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Division of Dockets Management (HFA-305)
Food and Drug Administration
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Prior Notice Regulations under the BioTerrorism Act
Dockets Nos. 02N-0276 and 02N-0278

Dear Sirs:

This comment is filed on behalf of our client, Pokon & Chrysal (P&C), an international plant and flower care business, founded in 1929, with branches in several European countries and in the United States. From its headquarters and production facility in Naarden, Holland, P&C exports its plant and flower products -- including pre-treatment, transport and conditioning products and cut flower food -- to more than 60 countries throughout the World, including the United States.

In the United States, Pokon & Chrysal USA (P&C-USA), located in Miami, Florida, services growers, wholesalers, and retailers in North America and Latin America with complete plant and fresh cut flower care products. Oftentimes, the Latin American flower growers export their products together with the P&C-USA post-harvest care products, including the cut flower food, to their own customers back in the United States. There has never been a time or a circumstance whereby the reimported flower food has been subject to FDA examination nor has there ever been any question about whether the article is intended for anything other than for use as a flower food.

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Nevertheless, the P&C cut flower food contains glucose and, as a result, is classified under HTS subheading 1702.30.40 when it is exported back to the United States. Pursuant to the Harmonized Tariff Codes Flagged for Prior Notice Submission under the BioTerrorism Regulation (the BTA Regulations) published by the FDA on November 20, 2003 (http://www.cfsan.fda.gov/~dms/htsguide.html), HTS number 1702.30.40 is flagged as FD4. As a result, importation of P&C flower food into the United States -- imported in bulk from Holland by P&C or as attachments to bundles of fresh-cut flowers from flower farms in Latin America -- will now hinge on transmission of a sufficient Prior Notice and on compliance by all supply chain partners with the BTA Regulations, including the registration requirements.

Without debate, given the literally thousands of Latin American flower growers operating within the global marketplace and the obvious distinction between fresh cut flowers and food for human or animals, flower growers are unlikely to register with the FDA, primarily out of a sincere and logical belief that no such action is required of processors of anything other than food for animal or human consumption. As a result, if the requirement for accurate Prior Notice is maintained for flower food that is shipped together with fresh flowers from these growers, those shipments will predictably be defective (for omitted or deficient notices) and refusal of the items will be an unavoidable consequence. This is true even though the products are never intended by anyone to be used as food for humans or animals subject to the requirements of the BTA Regulations and, in fact, are labeled to so indicate.

The following comments urge the FDA to provide Prior Notice filers with the necessary discretion to permit disclaimer of FDA jurisdiction for entries of multiple use products such as flower food. Providing this type of flexibility will maintain a competitive marketplace and eliminate unnecessary port delays and import expense.

I. Plant Food Is Not Within the Intended Governance of the BTA Regulations

According to its own website (www.fda.gov), the FDA ensures that the "...food we eat is safe and wholesome, that the cosmetics we use won't harm us, and that medicines, medical devices and radiation-emitting consumer products such as microwave ovens are safe and effective." The BTA Regulations define the food governed thereunder as, with certain exceptions, that food defined in section 201(f) of the Federal Food, Drug and Cosmetic Act (section 1.276(5)). Section 201(f) of the Federal Food, Drug and Cosmetic Act defines "food" as "....(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. "

While arguably the sugar components of the flower food produced by P&C that accompanies the fresh cut flowers exported from Latin American growers into the United States and produced by P&C qualify under subsection (3) of this definition (i.e, although P&C products are "usable" but never "used" for human or animal consumption), there is little doubt, given the context, that flower food is not a "food" product intended for FDA governance and is certainly not the type of product which Congress sought to address when it enacted the BioTerrorism Preparedness Act of 2002 (the "Act"). This item may qualify as glucose under the HTS subheadings, but it is, at most, a "multiple use" product, under the BTA Regulations, because this particular glucose product is not intended for food use while other items entered into the U.S. marketplace as "glucose" may be. In fact, P&C's flower food products are clearly labeled "Not for Human Use." Accordingly, these items are multiple use products in connection with which there is no need for Prior Notice submission because no one in the supply chain ever has reason to believe that the glucose will ever reasonably be directed to food use.

II. The "food" component of the P&C Products qualify as multiple use products under the BTA Regulations

In its preamble to the Interim Final BTA Regulations, the FDA responded to comments submitted in response to the proposed rules urging the FDA to exempt from Prior Notice requirements "multiple use" products that are, in fact, not used as consumable food products upon arrival in the United States. This FDA response indicated that, for such multiple use products, if "...any of the persons involved in importing or offering the product for import (e.g., submitter, transmitter, manufacturer, grower, shipper, importer, owner, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use..." then, and only then, will Prior Notice be required.

However, the BTA Regulations provide no means to provide the FDA with certification that any of the indicated persons do *not* reasonably believe that the substance is reasonably expected to be directed to a food use prior to arrival of that item at a U.S. port. Accordingly, because there is no method to avert classification of the P&C products as anything other than those flagged as FD4 articles requiring Prior Notice under the BTA Regulations, there is no method to avoid refusal of the goods upon arrival should such a Prior Notice not be filed. This is true even though there will not be a single person within the supply chain that reasonably believes these products will reasonably be directed to a food use.

III. The FD4 Designation Places P&C - and other non-U.S. manufactured plant food providers - at a competitive disadvantage sufficient to threaten continued business operations

Because the P&C Products, under the current BTA Regulations, may only be imported in the event a Prior Notice is accurately submitted to the FDA prior to arrival at a U.S. Port, every grower in Latin America purchasing these goods from P&C-USA with the intent of reimporting them back into the United States together with fresh flower products will be required to register with the FDA as a "shipper" and "holder" of these articles. However, in connection with the identical flower food sourced from U.S. manufacturers directly no such obligation will be imposed upon these same growers. This is because U.S. products may be returned to the United States under HTS classification 9801.00.1097, which, because this classification is flagged as FD1, permits filers to "disclaim" the need for FDA review.

Certain domestically manufactured products --- such as flower food --- that are not consumed or used by animals or humans are routinely and appropriately disclaimed as requiring FDA review upon reimportation into the United States under HTS subheading 9801.00.1097. As a result, the P&C Products, arguably of superior quality and reputation, are less likely to be purchased by Latin American growers who will instead elect to purchase domestically manufactured articles to avoid the burden of FDA registration and BTA Regulation compliance. This is true, also, of any other non-U.S. manufactured flower food that will be competing with the same articles that are domestically made. The BTA Regulations will, effectively, eliminate competition for U.S. producers of flower food by discriminating against foreign-made products, since US producers are the only parties that can assure their supply chain partners that the BTA Regulations will not impose further burdens upon the importation or reimportation of their products. Such discriminatory, protectionist measures are unacceptable in today's environment of global trade, are inconsistent and probably violative of our international obligations and all efforts should be undertaken to eliminate such an obvious non-tariff trade barrier.

In simple terms, due to the availability of U.S. manufactured flower food, there will be no incentive for flower growers outside of the United States to register with the FDA, since that obligation only arises if the identical products are manufactured outside of the U.S. As a result, our client --- and others like it --- will have been effectively put out of business by the BTA Regulations because use of its flower food by flower growers --- flower food which is similar in composition to other flower food manufactured in the United States, will be the only such product obligating unrelated flower growers to register with the FDA. This is true despite the fact that, to date, not one of these products been subject to FDA review or detention.

While the BTA Regulations may be new, P&C's flower food product is not. Nevertheless, because the technical requirements of the Regulations are unlikely to be met by our client's customers outside of the U.S. over which our client has no control, as a result of the BTA Regulations, effective competition for the flower food business will be eliminated. Up to 90% of the fresh flowers sold in the United States are imported from growers outside of its borders. Accordingly, the actions of these growers exclusively determine the competitiveness of the domestic marketplace. As stated above, given the fact that alternatives are available (i.e. U.S. manufactured flower food will not require Prior Notice submission), the Latin American flower growers that represent a substantial part of our client's customer base will not comply with the BTA Regulations' registration requirement – whether out of an intentional election not to or out of a sincere belief that they do not have to since the Act specifically only applies to food for humans or animals.

While P&C appreciates that the FDA's primary responsibility under the BTA is to protect the American food supply, it is respectfully submitted that the FDA also has an obligation to adopt standards which provide a level field for domestic and foreign competition in the US marketplace, consistent with domestic health or safety standards. In that regard, the FDA itself has specifically requested comments related to the impact of the BTA Regulations – particularly the registration requirements --- on domestic businesses. To this end, P&C-USA advises the FDA that because the FDA will require registration of its Latin American flower industry customers and Prior Notice submission as a condition to the reimportation of its flower food, it may very well be forced out of the domestic marketplace entirely. P&C-USA's 25 employees would be laid off and its offices vacated. The entire global distribution business of P&C's well-respected international enterprise that has been in existence for nearly a century would be seriously threatened.

IV. The Classification of Flower Food containing glucose as FD4 is improper

The Published List of HTS classifications flagged as FD3 or FD4 makes the distinction as follows:

> FD3 - indicates that FDA believes the article may be subject to prior notice under section 801(m) of the FD&C Act and 21 CFR Part1, subpart I., e.g., the article has both food and non-food uses.
>
> FD4 - indicates that FDA believes the article is food that is subject to prior notice under section 801(m) of the FD&C Act and 21 CFR Part1, subpart I.

As indicated above, the P&C plant food products are classified under HTS subheading 1702.30.40 because they are glucose based for continued nutrition of the fresh flower stem. Accordingly, even though flower food is not "animal or human" food specifically governable under the FDCA or the BTA Regulations, and even though flower food most certainly qualifies as a "multiple use" article in connection with which jurisdiction of these Regulations may be avoided, flower food is flagged as an FD4 item, which necessarily requires Prior Notice submission. Accordingly, by its own definition of what qualifies as FD3 versus FD4, it is inappropriate to qualify these particular goods under FD4.

V. The Burden of Post-Refusal Certification of Non-Food Use is Unjust and Unnecessary

Admittedly, certain brokers and U.S. importers may welcome the published HTS list of classification subheadings flagged as FD3 or FD4 in order to better know exactly which shipments will require submission of Prior Notice before arrival at a U.S. Port. Nevertheless, it is a disservice to the importing community to unilaterally hold that any such product arriving without a Prior Notice will automatically be refused because the FDA has, without reviewing any information related to the particular entry and without determining whether or not the article at issue qualifies as a multiple use article subject to a standard to evaluate applicability of the BTA Regulations, determined that it is subject to Prior Notice submission.

P&C appreciates the availability of FDA review for an importer to challenge an arguably unjust refusal after the fact. However, such a debate burdens both the importer and FDA in routine, unnecessary administrative procedures, delays release of shipments, and imposes unnecessary storage, demurrage and transportation costs on the importer. The probability of such delays, administrative burdens and additional expense could be easily avoided by adopting pre-arrival procedures that permit appropriate disclaimers of FDA review.

Moreover, the perishable nature of the fresh flowers entered together with the flower food that are the subject of this correspondence requires that the FDA do everything possible to avoid even the possibility of such a review, in connection with which the FDA has afforded itself up to five (5) days for final disposition. The flowers being imported in the present case will, without exaggeration, die within this timeframe. Again, solely as a result of the BTA Regulations, P&C-USA will be forced out of business since the conditions for reimport of its flower food product will no longer permit reasonable competition.

VI. Suggested Remedy

Importers of foreign-manufactured flower food and other multiple use articles should be provided with the means to avoid the need for Prior Notice submission prior to arrival in the United States. Otherwise, suppliers of these products will be eliminated as a result of a highly competitive marketplace in which other like traders are not burdened with BTA Regulation compliance.

Without exception, brokers and other CBP filers should be provided the ability to "disclaim" FDA review in the event the products arriving at a U.S. Port do not require Prior Notice submission--- even if the HTS classification seems to indicate otherwise. As transmitters of the Prior Notice documentation and other import-related documentation, brokers in particular rely upon the information provided to them by their clients to exercise the degree of "diligence and care" required of them under the BTA Regulations[1]. If, under existing regulation of these professionals, that discretionary responsibility permits disclaiming FDA review for products flagged as FD1, there is no reason to deny such discretion for any other article, regardless of HTS classification or FDA flag designation. Should these regulated professionals learn, *before* arrival, that no party within the supply chain reasonably believes that the multiple use article in question will reasonably be directed to a food use upon entry into the U.S. marketplace, there is no reason why this information should not be relied upon *before* arrival to disclaim the need for FDA review and/or Prior Notice submission. In this way, unnecessary and expensive port delays may be avoided and U.S. security regulations, such as those promulgated under the BTA, will not be used to eliminate otherwise lawful competition.

In addition, FDA can adopt rules which eliminate the need to comply with the registration and prior notice regulations where the nature of the import is sufficient to establish that the product is not used as food for human or animal consumption. Shipments of fresh-cut flowers which include glucose-based flower food are an example of a situation in which the CBP and FDA computer systems can easily recognize that the importer "glucose" is not subject to BTA requirements. The parties to the transaction are in the flower business, the commercial cargo in the shipment is flowers, and the "food" product in the shipment is a small addition to the shipment which is clearly present to feed the flowers and not the people and animals in the United States.

[1] These comments will not debate the issue of whether or not such a standard is appropriate for the FDA to impose upon Customs brokers otherwise solely regulated pursuant to CBP procedures.

Conclusion

Upon its review of the foregoing comments, it is respectfully requested that the BTA regulations and implementing directives be modified as requested here to allow the import of flower food without the necessity of compliance with the BTA. We also urge that the FDA contact the undersigned directly in order that the issues raised herein may be further discussed to the extent needed to remedy this situation while assuring compliance with BTA requirements. This type of ongoing dialogue is suggested as the appropriate means to remedy the concerns noted in regard to the BTA Regulations expeditiously and, in all events, before further enforcement or implementation of those Regulations results in unnecessary hardships to the domestic business community.

Respectfully submitted,
Pokon & Chrysal

By: _____
Gilbert Lee Sandler
General Counsel

cc: client
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