year from 1995 to 2013).

108. *Outlook for U.S. Agricultural Trade*, U.S. DEP'T AGRIC. (May 19, 2017), https://web.archive.org/web/20170519195133/https://www.ers.usda.gov/topics/international-markets-trade/us-agricultural-trade/outlook-for-us-agricultural-trade [http://perma.cc/GA96-GC3F] (accessing Internet Archive from May 19, 2017).

109. *See, e.g.*, Graciela Ghezan et al., *Impact of Supermarkets and Fast-Food Chains on Horticulture Supply Chains in Argentina*, 20 DEV. POL'Y REV. 389, 399 (2002) (discussing McDonald's export of the "US concept of fast food").

110. Maggie McGrath, *World's Largest Food and Beverage Companies 2017: Nestle, Pepsi and Coca-Cola Dominate the Field*, FORBES (May 24, 2017), http://www.forbes.com/sites/maggiemcgrath/2017/05/24/worlds-largest-food-and-beverage-companies-2017-nestle-pepsi-and-coca-cola-dominate-the-landscape [http://perma.cc/YT4H-NN5B]; Maggie McGrath, *World's Largest Restaurant Companies, 2017: McDonald's Slips While Darden Makes Gains*, FORBES (May 24, 2017, 7:00 AM), http://www.forbes.com/sites/maggiemcgrath/2017/05/24/worlds-largest-restaurant-companies-2017-mcdonalds-slips-while-darden-makes-gains [http://perma.cc/C766-W3HH].

111. *See, e.g.*, Thomas L. Leatherman & Alan Goodman, *Coca-Colonization of Diets in the Yucatan*, 61 SOC. SCI. & MEDICINE 833, 839 (2005) (noting increased frequency of advertisements for Coca-Cola and Pepsi and discussing Mexico's portion of Pepsi and Coke's international sales and the companies' "ongoing 'Cola War' . . . a fight over the 'stomach share' of the Mexican people"); Rowan Wilken & John Sinclair *Global Marketing Communications and Strategic Regionalism*, 8 GLOBALIZATIONS 1, 4-8 (2011) (discussing marketing by Coca-Cola and McDonald's); Mickey Chopra, *Globalization and Food: Implications for the Promotion of "Healthy" Diets*, WORLD HEALTH ORG. 5-6, 9-10 (2002), http://apps.who.int/iris/bitstream/10665/42609/1/9241590416.pdf [http://perma.cc/3QK9-ZX7L] (noting that the top ten transnational food manufacturing companies, many of which are headquartered and incorporated in the United States, have "evolved global marketing strategies" and discussing how these companies "penetrate into new market"). *See generally* Corinna Hawkes, *Marketing Activities of Global Soft Drink and Fast Food Companies in Emerging Markets: A Review*, WORLD HEALTH ORG. (2002), http://apps.who.int/iris/bitstream/10665/42609/1/9241590416.pdf [http://perma.cc/2WYY-9RZD] (discussing promotional activities of fast food and soft drink brands both in the U.S. and outside of the U.S., and noting that in 2000, Coca-Cola Corporation, PepsiCo, McDon-

and by doing so "aim to create demand by changing traditional drinking and eating habits."[112] These brands may transform food systems. As American fast food chains have moved overseas they have "import[ed] entire systems of agricultural production" into the countries where they operate.[113] For example, Graciela Ghezán et al., use McDonald's and frozen French fried potatoes in Argentina as a case study of how multinational supermarkets and fast-food chains have fundamentally changed horticultural supply chains.[114] Given the influence of the United States food and food systems, FDA's inaction with respect to insects as food may have implications beyond the United States.

The FAO has identified absent and unclear legal frameworks regarding insects as food as a major barrier to the development of insects for food use.[115] Indeed, as Section IV.A will argue, in the United States, FDA's regulatory inaction with respect to insects as food in the face of its extensive regulation of insects as filth has created uncertainty regarding how food uses of insects will be regulated. In addition, applying existing law and regulatory processes to insects used as food is likely to raise several significant issues and challenges. In the absence of FDA regulation specifically addressing insects as food, companies may conclude that it is too risky to invest in developing insects for human consumption. This may hinder the scientific and technological development that is needed for insects to reach their full potential in meeting future demands for food and animal protein in a sustainable manner.

In addition, Americans consume a disproportionate share of the resources used for food production. As discussed in Section I.B.2. above, food production and in particular livestock production, are significant drivers of climate change and other environmental issues. "Second to China, the U.S. consumes more meat than any other country."[116] In 2014, the average American ate 198 pounds of meat from cows, chickens, pigs, and sheep compared to the global average of

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ald's Corp., and Yum! Brands spent $2.21 billion U.S. dollars on media advertising outside of the United States, with Coca-Cola spending "a majority of its money outside the U.S."); Michelle Christian & Gary Gereffi, *The Marketing and Distribution of Fast Food*, *in* PEDIATRIC OBESITY (2010) (discussing the expansion and global rise of leading fast-food companies and their marketing strategies).

112. Hawkes, *supra* note 111, at iii; s*ee also* GOLDEN ARCHES EAST: MCDONALD'S IN EAST ASIA 6 (James L. Watson ed. 1997) (stating that "McDonald's *has* effected small but influential changes in East Asian dietary patterns," but that consumers have also transformed McDonalds).

113. ERIC SCHLOSSER, FAST FOOD NATION 230 (2002) (describing American fast food chains as not simply importing food to the countries where they operate, but "import[ing] entire systems of agricultural production"); *see also* Chopra, *supra* note 111, at 6-9; Hawkes, *supra* note 111, at 50.

114. Ghezán et al., *supra* note 108, at 407.

115. *See* FAO REPORT, *supra* note 6, at 154–61.

116. *What the World Eats*, NAT'L GEOGRAPHIC, http://www.nationalgeographic.com/what-the-world-eats/ [http://perma.cc/D8DC-LVWA].

75 pounds.[117] These amounts are projected to increase to 207.5 pounds and 78.3 pounds, respectively, by 2024.[118] Shifting even some meat consumption to less resource-intensive animal proteins such as insects may yield environmental benefits.[119]

## II. Regulating Insects and Food

While FDA has extensively regulated insects and insect-derived products in the food context, its regulation has focused on insects as something other than food. This Part provides an overview of FDA's extensive regulation of insects as

117. *See* Reubold, *supra* note 4.

118. *Id.* The average American meat intakes exceed recommended levels. *Dietary Guidelines for Americans 2015-2020*, U.S. Dep't of Health & Hum. Serv. & U.S. Dep't of Agric. 17 (2015), http://health.gov/dietaryguidelines/2015/guidelines/chapter-1/the-science-behind-healthy-eating-patterns/ [http://perma.cc/THL6-8JXD] (recommending twenty-six-ounce equivalents from the meat, poultry, and eggs subgroup at the 2,000-calorie level for the USDA Healthy U.S.-Style Eating Pattern and stating that the average intakes of these products for teen boys and adult men exceed these levels). And eating less meat may also have health benefits. *Meatless Meals: The Benefits of Eating Less Meat*, Mayo Clinic (Aug. 19, 2014), http://www.mayoclinic.org/healthy-lifestyle/nutrition-and-healthy-eating/in-depth/meatless-meals/art-20048193 [http://perma.cc/8CAB-AJQY].

119. *See, e.g.*, Reubold, *supra* note 4; Jonathan Kaplan, *Eat Green: Our Everyday Food Choices Affect Global Warming and the Environment—Fact Sheet*, Nat'l Res. Def. Council (2010), http://www.nrdc.org/sites/default/files/eatgreenfs_feb2010.pdf [http://perma.cc/5ZEX-39Y4]. Indeed, the legal recognition of insects as "food" for which this Article argues, may help erode the cultural barriers to such recognition, which may hinder such a shift. *See infra* Sections IV.A & C.

While some may question whether insects as food could ever expand beyond niche markets in the United States, dietary patterns can change quickly. *See* FAO Report, *supra* note 6, at 59 (stating that "history has shown that dietary patterns change quickly, particularly in a globalized world (the rapid acceptance of raw fish in the form of sushi being a good example)"); Klayman, *supra* note 9 (noting insects as food are "gaining traction with niche markets"); *see also* Theodore C. Bestor, *How Sushi Went Global*, *in* The Cultural Politics of Food and Eating: A Reader 13, 14 (James L. Watson & Melissa L. Caldwell eds., 2005) (stating that "[o]utside of Japan, tuna, especially raw tuna, hasn't always had it so good" as "Sushi isn't an easy concept to sell to the uninitiated," yet "[a]gainst all odds" sushi has "increasingly saturated North American . . . consumption and popular culture"); Paige A. Edwards, *Global Sushi: Eating and Identity*, 11 Persp. on Global Dev. & Tech. 211, 216 (2012) ("What is unique about sushi's development in America is that it challenges ideas of what people consider to be food, especially in terms of the raw and the cooked."); Virah D'Costa, *IBIS World Industry Report OD4308: Sushi Restaurants in the US*, IBISWorld 7 (2016), (noting that "sushi restaurants have become part of the food service mainstream" and that the expected estimated revenue of the sushi restaurant industry in the United States in 2016 will be $2.3 billion dollars).

defects or "filth," which may render a food adulterated in violation of the FDCA. It then discusses two instances in which FDA addressed the intentional addition of insects or insect-derived products to human food, but did not regulate the insect or insect-derived products as "food." Parts III and IV then build on this examination to consider the regulation of insects *as* food,[120] and argue that there is a need for FDA to specifically recognize insects as food and distinguish between insects as food and insects as filth.

The FDCA defines "food," in relevant part, as "articles used for food or drink for man" and "articles used for components of any such article."[121] The FDCA prohibits adulterating or causing the adulteration of food.[122] Accordingly, insects as defects in food or used as food or as a component of food are within FDA's jurisdiction.[123]

120. Although FDA's regulations reference several insect-produced products—e.g., honey, beeswax, and shellac—this Article does not discuss these products, as they pose distinct regulatory (and cultural) considerations vis à vis insects as food. *See, e.g.,* 21 C.F.R. § 101.12 (2017) (listing honey); 21 C.F.R. § 146.187 (2017) (canned prune juice) (identifying honey as an optional ingredient); 21 C.F.R. § 184.1973 (2017) (beeswax (yellow and white)); 21 C.F.R. § 101.4(b)(22) (2017) (providing, among other things, for the declaration of beeswax on fresh produce held for retail sale); 21 C.F.R. § 73.1(2017) (listing shellac as a diluent in color additives for food); 21 C.F.R. § 101.4(b)(22) (2017) (providing for the declaration of shellac-based wax or resin on fresh produce held for retail sale); *See generally* ARNOLD VAN HUIS ET AL., THE INSECT COOKBOOK: FOOD FOR A SUSTAINABLE PLANET 166 (2014) (noting that shellac is excreted by the lac scale insect).

121. Food, Drug, and Cosmetic Act § 201(f), 21 U.S.C. § 321(f) (2012). While the definition of "food" includes both food for humans and other animals, this Article focuses exclusively on food for humans. *Id.* FDA's regulations define "food" as it is defined in section 201(f) of the FDCA, noting that this term "includes raw materials and ingredients." 21 C.F.R. § 110.3(f) (2017).

122. *See* FDCA § 301, 21 U.S.C. § 331 (2012). There are interstate commerce connection requirements. *Id.*

123. *See* FDCA § 201-301, 21 U.S.C. §§ 321-331 (2012). A number of other federal agencies, however, play important roles in the regulation of food and food safety. *See, e.g.*, RENÉE JOHNSON, CONG. RESEARCH SERV., RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER (2016) (discussing the food safety responsibilities of a number of federal agencies). For example, the United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) inspects the slaughter of food animals and the processing of meat. Meats and meat food products regulated under the Federal Meat Inspection Act (FMIA) are exempt from FDA's jurisdiction. *See* Federal Meat Inspection Act, 21 U.S.C. § 601 (2012); 21 U.S.C. § 392(a) (2012); *see also* 9 C.F.R. § 300 (2017). FMIA defines "meat food product," with some exceptions, as "any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats . . . ." 21 U.S.C. § 601(j) (2012). The term also applies to "food products of equines." *Id.* USDA's jurisdiction under the FMIA extends to "amenable species," which in addition to the species listed above includes catfish as well as "any additional species of livestock that the Secretary [of Agriculture] considers appropriate." 21 U.S.C. § 601(w) (2012). FDA retains jurisdiction over

### *A. Insects as "Filth"*

Much of the public attention that FDA has given to the regulation of insects in human food has been focused on insects as defects or "filth" in food that may render the food adulterated under the FDCA. Section 402(a)(3) of the FDCA provides that "[a] food shall be deemed to be adulterated . . . if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food."[124] A number of courts have held, in FDA enforcement actions, that the references to "filth" in section 402 of the FDCA include insects and insect fragments.[125] Courts have also held that the presence of insects in a

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foods that are not subject to the FMIA (e.g., rabbit, bison, and deer), as well as live animals and meats and meat food products after processing. United States v. Tomahara Enters., Food, Drug Cosm. L. Rep. (CCH) ¶ 38,217 (N.D.N.Y. 1983). Under the Poultry Products Inspection Act (PPIA), FSIS is also responsible for regulating poultry products. *See* 21 U.S.C. § 451 *et seq.* (2012); *see also* 9 C.F.R. § 300 *et seq.* The PPIA defines "poultry product," with some exceptions, as "any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof," and defines "poultry" as "any domesticated bird, whether live or dead." 21 U.S.C. § 453(e), (f) (2012).

124. FDCA § 402(a)(3), 21 U.S.C. § 342(a)(3) (2012). This provision has been held to be disjunctive; hence, a product containing filth is adulterated under the Act, even if it is not filthy to the point of being unfit for food. United States v. 1,500 Cases More or Less, Tomato Paste, 236 F.2d 208, 211 (7th Cir. 1956); *see also* United States v. 449 Cases Containing Tomato Paste, 212 F.2d 567, 569 (2d Cir. 1954); Bruce's Juices, Inc. v. United States, 194 F.2d 935, 936 (5th Cir. 1952); Salamonie Packing Co. v. United States, 165 F.2d 205, 206 (8th Cir. 1948), *cert. denied*, 333 U.S. 863 (1948); United States v. 1851 Cartons Labeled in Part H. & G. Famous Booth Sea Foods Whiting Frosted Fish, 146 F.2d 760, 761 (10th Cir. 1945); United States v. 44 Cases, etc., Viviano Spaghetti With Cheese, 101 F. Supp. 658, 663-64 (E.D. Ill. 1951); United States v. 184 Barrels Dried Whole Eggs, 53 F. Supp. 652, 656 (E.D. Wis. 1943).

FDA has also indicated that insect contamination may render a food "otherwise unfit for food" under section 402(a)(3). Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food; Revised Current Good Manufacturing Practices, 51 Fed. Reg. 22,458, 22,462 (June 19, 1986) (stating that "contamination with pests, might render [a food] unfit within the meaning of section 402(a)(3) of the act" and defining pests as "any objectionable animals or insects").

125. *See, e.g.*, United States v. Cassaro, Inc., 443 F.2d 153, 156 (1st Cir. 1971); Golden Grain Macaroni Co. v. United States, 209 F.2d 166, 166-68 (9th Cir. 1953); United States v. Approximately 600 Sacks of Green Coffee Beans Seized from Café Rico, Inc., 381 F.Supp.2d 57, 63 (D.P.R. 2005); *44 Cases, etc., Viviano Spaghetti with Cheese*, 101 F.Supp. at 664; *see also* United States v. Swift & Co., 53 F.Supp. 1018, 1020 (M.D. Ga. 1943) ("Congress intended that the word 'filthy', as used in the Act, should be construed to have its usual and ordinary meaning."); United States v. 133 Cases of Tomato Paste, 22 F.Supp. 515, 516 (E.D. Pa. 1938) (holding that the Federal Food and Drugs Act of 1906, which provided that "'an article shall be deemed to be adulterated . . . in the case of food . . . if it consists in whole or in

food facility is an insanitary condition that creates a reasonable probability of contamination and renders a food adulterated under section 402(a)(4) of the FDCA.[126] That section provides that a food is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."[127] Section 402(a)(4) "is designed to prevent adulterations 'in their incipiency.'"[128]

FDA's Current Good Manufacturing Practice (cGMP) regulations, promulgated pursuant to its authority under section 402(a),[129] establish criteria "to help ensure a safe and sanitary food supply."[130] The cGMP regulations contain numerous references to controlling pests in food plants and on the grounds of food plants.[131] For example, the regulations provide that "[n]o pests shall be allowed in any area of a food plant" and "[e]ffective measures shall be taken to exclude pests from the processing area and to protect against the contamination

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part of a filthy . . . animal or vegetable substance,'" "does not require a food substance to be injurious to health in order to be filthy," and that "the apparent presence of worms and their excreta in food designed for consumption renders it filthy," and "[t]here can be no doubt that this section of the act was designed to protect the aesthetic tastes and sensibilities of the consuming public" (citations omitted)).

The FDCA as originally enacted and as amended does not specifically reference insects. *See generally* Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938), 21 U.S.C. §§ 321-399f (2012). Similarly, the Pure Food and Drug Act of 1906, which preceded the FDCA, did not mention insects. *See* Pure Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (1906).

126. *See, e.g.*, *Cassaro*, 443 F.2d at 157; United States v. 155/137 Pound Burlap Bags, Civ. A. No. 2:93CV63, 1993 WL 666701, at *3 (E.D. Va. Nov. 1, 1993).

127. FDCA § 402(a)(3), 21 U.S.C. § 342(a)(4) (2012)*; see also* Berger v. United States, 200 F.2d 818, 821 (8th Cir. 1952) (interpreting 21 U.S.C. § 342(a)(4)); United States v. 1,200 Cans Pasteurized Whole Eggs by Frigid Food Prods., Inc.—Detroit, Mich., 339 F.Supp. 131, 141 (N.D. Ga. 1972) (same).

128. *Berger*, 200 F.2d at 821.

129. Human Foods; Current Good Manufacturing Practice (Sanitation) in Manufacture, Processing, Packing, or Holding, 34 Fed. Reg. 6,977 (Apr. 21, 1969); Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food; Revised Current Good Manufacturing Practices, 51 Fed. Reg. 22,458 (June 19, 1986). *See generally* Current Good Manufacturing Practice in Manufacturing, Packaging, or Holding Human Food, 21 C.F.R. pt. 110 (2017); PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 528 (4th ed. 2014).

130. Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food; Revised Current Good Manufacturing Practices, 51 Fed. Reg. at 22,458.

131. *See* 21 C.F.R. § 110.20(a)(1), (3)-(4), (b)(3)(ii)-(iii), (7) (2017); *id.* at § 110.35(c); *id*. at § 110.37(f); *id*. at § 110.80(a)(4).

of food on the premises by pests."[132] "Pests" are defined specifically to include insects.[133] Insects in food can present very serious health risks.[134] For example, insects are known vectors of salmonella,[135] and salmonella is estimated to cause a million foodborne illnesses in the United States every year.[136]

In addition, FDA's Compliance Policy Guides, which "explain [FDA's] policy on regulatory issues,"[137] contain numerous references to insects as filth.[138] And consistent with the FDCA and these policies, FDA has sent warning letters

132. 21 C.F.R. § 110.35(c) (2017).

133. 21 C.F.R. § 110.3(j) (2017) (defining "[p]est" as "any objectionable animals or insects including, but not limited to . . . flies, and larvae").

134. *See, e.g.*, J. Richard Gorham, Reflections on Food-Borne Filth in Relation to Human Disease, *in* FUNDAMENTALS OF MICROANALYTICAL ENTOMOLOGY: A PRACTICAL GUIDE TO DETECTING AND IDENTIFYING FILTH IN FOODS 269, 269-70 (Alan R. Olson et al., eds. 1996) (noting that high levels of filth in food is indicative of insanitary handing and that while the filth may be "merely aesthetically unappealing" it may also be "allergenic, toxic, pathogenic, or directly traumatic"); J. Richard Gorham, *The Significance for Human Health of Insects in Food*, 24 ANN. REV. ENTOMOLOGY 209 (1979); *see also* Eur. Food Safety Auth. Sci. Comm., *Risk Profile Related to Production and Consumption of Insects as Food and Feed*, 13 EUR. FOOD SAFETY AUTHORITY J. 4257 (2015).

135. Jim Fredericks & Missy Henriksen, *Pests: Everyday Threats to the Human Food Supply*, FOOD SAFETY MAG. (Aug./Sept. 2012), http://www.foodsafetymagazine.com/magazine-archive1/augustseptember-2012/sanitation-pests-everyday-threats-to-the-human-food-supply [http://perma.cc/6XND-P2RG]; *see also infra* Section III.B.1.

136. *Salmonella and Food*, CTR. DISEASE CONTROL & PREVENTION (July 5, 2017), http://www.cdc.gov/features/salmonella-food [http://perma.cc/ZDB5-PPB8].

137. U.S FOOD & DRUG ADMIN., FOREWORD: COMPLIANCE POLICY GUIDE, INSPECTIONS COMPLIANCE, ENFORCEMENT, AND CRIMINAL INVESTIGATIONS (July 5, 2016), http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116271.htm [http://perma.cc/E4QQ-J2CV].

138. *See, e.g.*, U.S FOOD & DRUG ADMIN., FDA COMPLIANCE POLICY GUIDE, CPG SEC. 555.600 FILTH FROM INSECTS, RODENTS, AND OTHER PESTS IN FOODS (Mar. 20, 2015), http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074559.htm [http://perma.cc/9XAL-CN7B] (summarizing, among other things, FDA's "current thinking on filth from insects" and noting that such guidance is not binding); U.S FOOD & DRUG ADMIN., FDA COMPLIANCE POLICY GUIDE, CPG SEC. 580.100 FOOD STORAGE AND WAREHOUSING-ADULTERATION-FILTH (DOMESTIC AND IMPORT) (Mar. 20, 2015), http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074613.htm [http://perma.cc/R5VS-RETH]; *see also Introduction* to FDA COMPLIANCE POLICY GUIDE, https://web.archive.org/web/20160524182616/www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm116791.htm[http://perma.cc/X6H2-CW9R] (accessing Internet Archive from Sept. 6, 2016) (stating that the compliance policy guides "are not intended to create or confer any rights, privileges, or benefits on or for any private person, but are intended for internal guidance").

to companies alleging violations of the Act due to the presence of insects on or near food or the failure to exclude insects from a facility.[139]

FDA has recognized, however, that it is not feasible to avoid insects in food completely. Accordingly, FDA has established defect action levels for insects and insect filth that are natural or unavoidable defects that present no health hazards for humans in a number of foods.[140] As an example of one such defect action level, FDA will regard chocolate and chocolate liquor adulterated and subject to enforcement under section 402(a)(3) of the FDCA when the "[a]verage is 60 or more insect fragments per 100 grams when 6 100-gram subsamples are examined OR [a]ny 1 subsample contains 90 or more insect frag-

139. *See, e.g.*, Letter from Kirk D. Sooter, FDA District Director, Philadelphia District Office, to Xiaoping Sun, New Rich City Company (July 3, 2012), http://www.fda.gov/iceci/enforcementactions/warningletters/2012/ucm310936.htm [http://perma.cc/32WW-F3S2]; Letter from Miriam R. Burbach, District Director, FDA Washington District, to Joe M. Hoopes, President, Old Mill Bread Company (Oct. 17, 2014), http://www.fda.gov/iceci/enforcementactions/warningletters/2014/ucm420879.htm [http://perma.cc/9J42-9AVD]; Letter from Alonza E. Cruse, District Director, FDA Los Angeles District, to Anastasios Sotiropoulos, Owner, A.G.S. Wholesalers, Inc. (Jan. 26, 2011), http://web.archive.org/web/20170112194014/https://www.fda.gov/iceci/enforcementactions/warningletters/2011/ucm241666.htm [http://perma.cc/4TSW-HNDR] (accessing Internet Archive from Jan. 12, 2017); Letter from Ann Adams, Acting Dir., FDA, to Stanley F. Jide, CEO, BCS African Wholesale Food Supply Inc. (July 20, 2010), http://www.fdalabelcompliance.com/letters/ucm219912 [http://perma.cc/JB7F-D4CG].

140. *See* Natural or Unavoidable Defects in Food for Human Use that Present No Health Hazard, 21 C.F.R. § 110.110(a) (2017) (stating that FDA "uses [the defect action] levels in deciding whether to recommend regulatory action"); Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food; Revised Current Good Manufacturing Practices, 51 Fed. Reg. 22,458, 22,474 (June 19, 1986) (noting that these defect action levels "offer reliable guidance on whether a particular defect may result in the product being adulterated with the meaning of the [FDCA]"); *see also* DEFECT LEVELS HANDBOOK, *supra* note 35 (stating that FDA has "establish[ed] maximum levels of natural or unavoidable defects in foods for human use that present no health hazard" because "it is economically impractical to grow, harvest, or process raw products that are totally free of nonhazardous, naturally occurring, unavoidable defects"); Natural or Unavoidable Defects in Food for Human Use that Present No Health Hazard, 37 Fed. Reg. 6,497, 6,498 (Mar. 30, 1972) (making public defect levels and stating that "[f]ew foods contain no natural or un-avoidable defects . . . even with modern technology"); United States v. 1,500 Cases More or Less, Tomato Paste, 236 F.2d 208, 211 (7th Cir. 1956) (stating "that if the fact that almost all food contains some filthy, putrid, and decomposed substances had been called to the attention of Congress, that body would have directed the administrator to provide reasonable and acceptable tolerances for these substances just as it did in the case of poisons" and that FDA "should set definite standards [for filthy, putrid, and decomposed substances] in each industry which, if reasonable, and in line with expressed Congressional intent, would have the force of law").

ments."[141] Although levels of insects below the defect action level may not lead to enforcement, FDA still characterizes them as "defects."[142]

### *B. (Predacious) Insects Added to Food*

In the spring of 1988, the United States Justice Department brought an enforcement action against grain at Arrowhead Mills to which predatory and parasitic insects had been added to control pest insects.[143] FDA initially took the position that the presence of the added insects rendered the food adulterated.[144] *Food Chemical News* reported that a July 18, 1988 letter from FDA to bug farmer Malcom A. Maedgen, Jr. indicated that FDA considered "the practice of intentionally adding 'beneficial' insects to foods to control insect pests," "simply . . . either substituting one adulterant for another, or . . . changing the nature of the adulteration."[145] This position appears to be consistent with FDA's classification of insects as filth as discussed in Section II.A, despite the fact that the insects in Arrowhead Mill's grain were intentionally added to the food unlike the insects discussed earlier.

FDA stated that the burden was on Maedgen to demonstrate through a food additive petition that the added "insects are safe and effective under their intended conditions of use,"[146] and declared that the addition of predacious insects to food was "illegal in the absence of either an approved pesticide tolerance from the [Environmental Protection Agency (EPA)] or an approved food additive petition from FDA."[147]

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141. *FDA Defect Levels Handbook*, *supra* note 11.

142. *See id.* Food producers must still comply with the sanitation requirements of FDCA § 402(a)(4) and cGMP. *Id.*

143. *See* United States v. 300 Bushels, More or Less, of an Article of Food, Rye, Contained in Bulk Storage Bin #56, No. 2:88-cv-00069, (N.D. Tex. Apr 11, 1988); Patricia Sharpe, *Buddy Maedgen Is Bugged!*, TEX. MONTHLY (Mar. 1989), http://www.texasmonthly.com/articles/buddy-maedgen-is-bugged/ [http://perma.cc/AG8L-D4TU].

144. *Food Additive Petition Needed for Adding Beneficial Insets to Food*, 30 FOOD CHEM. NEWS 7, 7–8 (1988); *see also* HUTT ET AL., *supra* note 129, at 478 (discussing the intentional addition of insects to food).

145. *Food Additive Petition*, *supra* note 144, at 7-8 (quoting a July 18 letter from FDA to M.A. Maedgen, Jr. of Mathis, Texas); *see also* Sharpe, *supra* note 143.

146. *Food Additive Petition*, *supra* note 144, at 7-8.

147. HUTT ET AL., *supra* note 129, at 479. The FDCA provides that a food is adulterated if it bears or contains an "unsafe" pesticide chemical residue. Food, Drug, and Cosmetic Act § 402(a)(2)(A), 21 U.S.C. § 342(a)(2)(A) (2012). A pesticide chemical residue is "unsafe" unless a specific tolerance or exemption from the requirement of a tolerance is in effect. FDCA § 406, 21 U.S.C. § 346a. The EPA Administrator has the authority to establish a tolerance for a pesticide chemical residue. FDCA § 406(b), 21 U.S.C. § 346a(b); FDCA § 201(hh), 21 U.S.C. § 321(hh).

In January 1991, EPA—with USDA and FDA's "cooperation and concurrence"—proposed a rule exempting "parasitic (parasitoid) and predaceous insects used to control insect pests of stored raw whole grains" from the requirement of tolerance.[148] While the final rule permits the addition of predacious insects to food, it does not regulate the insects as "food," and provides that they are still subject to section 402(a)(3) of the FDCA—which deems food consisting in whole or in part of "any filthy . . . substance" or "otherwise unfit for food" adulterated.[149] The preamble to the final rule states that the expectation is "that parasitic insect parts will generally be removed" from the food during processing.[150]

### *C. Insect-Derived Color Additives*

Cochineal extract and carmine are produced from cochineal—a dye made from the bodies of female scale insects, which have been dried and ground—and are used to color a variety of foods.[151] FDA has specifically regulated these

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The case was closed in December 1988. *See 300 Bushels, More or Less*, No. 2:88-cv-00069.

148. Parasitic and Predaceous Insects Used to Control Insect Pests; Proposed Exemption from a Tolerance, 56 Fed. Reg. 234 (Jan. 3, 1991) (proposed rule). A substance that has been exempted from the "pesticide chemical" and "pesticide chemical residue" definitions are exempt from regulation under sections 402(a)(2)(B) and 408 of the FDCA. *See* FDCA §§ 402(a)(2)(B) & 408, 21 U.S.C. §§ 342(a)(2)(B) & 346a (2012); 21 C.F.R. § 180.4.

149. *Id.*; 21 C.F.R. § 180.1101; FDCA § 402(a)(3), 21 U.S.C. § 342(a)(3) .

150. Parasitic and Predaceous Insects Used To Control Insect Pests; Exemption from a Tolerance, 57 Fed. Reg. 14,644, 14,644 (Apr. 22, 1992).

151. Cochineal Extract; Carmine, 21 C.F.R. § 73.100 (2017); Listing of Color Additives Exempt from Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine, 71 Fed. Reg. 4,839 (Jan. 30, 2006); *see also* FREDERICK J. FRANCIS, COLORANTS 73 (1999) (noting that "[i]t takes 50,000-70,000 insects to produce 1 lb. of the colorant").

While demand for cochineal extract and carmine has increased with the food industry's interest in natural dyes, FAO REPORT, *supra* note 6, at 30, some have objected to use of these color additives. *See, e.g.*, Nancy Shute, *Is That a Crushed Bug in Your Frothy Starbucks Drink?*, NPR: THE SALT (Mar. 30, 2012), http://www.npr.org/sections/thesalt/2012/03/30/149700341/food-coloring-made-from-insects-irks-some-starbucks-patrons [http://perma.cc/F2Z3-BYUV] (reporting that some Starbucks patrons were "distressed to learn that [one of the chain's drinks] owe[d] its pink coloring to crushed insects"); Cliff Burrows, *President Starbucks U.S., Update Regarding Cochineal Extract*, STARBUCKS BLOG (Mar. 29, 2012), http://web.archive.org/web/20120502223834/http:/blogs.starbucks.com/blogs/customer/archive/2012/03/29/update-regarding-cochineal-extract.aspx [http://perma.cc/N4UT-57EY] (accessing Internet Archive from May 2, 2012); Cliff Burrows, *President Starbucks U.S., Cochinal Extract Update*, STARBUCKS BLOG (Apr. 19, 2012), http://web.archive.org/web/20120421184817/http:/blogs.starbucks.com/blogs/customer/archive/2012/04/19/cochineal-extract

products as color additives,[152] which the FDCA requires be listed (i.e., approved) before being use in food.[153]

FDA provisionally listed carmine and cochineal extract for food use in the early 1960s after the enactment of the Color Additive Amendments of 1960.[154]

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-update.aspx [http://perma.cc/7RVG-D6TA] (accessing Internet Archive from April 21, 2012) (stating that Starbucks "fell short of [customer] expectations by using natural cochineal extract as a colorant in four food and two beverage offerings in the United States" and that the company is "reformulating the affected products to assure the highest quality possible").

152. 21 C.F.R. § 73.100 (2017). A color additive is a material which "when added or applied to a food . . . is capable . . . of imparting color" to it. FDCA § 701(t)(1), 21 U.S.C. § 321(t)(1) (2012).

153. FDCA § 721, 21 U.S.C. § 379e (2012); FDCA § 402(c), 21 U.S.C. § 342 (providing that a food is adulterated if it contains an unsafe color additive). Color additives are excluded from the food additive definition. FDCA § 302(s)(3), 21 U.S.C. § 321 (2012). While substances that are generally recognized as safe (GRAS) are excluded from the definition of food additive and hence the pre-market approval requirements for food additives, there is no GRAS exception for color additives. *Compare* 21 U.S.C. § 321(s) (2012) *with* 21 U.S.C. § 379e (2012).

In the mid-1960s following the passage of the Food Additive Amendments, however, the Flavoring Extract Manufacturer's Association convened a panel of experts to consider "the status of flavoring substances" under that Act. FLAVORING EXTRACT MFRS. ASS'N, RECENT PROGRESS IN THE CONSIDERATION OF FLAVORING INGREDIENTS UNDER THE FOOD ADDITIVES AMENDMENT: III GRAS SUBSTANCES 15, 19 (1965), http://www.femaflavor.org/sites/default/files/3.%20GRAS%20Substances%282001-3124%29_0.pdf [http://perma.cc/FF2J-WR3K]. The panel concluded that cochineal extract and carmine were GRAS for the specified food use. *Id.* A substance may be GRAS and listed as a color additive. *See* 21 U.S.C. § 201(t) (2012); 21 C.F.R. § 70.3(f)-(g) (2016); Julie N. Barrows, *Color Additives: FDA's Regulatory Process and Historical Perspectives*, FOOD SAFETY MAG. (Oct./Nov. 2003), http://www.fda.gov/ForIndustry/ColorAdditives/RegulatoryProcessHistoricalPerspectives [http://perma.cc/NYY4-ZL9C]; Letter from Dennis M. Keefe, Dir., FDA CFSAN/Office of Food Additive Safety, to Susan Cho, INNOBIO (Mar. 16, 2015), https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm443039.htm[http://perma.cc/4E8Q-S9P5] (GRAS Notice No. GRN 000543).

154. Transitional Regulations Under Title II of Color Additive Amendments of 1960 to Federal Food, Drug, and Cosmetic Act, 26 Fed. Reg. 7,578 (Aug. 16, 1961) (provisionally listing carmine, among other things, for food use); Transitional Regulations Under Title II of Color Additives Amendments of 1960 to Federal Food, Drug, and Cosmetic Act, 25 Fed. Reg. 9,759 (Oct. 12, 1960) (provisionally listing cochineal, among other things, for food use); *see also* Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 (July 12, 1960). The Color Additive Amendments of 1960 defined the term "color additive" and specified the conditions under which a color additive may be "listed," or approved, as suitable and safe for use. Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 § 103 (July 12, 1960). It also permitted FDA to provisionally list "commercially established color additives to the extent consistent with the public health, pending

This provisional listing was based on the "prior commercial sale" of these products, which "have a long history of use" in the United States and elsewhere.[155] In the late 1960s, following petitions requesting that carmine and cochineal extract be permanently listed as safe and suitable for food use, FDA approved the use of these substances to color foods,[156] specifying in the regulations that the additives must "be pasteurized or otherwise treated to destroy all viable Salmonella microorganisms."[157]

In 1998 the Center for Science in the Public Interest (CSPI) petitioned FDA to require that cochineal extract and carmine "be listed by name in the "ingredient lists of all foods . . . to help protect individuals who know they are sensitive to the colorings."[158] At that time, FDA did not require food labels to declare cochineal extract and carmine, as both were certification-exempt color additives permitted to be declared on a food label with a general phrase such as "Color Added."[159]

In 2006—in response to CSPI's petition as well as "reports of severe allergic reactions, including anaphylaxis" to foods containing cochineal extract and

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the completion of the scientific investigations needed as basis for making determinations as to listing." 74 Stat. 397 § 203.

155. Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration, 71 Fed. Reg. at 4,840; FRANCIS, *supra* note 151, at 73; *see also* Yuan-Kun Lee & Hwee-Peng Khng, *Natural Color Additives*, *in* FOOD ADDITIVES (John H. Thorngate III et al. eds., 2001).

156. Carmine, Listing for Food and Drug Use; Exemption from Certification, 32 Fed. Reg. 6,131 (Apr. 19, 1967) (approving carmine, among other things, for food use); Cochineal Extract, 33 Fed. Reg. 18,577 (Dec. 14, 1968); *see also* 21 C.F.R. § 73.100(c) (listing cochineal extract and carmine). The petitions supporting the listing of these color additives included information on the history of their use. *See* Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration, 71 Fed. Reg. at 4,840-41.

157. *See* Carmine, Listing for Food and Drug Use; Exemption from Certification, 32 Fed. Reg. at 6,131 (approving carmine, among other things, for food use); Cochineal Extract, 33 Fed. Reg. at 18,577; *see also* 21 C.F.R. § 73.125 (2017).

158. Michael F. Jacobson, Exec. Dir., Center for Science in the Public Interest, Petition for Proposed Rulemaking and Regulatory Action to Provide Ingredient and Source Labeling, Scientific Review of Allergericity, and Possibble[sic] Prohibition of Cochineal Extract and Carmine Color Additives, FDA 98P-0724 (Aug. 24, 1998), http://web.archive.org/web/20170706004256/http://www.fda.gov/ohrms/dockets/dockets/98p0724/98p-0724-cp00001-01.pdf [http://perma.cc/5RUM-TWDU] (accessing Internet Archive from July 6, 2017).

159. *See* Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration, 71 Fed. Reg. at 4,840-41. FDA's regulations permit labels to declare a certification-exempt color additive as coloring without naming the additive. Foods; labeling of spices, flavorings, colorings and chemical preservatives, 21 C.F.R. § 101.22(k)(2) (2017); Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration, 71 Fed. Reg. at 4,844.

carmine—FDA proposed to amend its regulations to require that food labels specifically declare the presence of cochineal extract and carmine in products containing the color additives.[160] The regulation finalized in 2009 requires that the ingredient statement of a food containing cochineal extract or carmine declare the presence of the color additive by its common or usual name, "cochineal extract" or "carmine,"[161] to enable allergic consumers to avoid products that contain these color additives.[162] FDA, however, declined to require the labeling of the animal or insect origin of these color additives, stating that "[t]he origins of cochineal extract and carmine are clearly described in the color additive regulations" and that "[i]f consumers desire to avoid products containing these color additives, they will be able to identify such products by reading the ingredient list."[163]

160. *Id*. at 4,839 (proposed rule).

161. Listing of Color Additives Exempt from Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration, 74 Fed. Reg. 207, 208 (Jan. 5, 2009); *see also* Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration; Confirmation of Effective Date, 74 Fed. Reg. 10,483 (Mar. 11, 2009) (confirming the effective date for the final rule as Jan. 5, 2011); 21 C.F.R. § 73.100 (requiring that "the label of food products intended for human use, including butter, cheese, and ice cream, that contain cochineal extract or carmine . . . specifically declare the presence of the color additive by name, 'cochineal extract' or 'carmine,' in the statement of ingredients); *see also* U.S FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: COCHINEAL EXTRACT AND CARMINE: DECLARATION BY NAME ON THE LABEL OF ALL FOODS AND COSMETIC PRODUCTS THAT CONTAIN THESE COLOR ADDITIVES; SMALL ENTITY COMPLIANCE GUIDE (Apr. 2009), http://www.fda.gov/ForIndustry/ColorAdditives/GuidanceComplianceRegulatoryInformation/ucm153038.htm [http://perma.cc/R4JT-UZPG].

162. Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration; Confirmation of Effective Date, 74 Fed. Reg. at 207.

163. *Id*. at 209. CSPI's petition as well as comments on FDA's proposed rule had requested that FDA require that the animal or insect origin of cochineal extract and carmine be declared on the label. Jacobson, *supra* note 158; Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration; Confirmation of Effective Date, 74 Fed. Reg. at 209. CSPI argued that the origin of the color additives should be labeled "so as not to mislead vegetarians or consumers who follow religious dietary restrictions" and arguing that "[p]recedent for this type of labeling is found in the regulation of labeling for wax coating on fresh fruits and vegetables," which were revised "to require a declaration of [the] organic origin of the coating material." Jacobson, *supra* note 158, at 3–5. Many of the comments seeking declaration of the origin of cochineal extract and carmine on labels echoed this argument "stat[ing] that persons who wish to avoid consuming animal products need [disclosure of the animal or insect origin] in order to avoid such products and that labeling cochineal extract and carmine by name is not sufficient." Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine

Although the regulatory requirements for color additives differ from those for foods, several issues that FDA has addressed in the regulation of carmine and cochineal extract may arise in the regulation of insects as food or components of food. These issues include possible microbial contamination, allergens, and consumer demand for information about a product's animal or insect origin.

## III. Regulating Insects as Food and Components of Food

This Part considers how FDA might regulate insects in and as food using the existing law and regulatory processes. It highlights several significant issues and challenges related to insects as human food and their regulation. Part IV then argues that FDA should unambiguously provide by regulation that insects used as food are "food" under the FDCA and provide a principled way to distinguish between insects as "filth" and insects as "food." It suggests that one possible way for FDA to distinguish between insects as food and insects as filth is to use intent. FDA's regulatory inaction with respect to insects as food in light of the substantial regulation of insects as filth may reflect and reinforce cultural understandings of insects as something other than food. By legally recognizing that insects can be food, FDA may help to erode the cultural barriers surrounding insects as food and open the doors to the further exploration and development of insects as food.

### *A. Insects as Filth*

One possibility is that insects used as food or a component of food are "filth" and their addition to food renders the food adulterated under section 402(a) of the FDCA, and is prohibited under section 301.[164] This approach would be consistent with FDA's extensive regulation of insects as filth as well as its initial treatment of predacious insects intentionally added to stored grain to control pests.[165] Indeed, a March 1989 article by two FDA employees in *The Food Insects Newsletter* indicates that "[a]t one time there was some concern within the FDA" that an insect intentionally added to food (mescal or tequila) might be filth.[166] These examples suggest that the classification of an insect did

Declaration; Confirmation of Effective Date, 74 Fed. Reg. at 209; *see also* Kaycee L. Wolf, *Beetles for Breakfast: What the FDA Should Be Telling You*, 3 J. Food L. & Pol'y 229, 232 (2007) (arguing that "FDA should . . . require that labels disclose the insect-origin of [cochineal extract and carmine]").

164. *See supra* Section II.A (discussing insects as defects); *see also* Food, Drug, and Cosmetic Act § 301, 21 U.S.C. § 331 (2012); *id.* § 402(a)(3), 21 U.S.C. § 342(a)(3) (2012).

165. *See supra* Section II.A.

166. Paris M. Brickley, Jr. & J. Richard Gorham, *Preliminary Comments on Federal Regulation Pertaining to Insects as Food*, 2 Food Insects Newsl. 1 (Mar. 1989), http://labs.russell.wisc.edu/insectsasfood/files/2012/09/Volume_2_No_1.pdf

not hinge on whether it was intentionally added to a food or not. *The Food Insects Newsletter* article, however, notes that "a kinder and gentler interpretation of the law prevailed and it was eventually concluded that since the [insect] larvae [were] added *intentionally*, they bec[a]me part of the product and d[id] not constitute insanitation."[167] That interpretation, however, may not be binding on the agency and there is a risk that the agency could return to its prior interpretation of the law.[168]

### *B. Insects as Food and Components of Food*

Another possibility is that insects used as food or a component of food are "food" under the broad definition of food in the FDCA, which includes "articles used for food" and "articles used for components of" food.[169] Currently FDA appears, at least informally, to have accepted the use of insects as food or a component of food as being "food" under the FDCA.[170] For example, "FDA's Standard Response to Entomophagy Inquiries" as described in a slide deck from a speech by FDA's Dr. George Ziobro indicates that under the FDCA, "bugs/insects are considered food if they are to be used for food or as components of food."[171] This policy of recognizing insects used as food or components of food is consistent with the March 1989 *Food Insects Newsletter* article, which also stated that "[t]he fact that a food product consists largely or entirely of insects

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[http://perma.cc/QMT3-WS45] [hereinafter "March 1989 Food Insects Newsletter article"].

167. *Id.* (emphasis added).

168. *See generally* K.M. Lewis, *Informal Guidance and the FDA*, 66 FOOD & DRUG L.J. 507 (2011); Good Guidance Practices, 21 C.F.R. §10.115 (providing that speeches, journal articles, and editorials, among other things, are not guidance documents).

169. *See* FDCA § 201(f), 21 U.S.C. § 321(f) (2012); *see also* Ziobro, *supra* note 13, at slide 4.

170. *See, e.g.*, *id.*

171. *Id.* The slide deck indicates that Dr. Ziobro is with FDA's Center for Food Safety and Applied Nutrition [hereinafter "Ziobro slide deck"]. *Id.* at slide 1.

In response to a FOIA request by the author, FDA provided several emails regarding responses to inquiries relating to the regulation of insects as food that are largely consistent with response discussed above. E-mail from George C. Ziobro to Patricia El-Hinnawy & John Sheehan (Jan. 24, 2011, 10:46 AM) (on file with author) (stating that under the FDCA "bugs/insects are considered food if that is the intended use"); E-mail from Kenneth Nieves to George E. Ziobro (Mar. 11, 2015, 08:09 AM) (on file with author) (stating that "bugs/insects are considered 'food' if they are articles for food or are articles used for components of any other article"). FDA also provided one letter responding to an inquiry on behalf of the Worm Tequila Company. Letter from Cora E. Weeks, Assistant to the Director, office of Plant and Dairy Foods and Beverages, to Nicholas J. Kocz, James V. Hurson Associates (Dec. 1, 1994) (on file with author).

intentionally processed and packaged for use as human food does not automatically bar it from commercial distribution to the American consumer."[172]

That FDA as a matter of policy does not regard all insects used as food or a component of food as adulterated also is consistent with a 1993 warning letter from FDA concerning the product "Sugar-Free Hotlix Flavored Candy with Genuine [W]orm."[173] That letter alleged that the product was misbranded in violation of the FDCA for failing to include an appropriate standard of identity ("Artificial Tequila Flavored Candy with a Worm or with a Mealworm (if a mealworm is used)") and declare the ingredient by its common or usual name ("insect larva" or "mealworm larva").[174] The letter notably did not allege that the worm or mealworm-containing product was adulterated due to the inclusion of the worm or mealworm.[175]

If insects used as food are food, they would be subject to the regulatory framework for foods generally. Indeed, this is consistent with what several FDA employees have communicated informally.[176] For example, the March 1989 *Food Insects Newsletter* article states that "[i]f the *intended use* of [imported] insects is as food, then any such product would be subject to all pertinent sections of the [FDCA] under which foods are regulated."[177] Accordingly, insects as food would be subject to the FDCA's prohibitions concerning adulterated and misbranded food.[178] Consistent with its mission to protect and advance public

172. Brickley & Gorham, *supra* note 166; *see Paris M. Brickley Jr. Obituary*, WASH. POST (Aug. 1, 1995), http://www.washingtonpost.com/archive/local/1995/08/01/joseph-c-lone-eagle-vasquez-dies/2c40d377-783c-4a79-86ca-444cd51fb6a2 [http://perma.cc/U7WK-PLWY] (identifying Brickley as the "director of [FDA's] microanalytical evaluations division and an authority on sanitation" who had worked for FDA since 1961); *FDA's Gorham Retires*, 8 FOOD INSECTS NEWSL. 12 (July 1995), http://labs.russell.wisc.edu/insectsasfood/files/2012/09/Vol_8_No_2.pdf [http://perma.cc/HNN3-75KC] (noting Gorham's retirement from FDA).

173. *See* Letter from Elaine C. Messa, Dir., Los Angeles District, FDA, to Larry Peterman, Owner, S.S. Lollipop, Warning Letter WL-56-3 (Apr. 28, 1993); *see also* HUTT ET AL., *supra* note 129, at 478.

174. *See* Letter from Elaine C. Messa, Dir., Los Angeles District, FDA, to Larry Peterman, Owner, S.S. Lollipop, Warning Letter WL-56-3 (Apr. 28, 1993); *see also* HUTT ET AL., *supra* note 129, at 478.

175. *See* Letter from Elaine C. Messa, Dir., Los Angeles District, FDA, to Larry Peterman, Owner, S.S. Lollipop, Warning Letter WL-56-3 (Apr. 28, 1993); *see also* HUTT ET AL., *supra* note 129, at 478.

176. *See, e.g.*, Ziobro, *supra* note 13, at slide 4 ("FDA's Standard Response to Entomophagy Inquiries"); Feltman, *supra* note 20 (quoting FDA spokesperson).

177. Brickley & Gorham, *supra* note 166, at 1 (emphasis added); *see also* Regarding Letter from Floyd D. Spence, "Cricket Licket" lollipops, Memorandum from Richard E. Fisher (HFS-306) to Jack Boese, DME (HFS-315) (June 6, 1995) [hereinafter "Cricket Licket" Lollipops Memorandum] ("Concerning health and safety, insects *intended* as food are subject to the provisions of the Act under which foods are regulated.") (emphasis added).

178. *See* Food, Drug, and Cosmetic Act §§ 301, 402-403, 21 U.S.C. §§ 342-343 (2012).

health, FDA has interpreted the term "food" broadly,[179] and it includes items that are not fit for food due to adulteration.[180]

1. Adulteration and Misbranding

This Section begins by highlighting some of the complexities and challenges that may arise in using the adulteration provisions in section 402 of the FDCA to regulate insects as food.[181] It provides several examples of how insects as food may be deemed to be adulterated under the Act. First, insects used as food could contain *natural or non-added* poisonous or deleterious substances that ordinarily render the food injurious to health and adulterated under section 402(a)(1), cl. 2. Second, insects as food could contain *added* poisonous or deleterious substances that may render the food injurious to health and adulterated under 402(a)(1), cl. 1. Third, insects as food could be "otherwise unfit for food" and adulterated under section 402(a)(3) of the FDCA. Fourth, insects as food, like other foods, could be deemed to be adulterated under section 402(a)(3) or 402(a)(4) due to filth. This Section also considers some of complexities and challenges that may arise in using the misbranding provisions in section 403 of the FDCA to regulate insects as food.[182]

Insects used as food could contain poisonous or deleterious substances that render them adulterated under section 402(a)(1) of the FDCA, which provides that a food is adulterated "[i]f it bears or contains any poisonous or deleterious substance."[183] First, insects used as food could contain *natural or non-added* poi-

179. FDCA § 1003, 21 U.S.C. § 393 (2012) (FDA's mission statement); *What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/ [http://perma.cc/DNZ8-DEYB]; *see also* United States v. An Article of Drug . . . Baco-Unidisk, 394 U.S. 784, 798 (1969) (stating that "remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health").

180. *See* United States v. H.B. Gregory Co., 502 F.2d 700, 704 (2d Cir. 1974), *cert. denied*, 422 U.S. 1007 (1975) (rejecting the "defendant's argument that the lot[] of food w[as] not held for sale because . . . the one lot of corn meal was so filthy it was no more than 'garbage' and would not be offered for sale under any conditions").

181. FDCA § 402, 21 U.S.C. § 342.

182. FDCA § 403, 21 U.S.C. § 343.

183. FDCA § 402(a)(1), 21 U.S.C. § 342(a)(1). This provision distinguishes between a substance that is "not . . . added" and by implication one that is added, and provides different standards for each. *Id.*; *see, e.g.*, United States v. Anderson Seafoods, Inc., 622 F.2d 157, 159 (5th Cir. 1980) ("Whether a substance is added or not is important because of the evidentiary showing that the Food and Drug Administration must make to succeed in an enforcement action.").

A substance is "added" if it is "artificially introduced, or attributable to the acts or intervention of man." United States v. Anderson Seafoods, Inc., 447 F. Supp. 1151, 1155 (N.D. Fla 1978), *aff'd*, 622 F.2d 157, 160; *see also* Continental Seafoods, Inc. v. Schweiker, 674 F.2d 38, 43 (D.C. Cir. 1982) (noting that the court

sonous or deleterious substances that ordinarily render the food injurious to health and adulterated under section 402(a)(1), cl. 2.[184] An insect that produces a naturally occurring toxin that ordinarily renders it injurious to health could be deemed adulterated under this provision.[185] For example, the Ziobrio slide deck identifies blister beetles as an insect posing toxicogenic hazards, noting that "[t]here are estimates that ingesting as few as 1-3 blister beetles could cause injury or death."[186] Second, insects as food also could contain *added* poisonous or deleterious substances that may render the food injurious to health and adulterated under 402(a)(1), cl. 1.[187] For example, insects "may be infected with pathogenic micro-organisms," or contain harmful metals or pesticides,[188] due to

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in *Anderson Seafoods* "held that a showing of human intervention could be based on general scientific knowledge about the origin of the additive in question" and holding that FDA "need not prove that substances present in a particular lot were introduced by man"). For example, mercury in swordfish has been held to be "added" where "[t]here was sufficient evidence to show that some mercury is attributable to the acts of man." *Anderson Seafoods*, 622 F.2d at 162.

A food that "bears or contains any" added "poisonous or deleterious substance which *may* render it injurious to health" is adulterated. FDCA § 402(a)(1), 21 U.S.C. § 342(a)(1). *See, e.g.*, *Anderson Seafoods*, 447 F.Supp. at 1151; *Continental Seafoods*, 674 F.2d at 38.

In other words, if there is a "reasonable possibility" that the added substance will render the food injurious to health, it is adulterated. *See, e.g.*, *Anderson Seafoods*, 447 F.Supp. at 1155 ("A food is not adulterated within the meaning of the statute unless the added substance 'may render it injurious to health.' The word 'may' connotes a reasonable possibility."). In contrast, a poisonous or deleterious substance that is not added renders a food adulterated only if the quantity of the substance in the food *ordinarily* renders it injurious to health. FDCA § 402(a)(2), 21 U.S.C. § 342(a)(2); *see, e.g.*, United States v. 1232 Cases Am. Beauty Brand Oysters, 43 F.Supp. 749, 751 (W.D. Mo. 1942) (holding that the oysters were not adulterated based on the evidence in the case because "the presence of shell fragments . . . does not ordinarily render [the oysters] injurious to health").

184. FDCA § 402(a)(1), 21 U.S.C. § 342(a)(1); *see also 1232 Cases Am. Beauty Brand Oysters*, 43 F.Supp. at 751.

185. *See* FDCA § 402(a)(1), 21 U.S.C. § 342(a)(1).

186. Ziobro, *supra* note 13, at slide 11 nn.

187. FDCA § 402(a)(1), 21 U.S.C. § 342(a)(1). Some added poisonous or deleterious substances in food are required in the production of the food or cannot be avoided by current Good Manufacturing Practice (cGMP), and the FDCA permits FDA to establish tolerances for these defects. *See* FDCA § 406, 21 U.S.C. § 346. Establishing a tolerance is procedurally difficult, and FDA has only promulgated one tolerance. *Young*, 476 U.S. at 977; Tolerances for polychlorinated biphenyls (PCB's), 21 C.F.R. § 109.30 (2017); *see also* 21 C.F.R. § 109.4 (2017). FDA has used nonbinding action levels as a way to address these defects much more frequently. *See* Action Levels for Added Poisonous or Deleterious Substances in Food, 53 Fed. Reg. 5,043 (Feb. 19, 1988).

188. FAO REPORT, *supra* note 6, at xv, 119-22.

human activities. In California, dried grasshoppers that "contained significant amounts of lead" were investigated as a potential source of a lead poisoning outbreak.[189] As another example, the consumption of termites was linked to six cases of botulism, five of which were fatal, in Kenya.[190]

Third, insects as food could also be adulterated if they are "otherwise unfit for food" under section 402(a)(3) of the FDCA.[191] An insect or part of an insect that poses a choking hazard could potentially be considered adulterated under this provision.[192] For example, one article on insects as human food described someone cooking crickets, "pull[ing] off the ovipositors and the legs, which can stick in the throat."[193]

Fourth, even if insects used as food or as a component of food are not filth, FDA could take action against products that it deems adulterated under section 402(a)(3), which addresses food that "consists in whole or in part of any filthy, putrid, or decomposed substance," or under 402(a)(4), which addresses food

189. Eur. Food Safety Auth. Sci. Comm., *supra* note 32, at 27. The suspected grasshoppers were home-prepared. *Id.* Lead in the environment is a result of "its natural occurrence and its release into the environment by human activities." U.S. FOOD & DRUG ADMIN., REPORTED FINDINGS OF LOW LEVELS OF LEAD IN SOME FOOD PRODUCTS COMMONLY CONSUMED BY CHILDREN, http://web.archive.org/web/20170503041634/https://www.fda.gov/Food/FoodborneIllnessContaminants/Metals/ucm233520.htm [http://perma.cc/8WXK-XXK3] (accessing Internet Archive from May 3, 2017). In *Anderson Seafoods*, in considering whether mercury "is an 'added substance' within the meaning of the [FDCA]," the Fifth Circuit held "[w]here some portion of a toxin present in a food has been introduced by man, the entirety of that substance present in the food will be treated as an added substance and so considered under the 'may render injurious to health' standard of the Act.'" 622 F.2d 157, 161 (5th Cir. 1980).

190. K.W. Nightingale & E.N. Ayim, *Outbreak of Botulism in Kenya After Ingestion of White Ants*, 281 BRIT. MED. J. 1682, 1682 (1980) (stating that the termites were stored in "anaerobic conditions" and that "Botulism is an intoxication, the toxin being formed under anaerobic conditions in food containing living spores of *Cl botulinum*, an organism fairly widely distributed in soil"); *see also* Ziobro, *supra* note 13, at slide 15 (stating that "[m]ealworms have been traced to outbreaks of *Salmonella* in chicken houses"). Salmonella may be at least partially introduced by man and thus considered added under the FDCA. *See* Cont'l Seafoods, Inc. v. Schweiker, 674 F.2d 38, 43 (D.C. Cir. 1982) (noting that FDA's "observations provided more than enough support for the agency's conclusions that the bacteria had been at least partly introduced by man").

191. FDCA § 402(a)(3), 21 U.S.C. § 342(a)(3).

192. *See Seizure of "Konjac" Candy*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/ICECI/EnforcementActions/EnforcementStory/EnforcementStoryArchive/ucm105953.htm [http://perma.cc/7D98-UTYP] (noting that "konjac" candy (mini gel candies) were seized because FDA (in conjunction with the Consumer Product Safety Commission) concluded that the candies were "adulterated . . . in that they [were] unfit for food because they pose[d] a serious choking hazard").

193. Goodyear, *supra* note 53.

that "has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."[194] Indeed, the March 1989 *Food Insects Newsletter* article recognizes that an insect food can be contaminated with filth in the form of other insects. That article describes insects used as food—"[f]rozen steamed ant eggs"—"adulterated with," among other things "mites[] and insect fragments" in "violation of [section] 402(a)(3)[]."[195] Hence, an insect as food could be deemed to be adulterated due to the presence of other insects as filth.

A slide deck from a speech by Dr. Ziobro gives some indication of how FDA may regulate insects as food using the FDCA's adulteration provisions. A slide summarizing "FDA's Standard Response to Entomophagy Inquiries" states that under the law, FDA requires that food "be clean and wholesome (i.e. free from filth, pathogens, toxins) . . . [and] have been produced, packaged, stored and transported under sanitary conditions."[196] It also indicates that insects "must be raised specifically for human food following [cGMP]" and that "[i]nsects raised for animal or pet food" or "collected in the wild" cannot be sold as human food, "due to the potential [of insects collected in the wild carrying diseases or pesticides]."[197] Other slides identify concerns regarding hazards—including "vector," "structural," "allergenic," and "toxicogenic" hazards—that FDA may regulate under the FDCA's adulteration provisions.[198] The notes accompanying the slides provide several examples of insects as food or

194. FDCA § 402(a)(3)-(4), 21 U.S.C. §342(a)(3)-(4).

195. Brickley & Gorham, *supra* note 166, at 1; *see also* Ziobro, *supra* note 13, at slide 4. In addition, there have been reports of FDA blocking "Mimolette, a French cheese deliberately exposed to mites" from import when the cheese has "'unacceptable' mite levels." *See* Fiona Barry, *Mimolette "Mite" Be Blocked If Levels Are Too High, Says FDA*, FOOD QUALITY NEWS (Aug. 6, 2013), http://www.foodqualitynews.com/Industry-news/Mimolette-mite-be-blocked-if-levels-are-too-high-says-FDA [http://perma.cc/6M3S-VLQE]. One report indicates that an FDA spokesman said that the "excess cheese mites . . . were classed as 'filth'" under the FDCA. *Id.*

196. Ziobro, *supra* note 13, at slide 4.

197. *Id.* at slides 4, 14 nn.

198. *Id.* The EFSA's scientific risk assessment highlights several potential risks of insects as food or a component of food that could possibly render a food adulterated. *See* EFSA Sci. Comm., *supra* note 32; Brickley & Gorham, *supra* note 166, at 7 (stating that foods "composed largely or entirely of insects, must be harvested, stored, prepared, packaged and distributed under protocols that will prevent the proliferation and persistence of pathogens and toxins"); Sonny Ramaswamy, *Insects for Dinner? Potential Tool in the Toolkit to Achieve Global Food Security*, USDA BLOG (May 16, 2014), http://blogs.usda.gov/2014/05/16/insects-for-dinner-potential-tool-in-the-toolkit-to-achieve-global-food-security/ [http://perma.cc/4VMF-2R2S] ("[F]or all the advantages of eating insects, there are still many unanswered questions. Little is known about the nutritional quality and safety of eating certain insects.").

components of food that are identified as not permitted.[199] While the slide deck does not identify the specific provisions of the FDCA under which it claims that the foods would be prohibited, the legal basis of these claims appears to be the adulteration provisions in section 402(a) of the FDCA.

Insects as food would also be subject to the misbranding provisions in section 403 of the FDCA.[200] A food is misbranded if its labeling makes prohibited representations or its label fails to include required information.[201] For example, under section 403(a) a food is misbranded if "its labeling is false or misleading":

> [I]n determining whether the labeling . . . is misleading there shall be taken into account (among other things) not only representations made or suggested . . . but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to the consequences which may result from the use of the article.[202]

In addition, a food is misbranded if its label does not bear its "common or usual name" (if any), "the common or usual name of each . . . ingredient" if there are two or more, and the required nutrition facts information.[203]

FDA employees have made several cautionary statements in articles and speeches that discuss the labeling of insects as food. For example, two FDA em-

199. For example, the "vector hazard" slide indicates that "Casu Marzu"—"a cheese from Sardinia," which "is purposely infested with fly maggots"—is "banned in the United States because the eating of this product can cause a person's intestinal tract to become infested with maggots . . . [which] can bore through the person's intestinal tract [and] can lead to . . . death." Ziobro, *supra* note 13, at slide 8. The notes to the "toxicogenic hazards" slide provide the example of "a candy called an insect in amber," which the notes indicate is "considered adulterated under the [FDCA] because" the "stinger and poison sac [of the insect] are still attached." *Id.*

In addition, the notes for the "structural hazards" slide provide the "specialized hairs called hastisetae found on the larvae of dermestid beetles" as an example of a structural hazard. Ziobro, *supra* note 13, at slide 10. According to the notes, these hairs "are shed when a predator, or human, eat the larvae" and "get lodged in the mouth, esophagus, or digestive tract." *Id.* One company recalled "5 million containers of powdered infant formula . . . due to the presence of hastisetae in their product." *Id.*

200. Food, Drug, and Cosmetic Act § 403, 21 U.S.C. § 343 (2012).

201. *Id.*; *see also* FDCA § 201(n), 21 U.S.C. § 321(n) (2012). The FDCA defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article." *Id* § 201(k), 21 U.S.C. §321(k). It defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id* § 201(m), 21 U.S.C. § 321(m).

202. FDCA §§ 403(a), 201(n), 21 U.S.C. §§ 343(a), 321(n).

203. FDCA §§ 403(i), (q), 21 U.S.C. §§ 343(i), (q) (2012); *see also* Food Labeling, 21 C.F.R. pt. 101 (2017).

ployees wrote in the March 1989 *Food Insects Newsletter* that food, including insects as food, "must be properly labeled."[204] Similarly "FDA's Standard Response to Entomophagy Inquiries" as described in the Ziobro slide deck states that insects as food "must be properly labeled (Sec. 403),"[205] and that "[t]he label should include the scientific name of the insect."[206]

One of the few instances identified in which FDA has specifically addressed a product that intentionally contained insects and threatened enforcement action involved allegations of misbranding.[207] In an April 28, 1993 warning letter to the manufacturer of an insect-containing candy, FDA alleged that the candy was misbranded for, among other things, failing to include "the common or usual name of the food"—"Artificial Tequila Flavored Candy with a Worm or with a Mealworm"—on the principal display panel of the package and failing to declare the ingredient "'insect larva', by its common or usual name"—"'mealworm larva'"—in the ingredient statement.[208] FDA warned that failure "to take prompt action to correct these violations . . . may result in regulatory action without further notice, including seizure and/or injunction."[209]

While the limited available statements suggest insects as food are subject to the same general labeling requirements as other foods, an internal FDA memorandum dated June 6, 1995, discussing the labeling of insects as food suggests that insects as food may raise additional labeling concerns. That memorandum states that "the 'burden' placed on labeling may be greater than usual" for lollipops that intentionally contain insects ("'Cricket Licket' lollipops") as "the idea that an insect would be intentionally placed in a lollipop is novel, and therefore unexpected."[210] The memorandum suggests that existing policies concerning insects as food may not be appropriate for such products and notes that "[o]nce the label is removed (or can't be read, etc.), awareness of the nature of the product depends on the consumer's ability to see and recognize the insect in the product."[211]

If a product is adulterated or misbranded, FDA and DOJ can coordinate under the FDCA to bring an action in court to remove the product from the market.[212] Regulating products using the general adulteration and misbranding

204. Brickley & Gorham, *supra* note 166, at 1.

205. Ziobro, *supra* note 13, at slide 4.

206. *Id.*

207. Warning Letter from Elaine C. Messa, Dir., Los Angeles District, U.S. Food & Drug Admin., to Larry Peterman, Owner, S.S. Lollipop (Apr. 28, 1993).

208. *Id.*

209. *Id.*

210. "Cricket Licket" Lollipops Memorandum, *supra* note 177.

211. *Id.*

212. *See* Food, Drug, and Cosmetic Act § 301, 21 U.S.C. § 331 (2012) (prohibited acts); *id.* § 302, 21 U.S.C. § 532 (injunction proceedings); *id.* § 304, 21 U.S.C. § 334 (seizure); *id.* § 401, 21 U.S.C. § 342 (adulterated food); *id.* § 402, 21 U.S.C. § 343 (misbranded food); *see also* ARTHUR N. LEVINE, 1 FDA ENFORCEMENT MANUAL

provisions for food has several limitations. Actions brought to enforce the adulteration and misbranding provisions of the FDCA are a form of post-market enforcement; accordingly, if a food is adulterated or misbranded FDA must take action in order to remove it from the market,[213] and FDA bears the burden of proving that it is adulterated or misbranded.[214] In adulteration cases, FDA "must first conduct scientific studies of the food product in order to gather the data necessary to proving its case," an undertaking that "may take years," during which time "an unsafe food may remain on the market."[215] These limitations of post-market enforcement are not unique to insects as food. Indeed, the Food Additives Amendment of 1958, which established a premarket approval requirement for direct food additives, was enacted to address these limitations.[216] In addition, as discussed in Section IV.A below, using post-market adulteration and misbranding enforcement actions to regulate insects used as food may be insufficient to counter the extensive law categorizing insects as filth, which may reinforce cultural conceptions of insects as filth.

2. Food Additives

An insect, insect part, or insect derivative could be a "food additive" under the FDCA if the intended use of the substance "results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food" and the substance does not fall

¶ 110 (Administrative Enforcement Powers) (2015), 2000 WL 35466047 (discussing judicial enforcement); Lars Noah & Richard A. Merrill, *Starting from Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 334 (1998) (discussing enforcement of the FDCA's provisions regarding adulterated food); Jennifer L. Pomeranz, *A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels*, 39 AM. J.L. & MED. 617, 632 (2013) (discussing enforcement of the FDCA's provisions regarding the misbranded food); Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645, 1651-52 (2004).

213. Noah & Merrill, *supra* note 212, at 334 (describing the FDCA "retain[ing] the same basic system of after-the-fact policing for adulterants in food" as the 1906 Pure Food & Drugs Act); Pomeranz, *supra* note 212, at 632; Van Tassel, *supra* note 212, at 1651-52.

214. *See* James T. O'Reilly & Katherine A. Van Tassel, THE MODERN FDA REGULATORY STRUCTURE AND THE FDA'S GATEKEEPER ROLE, 1 FOOD & DRUG ADMIN. § 12:17 (2016).

215. Van Tassel, *supra* note 212, at 1651-52; *see also* Lars Noah, Legal Aspects of the Food Additive Approval Process, Enhancing the Regulatory Decision-Making Approval Process for Direct Food Ingredient Technologies: Workshop Summary, app. A (1999), http://www.ncbi.nlm.nih.gov/books/NBK224037/ [http://perma.cc/622B-DAXT].

216. Frederick H. Degnan, *Rethinking the Applicability and Usefulness of the GRAS Concept*, 46 FOOD DRUG COSM. L.J. 553, 554-55 (1991); *see also* Food Additive Amendments of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958).

into one of the exceptions to this definition.[217] If an insect, insect part, or insect derivative is a food additive, its use would be required to be approved by FDA. Specifically, the FDCA provides that there must be in effect "a regulation issued under [§ 409, 21 U.S.C. § 348 (2012)] prescribing the conditions under which [the] additive may be safely used" and "it and its use or intended use" must be "in conformity with" such regulation.[218] If not, it would be deemed to be unsafe and adulterated in violation of the FDCA.[219]

Using the food additive provisions to regulate insects as an intentional component of food may have several benefits, but ultimately would likely be unworkable due to the serious limitations of the food additive approval process. Unlike the general adulteration provisions, which place the burden on FDA to prove that a food is adulterated in order to remove it from the market,[220] the food additive "provisions are designed to protect consumers against *the introduction* of untested and potentially unsafe substances" and place the burden on the manufacturer to show "that the substance, when added to food, is generally recognized as safe" before it can be lawfully marketed.[221] Hence, if an insect were approved for use as a food additive, it would mean that there was a reasonable certainty among competent scientists that the additive may be safely used under the conditions prescribed in the regulation.[222]

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217. FDCA § 201(a), 21 U.S.C. § 3219(a). FDA at one point was reported to have taken the position that predacious insects added to food would need to be approved as food additives before use. *Food Additive Petition*, *supra* note 144, at 7–8; *see supra* Section II.B.

    A slide deck from a speech by Dr. Sonny Ramaswamy—the director of USDA's National Institute of Food and Agriculture (NIFA)—indicates that insect protein would be "[s]ubject to regulation like any other food ingredient, which means that the protein is a food additive unless the use of the substance is GRAS." Sonny Ramaswamy, *Setting the Table for a Hotter, Flatter, More Crowded Earth: Insects on the Menu?*, U.S. DEPT. OF AGRIC. & NAT'L INST. OF FOOD AND AGRIC. (July 10, 2014), http://nifa.usda.gov/sites/default/files/wageningen_insectsasfood_05142014.pdf [http://perma.cc/6GHM-7JQY]; *see also* Ramaswamy, *supra* note 198; *Arnold van Huis's Research*, WAGENINGEN UNIVERSITY & RESEARCH CTR., http://www.wageningenur.nl/en/Expertise-Services/Chair-groups/Plant-Sciences/Laboratory-of-Entomology/Research/Arnold-van-Huiss-research.htm [http://perma.cc/96GS-VUNY] (stating that the group's research "explore[s] the potential of the sustainable production of high quality edible insects and insect-derived products, in particular proteins, from side streams (organic waste)").

218. *See* FDCA § 409(a), 21 U.S.C. § 348(a).

219. *See* FDCA § 402(a)(2)(C), 21 U.S.C. § 342(a)(2)(C).

220. *See supra* Section III.B.1.

221. United States v. 29 Cartons of An Article of Food, 987 F.2d 33, 35 (1st Cir. 1993) (emphasis added).

222. FDCA § 201(u), 21 U.S.C. § 321(u); *see* 21 C.F.R. § 171 (2017) (food additive petitions).

A food additive regulation setting forth the approved conditions of use for the additive would serve as an affirmative statement by FDA of the permissible use of the insect as a (subcategory of) food. This would have particular significance in the context of the regulation of insects as food because, while FDA has recognized insect products as food and components of food, has allowed insect derivatives as color additives, and has at least acquiesced to the use of predacious insects in food, FDA has not affirmatively and unambiguously recognized an insect as "food" or a component of food in a regulation. An affirmative and specific legal recognition of an insect as a food additive—a legal subcategory of food—may help to assure consumers that the product is "safe" for the approved food use and may influence the cultural understandings of insects and food.

Regulating insects as food additives has several substantial limitations, which are likely to make using the food additive process to regulate insects used as (components of) food unworkable. First, when an insect is the sole component of a food, it may not be a food additive.[223] If it is not a food additive, it is not subject to the food additive approval requirement. Although dealing with active ingredients in what would now be considered dietary supplements, the Seventh Circuit held that a "single component [of a food] does not affect the characteristics of the food in question—rather, it constitutes the food."[224]

Second, the food additive approval process, which approves uses of substances,[225] may not be suited to the regulation of insects due to the diversity of insect species,[226] each of which could require a separate approval for use.[227] As

223. Noah & Merrill, *supra* note 212, at 346–49 ("[S]keptical judicial interpretations of the statute's food additive definition will continue to limit the FDA's choice of regulatory responses to more conventional foods and food components.").

In addition, as discussed in greater detail below, other exclusions, particularly the exclusion for GRAS substances, may significantly narrow the applicability of the food additive requirements. *See infra* Section III.B.3.

224. United States v. Two Plastic Drums, More or Less of an Article of Food, 984 F.2d 814, 818 (7th Cir. 1993); *see also 29 Cartons of An Article of Food*, 987 F.2d at 37 (stating that "[s]ince it defies common sense to say that a substance can be a 'food additive' when there is no (other) food to which it is added, we think that the FDA's reading of the Act is nonsensical").

225. FDCA § 409, 21 U.S.C. § 348; *see also* 21 C.F.R. § 171.

226. *See* Eur. Food Safety Auth. Sci. Comm., *supra* note 32, at 6 (noting that "[t]he Commission is aware that there are a high variety of insect species that would need to be considered [in conducting risk assessments], each with their specific characteristics of production and possible hazards"). In addition, there may be substantial differences among insects of the same species at different metamorphic stages, with different diets, and grown in different conditions. *Id.*; *see also* Lundy & Parrella, *supra* note 54. These differences, as well as differences in how an insect is transported, processed, and stored, may impact the suitability of the insect as human food. *See, e.g.*, FAO REPORT, *supra* note 6, at 67; Eur. Food Safety Auth. Sci. Comm., *supra* note 32.

227. *See* FDCA § 201(s), 21 U.S.C. 321(s); *id* § 409, 21 U.S.C. § 348; 21 C.F.R. pt. 171; *see also* Food Additives Permitted for Direct Addition to Food for Human Con-

noted earlier, estimates of the number of insect species put the number in the millions,[228] and even though the vast majority of these likely will never be used for food, reviewing the use of even a small fraction of these as food additives would likely overwhelm FDA's resources as the approval process is time and resource intensive for FDA.[229] Historically, with the exception of a period of time after the enactment of the Food Additives Amendment in 1958, FDA has approved very few new direct food additives for use in human food.[230]

The approval process is also time and resource intensive for food producers.[231] A 1998 article indicates that at that time the average amount spent on toxicological and other safety research for sponsors of novel direct food additives was $20 million.[232] There may be little incentive for food manufacturers to expend substantial resources in developing insect products as food additives because upon approval and issuance of a regulation, absent patent protection, competitors can sell products in compliance with the regulation.[233]

In addition, there is a lack of research regarding insects used as food and, accordingly, many uncertainties surround their food use.[234] The uncertainties regarding insects used as food include the benefits and potential benefits, technological development and best practices, and the risks and potential risks. As the FAO report on the potential of insects as food notes, "a tremendous amount of work still needs to be done by a wide range of stakeholders over many years to fully realize the potential that insects offer for food [security]."[235] These uncertainties may serve as a barrier to food additive approval because the sponsor

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sumption; Aspartame, 61 Fed. Reg. 33,654 (June 28, 1996) (to be codified at 21 C.F.R pt. 172)(approving Aspartame as a general-purpose sweetener following approval of 27 separate food additive petitions).

228. GULLAN & CRANSTON, *supra* note 30, at 6.

229. *See* Noah & Merrill, *supra* note 212, at 345, 368, 433; Peter Barton Hutt, *Regulation of Food Additives in the United States*, *in* FOOD ADDITIVES 199–224 (A. Larry Branen et al. eds., 2d ed. 2001), *reprinted in* HUTT ET AL., *supra* note 129, at 603 [hereinafter Hutt, *Regulation of Food*]; Peter Barton Hutt, *Approval of Food Additives in the United States: A Bankrupt System*, 50 FOOD TECH. 118 (1996) [hereinafter Hutt, *Approval of Food Additives*].

230. *See* Hutt, *Approval of Food Additives*, *supra* note 229, at 121 (noting that from 1970 to 2000, FDA approved eight direct food additives); *see also* HUTT ET AL., *supra* note 129, at 607 (noting that in the following dozen years, FDA approved "three additional direct or secondary direct human food additives that are arguably new").

231. *See* Hutt, *Regulation of Food*, *supra* note 229, at 199–224; Hutt, *Approval of Food Additives*, *supra* note 229; Noah & Merrill, *supra* note 212, at 345.

232. Noah & Merrill, *supra* note 212, at 369.

233. Hutt, *Approval of Food Additives*, *supra* note 229, at 122; Noah & Merrill, *supra* note 212, at 376, 421.

234. *See, e.g.*, Yen, *supra* note 76, at 291.

235. FAO REPORT, *supra* note 6.

of the petition must show that the food additive is safe under the conditions of its intended use.[236]

3. GRAS

An insect, insect part, or insect derivative that otherwise meets the definition of a food additive, but is generally recognized as safe (GRAS) would be exempt from the food additive approval requirements.[237] A substance can become GRAS in one of two ways: First, a substance can be "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use."[238] Second, a substance used in food before January 1, 1958 can also be GRAS through "experience based on common use in food."[239]

Whereas food additives must be approved by FDA before use,[240] GRAS substances do not. Since 1997 FDA has employed a voluntary notification procedure whereby "[a]ny person may notify FDA of a claim that a particular use of a substance is exempt from [the food additive approval requirements] based on the notifier's determination that such use is [GRAS]."[241] Because this procedure

236. Food, Drug, and Cosmetic Act § 409, 21 U.S.C. § 348 (2012); *see also* Food Additive Petitions, 21 C.F.R. pt. 171 (2017); Noah & Merrill, *supra* note 212, at 3689. FDA has discretion to determine whether a substance is GRAS. *See* Monsanto Co. v. Kennedy, 613 F.2d 947, 956 (D.C. Cir. 1979).

237. *See* FDCA § 201(s), 21 U.S.C. § 321(s); *see also* Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960 (Aug. 17, 2016).

238. FDCA § 201(s), 21 U.S.C. § 321(s).

239. *Id.*

240. FDCA § 409, 21 U.S.C. § 348; *id.* § 402(2)(C), 21 U.S.C. § 342(2)(C).

241. Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,960 (Apr. 17, 1997) (proposing that "[a]ny person may notify FDA that a particular use of a substance is exempt from the statutory premarket approval requirements based on the notifier's determination that such use is [GRAS]"); *see also* Substances Generally Recognized as Safe, 81 Fed. Reg. at 54,960. While FDA operated the GRAS notification process for almost two decades based on a proposed rule, the Center for Food Safety challenged FDA's reliance on the proposed rule and FDA agreed to finalize a rule regarding GRAS substances, which it did on August 17, 2016. *Id.* (stating that "[t]o date, the GRAS program has been administered under the[] proposed procedures"); *see also* Consent Decree, Ctr. for Food Safety v. Burwell, 1:14-cv-00267-RC (D.D.C. Oct. 20, 2014).

Prior to proposing the GRAS notification procedure, FDA used a "GRAS affirmation process—by which an individual could petition FDA to review the GRAS status of a substance not being considered as part of the agency's GRAS review." HUTT ET AL., *supra* note 129, at 575; *see also* Affirmation of Generally Recognized as Safe (GRAS) Status, 21 C.F.R. § 170.35 (2017).

is voluntary, a manufacturer can make its own determination that a substance is GRAS without FDA's participation—or even awareness.[242]

One potential benefit of using the GRAS process to regulate the use of insects in food is that once a food producer makes a self-determination that a substance is GRAS for its intended use, the producer can market the substance immediately without having to wait for FDA to review or approve the determination.[243] In addition, even if the producer decides to submit a voluntary GRAS notification to FDA, this process is less resource-intensive for both FDA and industry than the food additive approval process.[244]

Regulating insects as food using the GRAS notification process, however, has several limitations.[245] Manufacturers are not required to notify FDA of their self-determination that a substance is GRAS.[246] As a result, neither FDA nor

242. *See,* Eligibility for Classification of Food Substances as Generally Recognized as Safe, 53 Fed. Reg. 16,544, 16,545 (May 10, 1988) (stating that FDA "acknowledges that persons have the right to make independent GRAS determinations on substances"). FDA's regulations do, however, list *some* substances that are GRAS for their intended use. Substances Generally Recognized as Safe, 21 C.F.R. pt. 182 (2017); Direct Food Substances Affirmed as Generally Recognized as Safe, 21 C.F.R. pt. 184 (2017); Indirect Food Substances Affirmed as Generally Recognized as Safe, 21 C.F.R. pt. 186 (2017); Substances that Are Generally Recognized as Safe, 21 C.F.R. § 182.1(a) (2017) ("It is impracticable to list all substances that are generally recognized as safe for their intended use."). The GRAS notification regulations finalized in August 2016 "retain[] the voluntary nature of the GRAS administrative procedure." Substances Generally Recognized as Safe, 81 Fed. Reg. at 54,971.

243. *See* HUTT ET AL., *supra* note 129, at 605–06 (arguing that the regulation of GRAS substances "has been an enormous success").

244. *See* Laurie J. Beyranevand, *Generally Recognized as Safe?: Analyzing Flaws in the FDA's Approach to GRAS Additives*, 37 VT. L. REV. 887, 905 (2013); *see also* Noah & Merrill, *supra* note 212, at 381.

245. For a more in depth examination of the limitations of the notification process, see *Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)*, U.S. GOV'T ACCOUNTABILITY OFFICE (Feb. 2010), http://www.gao.gov/assets/310/300743.pdf [http://perma.cc/2VC5-YEPU] [hereinafter GAO Food Safety]; Beyranevand, *supra* note 244; Martha Dragich, *GRAS-Fed Americans: Sick of Lax Regulation of Food Additives*, 49 IND. L. REV. 305, 311 (2016).

246. Substances Generally Recognized as Safe, 81 Fed. Reg. at 54,960; Substances Generally Recognized As Safe, 62 Fed. Reg. 18,938 (Apr. 17, 1997) (proposed rule); Substances Generally Recognized as Safe; Reopening of the Comment Period, 75 Fed. Reg. 81,536 (Dec. 28, 2010) (comment period reopened Dec. 28, 2010); *see also Guidance for Industry: Frequently Asked Questions About GRAS*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm061846.htm#Q10 [http://perma.cc/ED2J-STFJ]; *About the GRAS Notification Program*, U.S. FOOD & DRUG ADMIN., (Mar. 2009), http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm2006851.htm [http://perma.cc/PNY3-WMXG].

consumers may know that a producer has made a self-determination that a substance is GRAS, undermining FDA's ability to effectively oversee such determinations.[247] Furthermore, even when a producer submits a GRAS notification to FDA, the agency's oversight is limited.[248] The limitations of the GRAS notification process may be particularly significant in the context of insects because utilization of this process does not result in a legally binding statement from FDA that the substance is GRAS and a manufacturer's self-determination that a substance is GRAS would occur against the backdrop of the pervasive law categorizing insects as filth.

In addition, because "the same degree of scientific evidence" is required for a substance to be GRAS based on scientific procedures as is required for the approval of a food additive,[249] the lack of information and uncertainties regarding entomophagy that may serve as a barrier to approval of a food additive may also serve as a barrier to GRAS status based on scientific procedures.

A substance may be GRAS, however, "based on common use in food prior to January 1, 1958."[250] The person making the GRAS determination would have to show that the substance is "*generally recognized*, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown . . . through experience *based on common use in food . . . to be safe* under the conditions of its intended use."[251] The same quantity and quality of evidence that is needed for food additives and substances that are GRAS based on scientific procedures is not required for GRAS based on common use.[252] Instead, GRAS status must be "based solely on food use of the substance prior to January 1, 1958, and [must] ordinarily be based upon generally available data and information."[253] Common use outside of the United States can be used, although FDA has been described as "reluctant" to rely on such use.[254] FDA's regulations provide that the use can have "occurred exclusively or primarily

247. *See* Dragich, *supra* note 245, at 307 ("It is estimated that for at least one thousand additives currently in use in food, the FDA has no information whatsoever."); GAO Food Safety, *supra* note 245.

248. *Id.*

249. Eligibility for Classification as Generally Recognized as Safe (GRAS), 21 C.F.R. § 170.30(b) (2017); Substances Generally Recognized as Safe, 81 Fed. Reg. at 54,977.

250. 21 C.F.R. § 170.30.

251. Food, Drug, and Cosmetic Act, § 201(s), 21 U.S.C. § 321(s)(2012) (emphasis added).

252. *Id.*; Eligibility for Classification as Generally Recognized as Safe (GRAS), 21 C.F.R. § 170.30(b) & (c)(1); Substances Generally Recognized as Safe, 81 Fed. Reg. at 54,977, 55,004.

253. Eligibility for Classification as Generally Recognized as Safe (GRAS), 21 C.F.R. § 170.30(c)(1); Substances Generally Recognized as Safe, 81 Fed. Reg. at 54,977.

254. HUTT ET AL., *supra* note 129, at 583; *see also* Fmali Herb, Inc. v. Heckler, 715 F.2d 1385 (9th Cir. 1983).

outside of the United States."[255] FDA's regulations detail information requirements for establishing GRAS status for a substance based on use—including use outside of the United States.[256] In the case of insects used in food, the fact that a GRAS determination can be based on the general recognition of the safety of the substance under the conditions of its intended use by qualified experts based on common use outside of the United States is likely to be significant because, as discussed in Section I.B, many cultures have a long history of the use of insects as food.

## IV. Recognizing Insects as Food

### *A. The Need for Regulatory Action*

FDA "has been receiving inquiries about insects as a food source for decades,"[257] and decades have passed since FDA first considered the issue of the

255. 21 C.F.R. § 170.30; Substances Generally Recognized as Safe, 81 Fed. Reg. at 54,977. FDA amended its regulations to this effect after the Ninth Circuit held that FDA's interpretation of "common use in food" as "a substantial history of consumption of a substance by a significant number of consumers in the United States" was invalid. Fmali Herb, Inc. v. Heckler, 715 F.2d 1385, 1385 (9th Cir. 1983). FDA noted in the preamble to its amended regulations, however, that "prudence suggests that an importer who has made an independent determination that a substance is GRAS on the basis of its history of use outside of the United States seek FDA concurrence in that judgment . . . before seeking to bring the product into [the United States]." Eligibility for Classification of Food Substances as Generally Recognized as Safe, 53 Fed. Reg. 16544, 16,545 (May 10, 1988) (to be codified at 21 C.F.R. pt. 170). This regulation was amended in 2016 to provide that "persons who claim that use of a substance is GRAS through experience based on its common use in food outside of the United States should notify FDA of that claim in accordance with the GRAS notification procedure." Substances Generally Recognized as Safe, 81 Fed. Reg. at 54,977.

256. *See* Eligibility for Classification as Generally Recognized as Safe (GRAS), 21 C.F.R. § 170.30(c)(2) ("Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance. The information used to document and to corroborate the history and circumstances of use of the substance must be generally available; that is, it must be widely available in the country in which the history of use has occurred and readily available to interested qualified experts in this country."); Eligibility for Classification of Food Substances as Generally Recognized as Safe, 53 Fed. Reg. at 16,544 (to be codified at 21 C.F.R. pt. 170); Eligibility for Classification of Food Substances as Generally Recognized as Safe, 50 Fed. Reg. 27,294 (proposed July 2, 1985) (to be codified at 21 C.F.R. pt. 170).

257. Mary Ellen Kuhn, *Exploring the Brave New World of Insect-Based Ingredients*, IFT16 News (July 13, 2015), http://news.ift.org/2015/07/13/exploring-the-brave-new-world-of-insect-based-ingredients/ [http://perma.cc/RZ7B-FHQP] (quoting

regulation of insects as food. For example, in the March 1976 government-published *FDA By-Lines*, J. Richard Gorham, an FDA scientist, discussed the regulation of insects as food[258] and referenced several instances in which FDA had considered how to regulate insects as food.[259] In addition, FDA's Standard Response to Entomophagy Inquiries has been described as being "over 25 years" in the making.[260]

Despite the length of time that FDA has had to consider the regulation of insects as food, FDA's approach to the regulation of insects as food or components of food, with few exceptions, has been characterized by inaction.[261] The law currently contains no specific references to insects as food,[262] and FDA has not issued any official guidance documents on this topic. The little that FDA has communicated publicly regarding insects as food has been communicated informally—in speeches and articles by FDA employees, in responses to indi-

FDA's George Ziobro as stating that "[t]here's been interest in entomophagy for over 40 years").

258. Gorham, *supra* note 63.

259. *Id.*

260. Ziobro, *supra* note 13, at slide 4 nn.

261. The term "inaction" refers to an absence of specific regulatory action such as agency threats, enforcement activity, and rulemaking. *See generally* Tim Wu, *Agency Threats*, 60 DUKE L.J. 1841 (2011) (discussing "agency threats" and alternative approaches to regulation). It is used to describe situations in which an agency "ignore[s] the area altogether," as well as situations where an agency makes a non-enforcement decision. *Id.* at 1842; Cass R. Sunstein & Adrian Vermeule, *The Law of "Not Now": When Agencies Defer Decisions*, 103 GEO. L.J. 157, 159 (2014) (discussing ways in which an agency may not decide). The absence of specific regulatory action regarding insects as food, however, does not equate with the absence of law; as discussed in Section II.A and Part III *supra*, there is substantial law regarding insects as filth and the general regulatory framework for food applies to insects as food. Also, the absence of action is not necessarily an absence of policy; inaction can be a regulatory choice in and of itself as "[a]gencies often set policy by doing nothing at all." Christina Larsen, *Is the Glass Half Empty or Half Full? Challenging Incomplete Agency Action Under Section 706(1) of the Administrative Procedure Act*, 25 PUB. LAND & RESOURCES L. REV. 113, 114 (2004); *see also* Peter H. A. Lehner, *Judicial Review of Administrative Action*, 83 COLUM. L. REV. 627, 689 (1983) (discussing administrative inaction).

262. Research identified no statutory provisions or regulations that specifically reference insects as human food. In addition, searches on Westlaw and Lexis identified no case law addressing the voluntary and intentional human consumption of insects as food.

The author submitted a Freedom of Information Act request to FDA seeking all documents addressing insects as human food or a component of food. FDA responded by providing 30 pages of documents. The author asked FDA to review for additional documents responsive to the request and was informed the request was closed. FOIA Communications with U.S. Food and Drug Admin. (on file with author).

vidual or firm inquiries, and in one instance, in an agency threat (i.e., warning letter)—and does not bind FDA.[263] Indeed, FDA's approach to the regulation of insects as food is arguably even more informal than its approach to the regulation of medical device software as described by Nathan Cortez in his article *Regulating Disruptive Innovation*.[264] To regulate medical device software, FDA used draft software policies, a threat delivered in a speech by the Commissioner, several guidance documents, and the occasional investigation of product failures.[265] In contrast, as noted earlier, FDA has promulgated no official guidance documents on insects as food and lower-level FDA employees have largely communicated the agency's policy regarding these products.[266] The defects in timing ("it was late") and form ("it was casual") that Cortez argues plagued FDA's regulation of software are also arguably present in the context of FDA's (lack of) regulation of insects as human food and counsel against FDA's continued reliance on inaction and informal threats to regulate insects as human food.[267]

263. Brickley & Gorham, *supra* note 166; Gorham, *supra* note 63; Ziobro, *supra* note 13; E-mail from Kenneth Nieves to George C. Ziobro (Mar. 11, 2015, 08:09 AM) (on file with author); E-mail from Pat El-Hinnawy, Public Affairs Officer, U.S. Food and Drug Admin., to George C. Ziobro (Jan. 24, 2011, 10:46 AM) (on file with author); Letter from Cora E. Weeks, Assistant to the Director, Office of Plant and Dairy Foods and Beverages, to Nicholas J. Kocz, James V. Hurson Associates (Dec. 1, 1994) (on file with author); Messa, *supra* note 207; Holistic Candlers & Consumers Ass'n v. FDA, 664 F.3d 940, 943 (D.C. Cir. 2012) ("FDA's warning letters . . . neither mark the consummation of the agency's decisionmaking process nor determine the appellants' legal rights or obligations."); *Regulatory Procedures Manual*, U.S. FOOD & DRUG ADMIN. § 4-2 (July 2012), http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074330.pdf [http://perma.cc/Y79C-CGBV] (describing warning letters as "informal and advisory"); Wu, *supra* note 261, at 1842, 1848 (defining threats and making a case for the use of threats in certain regulatory contexts).

264. Nathan Cortez, *Regulating Disruptive Innovation*, 29 BERKELEY TECH. L.J. 175, 180, 191 (2014). Indeed, Cortez observes that FDA's experience with software is not unique, but rather a pattern. *Id.* at 182.

265. *Id.* at 192, 204–05. The software policies consisted of a 1987 draft policy and a 1989 update, which was withdrawn in 2005. *Id.* at 192–93.

266. *See supra* Sections II.B & C; Ziobro, *supra* note 13, at slide 4; *see also FDA Response to Inquiry*, THE FUTURE OF EDIBLE INSECTS BLOG (Oct. 10, 2015), http://thefutureofedibleinsects.com/2015/10/10/fda-response-to-inquiry/ [http://perma.cc/FQF4-M2BM] (discussing communications with FDA regarding insects as human food); *see, e.g.*, Messa, supra note 207, Ziobro, *supra* note 13; Gorham, *supra* note 63. As FDA has largely avoided rulemaking in the context of software, it has largely avoided rulemaking in the context of insects as food. *See* Cortez, *supra* note 264, at 193. The few regulations FDA has promulgated address insect-produced products or regulate insects as something other than "food." *See supra* Section II.B & C.

267. Cortez describes FDA's regulation of software as "the Quarter-Century-Long Threat," a reactive approach characterized by a heavy reliance on guidance and

If FDA does not address insects as food in a timely manner, it may forgo many of the benefits of regulation—such as "added certainty," "reduced costs of compliance" for industry, and regulatory oversight over new food technologies[268]—that may arise if FDA were to regulate the insect food industry in the United States while it is still relatively young.[269] As Cortez argues, regulatory interventions, and specifically "early" regulatory interventions, can create benefits.[270] Waiting until there is a crisis to regulate, as has happened numerous times in the context of food,[271] may "undervalue" the information available before the crisis and "overvalue" that which arises in the crisis.[272]

In light of the existing regulatory framework, which characterizes insects as defects or filth, FDA's regulatory inaction with respect to insects as food is not neutral. It is important that FDA specifically recognize that insects used as food or components of food are "food."[273]

FDA's failure to specifically recognize insects as food creates uncertainty about how FDA will regulate insects used as food or as components of food in the future. For example, in the past FDA has taken the position that such products are filth.[274] This uncertainty may deter companies from making substantial investments in and studying the development of insects as food. In turn, this may be an obstacle to the realization of the potential of insects as a way to meet

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spurred by tragedies attributed to software and user errors. Cortez *supra* note 264, at 200. In addition to the defects identified in the text above, Cortez argues that FDA's use of threats to regulate software was flawed because "on durability, it was transient; and on enforcement, it was spotty." *Id*. at 179, 200.

268. *See* Cortez, *supra* note 264, at 204.

269. In 1989, Brickley and Gorham while not foreclosing the possibility that such products may exist, indicated that they were "not aware of any food products composed of insects . . . manufactured within the United States . . . and offer[ed] for sale in interstate commerce." March 1989 Food Insects Newsletter article, *supra* note 166, at 1; *see also* Ligman, *supra* note 656 (discussing "the burgeoning insect-protein industry").

270. Cortez, *supra* note 264, at 203–04, 308; David A. Super, *Against Flexibility*, 96 CORNELL L. REV. 1375, 1380 (2011). Cortez draws upon David A. Super's work, *Against Flexibility*, which considers when legal decisions should be made and argues that "the law often postpones decision making counterproductively." *Id.* (citation omitted).

271. *See, e.g.*, HUTT ET AL., *supra* note 129, 523.

272. *See* Super, *supra* note 270, at 1382; Cortez, *supra* note 264, at 179, 200 (arguing that threats "work[] best as a temporary stopgap that presages more traditional regulatory intervention").

273. The recognition of insects as food, while an important first step, will still leave many questions about how FDA will regulate insects as food unanswered. The Author intends to consider in future work the question of how FDA should regulate insects as food in light of the risks that insects used as food may present.

274. March 1989 Food Insects Newsletter article, *supra* note 166.

the growing demands for food and meat.[275] A lack of investment in insects as food may hinder the development of insects as a sustainable food source in light of the current state of knowledge regarding insect rearing,[276] and the fact that "there is a dearth of information on the sustainability of the wild-harvesting."[277] Technological innovations may also help to reduce the production costs, and ultimately the price, of insects as food.[278]

While the argument that insects should be treated like any other food source and there is no need for FDA to specifically recognize that insects can be food may initially seem compelling, the reality is that because of the extensive law categorizing insects as filth, insects used as food are not like other foods. Specific formal recognition of the fact that insects can also be food is needed to remove some of the uncertainty about the use of insects as food and provide an alternative to the pervasive categorization of insects as filth.

In addition, this argument overlooks the fact that FDA has specifically promulgated regulations for many foods. As noted in the Section III.B.2, when a food additive is approved, a regulation setting forth the parameters of the approval is published.[279] FDA has also recognized a variety of substances are GRAS for use in food.[280] FDA's recognition of products as food (or subcategories of food) and its establishment of specific regulatory requirements for these products are not limited to the food additive context. For example, FDA has promulgated manufacturing requirements for specific foods using its authority pursuant to section 402(a)(4) of the FDCA.[281] The EFSA in its scientific assessment of the risks of using insects as food concluded that when permitted feed materials are used "the possible occurrence of microbiological hazards is expected to be comparable" to "other non-processed sources of protein of animal origin."[282] Of course, this does not mean that insects used as food do not present microbiological risks; the microbiological hazards of other non-processed sources of

275. FAO REPORT, *supra* note 6, at xvi, 40, 154. The FAO argues that "[s]pecific legal provisions on the use of insects for food . . . production would serve to control and regulate the use of insects by industry processors and would guarantee consumer access to information." *Id.* at 15.

276. *See supra* note 13 and accompanying text.

277. FAO REPORT, *supra* note 6, at 46-47, box 4.2.

278. *See* Asche & B*jørndal*, *supra* note 13, at 60, 64; *supra* note 13.

279. *See* Food, Drug, and Cosmetic Act § 409(a), 21 U.S.C. § 348(a) (2012).

280. *See, e.g.*, Food Additives Permitted for Direct Addition to Food for Human Consumption, 21 C.F.R. pt. 172 (2017); Direct Food Substances Affirmed as Generally Recognized as Safe, 21 C.F.R. pt. 184 (2017).

281. *See, e.g.*, Production, Storage, and Transportation of Shell Eggs, 21 C.F.R. pt. 118 (2017); Fish and Fishery Products , 21 C.F.R. pt. 123 (2017).

282. EFSA Sci. Comm., *supra* note 32; *see also supra* note 92 for a discussion of the EFSA's environmental assessment of insects as food.

animal protein are well documented and have led to regulation.[283] Of particular note is the fact that FDA has established regulations for the production, handling, and transport of shell eggs[284] and cGMP and hazard analysis critical control point (HACCP) regulations for fish and fishery products.[285]

As another example, FDA has required the disclosure of some allergens in food in addition to the "major food allergens" (i.e., milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans) required to be labeled under section 403(w) of the FDCA.[286] This is relevant to insects used as food because there is evidence of consumed insects inducing allergic reactions in some people.[287] Indeed, as noted in the Section II.C, cochineal extract and carmine—two insect derived color additives—are required to be labeled in food in "response to reports of severe allergic reactions" to these additives.[288] According to the EFSA's risk assessment, more information is needed about human consumption of insects and allergens.[289]

283. *See, e.g.*, Food Safety and Inspection Serv., *Foodborne Illness: What Consumers Need to Know*, U.S. DEP'T OF AGRIC. (May 2011), http://www.fsis.usda.gov/wps/wcm/connect/602fab29-2afd-4037-a75d-593b4b7b57d2/Foodborne_Illness_What_Consumers_Need_to_Know.pdf?MOD=AJPERES [http://perma.cc./AR9H-ULXR] (listing the symptoms and potential impact of a number of bacteria and the foods that the bacteria are associated with, including various animal proteins); Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation, 74 Fed. Reg. 33,030, 33,030 (July 9, 2009) (noting that "[*Salmonella* Enteritidis (SE)] is among the leading bacterial causes of foodborne illness in the United States, and shell eggs are a primary source of human SE infections"). In many cases, these products have been specifically regulated. *See, e.g*, *id.* at 33,030 (promulgating a final rule requiring egg producers to implement measures to prevent SE contamination of eggs).

284. *Id.* at 33,095.

285. Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65096, 65,197 (Dec. 19, 1995).

286. Food, Drug, and Cosmetic Act § 403(w), 21 U.S.C. § 343 (w) (2012); *see, e.g.*, 21 C.F.R. 101.100(a)(4) (2017) (sulfating agents); 21 C.F.R. 101.22(h)(5) (2017) (monosodium glutamate); *see also* HUTT ET AL., *supra* note 129, at 399; Laura E. Derr, *When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004*, 61 FOOD & DRUG L.J. 65, 160 (2006).

287. *See, e.g.*, FAO REPORT, *supra* note 6, at xv, 123; *see also* Joel Phillips & Wendell Burkholder, *Allergies Related to Food Insect Production and Consumption*, 8 FOOD INSECTS NEWSL. (July 1995); Gorham, *supra* note 63; EFSA Sci. Comm., *supra* note 32, at 31–33, 40; Rumpold & Schlüter, *supra* note 54, at 802; PETER MENZEL & FAITH D'ALUISIO, MAN EATING BUGS: THE ART AND SCIENCE OF EATING INSECTS (1988).

288. Listing of Color Additives Exempt from Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration, 74 Fed. Reg. 207, 208 (Jan. 5, 2009).

289. EFSA Sci. Comm., *supra* note 32, at 40.

As a final example, FDA has promulgated product-specific food definitions and standards of identity.[290] These food standards are like a "recipe," which is assigned a "name under which all conforming products shall be sold."[291] The standards "typically define[] the composition of a food, prescribing the ingredients that must be included (mandatory ingredients), as well as those that may be included (optional ingredients), and fixing the amounts or relative proportions of each ingredient" and "[m]any . . . prescribe a method of production or formulation."[292] FDA has promulgated food standards for, among other things, certain fish and shellfish products.[293]

### *B. Distinguishing Insects as Filth from Insects as Food*

If FDA affirmatively recognizes that insects used as food are food, it will need to determine how to distinguish between insects as food and insects as filth. This Section provides some initial thoughts about one possible approach that FDA should consider: using the concept of intent to distinguish between insects as food and insects as filth.[294] Indeed, several of the statements regarding entomology from FDA employees include the concept of intended use.[295] In addition, FDA's response to entomophagy inquiries previously contained a refer-

290. *See, e.g.*, 21 C.F.R. pt. 130 (2017); *see also* Food Standards; General Principles and Food Standards Modernization, 70 Fed. Reg. 29,214 (May 20, 2005); Richard A. Merrill & Earl M. Collier, Jr., *"Like Mother Used to Make": An Analysis of FDA Food Standards of Identity*, 74 COLUM. L. REV. 561, 566 (1974) (indicating that in "1954 standardized foods accounted for more than half of all food purchases by American consumers").

291. Merrill & Collier, *supra* note 290, at 563.

292. *Id.*

293. *See* 21 C.F.R. pt. 161 (2017).

294. There are several other possible ways that FDA could potentially distinguish between insects as food and insects as filth, but each has substantial limitations. For example, FDA could distinguish between insect species that are "pests" and insects that are not pests by designating insect species as one or the other, but doing so would fail to recognize that "[m]any edible insects are considered pests and threats to agricultural crops." *See* FAO REPORT, *supra* note 6, at 55. Another possibility would be for FDA to distinguish between objectionable and non-objectionable insects, which may take into account the context, but this may be subjective as even a properly labeled snack bar made with cricket flour may be objectionable to some. *See* 21 C.F.R. § 110.3 (2017) (defining pests as "any objectionable animals or insects").

295. March 1989 Food Insects Newsletter article, *supra* note 166; "Cricket Licket" Lollipops Memorandum, *supra* note 177; *see also* Ziobro, *supra* note 13, at slide 13; Ramaswamy, *supra* note 217 ("Under the [FDCA] as amended, bugs/insects are considered food if that is the intended use." (citation omitted)).

ence to intended use;[296] however, FDA eliminated that reference and the available materials offer no explanation for its elimination.[297]

Insects intended to be used as food or a component of food should be treated as such. Using intent would distinguish, for example, between mealworm larva that had infested grain or a processed cereal product (filth),[298] and mealworm larva used as a snack or a component of a snack bar (food).[299] Mealworms, or other insects that have infested another food are an indicator of a failure of sanitary control and cGMP compliance.[300] Such insects, which have not been raised in a controlled environment, may present serious risks to human health. For example, insects that have not been raised in a controlled environment may be contaminated with contaminants such as heavy metals, pesticides, or pathogens.[301] Insect infestation can also lead to food loss due to insect consumption.[302] In addition, the presence of insects in food due to a lack of control could pose risks to individuals with allergies to insects, who might be unaware of the insects' presence.[303] The presence of such insects may also run counter to consumer expectations.[304]

296. Ziobro, *supra* note 13.

297. *See id.*; Ziobro emails (Mar. 2015) (on file with author) (noting that "an interim re-write" of the response eliminated a reference to "intended use").

298. *See, e.g.*, Richard M. Houseman, *Insect Pests of Stored Products*, UNIV. OF MO. EXTENSION, http://extension.missouri.edu/p/g7370 [http://perma.cc/T6E9-YKGN] (stating that "[m]ealworms . . . infest cereal products").

299. *See, e.g.*, LARVETS ORIGINAL WORM SNAX, http://hotlix.com/candy/index.php?route=product/product&path=96&product_id=97 [http://perma.cc/6J8A-C8SU]; MEALWORM SAMPLE PACK, http://www.edibleinsects.com/entomophagy/the-mealworm-three-pack/ [http://perma.cc/LN26-KN38]; MEALWORM POWDER, http://entomofarms.com/product/meal-worm-powder/ [http://perma.cc/TV6F-UKLD]. There are a variety of other insect foods, and mealworms are simply used as one example. *See supra* note 66 (providing examples of insect foods).

300. *See* Food, Drug, and Cosmetic Act § 402, 21 U.S.C. § 342 (2012); FDA, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food, 21 C.F.R. § 110 (2017); *Sanitation and Safety*, 4 ENCYCLOPEDIA OF FOOD SCIENCE AND TECHNOLOGY 2292 (Y.H. Hui ed., 1992) (discussing the sanitation provisions of the FDCA).

301. *See, e.g.*, J. Richard Gorham, FDA, *Food Pests as Disease Vectors*, *in* ECOLOGY AND MANAGEMENT OF FOOD-INDUSTRY PESTS, FDA TECHNICAL BULLETIN 4 at 477 (1991) (discussing how food pests can vector pathogens); FAO REPORT, *supra* note 6, at 13 (noting that because locusts are "agricultural pests they may be sprayed with insecticides").

302. *See, e.g.*, James F. Campbell et al., *Insect Management in Food Processing Facilities*, 48 ADVANCES IN FOOD & NUTRITION RES. 239 (2004).

303. *See, e.g.*, FAO REPORT, *supra* note 6, at 123 ("There is a certain amount of evidence of allergies induced through the ingestion of insects."); Joel Phillips & Wendell Burkholder, *Allergies Related to Food Insect Production and Consumption*, 8 FOOD INSECTS NEWSL. (July 1995) (hypothesizing that sensitivities to common food-

In contrast, mealworms and other insects that are intended for human food use, like any other food, can be raised, produced, and processed using good sanitation practices and controls, and cGMP.[305] For example, the producers can control the diet of the insects, which may impact both their safety for food use and their nutritional content.[306] They may also process the insects to destroy pathogens, such as salmonella.[307] In addition, insects when sold in packaged form, would be required to be properly labeled.[308]

Unlike other major product categories defined in the FDCA[309] and the definitions of the subcategories of food—food additives and dietary supplements[310]—the definition of "food" does not incorporate the concept of intent or intended use.[311] In fact, courts have rejected arguments that intended use should

infesting insects may be "the result of ingesting small quantities of insect material in food over a lifetime"); G. Reese, et al., *Tropomyosin, An Invertebrate Pan-Allergen*, 119 INT. ARCH. ALLERGY IMMUNOL. 247, 248 (1999) (stating that "[i]t is established that patients allergic to shrimp may also be allergic to other crustaceans and mollusks and some evidence suggests that shrimp may cross-react with . . . insects including chironomids, cockroaches, and grasshopper and fruit fly") (internal citations omitted); s*ee also* Food, Drug, and Cosmetic Act, § 403(i), 21 U.S.C. § 343(i) (2012); 21 C.F.R. § 101.3-.4 (2017). *But see* MELVIN J. HINICH & RICHARD STAELIN, REGULATION OF THE U.S. FOOD INDUSTRY, S. DOC. No. 96-14, at 427 (1978) (asking "what would happen if all producers were required to affix a label which indicated the level of aesthetically unpleasant contamination," "[i]nstead of taking legal action related to aesthetic adulteration").

304. *See, e.g.,* United States v. 133 Cases of Tomato Paste, 22 F. Supp. 515, 516 (E.D. Pa. 1938).

305. The possible hazards of insects as food would depend on how they were produced. *See* EFSA Sci. Comm., *supra* note 32; Simone Belluco et al., *Edible Insects in a Food Safety and Nutritional Perspective: A Critical Review*, 2 COMPREHENSIVE REV. IN FOOD SCI. AND FOOD SAFETY 296 (2013).

306. *See, e.g.*, EFSA Sci. Comm., *supra* note 32; Lundy & Parrella, *supra* note 54.

307. *See, e.g.*, EFSA Sci. Comm., *supra* note 32, at 20 (stating that "the risk of transmission of [pathogenic bacteria such as Salmonella] could be mitigated through effective processing").

308. *Supra* pages 33, 38-40 (discussing labeling); *see also* FDCA § 403(i), 21 U.S.C. § 343(i); 21 C.F.R. pt. 101.3-.4.

309. The definitions of "drug," "device," "cosmetic," and "tobacco product" in the FDCA all incorporate the concept of intent. *See* FDCA §§ 201(g) (drug), 201(h) (device), 201(i) (cosmetic), 201(rr) (tobacco product), 21 U.S.C. §§ 321(g), (h), (i), (rr).

310. *See* FDCA § 201(s) & (ff), 21 U.S.C. § 321(s) & (ff).

311. *Compare* FDCA, § 201(f), 21 U.S.C. § 321(f) (2012), *with* FDCA § 201(g), 21 U.S.C. § 321(g) (definition of drug), FDCA § 201(h), 21 U.S.C. § 321(h) (definition of device). S*ee also* FDCA § 201(s) & (ff), 21 U.S.C. § 321(s) & (ff) (food additives and dietary supplements). As Grossman has observed, "modern food and drug law is bedeviled by the questions of how the phrase 'intended to' in [the FDCA] definitions should be construed." Lewis A. Grossman, *Food, Drugs, and*

be read into the FDCA. For example, in *United States v. Technical Egg Products, Inc.*, the United States District Court for the Northern District of Georgia stated that "the test for determining whether an item is a food under the Act cannot be one of intended use. It must of necessity be one which regards items as food which are generally so regarded when sold in a food form."[312] Concern about manufacturers trying to avoid the reach of the FDCA "by claiming that a product which looks like food and smells like food is not food because it was not intended for consumption" and the product being diverted for food use seem to underlie this decision.[313]

But intent, as it has been used in other contexts under the FDCA, is arguably broad enough to avoid these issues.[314] For example, in the context of drugs, FDA has defined "*intended uses* or words of similar import" as "refer[ing] the objective intent of the persons legally responsible for the labeling of drugs."[315] The regulation provides that "[t]he intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article."[316] Furthermore, the regulation provides that the intent may be shown, among other things, "by labeling claims, advertising matter, or oral or written statements by such persons or their representatives" or "by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor ad-

*Droods: A Historical Consideration of Definitions and Categories in American Food and Drug Law*, 93 CORNELL L. REV. 1091, 1107 (2008); *see also* HUTT ET AL., *supra* note 129.

312. 171 F. Supp. 326, 328 (N.D. Ga. 1959) (internal citation omitted); *see also* Nutrilab, Inc. v. Schweiker, 713 F.2d 335 (7th Cir. 1983); United States v. 52 Drums Maple Syrup, 110 F.2d 914, 915 (2d Cir. 1940) (holding, in a case brought under the Pure Food and Drug Act, that "[t]he intended use to which adulterated food is to be put after it has been shipped in interstate commerce is immaterial on the question of the government's right to forfeit because of such shipment").

313. *See* Tech. Egg Prods., 171 F. Supp. at 326; *Nutrilab*, 713 F.2d at 337 (discussing *Tech. Egg Prods.*).

314. *See, e.g.*, 21 C.F.R. §§ 201.128, 801.4 (2017). In January 2017, FDA amended the definition of "intended uses," but the effective date of this change has been delayed until March 19, 2018. *See* Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses", 82 Fed. Reg. 2,217 (Jan. 9, 2017); Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Delayed Effective Date, 82 Fed. Reg. 9,501 (Feb. 7, 2017); Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses"; Further Delayed Effective Date; Request for Comments, 82 Fed. Reg. 14,319 (Mar. 20, 2017). Accordingly, the language discussed herein is that which predates the amendment.

315. 21 C.F.R. § 201.128 (2017)(emphasis added).

316. *Id.*

vertised."[317] For example, in the context of determining whether an article was a "drug" under the FDCA, as a result of an intended therapeutic use, the Second Circuit observed, "the FDA is not bound by the manufacturer's subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence. Such intent also may be derived or inferred from labeling, promotional material, advertising, and "any other relevant source."[318]

And the United States District Court for the District of Columbia held in a case where there was no labeling on the product, that "nothing limits the attempt to discern . . . intent to labeling or advertising," and "the environment" and "surrounding circumstances" may provide a sufficient showing of intent.[319] Hence, if FDA were to use intent to distinguish insects as food from insects as filth, it would not have to rely on a manufacturer's subjective claim that a product was or was not intended to be used as food.

Using intent to distinguish between insects as food and insects as filth would not be duplicative of the cGMP requirements for food. While following cGMP for an insect product could support a conclusion that the product was food, not following cGMP would not necessarily indicate that the product was not food. The product could not be food, but the product also could be an adulterated food under section 402(a)(4) of the FDCA. The objective intent regarding the use of the product as a food could be used to distinguish between these two circumstances.

### *C. Food Law as Culture*[320]

As noted earlier, the FAO in its 2013 report on the "potential of insects as food" stated that "the acceptance or rejection of entomophagy is a question of culture," and "consumer acceptance remains one of the largest barriers to the adoption of insects as" food in many Western countries.[321] Indeed, in the United States, insects are not generally regarded as food as a cultural matter.[322] As a result of the aversion to insects as food, new insect-based food products may perform far worse with many consumers in terms of acceptance than products that are more widely accepted as food.[323] As discussed in Section IV.A, there is

317. *Id.*

318. Nat'l Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 334 (2d Cir. 1977).

319. United States v. Travia, 180 F. Supp. 2d 115, 119 (D.D.C. 2001).

320. *See* Naomi Mezey, *Law as Culture*, 13 YALE J. L. & HUMAN. 35 (2001) (discussing "law as culture"). This Article adopts Mezey's provisional definition of culture as "any set of shared, signifying practices—practices by which meaning is produced, performed, contested, or transformed." *Id.* at 42. She argues that this definition "necessarily implicates law because law is one of the most potent signifying practices." *Id*. at 45.

321. FAO REPORT, *supra* note 6, at 36.

322. *See supra* notes 58–59 and accompanying text.

323. *See* Joseph L. Bower & Clayton M. Christensen, *Disruptive Technologies: Catching the Wave*, 73 HARV. BUS. REV. 43, 43, 45 (1995).

an absence of law specifically categorizing insects as food (or a subcategory of food) to counter the extensive law that characterizes insects as filth. That serves as the background against which any discussion of insects as food necessarily must occur.

FDA's absence of specific regulatory action with respect to insects as food may help to sustain the cultural stigma against insects for human consumption. By explicitly recognizing that insects can be "food" under the FDCA, FDA may help to establish and legitimize an alternative narrative with respect to insects—one in which insects are legally food and not just filth. In addition, establishing a test to distinguish between insects as food and as filth may have implications for consumers' perceptions of insects in the food context. Consumers' failure to distinguish between "'edible' insects' and 'disease transmitting' insects can augment perceived physical risks."[324] By explicitly recognizing that insects can be food, FDA may help to erode the cultural barriers that may prevent full exploration and realization of the potential of insects as human food.[325]

Food and its consumption are important components of human identity:[326]

> By accepting certain items as 'food' and rejecting others, and also by culturally processing raw items and combining them in structured and patterned ways, human beings define what it means to be a particular kind of human being, one who belongs to a particular community or identifies with a particular social class or way of life.[327]

Eating "defines who one is, culturally speaking, and, conversely, who one is not."[328] As one culinary historian has remarked "food is culture."[329]

As food and culture are inextricably intertwined, so are food law and culture. By defining the legal category of "food" based on what is "used for

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324. Melissa A. Baker et al., *An Exploration and Investigation of Edible Insect Consumption: The Impacts of Image and Description on Risk Perceptions and Purchase Intent*, 33 PSYCHOL. & MARKETING 94, 97 (2016).

325. Of course, culture also influences the law. The "mutuality and endless recycling between formal legal meaning-making and the signifying practices of culture" is eloquently captured in Mezey's description of "law as culture as law" in her work *Law as Culture.* Mezey, *supra* note 320, at 55. She also suggests that "law as culture" can also be understood by "emphasizing the pervasive power of law" and by "emphasizing the pervasive power of culture." *Id.* at 48–57; *see also* LAW IN THE DOMAINS OF CULTURE 10 (Austin Sarat & Thomas R. Kearns eds., 2000) ("To recognize that law has meaning-making power, then, is to see that social practices are not logically separable from the laws that shape them and that social practices are unintelligible apart from the legal norms that give rise to them.").

326. PAMELA GOYAN KITTLER ET AL., FOOD AND CULTURE (6th ed. 2012).

327. Ellen Messer, *Food Definitions and Boundaries: Eating Constraints and Human Identities*, *in* CONSUMING THE INEDIBLE, *supra* note 47, at 53.

328. KITTLER ET AL., *supra* note 326, at 4

329. MASSIMO MONTANARI, FOOD IS CULTURE (2006).

food,"[330] the law incorporates cultural conceptions of "food" into the legal definition. What is used as food is, at least in part, determined by culture; not everything that "can function as food" is considered edible and eaten.[331] As Lewis Grossman demonstrates through a historical examination of food, food is a "fundamental cultural concept[]" and the "cultural matrix" and extralegal understandings of food constrain the legal definition and category of food.[332]

The impact of culture on food law, however, can be seen not only in how "food" is defined as a legal category, but also in how subcategories of foods are defined and regulated. For example, the definition of "food additive" excludes, among other things, a substance that is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety through experience based on common use in food [prior to 1958], to be safe under the conditions of its intended use."[333] By relying in part on the "common use" of a substance to establish safety, the exception for GRAS substances implicitly recognizes and incorporates cultural understandings of food because what is used as food is, at least in part, determined by culture. By modifying the term "use" with the adjective "common," the law, through the GRAS exception, recognizes not just any use, but "a substantial history of consumption" that is shared "by a significant number of consumers"[334]—i.e., culture.[335] Hence, if a substance was not commonly used in food prior to 1958 because of a cultural barrier, that cultural barrier would become a legal hurdle as the GRAS exception based on common use would not be available for that substance.[336] The legal category of "food" also incorporates culture via use.[337]

The very concept of food safety is culture-specific. For example, Marsha A. Echols demonstrates the influence of "local culture and attitudes" on the regulation of food in the European Union and the United States, describing culture as playing "a silent role in the regulatory process and resulting rules" for

330. Food, Drug, and Cosmetic Act § 201(s), 21 U.S.C. § 321(s) (2012).

331. *Acceptance and Rejection*, 1 ENCYCLOPEDIA OF FOOD & CULTURE, *supra* note 61, at 1; *Taboo*, 3 ENCYCLOPEDIA OF FOOD & CULTURE, *supra* note 61, at 384; Grossman, *supra* note 311.

332. Grossman, *supra* note 311, at 1092.

333. Substances Generally Recognized as Safe, 81 Fed. Reg. 54,960, 55,004 (Aug. 17, 2016); FDCA § 201(s), 21 U.S.C. § 321(s).

334. 21 C.F.R. § 170.3 (2017) (defining "common use in food").

335. *See* Mezey, *supra* note 320, at 48–57.

336. Of course, in such case, a food could still be determined to be GRAS for a use based on scientific procedures, FDCA § 201(s), 21 U.S.C § 321(s), and the company could make a self-determination to that effect, Substances Generally Recognized as Safe, 81 Fed. Reg. at 54,960. *See supra* Section III.B.3.

337. *See* FDCA § 201(f), 21 U.S.C. § 321(f) (2012) (defining "food" to include "articles used for food").

foods.[338] Although legal constraints limit the impact of culture on food safety measures, Echols compares and contrasts European and American attitudes towards food regulation in the context of "traditional production processes and artisanal products" and "new technologies and novel foods" to illustrate how "[d]ifferent cultures and attitudes influence the legal determination of when there is a food safety risk and how to respond to such a risk."[339]

The influence of culture on food law can also be seen in how "the aesthetic problem of 'filth' in food" has been addressed in the United States.[340] The FDCA's adulteration provisions reach a food that contains filth even if the food is not filthy to the point of being unfit for consumption.[341] In addition, they reach food prepared "under insanitary conditions whereby it may have been contaminated with filth" even if the food has not been contaminated or rendered injurious to health.[342] For example, in a case in which a food was alleged to be adulterated due to "a large number of worm fragments," a U.S. district court observed that there was "no doubt that [the Pure Food and Drugs Act of 1906] was designed to protect the aesthetic tastes and sensibilities of the consuming public."[343] As Hutt, Merrill & Grossman, observe:

> Although filth was once regarded as a potential indicator of contamination by pathogenic microorganisms, and thus evidence of a potential health hazard, modern food technology allows products to be processed in a way that eliminates the risk of disease even in the presence of filth. Nonetheless, even sterilized filth, however harmless, is prohibited on aesthetic grounds alone.[344]

In this way, cultural sensibilities can be seen as being reflected in the law's protections. Prohibiting filth on aesthetic grounds, of course, also may be protective of human health as "Congress may . . . have wanted to set a standard or purity well above what was required for the health of the consuming public" as

338. Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 542 (1998).

339. *Id.* at 530.

340. *See* HUTT ET AL., *supra* note 129, at 470; *see also* Food, Drug, and Cosmetic Act § 402(a)(3)-(4), 21 U.S.C. § 342(a)(3)-(4) (2012).

341. *See supra* Section II.B.

342. *See* FDCA § 402(a)(4), 21 U.S.C. § 342(a)(4) (2012).

343. United States v. 133 Cases of Tomato Paste, 22 F. Supp. 515, 516 (E.D. Pa. 1938); *see also* Pure Food and Drugs Act of 1906 § 8, 21 U.S.C. § 8 (1934) (providing that a food is adulterated "[i]f it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance"). That statement has been cited favorably in several cases interpreting the FDCA. *See* United States v. 1,500 Cases More or Less, Tomato Paste, 236 F.2d 208, 210 (7th Cir. 1956); United States v. 71/55 Gallon Drums, More or Less, of Stuffed Green Olives in Brine, an Article of Food, 790 F. Supp. 1379, 1382 (N.D. Ill. 1992).

344. HUTT ET AL., *supra* note 129, at 470.

such a standard will "allow fewer products to drop below that level" and "encourag[e] more careful industry inspection."[345]

The predominant cultural and legal treatments of insects in food in the United States are congruent. The *Encyclopedia of Food and Culture* entry for "Aversion to Food" provides insects and milk that used to have an insect (a cockroach) in it as examples of disgusting foods.[346] Foods can become disgusting because we learn that the food is disgusting from others as "most American children learn from others that insects are disgusting foods" or because it has contacted something considered disgusting such as an insect.[347] The law, as discussed in the Section II.A, has largely treated insects in food as "filth" that renders the food adulterated in violation of the FDCA.[348] Indeed, insects do not even have to contact a food for the food to be adulterated as the law treats food that has been produced "under insanitary conditions where by it may have become contained with filth" as adulterated.[349] As one court remarked, this "almost reach[es] the aim of removing from commerce those products produced under circumstances which would offend a consumer's basic sense of sanitation and which would cause him to refuse them had he been aware of the conditions under which they were prepared."[350]

Food law in turn influences and informs cultural understandings and acceptance of food. As Grossman persuasively illustrates "[a]lthough the regulatory apparatus has always had to take into account the extralegal understandings" of 'food[,]' . . . the law, in turn, has exerted significant influence over [its] meaning in broader culture."[351] He provides a number of examples of how the law has shaped cultural understandings of the categories of products that it regulates.[352] For example, he describes how the Nutrition Labeling and Education Act (NLEA) and FDA's regulations authorized under the NLEA changed the cultural conceptions of food by blurring the lines between "food" and "drug,"[353] and discusses how the Dietary Supplement Health and Education Act of 1994

345. *1,500 Cases More or Less, Tomato Paste*, 236 F.2d at 210.

346. *Aversion to Food*, 1 ENCYCLOPEDIA OF FOOD & CULTURE, *supra* note 58, at 145; *see also Taboos*, 3 ENCYCLOPEDIA OF FOOD & CULTURE, *supra* note 61, at 384 (discussing insects as a taboo food in the United States).

347. *Id.*

348. *See supra* Section II.A (discussing the law's treatment of insects as "filth" or evidence of "insanitary conditions").

349. *See* Food, Drug, and Cosmetic Act § 402, 21 U.S.C. § 341 (2012). Again, as with aesthetic adulteration, this is not to say that these provisions are not also protective of health.

350. United States v. 1,200 Cans Pasteurized Whole Eggs by Frigid Food Prods., Inc., 339 F. Supp. 131, 141 (N.D. Ga. 1972).

351. Grossman, *supra* note 311, at 1093.

352. *See generally id.*

353. *Id.* at 1137.

(DSHEA) may have helped usher the term "dietary supplements" into popular use.[354]

Drawing upon Mezey's framing of the relationship between law and culture, the relationship between food, law, and culture can be described as "food law as culture as food law."[355] In his essay *FDA and the Rise of the Empowered Consumer*, Grossman illustrates how developments in the regulation of food "both reflected and reinforced" societal and cultural changes, including declining trust, the rights revolution of the 1970s, and the changing health information environment for laypersons.[356] Similarly, FDA's regulatory inaction with respect to insects as food, compared with the substantial regulation of insects as filth in food, may reflect and reinforce cultural aversions to insects as food. By explicitly recognizing insects as food, FDA may help erode the cultural barriers to using insects as food. As a first step, legal recognition of insects as "food" may help to change the culture and normalize insects for food use,[357] although additional regulation will likely be needed to help assure consumers that insects used as food are safe and provide a clear regulatory pathway for companies looking to sell insects as food.

## Conclusion

Much of FDA's existing regulation, to the extent that it considers insects in the context of food, regards insects as food defects. Against this extensive background of insects as defects or filth, FDA's failure to legally recognize insects as food may reinforce cultural aversions to insects as food and serve as a barrier to the realization of the potential benefits of insects as food. There is a need to reconceptualize insects in the context of food. Insects in food may be filth, but as an estimated two billion people recognize, insects may also be "food," and as such offer substantial potential to help address the challenges of feeding an increasing global population in a sustainable manner.

FDA's failure to regulate innovative foods such as insects may hinder the development and acceptance of these foods, particularly where the new food does not align with existing cultural norms regarding what is food. Informal recognition of insects as food is not enough in light of the pervasive regulation of insects as filth. FDA should specifically provide that insects intended to be used as food or components of food are food. FDA should also establish a test for distinguishing between insects as food and insects as filth. As population growth, dietary transitions, and environmental changes put increasing pressure on our existing food systems, insects may help to meet the growing demands for

354. *Id.* at 1144.

355. *Id.*; Mezey, *supra* note 320, at 55.

356. Lewis A. Grossman, *FDA and the Rise of the Empowered Consumer*, 66 Admin. L. Rev. 627, 640–41 (2014).

357. *See* Sarah Schindler, *Unpermitted Urban Agriculture: Transgressive Actions, Changing Norms, and the Local Food Movement*, 2014 Wis. L. Rev. 369, 390–91 (2014) (discussing "normalization and legitimization through the law").

sustainable foods and animal proteins and should be among the new food sources we explore.