Chocolate Manufacturers Association

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April 4, 2003

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

Re: Prior Notice of Imported Food; Docket No. 02N-0278

The Chocolate Manufacturers Association (CMA), the National Confectioners Association (NCA), and the Cocoa Merchants' Association of America (CMAA) appreciate this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule on prior notice of imports. 68 Fed. Reg. 5,428 (Feb. 3, 2003).

CMA is the not-for-profit trade association representing the majority of chocolate manufacturers in the United States. In addition to supplying the trade with bulk chocolate products, CMA members also manufacture a wide variety of finished chocolate and chocolate-containing confectionery products for the consumer market. NCA is the not-for-profit trade association representing more than 650 confectionery manufacturers and suppliers in the United States. CMAA is a not-for-profit organization founded in 1924 that counts as its members all major importing dealers of cocoa beans and cocoa products, the total import value of which was $1.20 billion in 2002.

We strongly support the purposes of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the proposed rule, and we appreciate the need for increased vigilance with respect to imported food. However, the chocolate, confectionery, and cocoa industries have serious questions and concerns about the practical implementation of this proposed rule. In our view, the proposed rule goes far beyond the Bioterrorism Act and threatens to impose unnecessary and unreasonable burdens on international trade.

The proposed rule represents a new task for FDA (*i.e.*, determining whether to inspect food imports prior to arrival) and a new reporting obligation for industry. The proposed rule is also highly complex, and its ramifications are difficult to foresee. Given its novelty and complexity, we believe it makes sense to adopt an incremental approach. Rather than requiring every item of information that might conceivably be useful in determining whether to inspect imported food (some of which may later prove unnecessary), a more sensible approach would be to initially require only

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that information which the agency is certain will aid its inspection determination. Later, once FDA has gained experience in performing its new task, the information required in the prior notice can be expanded. In short, we believe a realistic balance must be achieved between FDA's need for information and the realities of international trade. In our view, the proposed rule does not do this.

1. **FDA's Prior Notice System must be designed so that it does not reject prior notices that omit information that is not required.**

In the preamble to the proposed rule on prior notice, FDA states that "a prior notice that does not contain all of the information listed in proposed § 1.288 will be considered inadequate." 68 Fed. Reg. 5,428, 5,435 (Feb. 3, 2003). However, the proposed rule does not seem to recognize that many of the items of information listed in proposed § 1.288 would not be required for all articles of food.

It is essential that the new Prior Notice System not automatically reject a prior notice as incomplete if it lacks information that, in the case of that particular article of food, is not required. Frankly, we wonder how a system can be devised that will know which information is required and which information is not required for a particular article of food.

Many items of information listed in proposed § 1.288 will not be required in all cases, for example:

- If the article of food is a raw agricultural commodity, it may not have a trade or brand name.
- Many foods, including raw agricultural commodities, will not have a lot or code number.
- If the article of food is a raw agricultural commodity, it will not have a manufacturer.
- Grower information is not required if not known.

We are very concerned that prior notices will be rejected as incomplete, and shipments will be held for failure to submit a prior notice, because the prior notice did not include information that was not required.

2. **The definition of "food" should be modified to omit food packaging and food contact articles.**

The proposed rule provides an expansive definition of "food." 68 Fed. Reg. 5,430. Proposed § 1.277 would refer to the definition of "food" in section 201(f) of the Federal Food, Drug, and Cosmetic Act (FDCA), which includes "substances that migrate into food from food packaging and other articles that contact food." 21 U.S.C. § 321(f). However, we believe that Congress did not intend the Bioterrorism Act to cover food packaging materials.

The expansive definition found in the FDCA enables FDA to regulate a broad category of industry in its role of protecting the public health, whereas the Bioterrorism Act has a much more limited purpose. We believe that Congress specifically referenced "food intended for consumption in the United States" in Section 305 of the Act to restrict the breadth of the Act to edible food items.

To require such manufacturers to provide prior notice of import for their products would be very burdensome on the manufacturers, and would provide an impractically large amount of information to the agency. Further, such a large volume of information concerning non-edible items would do little to assist FDA. If, in some unlikely event, it were necessary to contact the suppliers of the food contact materials, FDA would have access to full information from the actual food manufacturer.

The proposed requirements are more burdensome than is necessary to accomplish the goal of the Bioterrorism Act, enhancing FDA's ability to respond quickly to a threatened or actual attack on the U.S. food supply. We ask that the final rule restrict the definition of "food" to that set forth in the specific purpose and requirements of the Act. Alternatively, we request that the final rule justify the overly burdensome application of the prior notice requirement to manufacturers of non-food items.

3. The final rule should clarify what is an "article" of food.

Under the proposed rule, a separate prior notice would be required for each article of food imported. Although not defined in the proposed rule, the preamble defines "each article of food" as "any food product identified by a specific FDA product code and quantity description produced by a single manufacturer (or grower, if fresh) associated with a single entry line number (U.S. Customs entry number plus ACS line number plus OASIS/FDA line number)." 68 Fed. Reg. at 5,425. Thus, in the example FDA offers, Brand X tuna produced by the same manufacturer but in two different can sizes constitute two separate articles of food, each requiring a separate prior notice.

We request clarification of how the definition of "article" of food will apply to cocoa beans. It is our understanding that a single shipment of cocoa beans, consisting of multiple bags of beans, constitutes one article of food, requiring only one prior notice. We request that FDA confirm this interpretation.

We also request clarification that a single shipment of cocoa beans constitutes one article of food, even though it includes beans from many different growers. As quoted above, FDA has stated that each food product "produced by a single manufacturer *(or grower, if fresh)*" is a separate "article" of food. 68 Fed. Reg. at 5,435 (emphasis added). The parenthetical "(or grower, if fresh)" has created some confusion, because it suggests that, for example, a shipment of cocoa beans that includes product from numerous different growers may not be considered a single article of food. We assume that FDA did not intend that result. We request that the final rule clarify that a shipment

of cocoa beans containing product from numerous different growers is, nevertheless, a single article of food requiring only one prior notice.

4. Grower information should not be required for processed foods.

The proposed rule would require that the prior notice include the identity of all growers "if known." Grower information must include the grower's name, address, telephone number, fax number, email address, and (if the grower is required to register with FDA) its facility registration number. If the grower does not have a fax number or email address, "the prior notice submission should declare this." 68 Fed. Reg. at 5,436. The grower's location must also be provided if different from the grower's business address. According to the preamble to the proposed rule, "this information is not optional; if it is known, it must be submitted." 68 Fed. Reg. at 5,437. However, FDA requests comments on whether the Bioterrorism Act permits the agency to exempt processed foods from the requirement to provide grower information.

There is no evidence that Congress intended to require grower information for processed foods.

Requiring grower information for processed foods would lead to absurd results. For example, it would mean that the prior notice for a candy bar must provide the growers of the sugar cane or sugar beets from which the product's sugar was derived, the growers of the corn from which its cornstarch was derived, and so on. Such detailed information generally is not known by manufacturers, and it is certainly not known by importers.[1]

5. The final rule should state explicitly that there is no affirmative duty to ascertain the identity of grower(s).

The Bioterrorism Act requires grower information "if known within the specified period of time that notice is required to be provided." 21 U.S.C. § 381(m)(1). Accordingly, the proposed rule would require the identity of all growers "if known." According to the preamble, "this information is not optional; if it is known, it must be submitted." 68 Fed. Reg. at 5,437. However, the proposed rule makes no mention of any requirement to take affirmative steps to ascertain grower information if not known.

We request that the final rule clarify that the submitter has no legal duty to seek out grower information if not known at the time prior notice is submitted. In the case of cocoa beans, such a duty would impose enormous burdens on submitters. Cocoa beans are grown on more than 2 million farms worldwide. In the Ivory Coast alone, over 600,000 growers produce cocoa beans for export.

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[1] As discussed above, the absence of grower information should not trigger rejection of the prior notice or detention of the shipment.

Between the grower who grows the beans and the exporter who ships the beans to the United States, cocoa beans change hands several times and undergo commingling, blending, sorting, cleaning, drying, grading, and re-bagging. Under these circumstances, it is usually not possible for the submitter to know the identity of the growers of the beans that make up a particular shipment. Submitters should have no obligation to attempt to obtain grower information if it is not readily available.[2]

6. **The final rule needs to address how the requirement of grower information will apply to foods that consist of commingled product from numerous growers.**

The proposed rule does not explain how the requirement of grower information applies to products like cocoa beans that are blended or commingled many times prior to export. As discussed above, a single shipment of cocoa beans may contain beans from hundreds or even thousands of growers. After being harvested, cocoa beans change hands several times and undergo commingling, blending, sorting, cleaning, drying, grading, and re-bagging. Once the beans are commingled, it is not possible to identify a particular cocoa bean to a particular grower.

Even if the submitter does know the names of some or all of these growers, we question whether reporting the names of so many growers would provide FDA with meaningful or useful information. If the purpose of the prior notice requirement is to help FDA determine whether to inspect a particular imported food product, requiring grower information does not serve that purpose unless that food product can be identified as having come from the grower whose information is provided. In the case of commingled products like cocoa beans, that cannot be done. Moreover, the prior notice submission would provide space for the names of only three growers. If an article of food contains commingled product from numerous growers, reporting the names of three of those growers also would not provide FDA with useful information.

For commingled products like cocoa beans, we believe that grower information should not be required. Alternatively, the prior notice submission might provide a field for "Numerous Growers" to be checked off for this type of product.

7. **The final rule should not require precise quantity information.**

The proposed rule would require that the prior notice include precise information as to the quantity of food described "from smallest package size to largest container" (*e.g.*, "300 cases of 24/12 oz cans each of Brand X tuna"). This information could be subsequently amended, subject to the restrictions on amendments of product identity information.

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[2] As discussed above, the absence of grower information should not trigger rejection of the prior notice or detention of the shipment.

We believe that precise quantity information should not be required. The quantity of a food shipment frequently changes up to the last minute for a variety of reasons, such as fluctuations in supply, changes in weather, and production problems. Given the frequency of changes in quantity, submitters cannot realistically be expected to report quantity information with pinpoint accuracy. We also question whether FDA needs precise quantity information in order to determine whether to inspect a particular article of food. For example, we doubt that the decision whether to inspect an article of food would change depending upon whether it consists of 200 cases or 250 cases. Quantity information is not required at all by the Bioterrorism Act. The final should require that the prior notice include only a reasonable estimate of quantity.

8. The requirement of U.S. Customs entry number, entry type, and date of entry are problematic.

The proposed rule would require that the prior notice include the U.S. Customs entry number, entry type, and date of Customs entry. While we understand the need for FDA to coordinate its activities with U.S. Customs, these information items will be very difficult to provide in advance. This highlights the problems of having two separate reporting systems rather than a single, unified system for both FDA and Customs.

The Customs entry number is generated by the Customs broker, not the importer, and it is not generated until the Customs broker enters the shipment. The Customs entry type may change after arrival. For example, if a food is subject to an import quota and that quota has been exceeded, the importer may have to change the Customs entry type from consumption entry to warehouse entry. The date of Customs entry is also difficult to predict in advance. The port where entry will be made for Customs purposes may be a considerable distance from the actual port of entry, and the Customs date of entry may be several days after the date of arrival at the port of entry. The submitter cannot be expected to know the date of Customs entry with certainty at the time the prior notice is submitted.

9. The final rule should clarify the requirement of "lot or code numbers or other identifier of the food."

The proposed rule would require the prior notice to include the "lot or code number or other identifier of the food if applicable." We are not sure what FDA means by a "code number or other identifier." In addition, it is not clear how a submitter will be able to determine whether this information requirement is applicable to a particular product. We request that the final rule provide clarification.[3]

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[3] As discussed above, the absence of this information should not trigger rejection of the prior notice or detention of the subject food.

10. The final rule should provide for a rolling minimum notice period.

The proposed rule would require that prior notice be submitted to FDA no later than noon of the calendar day before the article of food is to arrive at the border crossing in the port of entry. FDA believes that all of the information required to appear in the prior notice will be known by the submitter by that time.

We respectfully disagree with the agency's assessment that the information required in the prior notice will be "sufficiently fixed" by noon of the calendar day before arrival. Particularly in the case of overland shipments from Canada and Mexico and air shipments, it is unrealistic to assume that all of the required information will be fully known by that deadline. For example:

- For a product produced at a facility in Canada or Mexico that is located within one hour of the border, the product may not have been produced by noon of the calendar day before arrival. If the product has not even been produced, lot number and product quantity information may not yet be available.

- The U.S. Customs date of entry, which may be several days after the date of arrival at the port of entry, may not be known when the prior notice is submitted.

- The U.S. Customs entry number is not known until the Customs broker enters the shipment.

- Because air cargo shipments have very tight time schedules, the information that would be required by the proposed rule likely would not be available by noon the previous day.

We propose that FDA use a rolling minimum notice period of 8 to 12 hours prior to arrival at the port of entry. In addition, FDA should consider establishing a program allowing a shorter notice period for importers or products coming from Canada and Mexico that are identified as low-risk.

11. The rules governing amendments to a prior notice should be more flexible.

The proposed rule would allow submitters to amend a prior notice previously submitted, but this right of amendment has the following limitations: (a) only one amendment is permitted; (b) only product identity information may be amended; (c) the amendment may provide more detailed information about the product identity, but may not change the general identity of the article of food, (d) such information may be amended only if complete information did not exist by noon of the calendar day before the day of arrival, and only if the prior notice indicated an intention to amend, and (e) the amendment must be submitted no later than two hours prior to the time of arrival. Otherwise, the submitter must cancel the prior notice and submit a new one, thereby delaying entry of the shipment.

We believe these limitations are far too restrictive. We believe that FDA is underestimating the frequency with which product identity information changes in the normal course of international trade. For example, it is common for a buyer in the United States to change its mind at the last minute and request 2-ounce candy bars instead of 5-ounce bars.

We believe that the final rule should provide for a more flexible right of amendment. We propose the following changes:

- **FDA should allow for correction of minor, inadvertent errors.** As the proposed rule is written, any error in prior notice information could theoretically result in refusal of admission. A minor error in entering contact information for the submitter or other party (*e.g.*, an error in a zip code or phone number) may not be amended; the submitter would be required to cancel the prior notice and submit a new one. A submitter should be permitted to correct such minor, inadvertent errors at any time without having to cancel the prior notice and submit a new one.

- **The right to amend product identity information should not be limited to particular food products.** The proposed rule appears to allow further specification of product identity only in the case of "fresh produce" and "fresh, wild-caught fish." 68 Fed. Reg. at 5,462. Further specification of product identity should be permitted for other products as well. For example, a prior notice for chocolate or hard candy should be permitted to be amended to provide further specification (*e.g.*, from "chocolate" to milk chocolate, dark chocolate, or white chocolate, or from "hard candy" to butterscotch candy or Starlite mints).

- **FDA needs to provide clearer guidance regarding what it means when it says that an amendment may not change the "general identity" of the article of food.** If the change is from 5-ounce to 2-ounce size candy bar, or from milk chocolate to dark chocolate, is that a change in the "general identity"? In our view, these would not constitute a change in the general identity of the product.

- **Minor changes in quantity should not require an amendment.** As discussed above, we believe that precise quantity information should not be required. In addition, we believe that the submitter should be permitted to amend quantity information at any time without restriction.

- **Notifying FDA of an intention to amend should not be a precondition for amendment.** A submitter may believe it has complete information at the time it submits the prior notice, but that information may subsequently change for reasons beyond the submitter's control. FDA should accept amendments even if the submitter did not indicate an intention to amend in the original prior notice.

- **More than one amendment should be allowed.** The proposal to allow only one amendment is unnecessarily restrictive. We believe allowing more than one amendment will save both FDA and industry time.

12. The proposed provisions for updating arrival information should be more flexible.

The proposed rule would require the submitter to update arrival information (*i.e.*, anticipated time and location of arrival) if such information changes after the prior notice is submitted. Time of arrival must be updated if more than one hour earlier, or three hours later, than the time given in the prior notice. The update must be submitted at least two hours prior to arrival at the port of entry.

We request that the final rule explain how FDA intends to determine the time of arrival for the various modes of transportation. For example, how will arrival time be determined for a truck that arrives at the border on time but must wait several hours to cross the border? In the case of a ship, is the time of arrival the time that the ship docks or when its cargo is unloaded?

In addition, we request that the proposed four-hour window (*i.e.*, one hour early to three hours late) during which arrival time information is not required to be updated be expanded to at least eight hours (*i.e.*, one hour early to seven hours late). Estimating the time of arrival at the port of entry is particularly difficult for products imported from Mexico. Currently, Mexican carriers are not permitted to transport shipments into the United States. After clearing Mexican Customs, the Mexican carrier must transfer the trailer to a drayman carrier; the drayman carrier then takes the shipment across the border to U.S. Customs. This process is subject to delays at each point, making it very difficult to accurately predict the time of arrival at the port of entry. If a truck is stuck in a long line at any point, it may not be feasible for the truck driver to know the length of the delay or to notify the submitter of the change in arrival time. Air cargo is subject to similar delays. In the case of sea cargo, it is also very difficult to know the precise time at which the vessel will arrive in port. Shippers generally notify the importer of the day of arrival, not the time, and even this may change. An expanded window for updates would solve this problem.

We request that the final rule expand the proposed window during which arrival time information is not required to be updated to at least eight hours. Alternatively, we suggest that FDA obtain this information from the U.S. Customs Service. Customs has direct communication with vessels, airlines, airports, and port authorities. Another option would be to permit carriers to provide updates of arrival time.

13. The final should clarify that the anticipated U.S. Customs date of entry is not required to be updated, even if it proves to be inaccurate.

The proposed rule would require that the prior notice include the anticipated date of U.S. Customs entry. As FDA notes, the port where entry will be made for U.S. Customs purposes may be

a great distance from the actual port of entry, and the Customs date of entry may be several days after the date of arrival at the port of entry. Consequently, the submitter cannot always be expected to know the date of Customs entry with certainty at the time the prior notice is submitted.

We request that submitters have no obligation to update the anticipated Customs date of entry, even if it proves to be wrong. The Customs date of entry is not required by the Bioterrorism Act. As FDA states, the purpose of this information is to enable efficient communication and proper allocation of inspection resources between FDA and the U.S. Customs Service. This purpose will not be undermined if the anticipated Customs date of entry provided in the prior notice is off by a day or two.

14. If an article of food is refused admission and held at the port of entry for failure to submit a prior notice, that determination should be reviewable.

Under the proposed rule, an article of food is to be refused admission if it is offered for import with no prior notice or an inadequate prior notice. According to FDA, "Congress did not provide for any kind of application, petition, or appeal of FDA's determination that an article shall be refused admission for failing to comply with prior notice requirements." 68 Fed. Reg. at 5,432. While not entirely clear, it appears to be FDA's position that, because Congress did not explicitly provide a right to appeal a refusal of admission under the prior notice provision of the Bioterrorism Act, no such right exists. If this is FDA's contention, we believe the agency is in error.

It is the rare instance in which an aggrieved party may not seek judicial review of an agency action. The Administrative Procedure Act states that judicial review shall apply to agency action "except to the extent that—(1) statutes preclude judicial review; or (2) agency action is committed to agency discretion by law." 5 U.S.C. § 701(a). The courts have held that "there is virtually a presumption in favor of judicial review unless a contrary purpose is fairly discernable in the statutory scheme." *Hayes Intern. Corp. v. McLucas*, 509 F.2d. 247 (5th Cir. 1975) (*citing Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967)). The absence of express statutory language authorizing judicial review is not enough to overcome this presumption of reviewability. Agency action typically is found to be non-reviewable only if there is a showing of "clear and convincing evidence" of a legislative intent not to allow review. *Abbott Laboratories v. Gardner*, 387 U.S. 136, 140 (1967)) (*citing* H. R. Rep. No. 1980, 79th Cong., 2d Sess., 41 (1946) ("To preclude judicial review under this bill a statute, if not specific in withholding such review, must upon its face give clear and convincing evidence of an intent to withhold it. The mere failure to provide specially by statute for judicial review is certainly no evidence of intent to withhold review.")).

While Congress did not expressly provide for review of agency decisions in the Bioterrorism Act, there is no evidence in the statute or its legislative history to overcome the presumption in favor of review of agency decisions. Accordingly, the final rule should provide a mechanism for review,

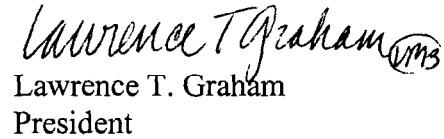
both administrative review within FDA and judicial review in court if an article of food is refused admission for failure to submit a prior notice.

15. FDA should provide for appropriate storage of imported foods held at the port of entry for failure to submit a prior notice.

Especially in the first days of implementation, we anticipate that some products will be held at the port of entry due to minor errors in the submission of prior notice. Should a shipment be held due to inadequate prior notice, we ask that the final rule clearly provide for appropriate storage of such detained goods, including the provision of climate-controlled storage facilities for fresh and/or perishable products.

We appreciate this opportunity to comment.

Respectfully submitted,



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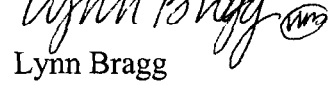

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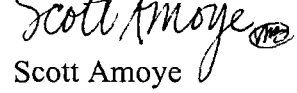

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