Laura Shumow, Regulatory Update 2015 (Speaker #5)
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Questions

1. Would fruit juice be labeled as added sugars or not, as they are free sugars?

FDA defines added sugars as: "sugars that are either added during the processing of foods, or are packaged as such, and include sugars (free, mono- and disaccharides such as sucrose, lactose, and glucose), syrups (e.g., corn syrup, tapioca syrup, maple syrup), naturally occurring sugars that are isolated from a whole food and concentrated so that sugar is the primary component (e.g., fruit juice concentrates), and other caloric sweeteners." Sugar alcohols would not be included in the definition of added sugars.

The WHO definition of "free sugars" is "monosaccharides (such as glucose, fructose) and disaccharides (such as sucrose or table sugar) added to foods and drinks by the manufacturer, cook or consumer, and sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates."

These definitions are very similar and are intended to target sugars/sweeteners used in processed foods.

Under the FDA definition of added sugars, fruit juices that have been concentrated and added during processing would be considered to be added sugars, while the sugars intrinsic to un-concentrated fruit juice would not be considered to be added sugars.

2. Is the FDA milk in dark chocolate study an indication that the FDA may be moving away from allowing "may contain," "processed on shared equipment," etc.?

FDA is clearly very interested in milk in dark chocolate. FDA's first priority is the publication of the final rule on preventive controls and updates to current good manufacturing practices. FDA does plan to issue a guidance document on this final rule that will addresses allergen handling within the context of good manufacturing practices. Additionally, FDA has indicated that they are prioritizing products that carry inconsistent labeling practices in conjunction with advisory statements, such as "dairy-free," "vegan," "lactose-free," along with a "may contains" statement. It is unclear at this time how advisory statements will be handled in the future and FDA is seeking input from the chocolate industry on how to address advisory statements for milk in dark chocolate.

3. Which laboratory/ies is the Cd coalition (US-NCA) using for Cd testing? If a company not currently involved in suits wants to analyze their chocolate or cocoa beans how can this be done?

There are a number of laboratories in the US that test for Cd in cocoa and chocolate products, including Covance Laboratories (NCA has consulted with Darryl Sullivan: Darryl.Sullivan@Covance.com). Any chocolate company may contract with a laboratory to

analyze their products for heavy metals.

4. **If the FDA clearly defines cocoa beans as a "raw agricultural commodity," would it exempt this component from the foreign supplier inspection requirement?**

Under the proposed rule on the FSVP, raw agricultural commodities would only be required to retain documentation back to latest point of comingling. NCA has advocated to FDA that cocoa beans should be considered a "raw agricultural commodity" for the purposes of the FSVP.

5. **On sugars added labeling – the analytical measurement of total sugars do not always correlate well with diabetic (type II) response – especially when in original food context (e.g. within fruit). How do we measure and label free/added sugars? What is the NCA position on this?**

Recognizing that there is no analytical test that can distinguish between intrinsic and added sugars, FDA is requiring that documentation be retained to demonstrate compliance with the added sugars labeling. Documents that may be used for compliance are left to the discretion of the manufacturer, but may include formulations, batch records, etc. NCA advocated against this recordkeeping requirement.

6. **Which is more likely to be favored by FDA, hydrogenated, fully hydro or complete?**

It is my understanding that any of these terms would be considered acceptable by FDA for hydrogenated ingredients with an iodine value less than or equal to 4.

7. **What were the testing parameters FDA used for testing milk in dark chocolate? Lactose, milk proteins?**

FDA tested qualitatively and quantitatively for both total milk proteins and casein.

8. **PHO – will the regulation apply to all companies or is there a small business exemption?**

Since FDA considers this to be a food safety issue there will be no exemptions or extended compliances timeline for small businesses.

9. **Is there research showing added sugar contributing calories >10% are health neutral?**

There have been many studies investigating the impact of added sugars on health outcomes. Depending on the study, different outcomes and associations have been observed. However, only certain studies have been used as the basis for the recent conclusions by the health authorities. The WHO identified >1000 studies that fit their inclusion criteria, but selected only 30 to use for their systematic review. The WHO acknowledges that only very weak evidence is available for recommending that benefits may be observed by limiting added sugars to <5% of calories.

10. **Small business for FSMA – are these any one qualifies or must both be met to qualify (number of employees, sales volume (gross))?**

Under FSMA, "small businesses" and "very small businesses" are defined differently and entitled to different benefits.

The definition of "small business" is having fewer than 500 employees and generally entitles these companies to an extended timeline of an additional year beyond the published compliance date.

The definition of "very small business" is a less than $1 million in sales and generally entitles these companies to an extended timeline of two additional years.

11. I find the proposed FDA labeling scheme confusing. Why doesn't FDA 1) do its own consumer surveys or 2) rely on expert surveys offered to them?

FDA is conducting their own consumer research and has seen the data from surveys submitted by industry groups. However, the added sugars labeling initiative is a priority of the Obama Administration and regardless of the research findings, it is anticipated that FDA will move forward with the added sugars labeling requirement.

12. We will be using one ingredient with less than 20 ppm gluten content. This is part of an assorted box. Can we claim gluten free? What can we say?

Assuming the product doesn't contain any gluten-containing grains (wheat, oats, etc) and it has been verified that the entire product contains <20 ppm gluten, the product may carry a gluten-free claim.

13. Where is the cadmium coming from that it may be present in toxic amounts in chocolate and cocoa?

The cadmium in cocoa and chocolate products is naturally-occurring in the soil in the regions where cocoa is grown. This issue is not a food safety or toxicity concern because cocoa and chocolate are consumed in such small amounts and the cadmium naturally present is at low concentrations. The concern is legal/regulatory in nature, rather than a true food safety risk. Under California's prop 65, certain levels of contaminants require a warning label, however many of these levels are extremely low – well under the amount that would cause food safety concerns.

14. Is there any move to get FDA to go to a specified minimum font size for FOP vending labeling – like 16 pt Arial – something that a person with 20/10 vision could read at 2 ½ feet before vision correction?

Yes, there is a coalition of trade organizations working to try to convince FDA to revise the final rule to recognize the format of existing voluntary FOP labeling programs.

15. Is the size of a company relevant in labeling guidelines? Is a small company required to change their labels in the same time frame?

Currently, FDA has not proposed an extended compliance timeline for small companies, nor do we anticipate that they will in the final rule.

16. How can a company or an individual consumer provide the FDA with comments?

There is a comment period (generally 30-60 days) for all proposed regulations in which FDA collects comments that they will review before the final rule is issued. Comments are generally submitted electronically at Regulations.gov and filed under the docket # for that proposed rule. The docket # can be found in the federal register notice announcing the proposed rule.

17. FSMA please help us with the distinction between HAACP and HARCP.

These are two very similar concepts. From a practical standpoint there are few differences (which hazards are included, recordkeeping requirements, etc), but the regulatory framework is different for these 2 systems. HACCP is only required for seafood and juice products per FDA regulations, however under the FSMA statute sec 103 HARCP is required for all food products. The HARCP requirements will be finalized in the release of the final rule in August 2015.

18. Andrew Bunger/Jeff Fine noted that the definition of PHO would apply to feedstock/blending fats:

SBO=IV 125

HSBO=IV 4

50/50 blend =

IV= 65 but no trans

How does FDA propose to account for this?

Currently, the definition under consideration for fully hydrogenated oils is an IV of 4 or less; thus every hydrogenated oil with an IV higher than this would be considered to be partially hydrogenated, despite trans fat content.

19. Are voluntary recalls included in the FDA reports of recalls?

Yes.

20. Has any research been conducted to indicate if consumers understand partially vs. completely hydrogenated oils?

I am not aware of research on this topic; however media surrounding the issue suggests a lack of understanding by the consumer of the distinction between the two categories.

21. With the various changes in regulatory requirements on labels, can't FDA "bundle" these changes so that they will be less of a burden?

NCA has requested that FDA harmonize the labeling deadlines, however this is not expected to happen. Since the PHO determination is coming from a court decision, rather than a rulemaking process, it is more difficult to for FDA to harmonize with the NFP update.

22. Is the candy industry becoming the next cigarette industry?

This is a very interesting question and in fact, the same tactics used by the public health community to reduce smoking of cigarettes has been proposed as a model of how to address obesity broadly.

23. Are vending labels just for snack foods or would they apply to beverages and sandwiches also?

Yes, all vended food products sold by vending machine operators that own/operate >20 vending machines are covered by the vending labeling rule.