IFAC 2022 Virtual Annual Meeting
Regulatory Committee Meeting
January 18, 2022 ~ 2:00 – 3:30 PM US ET

Minutes of the Meeting

I. Call to Order and Antitrust Statement

Robert Rankin called the meeting to order, noting all IFAC meetings are conducted in accordance with antitrust guidelines. A list of attendees is attached to these Minutes.

II. Approval of the Minutes of the June 16, 2021 Meeting

On a motion duly made and seconded, the Minutes of the June 16, 2021 meeting were approved without modification.

III. Global Regulatory Updates

A. United States

1. Feedback on Covington Presentation

It was noted Brian Sylvester from Covington delivered a detailed U.S. regulatory update presentation earlier in the day, and that many topics are addressed throughout the agenda. Staff suggested reviewing all agenda items and revisiting Mr. Sylvester's presentation to determine additional topics for discussion.

2. Food and Drug Administration (FDA)

In addition to the update provided by Mr. Sylvester regarding Dr. Robert Califf, who has been nominated as the next FDA Commissioner, staff noted the Alliance for a Stronger FDA expects his food initiatives will focus on ensuring a safe food supply, advocating for data and technology modernization, recruiting and retaining FDA employees, and supporting a more efficient, accurate, and responsive agency. It was also noted the Pharmaceutical Research and Manufacturers of America (PhRMA), Research!America, the Consumer Healthcare Products Association (CHPA), and Friends of Cancer Research support Dr. Califf's nomination.

Action: Staff will monitor for updates on the confirmation of Dr. Califf and share with members.

a. Food Additives and GRAS

i. Outcome of GRAS Final Rule Lawsuit

While Mr. Sylvester reported the U.S. District Court for the Southern District of New York granted FDA's motion for summary judgment and rejected all claims made in the 2018 consumer advocacy group

lawsuit challenging the GRAS final rule, staff reminded the Committee IFAC was one of several organizations that funded an *amicus curiae* brief that was submitted to the court and supported FDA's position and the safety of the GRAS program. The *amicus* brief was cited throughout the judge's decision.

ii. IFAC Follow Up Meeting with Division of Food Ingredients on GRAS Topics

The Committee was reminded of the February 2021 meeting with FDA's Division of Food Ingredients to share IFAC member feedback on the GRAS Notice process and seek clarification on issues/ questions arising from member experiences. The meeting was informative, and Division Director Dr. Susan Carlson welcomed additional dialogue with IFAC. IFAC was working toward holding a follow up meeting to continue discussion on certain topics as well as raise new topics. However, it was agreed to wait to request the meeting until after hearing Dr. Carlson present on GRAS topics during the Toxicology Forum's 2022 Virtual Winter Meeting.

Staff noted the revised draft agenda for the follow up meeting with FDA was shared with the final meeting materials. Staff clarified member questions regarding the inclusion of bioactive ingredients as a potential agenda topic, and it was suggested starter cultures could be an example of a bioactive ingredient to help allay potential questions about long-term safety. A member noted continuing to receive the same questions that slow down GRAS Notice reviews and suggested that IFAC focus on these specific questions as well as potential GRAS Notice quality issues (i.e., from new companies) to understand what FDA is looking for and help expedite the overall process for all stakeholders. The Committee also agreed to ensure allergenicity is included on the agenda topic related to safety.

Action: Staff will schedule a Regulatory Committee call to debrief from Dr. Carlson's presentation and align on agenda topics/next steps for scheduling the follow up meeting.

iii. Closer to Zero Action Plan for Baby Foods

Berit Dockter reported attending the November 18 FDA public meeting on the Closer to Zero action plan. The meeting largely focused on reviewing data from FDA's Total Diet Study and there were no mentions of food additives. IFAC did not comment during the open comment period but there will be additional dockets and opportunities to comment as the action plan is developed. Staff also attended a December 9 FDA Grand Rounds on heavy metals which reiterated information shared at the November public meeting.

Members agreed that staff should continue to monitor this topic as certain food additives could be included if they are derived from minerals/crops and depending on the level used in foods.

Action: Staff will contact the Food & Beverage Issue Alliance (FBIA) to determine planned/ongoing activities within the broader food industry.

iv. Possible IFAC Comment Supporting Lallemand Food Additive Petition on Inactivated Yeast

It was noted Lallemand filed a food additive petition proposing that amend the food additive regulations to allow for the safe use of vitamin D2 heat-killed baker's yeast as a source of vitamin D2 in specific food categories. Staff noted Lallemand would appreciate IFAC submitting a comment in support of the proposal. Members agreed to review a comment letter.

Action: Staff will circulate a draft comment supporting Lallemand's petition for member review.

v. NGO Citizen Petition on Cumulative Effects

The Committee was reminded of the September 2020 citizen petition filed by consumer advocacy groups which calls on FDA to define key terms essential to consider the cumulative effect of a food additive, food contact substance, GRAS substance, and color additive, taking into account similar substances in the diet, when assessing safety. FDA's initial response in March 2021 stated the agency has not reached conclusion due to competing priorities.

The Safe Food Ingredient Coalition (SFIC), of which IFAC is a co-facilitator, formed a small group to review the petition and explore possible industry activities to address. This work has slowed due to other priority issues but SFIC principals are reconvening to restart this work. Additional updates will be shared as available.

vi. Federal Legislation Addressing Food Additives

Staff flagged two federal bills mentioned by Mr. Sylvester and one additional bill discussed during the 2022 Mid-Year Meeting.

- H.R.3699, the Toxic Free Food Act of 2021, would prohibit manufacturers from marketing a substance as GRAS unless it has been notified to FDA and the assessment considers the cumulative effects of the substance, prohibit certain substances from being called GRAS, call for mandatory re-reviews of GRAS

substances, and reconvene the Food Additive Committee, among other requirements.

- H.R.4694, the Food Chemical Reassessment Act, would establish the Office of Food Safety Reassessment within FDA that would be tasked with reassessing all the safety of all food additives, food contact substances, GRAS substances, and prior-sanctioned substances. The bill contains a list of 10 substances the new Office would need to reassess during its first year.
- H.R.4917/S.2594, the Food Labeling Modernization Act, addresses numerous food labeling topics, including front of pack nutrition labeling, claims, ingredient list formatting, requiring that phosphorus be declared on the ingredient list or Nutrition Facts Label, allergen labeling, and standards of identity (e.g., the bill would require that yogurt, low fat yogurt, and nonfat yogurt contain a minimum level of live and active cultures per gram).

Following the Mid-Year Meeting, staff reached out to associations that have legislative programs and all are monitoring but not taking action to oppose bills as they do not have bipartisan support and the groups don't want to raise unnecessary attention. Staff also reached out to the Kellen Public Affairs Department and they have the same perspective. At this time, staff does not expect the bills will move. Members agreed and noted FDA does not have the resources to implement any of the requirements.

Action: Staff will ask FDA representatives about the bills as appropriate to determine their perspectives on the proposals and possibility of them being implemented if passed.

b. Food Safety

i. Final Rule on Lab Accreditation

Staff reported FDA published the final rule on Laboratory Accreditation for Analyses of Food in December. The rule is part of the Food Safety Modernization Act (FSMA) and establishes a lab accreditation program whereby FDA-recognized certification bodies will accredit labs based on the standards laid out in the final rule. The rule does not apply to all food testing – the FDA website lists the testing that is covered under the rule.

ii. Revision to Preventive Controls Guidance

It was noted FBIA has discussed advocating FDA to rescind Appendix 1 of the 2016 FDA draft guidance for industry on Hazard Analysis and Preventive Controls for Human Food. Appendix 1 addresses Potential Hazards for Foods and Processes and lists

potential food- and process-related biological, chemical, and physical hazards for 17 food categories, including food additives. Staff are trying to learn more from FBIA but apparently FBIA members are requesting a meeting with FDA to address their concerns. IFAC staff is in the process of rejoining FBIA and we plan to participate in this activity. Members agreed that staff should follow this activity and suggested IFAC's GMP Guide could be utilized with FDA.

Action: Staff will participate in FBIA discussions and report back to members on next steps.

c. Nutrition Innovation Strategy

Staff are monitoring for FDA Nutrition Innovation Strategy updates including publication of the FDA proposed rule establishing a definition for the labeling term "healthy". The rule was recently sent to the Office of Management and Budget for review so its publication is imminent. Once published, staff will share the proposed rule for member review and possible IFAC comments.

d. Dietary Supplement Health and Education Act of 1994 (DSHEA)

i. DSHEA 2.0 Updates

IFAC staff have remained in contact with Consumer Healthcare Products Association (CHPA) staff, which are coordinating industry stakeholders in a "DSHEA 2.0" workgroup. Discussions have focused on legislative and regulatory opportunities to update DSHEA and one of the primary goals has been to draft legislation that would update or replace DSHEA. IFAC joined the workgroup to provide perspectives on behalf of cultures/probiotics producers, which CHPA has indicated are not represented by other workgroup members. Next steps include organizing a planning call to discuss workgroup member priorities and drafting bill language, although progress seems to have stalled.

Action: Staff will continue to participate in the DSHEA 2.0 workgroup and share updates with members as available.

e. Other

i. Proposed Repeal of HHS SUNSET Rule

The Committee was reminded the Department of Health and Human Services (HHS) published a proposed rule on Securing Updated and Necessary Statutory Evaluations Timely (SUNSET) in November 2020 which would set expiration dates for virtually all regulations issued by HHS and its agencies – including FDA. IFAC submitted

extensive comments opposing the rule but it was finalized in January 2021 prior to the change in the U.S. Administration. A legal challenge was raised in March 2021 which put the implementation date on hold, and then in October 2021 HHS published a proposed rule requesting comments on withdrawing or repealing the rule. IFAC submitted comments supporting repeal of the rule in December; staff will monitor for the final rule and other updates.

ii. Sodium Reduction Update

In October, FDA issued final guidance for industry that provides voluntary, short-term (2.5-year) sodium reduction targets for a broad range of processed, packaged, and prepared foods. The final guidance updated draft guidance published in 2016 which contained short- (2-year) and long-term (10-year) reduction targets.

Staff continues to participate in the Sodium Reduction Coalition based on the interests of some members. Sodium Coalition members met with FDA in December and asked questions about implementing the final guidance. FDA requested more time to review and agreed to follow up with the Coalition. Staff will continue to share relevant updates as available.

3. Department of Agriculture

a. Agricultural Marketing Service

i. National Organic Program (NOP)

Staff summarized IFAC's activities to address the 2021 National Organic Standards Board's (NOSB) review of sunset materials. IFAC was successful in having all priority ingredients, including agar-agar, animal enzymes, carrageenan, cellulose, and silicon dioxide, voted for relisting. This was notable as staff expected significant pushback in keeping carrageenan on the National List. IFAC submitted written comments for both the spring and fall meetings and staff delivered oral comments at public webinars in advance of both meetings. Staff noted another valuable takeaway was the apparent weight carried by providing market data on new product launches containing priority additives. IFAC informed the NOSB of 160 new organic product launches containing carrageenan since 2016 and this statistic was very important in the NOSB's final decision. Next steps are for the NOP to initiate rulemaking to relist these additives on the National List for the next five years.

Staff are monitoring for agenda topics for the Spring 2022 NOSB meeting, which is scheduled to take place April 26-28 in Crystal City, Virginia, and will share updates with the Committee.

Staff also noted a member request to consider proposing to revise the listings for phosphates on the National List. Calcium, potassium, and sodium phosphates have different annotations and a member would like to make the listings consistent if possible.

Action: Staff will convene phosphate and other interested members to review options for addressing this topic.

ii. National Bioengineered Food Disclosure Standard

Staff noted the Standard is now in place for all industry stakeholders as of January 1, 2022. No major issues have been reported.

b. Foreign Agricultural Service/2022 Emerging Markets Program (EMP) Opportunities

Staff reviewed possible 2022-2023 EMP activities in China/India, Colombia, Saudi Arabia/Middle East, Dubai, and Thailand/SE Asia. All depend on USDA grants and the ability to travel/meet due to COVID. Staff will continue to monitor for updates on EMP sessions and consider participation as appropriate.

c. Food Safety and Inspection Service/Nitrite/Nitrate Naming

Staff reminded the Committee of a previous member request regarding a possible USDA proposal on the labeling of plant-based nitrates and nitrites. Staff have not seen any proposals and members did not express interest in continuing to follow this topic so it will be dropped.

B. Other Global Regulatory Issues/Updates

1. Europe

a. Feedback on Joy Hardinge Presentation

Staff and members discussed Ms. Hardinge's update on the EU Farm to Fork Strategy, particularly the focus on reducing food waste, and agreed it would be a good topic for the Communications & Outreach Committee. For the Regulatory Committee, members suggested that IFAC consider commenting on public consultations including the workstream on developing a sustainable framework for the regulation of new products which could include evaluating environmental metrics and sustainability criteria.

Action: Staff will monitor for updates and opportunities to comment on EU Farm to Fork initiatives and share for member consideration.

b. Titanium Dioxide

It was reported earlier in the day that the European Commission (EC) published its anticipated regulation removing titanium dioxide (TiO_2) from the list of permitted additives. IFAC submitted comments opposing the proposed ban in December 2021. The regulation comes into force in 20 days and, as expected, allows TiO_2 to be sold for six months (until August 7, 2022). After that date, goods already containing TiO_2 may be sold until stocks are exhausted. The ban only covers food uses but TiO_2's use in medicines will be reviewed within three years and the EC suggests alternatives should be sought during this period.

c. Silicon Dioxide Genotox Project Update

The Committee was reminded IFAC is sponsoring a project for ToxStrategies to study the potential genotoxicity of silicon dioxide (SiO_2) in the wake of the European ban of TiO_2, which was based on the European Food Safety Authority's negative opinion that raised questions about potential genotoxicity effects. ToxStrategies is putting together an introductory presentation for a kickoff meeting with IFAC members.

d. Microplastics

The EC is expected to publish a proposal on the reduction/restriction/mitigation of microplastics which could involve some food additives. Staff will continue to monitor and share updates as available.

2. Health Canada

Staff reminded the Committee of two recent updates that were included in the monthly IFAC Regulatory Update. First, it was announced in November that the Food Directorate launched an online application form for filing food additive, infant formula, and novel food notifications. Then in December, Health Canada published a proposal to modify the structure of its Lists of Permitted Food Additives and to modernize the titles of certain Lists. The deadline to comment on this proposal is February 2.

3. China

a. NHC National Food Safety Standard on Nutrition Labeling of Prepackaged Foods

Staff reminded the Committee that IFAC submitted joint comments along with the Association of Manufacturers and Formulators of Enzyme Products (AMFEP) and the Enzyme Technical Association (ETA) regarding the National Health Commission's (NHC) draft National Food Safety Standard on General Rules for Nutrition Labeling of Prepackaged Foods in

2020. The comments addressed a proposed definition of total sugars which excluded lactose and galactose. NHC responded to the joint comment in February 2021 and published a revised Standard in September 2021 but the definition of total sugars was not updated. IFAC/AMFEP/ETA submitted additional comments to NHC in November and also submitted comments through the World Trade Organization in December.

b. GACC Decree 248 (Regulations on Registration and Administration of Overseas Manufacturers of Imported Food)

Staff continued to share updates with the Committee regarding China's General Administration of Customs (GACC) Decree 248 on registering and administering overseas manufacturers of imported food. Members flagged that the regulation was to go into effect in 2022 but GACC had not published any guidance for implementing the rules. IFAC worked with IFAC China staff to submit comments to GACC in November which requested supplementary information detailing the registration process and other aspects of the regulation. Staff also shared updates from FDA and USDA regarding self-registration.

c. Jan 20 meeting on IFAC China

It was noted the IFAC Board and interested members are meeting with IFAC China staff to explore how the IFAC China program can be enhanced and provide greater value.

IV. Other Business

A. Committee Objectives

IFAC will continue to work toward the same objectives as in 2021.

B. Plans for Committee Meetings/Calls

Staff will plan to hold quarterly Committee meetings and ad hoc calls as needed.

V. Adjourn

The meeting was adjourned at 3:40 PM.

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Attendees

Katie Davis Evan Doria Allie Gebbie Catalina Miranda	Apeel Sciences
Witty Brathwaite	Cargill
Arie Carpenter Svend Laulund Kate Urbain	Chr. Hansen
Sachin Bhusari	The Coca-Cola Company
Sabrina Caldwell Shannon Helms Adrianna Herrera Frederique Respondek Chinyere Ubani	CP Kelco
Emanuela Pizzitulo	Decernis
Michael Huber Eric Park	ICL Food Specialties
Rita Martins de Piedade Liz McCartney Sam McCutchin Jeff Pitt Tara Ruoff Vince Sewalt Amy Smith Priscilla Zawislak	IFF
Tony Kiefner Bryan Kirkland	Innophos
Levashni Bijou Susan Bond Betsy France Stephanie Speers	Kerry

Farah Dib Richard Ethier	Lallemand
Jackie Dillon Michael Rizzo Travis Schmidt	PepsiCo
Conrad Shannon	Pinova
Frederic Martens	Prayon
Andrea Bosse	Lanxess (prospective member)
Berit Dockter Eric Fleming Delia Murphy Robert Rankin	IFAC Staff