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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

***RE: Docket No. FDA-2009-D-0260 – Draft Guidance for Industry:  
Questions-and-Answers Regarding the Reportable Food Registry (Edition 2)***

The National Grain and Feed Association (NGFA) and National Oilseed Processors Association (NOPA) respectfully submit this joint statement in response to the Food and Drug Administration's (FDA) request for comments in the May 25, 2010 *Federal Register* concerning Edition 2 of the Draft Guidance for Industry regarding implementation of the Reportable Food Registry established under the Food and Drug Administration Amendments Act of 2007 (FDAAA).

The NGFA, established in 1896, consists of more than 1,000 grain, feed, processing, exporting and other grain-related companies that operate more than 7,000 facilities and handle more than 70 percent of all U.S. grains and oilseeds. Its membership includes grain elevators, feed and feed ingredient manufacturers, biofuels companies, grain and oilseed processors and millers, exporters, livestock and poultry integrators, and associated firms that provide goods and services to the nation's grain, feed and processing industry.

NOPA is a national trade association that represents 15 companies engaged in the production of vegetable meals and oils from oilseeds, including soybeans. NOPA's member companies produce more than 1.7 billion bushels of oilseeds annually at 64 plants located throughout the country, including 59 plants that process soybeans.

The NGFA and NOPA appreciate FDA's efforts to issue the second edition of its draft guidance. In particular, we commend the agency for seeking input on an appropriate definition of "transfer" as that term is used in FDAAA with respect to its application to the reporting responsibilities of persons registered with FDA under Section 415 of the federal Food, Drug and Cosmetic Act, which FDAAA defines as "responsible parties."

Section 417 of the federal Food, Drug and Cosmetic Act, as amended by FDAAA, requires responsible parties to submit a report to FDA for any food for which "there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals" (reportable food). However, the Act provides an exception for cases in which "the adulteration originated with the responsible party" and that party, among other things, "detected the adulteration prior to any transfer to another person of such article of food."

As FDA notes, Congress did not define the term "transfer." However, in this context, the exemption clearly reflects the intent of Congress to exclude from reporting those foods whose disposition remain under the control of the responsible party, which can recondition or divert the affected food to safe uses, or destroy it. In such cases, the food has not been released in commerce where it could pose a danger to human or animal health. Congress recognized that no useful purpose would be served by requiring reporting when the source of adulteration was known and the reportable food would not enter the food or feed supply. In so doing, we believe the intent of Congress was to exclude from reporting those products whose disposition remains under the control of the responsible party to avoid overtaxing FDA's limited human resources with a plethora of unwarranted reports while fully protecting public health.

The NGFA and NOPA believe FDA's current interpretation of the term "transfer" – equating it with the physical "release" of the food to another person – neither complies with congressional intent nor common commercial trade practices. Rather, FDA's current interpretation perversely results in a reporting obligation whenever a responsible party has, or has relinquished, physical possession of a reportable food. This expansive interpretation means that foods meeting the reporting threshold would be reportable even though the responsible party still has the effective ability to control the disposition of the product (e.g., through storage, rework, shipment, return or destruction).

As an alternative definition, the NGFA and NOPA respectfully urge FDA to deem that transfer occurs only when the food is under the "**ownership, acceptance and control**" of the responsible party. In the industry sectors our members represent, this typically occurs when the food (e.g., grains, oilseeds, ingredients, feed, processed commodities, etc.) has been inspected and unloaded (i.e., "accepted") at a facility, as opposed to FDA's current interpretation of transfer occurring merely when a conveyance (e.g., truck or rail car) containing the food physically has been delivered to, or departed from, a responsible party's facility site.

Both the NGFA and NOPA operate separate sets of industry trading rules that govern the vast majority of commercial transactions in the grain, feed, feed ingredient and oilseed industries. The NGFA's Grain Trade Rules first were adopted in 1902, while its Feed Trade Rules first were adopted in 1921. Both sets of Trade Rules, and separate sets of NGFA Trade Rules addressing trading of commodities transported by barge, as well as barge freight and secondary rail freight, have been updated as necessary to reflect current trade practice. For NGFA members, the Trade

Rules automatically are incorporated into commercial contracts unless the parties mutually agree to exclude or modify their terms. However, parties have the flexibility to modify or amend these Trade Rules to be appropriate to the needs of the buyer and seller.

Likewise, NOPA operates a set of industry trading rules that apply to the purchase and sale of soybean meal and soybean oil. These rules, which were adopted in 1933 and 1930, respectively, also are updated as necessary to reflect trade practices.

Importantly for purposes of this statement, these widely used trading rules are replete with provisions stipulating that commodities meet contract terms, including for product safety and quality, and spell out procedures under which the buyer is authorized to accept or reject shipments upon physical arrival (e.g., constructive placement) if they do not meet such contract specifications. Receivers of grains, oilseeds, processed grain products and other food are fully cognizant of their legal obligation to manufacture food and feed that are safe and wholesome, and specifically condition acceptance of ingredients from suppliers based upon inspection to ensure safety and quality standards. Further, as pointed out in the statement submitted by Pet Food Institute, even absent specific contractual product safety or quality requirements, commercial contracts assume that goods are fit for their intended purpose, and a breach of this implied warranty is grounds for rejection of the contract.<sup>1</sup> These circumstances include, but are not limited to, situations in which the commodity or product is inspected upon arrival of the conveyance on the premises of a facility.

In cases where all or a portion of the shipment is rejected, the buyer has not accepted receipt of those foods. Hence, the NGFA and NOPA strongly urge FDA **not** to define the term “transfer” as meaning the physical transfer of the food from one responsible party to another. Rather, we believe that a determination as to whether a food has been transferred should be based upon “**ownership, acceptance and control**” of the food by a responsible party.

Further, defining transfer based upon **ownership, acceptance and control** of the food would be consistent with FDA’s recall policies, under which an adulterated food is not subject to recall if it remains “on premises owned by, or **under the control of**” the company (*emphasis added*). In FDA’s recall regulations, stock recovery is defined to mean “a firm’s removal or correction of a product that has not been marketed or that has not left the **direct control of the firm, i.e., the product is located on premises owned by, or under the control of the firm and no portion of the lot has been released for sale or use.**”<sup>2</sup> [*Emphasis added.*] Given that the reporting obligation under FDAAA equates closely with the criteria used by FDA for a Class 1 recall (as noted in Question D.5.), we believe that the Reportable Food Registry should reflect the same criteria to provide for consistent interpretation, as they are designed for the same public health purpose – namely, facilitating FDA’s ability to remove seriously adulterated food from commerce to protect human and animal health.

The definition for “transfer” being recommended by the NGFA and NOPA (i.e., ownership, acceptance and control of food) also would rectify several other problematic FDA interpretations of Reportable Food Registry reporting obligations that are incongruous with commercial business practices, including:

<sup>1</sup> Uniform Commercial Code at §2-314.

<sup>2</sup> 21 CFR §7.3(k).

- **Storage of Food in Third-Party Warehouses:** FDA currently takes the position that food has been “transferred” – and that no reporting exemption applies – if it is stored in an independent, third-party warehouse not owned by the responsible party, even though “...the responsible party maintains ownership and direct control over distribution.” As justification, FDA states in its second edition guidance that transfer has occurred to another person, citing the definition of “person” in Section 201(e) of the federal Food, Drug and Cosmetic Act<sup>3</sup> as including individuals, partnerships, corporations and associations. FDA states in response to question E.5.: “...[I]n this situation, the warehouse operator is a distinct legal person.”

The NGFA and NOPA believe such an interpretation of the statute contravenes the congressionally identified purpose of the Reportable Food Registry and defies commercial reality. In cases in which food is stored in a third-party warehouse, there typically is a written agreement under which the company (responsible party) retains the right to control any further disposition of the food; the third-party warehouse certainly does not possess such authority.

Further, we believe that such an interpretation contradicts FDA’s policy pertaining to transfers and vertically integrated companies as established for the recordkeeping requirements of the Bioterrorism Act. Specifically, FDA’s response to question 35.9 of its final recordkeeping guidance states that in the case of a vertically integrated company that has dedicated use of a second firm’s warehouse, the vertically integrated company using the warehouse meets the requirement for continuous and sole possession of the food within its “person.” Clearly, FDA’s answer indicates that no transfer of food has occurred so long as the responsible party has control over the disposition of the food.

We respectfully submit that FDA should not deem that transfer has occurred for food stored in a third-party warehouse based merely upon physical possession. Instead, transfer should be considered to have occurred only if the responsible party has relinquished effective control of the disposition of the product(s).

- **Transportation of Food on Common Carriers:** Similarly, FDA’s guidance currently states that food has been “transferred” once loaded in a transport conveyance (i.e., a common carrier railroad or contract trucker) not owned by the responsible party. Again, FDA’s reliance on physical possession – rather than control of the disposition – of the food leads to an interpretation of transfer that is ill-suited to commercial practice. Again, we believe the determining factor as to whether transfer has occurred should be whether the responsible party has the ability to control the disposition of the food. This would include, but not be limited to, the ability to have the product returned and reconditioned, diverted to an acceptable safe use, or destroyed prior to the product being accepted and controlled by another responsible party. In each case, human and animal health is protected.
- **Intercompany Transfers Among Subsidiaries, Affiliated Companies:** FDA’s guidance states that a food is not considered to have been transferred if the physical

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<sup>3</sup> 21 U.S.C. 321(e)

movement occurs between facilities or plants owned by the same corporate entity. But the agency does not apply this reasoning to subsidiaries, affiliates or other corporate ownership arrangements in which the parent company (responsible party) retains ownership of the food and an equivalent ability to accept and control its disposition. Rather, FDA again cites the definition of “person” under the Act to define each individual corporate entity as a distinct “person.”

This distinction is out-of-step with current business practices, in which a company may maintain separate legal entities for business and tax purposes, and does not contribute demonstrably to human or animal health. Further, we believe it is inconsistent with FDA’s own general labeling provisions that apply to drug products, in which the name of the manufacturer on the labeling for a drug product may be satisfied by specifying the “name of a parent, subsidiary or affiliate company where the related companies are under common ownership or control.”<sup>4</sup> Again, our recommendation - basing a decision on whether “transfer” has occurred on the responsible party’s “ownership, acceptance and control” of the disposition of the food - would alleviate this incongruity.

Please consider the previous statements to constitute the input of the NGFA and NOPA on the issue of “transfer” as contained in questions-and-answers E.4, E.5, E.7 and E.10

## **Recommended Changes to Guidance Document Edition 2 Questions-and-Answers**

The remainder of this statement provides recommendations to FDA concerning the questions-and-answers posed in the second edition of the draft guidance; proposes additional questions-and-answers that we believe should be included in the final guidance; and provides recommended changes concerning the electronic portal itself.

The NGFA and NOPA generally believe the questions-and-answers developed by FDA in the second edition of its Draft Guidance for Industry accurately reflect the requirements of the Reportable Food Registry section of FDAAA. However, there are several exceptions and we offer the following recommended changes to correct what we believe are inaccuracies or to clarify what we believe is FDA’s intent. Several of these recommendations reiterate the recommendations made by NGFA, NOPA and Pet Food Institute in a joint statement submitted to the agency on August 12, 2009:

- **Question A.5:** Responsible parties may choose to use the “guest” feature because it is easier to authorize a different person within the company to amend or submit reports if the principal person responsible for these duties is traveling or vacationing. We believe FDA should make every effort to facilitate the submissions of reports of reportable food, without making a distinction of whether a responsible party creates an account or signs on as a guest. This is particularly true given the expedited time deadlines for gathering information and submitting reports once a determination is made that a food is reportable. In particular, we believe the functionality of FDA’s Reportable Food Registry portal should enable responsible parties signing on as guests to be able to save and retrieve reports that are in progress. This change

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<sup>4</sup> See 21 CFR 201.1(g)

would enhance the end-purpose of the Reportable Food Registry – to protect human and animal health. We urge FDA to change the functionality of its Reportable Food Registry software to provide this capability to reporting by guests.

- **Question A.7:** We encourage FDA to amplify its response to this question concerning the ability of responsible parties to attach documents to their reports. Currently, within the electronic portal, the NGFA and NOPA have been told it appears that attaching documents is a mandatory screen. We believe it would be useful if FDA would clarify that attachments are optional, both in response to this question and within that screen of the electronic portal.
- **Question F.2:** We reiterate that we believe this question should be expanded to address initial reports that do not include all of the required data elements, as well as inaccurate information that can be corrected later based upon subsequent findings that may not be available within 24 hours after a responsible party determines that a food is reportable. Further, we believe the last sentence of the answer to this question should be modified to indicate that FDA “recommends that the responsible party submit an amended report to FDA, including the new or corrected information, as soon as it is reasonably available” rather than “immediately.”
- **Question I.1:** We believe this question-and-answer still is convoluted, confusing and appears to impose a mandatory reporting and notification requirement on immediate previous source(s) and/or immediate subsequent recipient(s) that is **not** in conformance with the statutory language found in Section 417(d)(7)(C) of FDAAA. Specifically, FDA’s current phraseology inaccurately implies that there is a statutory requirement that immediate previous sources or immediate subsequent recipients (Party B) who are notified by a responsible party (Party A) about a reportable food that ostensibly originated with Party A are also required to notify Party B’s immediate previous source(s) and/or immediate subsequent recipient(s). Further, the question-and-answer does not differentiate between situations in which the reportable food may have been distributed in commerce by Party B or still may be under Party B’s control. Nor does the question-and-answer differentiate between situations in which the immediate subsequent recipient(s) of Party B may have actually received the reportable food from Party B. In any event, it would appear that the statute only allows FDA to request or recommend that Party B notify its immediate previous source(s) and/or immediate subsequent recipient(s) in situations where Party B may have received or further distributed a reportable food from Party A.

We believe it would be more accurate to rephrase this question and answer as follows [*New language underscored; deleted language stricken through*]:

“Question I.1. If a responsible party (Party A) notifies FDA and the immediate previous source(s) or immediate subsequent recipient(s) to which Party A believes it has distributed of the article of reportable food (Party B), as required by FDA, should Party B submit a report to FDA or provide a notification to Party B’s own immediate previous source(s) and/or immediate subsequent recipient(s)?”

“A: ~~Yes,~~ If Party B meets the definition of a responsible party, FDA recommends that Party B should submit a report to FDA as soon as practicable, and within 24 hours after receiving the notification from Party A regarding the reportable food. FDA may ~~require~~ request that

Party B to submit a report to FDA as soon as practicable, but in no case later than a time specified by FDA, and/or to provide a notification to Party B's own immediate previous source(s) and/or immediate subsequent recipient(s) of the reportable food. See the response to Question I.5 for more information.” (Sections 417(d)(6) and 417(d)(7) of the FD&C Act)

- **Question I.5:** For the same reasons as articulated above regarding question I.1, we recommend that this question-and-answer be reworded as follows [*New language underscored; deleted language stricken through*]:

“I.5: What activities may FDA require a responsible party that is the immediate previous source or immediate subsequent recipient of an article of reportable food to perform after receiving notification?”

“A: FDA may require such a responsible party to perform, as soon as practicable, but in no case later than a time specified by FDA, one or more of the following actions:

- Submit a report to FDA through the Reportable Food electronic portal that includes the data elements listed in the answer to question G.1 above and any other information FDA deems necessary.
- Investigate the cause of the adulteration if the adulteration of the article of reportable food may have originated with the responsible party that is the immediate previous source or immediate subsequent recipient.
- If the reportable food is no longer under the control of the responsible party, Pprovide a notification to the immediate previous source(s) and/or immediate subsequent recipient(s) to which the reportable food may have been distributed that includes the data elements listed in the answer to question G.1 above.”

- **Questions J.1 and J.2:** In the response to Question J.1, FDA “encourages” responsible parties of reportable food to also “contact their FDA district office and state or local public health or regulatory officials as soon as possible....” Meanwhile, question J.2 correctly states that contacting the FDA district office or state/local public health officials about a reportable food does not relieve the responsible party of submitting a report to the Reportable Food Registry. We continue to question the advisability of having responsible parties notify FDA district offices and state or local public health or regulatory officials directly, and believe that function could best be performed by FDA. This would help avoid duplicative or erroneous notifications, particularly in situations in which, upon subsequent review and investigation by FDA, initial reports are found not to rise to the threshold of being a reportable food. Further, this would provide a single, direct line of reporting between the responsible party of reportable food and FDA, rather than diluting limited human resources with multiple reporting and follow-up inquiries to multiple federal and state agencies.

- **Question K.3:** We reiterate our previously expressed appreciation to FDA for reflecting in its draft guidance FDAAA’s provision that notices of reportable food submitted by responsible parties are considered product safety reports, and are not admissions that the food

involved is adulterated or caused or contributed to a death, serious injury or serious illness of humans or animals.

However, FDA's response to this question leaves uncertain whether the safety report disclaimer language needs to be submitted by the responsible party each time it reports a reportable food, or whether that disclaimer will be automatically generated by the Reportable Food Registry electronic portal itself. We urge that the latter – automatic inclusion of the safety report disclaimer language – be the case for each report submitted, and that FDA reflect that policy in its response to this question.

### **Suggested Topics/Issues for Additional Questions-and-Answers to Guidance Document**

The NGFA and NOPA encourage FDA to add questions-and-answers to its final guidance to address the following additional topics, issues and concerns related to the Reportable Food Registry:

- **Promptly Sharing Incidents Reported by Public Health Officials with Affected Responsible Party(ies):** We strongly urge FDA to include a question-and-answer addressing the process it will use, when reportable food is reported to the Registry by public health officials, for contacting the responsible party of the establishment where the reportable food may have originated to enable timely investigation and response to limit the potential scope or impact of any such incident. We believe these issues are not addressed in existing questions M.1 and M.2, which remain virtually unchanged from questions 37 and 38 in FDA's initial draft guidance.

During the incidents involving melamine and related compounds, one of the major difficulties affected firms encountered was a lack of timely information as to what FDA and other government agencies knew – information that could have helped reduce the spread of adulterated products. FDA should rectify this deficiency by establishing clear procedures for immediately (not later than 24 hours, maximum) notifying the affected responsible party(ies) after receiving a potential reportable incident. Doing so would be consistent with congressional intent in enacting FDAAA and protect public health.

Further, we believe such a question-and-answer should state that FDA will notify the responsible party(ies) of reported incidents, in detail, since a firm can and will search its consumer contact databases to determine if there are any other similar or related reports. Any delay by FDA in conveying such information to the responsible party(ies) – or failure to do so – will undermine the ability of the industry to react quickly in the event of an actual food safety incident. The net result of that failure would be to lessen, rather than enhance, consumer protection and human and animal health.

Finally, any notification to the public of an incident should be made only after the affected responsible party has had sufficient and reasonable time to evaluate and respond to the notice.

- **Time Sequence for Initiating Recalls Vis-à-vis Notifications of Reportable Food:** FDA should add a question-and-answer noting that a responsible party's decision on whether to initiate a product recall can be made separate and apart from a notification to the Reportable Food Registry. This would avoid any misunderstanding that the notification of FDA that the food is reportable is required to occur before a recall begins.
- **Confidentiality of Reportable Food Notifications Released to Public:** During the July 23, 2009 public workshop on the Reportable Food Registry, FDA officials indicated that information provided by responsible parties to the registry will be kept secure to a certain extent. Specifically, it was indicated that reportable food incidents would **not** be made publicly available on FDA's website or on the electronic portal where they could be viewed by the public or other submitters. Instead, the agency indicated it would issue an alert or notification to the public with respect to a reportable food if deemed necessary after consultation with the responsible party. We commend FDA for this policy decision.

However, FDA officials indicated such information would be subject to public disclosure in response to Freedom of Information Act (FOIA) requests with "appropriate redactions." We believe it is important to include this clarification in the final version of the guidance document. In so doing, we encourage FDA to be more specific on the policy it will use to determine which types of data elements provided by the responsible party are considered proprietary and subject to redaction (e.g., the Bioterrorism Act registration number; the results of any investigation into the adulteration incident; contact information for immediate previous sources and/or immediate subsequent recipients directly linked in the supply chain, etc.) in any FOIA reports ultimately made available to the public.

We believe that FDA's policy with respect to these topics is not addressed adequately in new guidance question K.5, and is deserving of one or more questions-and-answers that should be added to the final guidance.

- **Reporting Through Non-Electronic Means:** Given the huge diversity in the types, sizes and locations of domestic and foreign food and feed facilities subject to the Reportable Food Registry provisions of FDAAA, we encourage FDA to include information in its guidance on how responsible parties without access to the Internet may submit reportable food notifications to FDA. For instance, would it be feasible for such parties to report to FDA telephonically or by fax, with FDA personnel entering the required information into the Reportable Food Registry portal?

In question A.9 of the second edition of the guidance document, FDA's response is limited to situations in which the Reportable Food Registry electronic portal is unavailable because of technical difficulties. We believe an additional question is warranted to provide reporting options for responsible parties that lack internet access.

### **Suggested Technical Revisions to Reportable Food Registry Portal**

Finally, the NGFA and NOPA want to take this opportunity to convey suggested improvements several of our member companies have offered that would improve the functionality of the

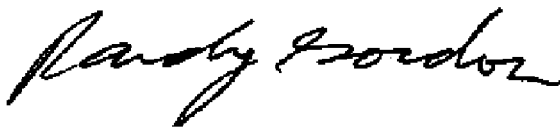
Reportable Food Registry electronic portal. The references are to the specific sections that appear on the portal screens:

- **Section – Product Problem; Question #3:** This screen poses a question concerning how the location where a determination of a reportable food was made first learned about the problem. The only available responses are: 1) “Notified by another firm...”; or 2) “Self Discovery or Other.” We suggest that the latter response – “self discovery or other” should be split apart and made into two separate options. Currently, the summary report issued once the report is submitted only provides the “self discovery” response for those selecting the “self discovery or other” response.
  
- **Section – Product Problem; Supply Chain Information; Question #1:** This screen poses a question asking the respondent submitting the reportable food report to choose whether it received the product, distributed the product or is not ready to report. Currently, the Reportable Food Registry portal allows the respondent to pick only one answer. This does not enable a respondent to select a response if it both received and distributed the reportable food.

### Conclusion

The NGFA and NOPA appreciate this opportunity to provide our collective thoughts in response to FDA’s request for comments, and thank the agency for its consideration of our views. Please contact us if you require any further information.

Sincerely,



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