Review of U.S. State-Level Entomophagy Regulation 2015

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Abstract

This study examined state-level food safety regulatory response to the use of insects for human consumption, or “entomophagy.” Interviews were conducted with state regulatory officials from the 50 states; multiple interviews were conducted in states where regulation of retail and manufacturing of food are carried out by different agencies or delegated to a local agency. The study identified states where insects are sold at retail and the number of insect manufacturers; current regulations; types of insect food products; regulatory challenges regarding manufacturing facilities; and perceived food safety risks. Twenty states either reported receiving inquiries related to beginning an entomophagy-based business within their state; had previously regulated entomophagy facilities; or currently regulate entomophagy at the manufacturing or retail level. However, while the Food and Drug Administration (FDA) has jurisdiction over food being made using insects that is wholesaled and crosses state lines, there is no clearly-defined guidance at present for state regulators from the FDA. The study concludes that present state-level food safety regulation is fragmented, inconsistent, and does not address the current widespread use of insects as food. Recommendations include increased FDA-industry collaboration in order to create an entomophagy guidance document for the successful implementation of a preventive control system in order to provide consistent regulation of entomophagy processing and manufacturing facilities.

Keywords: 50 states, approved source, crickets, food safety, Food Safety Modernization Act (FSMA), guidance document, hazards, insects as food, insects for human consumption, Preventive Controls for Human Food (PCHF)

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Background

People throughout the world have been eating insects as a regular part of their diets for millennia (van Huis et al., 2013, p.1). More than 1900 species are regarded as edible, including beetles, caterpillars, bees, wasps, ants, grasshoppers, locusts, crickets, cicadas, leaf- and planthoppers, scale insects, termites, dragonflies, and flies (van Huis et al., 2013, p.1). The benefits of entomophagy include utilizing a nutrition source that is high in calcium, zinc, and iron; environmental friendliness (e.g., requiring 12 times less feed than cattle to convert feed into the same amount of protein); and economic benefit, as the cost of start-up is significantly less than traditional farm-raised animals (van Huis et al., 2013, p.2).

Insect food producers are currently regulated by the FDA using Good Manufacturing Practices (GMPs) (Halloran & Munke, 2014); however, these GMPs are subject to a variety of interpretations. The FDA has published guidance documents and provided regulations for seafood and juice processors incorporating hazard analysis and critical control point (HACCP) principles which provide industry and regulators with consistent, sound scientific evidence to ensure the product and process is safe. However, the FDA has not provided guidance for insect food processors.

The Food Safety Modernization Act (FSMA) Preventive Controls for Human Food (PCHF) rule is now final (U. S. Food and Drug Administration [FDA], 2016) and uses HACCP-based principles that food facilities must follow unless the facilities are covered by an exemption. If not, the firm has the responsibility for: conducting a hazard analysis, preventive controls, monitoring, verification, corrective actions, and making corrections.

Farms are exempt from the preventive controls rule unless raw agricultural commodities (RACs) are changed into a processed food. The FDA identifies multiple activities that change an RAC to a processed food, including slaughtering of animals and freezing. Insect farms would be exempt from the new FSMA PCHF rule unless facilities are slaughtering insects, freezing them, or conducting activities that would change the product into a processed food. FDA is developing guidance documents addressing the following: hazard analysis and preventive controls, environmental monitoring, food allergen controls, and validation of process controls. However, no guidance document currently exists for insect processors despite the fact that insects are rich in nutrients and moisture, and provide a favorable environment for microbial survival and growth (van Huis et al., 2013, p.117).

Problem Statement

At present, there is no comprehensive description of the state regulation of the processing and sale of insects for human consumption.

Research Questions

1. What types of insects are most commonly being processed and consumed for human consumption?
2. What types of foods are produced using insects?
3. What are the challenges associated with the regulation of insect-processing facilities?
4. What are the food safety risks related to insect processing and consumption based on the current understanding of state food safety regulators?

Methodology

A telephone survey of state agriculture and local health officials was carried out using the Directory of State and Local Officials (Association of Food and Drug Officials [AFDO], 2015). An introductory e-mail provided the subjects with thirteen questions to be asked in the telephone survey. Eight questions focused on the subject's regulatory framework and five questions related to the regulatory process. Responses to the survey questions were analyzed to address the four research questions above.

Results

All 50 states responded to the survey. Twenty states indicated that they had either received inquiries related to beginning an entomophagy-based business within their state; had previously regulated entomophagy facilities; or currently regulate entomophagy at the manufacturing or retail level. Six of the 20 states were currently regulating crickets or cricket products using Good Manufacturing Practices (GMPs) (see Table 1). Two of the 20 states had previously regulated cricket entomophagy products using the GMPs (Louisiana and Utah); nine of the 20 states had received inquiries related to cricket entomophagy (Alaska, Idaho, Maine, Michigan, Minnesota, South Carolina, Texas, Vermont, and Washington); and two states (Arizona and New York) reported currently regulating entomophagy at the retail level.

Several responses to the survey questions illustrate the diversity of regulatory experiences related to entomophagy. A Montana regulatory official stated, "There has been talk and phone calls about insects for human food, and we have seen insects used for human food that fall under our temporary food exemption." An Arizona regulatory official said, "The State Fair is primarily where insects for human

consumption are offered for sale, and the insects used at the State Fair are primarily from California. There are also numerous retail stores selling packaged entomophagy products including novelty items such as lollipops with an edible insect such as scorpions inside of the lollipop." From Kansas, a regulatory official commented that "There was a startup for mealworm flour, and at this point the start-up operation falls under the cottage food retail exemption."

The widespread nature of entomophagy is illustrated by two manufacturers: Chapul and Exo. Chapul produces cricket bars using cricket protein powder that is dairy- and soy-free. Exo produces protein bars using cricket flour and claims that the bars are all natural, dairy-free, gluten-free, paleo-friendly, soy-free, and contain 10g of protein. These two companies distribute products to 42 of the 50 states, primarily to retail establishments (Exo, n.d.; Chapul Bars, n.d.).

All of the states using the GMPs (or a modified form of the GMPs) to regulate entomophagy facilities identified crickets as an ingredient, or sold as a whole insect as shown in Table 1.

Table 1

States Currently Regulating Entomophagy Using Good Manufacturing Practices

State	Regulating cricket product entomophagy?	Cricket used as an ingredient?	Selling whole crickets?	Regulating other insect products using GMPs?	Food products manufactured
California	Yes	Yes	No	Yes	Chocolate-dipped insects, hard candy w/insects, cricket flour
Illinois	Yes	Yes	No	No	Power bars
Massachusetts	Yes	Yes	No	No	Snack products, chips
North Carolina	Yes	Yes	No	No	Baked goods
Ohio	Yes	Yes	Yes	No	Whole crickets
Oregon	Yes	Yes	No	No	Cricket flour, instant oatmeal

The potential size and evolution of large producers is illustrated by two other manufacturers: Big Cricket Farms in Ohio and Aspire, located in Texas. According to its website, Aspire has the capacity to process up to 7 million crickets on a weekly basis (Aspire Food Group, 2016). Big Cricket Farms, whose mission statement starts with “To drive the edible insect industry forward” also raises crickets specifically for human consumption; the company bills itself on its website as “the first American insect farm to obtain food-grade certification from their state Department of Agriculture and the FDA.” The firm raises *Gryllodes sigillatus*, a.k.a. the Tropical Banded Cricket (Big Cricket Farms, 2014). An Ohio regulatory official who has been to the facility identified jurisdiction as one of the biggest challenges in regulating insect facilities, as the Ohio

Department of Agriculture does not have jurisdiction until the crickets are dead—in effect, after an important part of the manufacturing process has already taken place.

California was the lone state in the survey to regulate products other than crickets or cricket products using the GMPs. A California regulatory official identified insects in hard candies such as ants and scorpions (which are regulated under the GMPs) and chocolate-covered grasshoppers during the interview. Products found on the website of California's Hotlix Candy Store include ant wafers and whole crickets flavored with bacon and cheddar, sour cream and onion, and salt and vinegar. Worm snacks were also offered in BBQ, Mexican spice, and cheddar cheese flavors (Hotlix Candy Store, 2015).

During each interview, state representatives were asked to identify challenges related to regulating entomophagy facilities. Table 2 shows what challenges were identified for all states participating in the survey. Approved source, understanding the process, and understanding the hazards accounted for 66% of challenges identified. Of the six states indicating that entomophagy regulation was occurring and applying the GMPs in Table 1, ten responses to challenges were noted. The challenges identified (from the states listed in Table 1) included understanding the process (40%), determining approved source (20%), understanding the hazards (20%), the unknown (10%), and establishing jurisdiction (10%).

Table 2

Challenges Identified by Regulators Regarding Entomophagy

Challenges	Number of Responses	Percent of Total Responses
Approved Source	24	30%
Understanding the Process	18	23%
Understanding the Hazards	10	13%
No Response	9	11%
Training Staff	7	9%
No Specific Regulation	4	5%
No Challenges	3	4%
Establishing Jurisdiction	2	2%
No Scientific Evidence	2	2%
The Unknown	1	1%
Total	80	100%

Of the eight states that regulated entomophagy firms or had previously regulated entomophagy firms using the GMPs, none indicated that any hazards were identified during inspection work. A New York State regulatory official pointed to a 2001 incident where approximately 15 people became ill following the annual Explorers Club dinner in New York City. The primary symptom was burning mouth/throat due to the mechanical irritation caused by the urticating hairs of tarantula. A food prep review found that some of the tarantulas may not have been adequately singed to remove the hairs. The tarantula example illustrates the hazards within entomophagy which could easily be overlooked without scientific guidance provided to industry and regulators.

A Georgia regulatory official shared information received from the FDA that there is a growing body of scientific literature that people who are allergic to shellfish (shrimp, lobster, etc.) may also be allergic to insects either as food or as adulterants in foods.

The FDA has provided e-mail guidance to a Pennsylvania regulatory official that states there is no specific FDA regulation that either prohibits or condones the use of insects as food. The Food, Drug, and Cosmetic Act requires food products to be “fit for food” (FDA, 1938). In general, “fit for food” means the product is safe and wholesome and does not present a health hazard. Firms, not the FDA, must determine if this is the case and FDA’s role should be to oversee that firms meet this charge.

Conclusions

Entomophagy regulation lacks national standardization and existing regulation is fragmentary and often ad hoc. However, entomophagy is found in most states; nationally, the volume of product is increasing. States are currently regulating entomophagy manufacturers using GMPs, which is not a food process- or product-specific regulation. Insect processors may fall under the Preventive Controls for Human Food (PCHF) rules, in which case regulators would rely on industry to provide information related to hazards in the product and process. The PCHF rules will also require manufacturers to identify hazards in their operation and validate and verify control of these hazards based on scientific data. Additionally, the FDA has not provided guidance to state regulators or to industry regarding hazards, processes, and sources. As a result, there is a current and significant need for increased guidance for consistent entomophagy regulation.

Recommendations

The FDA should work with the manufacturers of entomophagy products to provide a guidance document for entomophagy. The guide would be used as a resource for industry and regulators to provide consistent, sound, scientific evidence ensuring the product and process is safe.

An expanded study should be conducted to identify potential hazards associated with the production of insect-based foods in order to assist in the continued effort to achieve a comprehensive description of the regulation and sale of insects for human consumption.

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