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BY HAND DELIVERY

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

Re: Proposed Rules on Registration of Food Facilities and Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Docket Nos. 02N-0276 and -0278 (RIN0910-AC40 and -AC41)

Dear Sir or Madam:

On February 3, 2003, the Food & Drug Administration published two proposed regulations implementing certain provisions of Title III of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act" or "the Act") aimed at protecting the U.S. food supply from threats of bioterrorism. *See* 68 Fed. Reg. 5378, 5428 (Feb. 3, 2003). The first would implement Section 305 of the Act, which requires that all domestic and foreign facilities "engaged in manufacturing, processing, packing, or holding food for consumption in the United States" be registered with the agency. *See* 21 U.S.C. § 350d(a)(1). The second would implement Section 307's requirement that all importers of "food" provide "prior notice" of upcoming importations to FDA in order to facilitate FDA officials' inspection of the merchandise prior to its entry into commerce. *See id.* § 381(m).

On behalf of the Coalition for Safe Ceramicware, Inc. ("CSC" or "Coalition") and the International Crystal Federation, Inc. ("ICF" or "Federation"), voluntary non-profit trade associations whose memberships comprise the majority of the world's leading manufacturers and distributors of ceramic and lead crystal tableware, respectively, we are writing to comment briefly on whether the above-referenced proposed regulations should properly apply to tableware and other food contact articles other than packaging materials used as such. While there are many aspects of the proposed rules that will doubtless be the subject of comments filed by other interested parties, the CSC's and ICF's comments will be confined to the fundamental issue of whether the proposed regulations should be imposed with regard to tableware articles in the first place.

Frankly, the notion that the provisions of the Bioterrorism Act and FDA's rules implementing the Act's food facility registration and prior notice provisions might apply to something like china plates or crystal wine glasses took both us and our clients by surprise. We recognize, of course, that FDA and the courts have long interpreted the definition of "food" in section 201(f) of the Federal Food, Drug & Cosmetic Act ("FD&C Act")(21 U.S.C. § 321(f)) as extending to indirect food additives contained in packaging and other food contact articles, thereby giving the agency authority to take enforcement action when these articles are deemed "adulterated" under section 402(a) (*id.* § 342(a)). *See, e.g., Natick Paperboard Corp. v. Weinberger*, 389 F. Supp. 794 (D. Mass. 1975), *aff'd*, 525 F.2d 1103, *cert. denied*, 429 U.S. 819. But this has always been something of a legal fiction designed to deal with the limitations of the statutory language originally enacted in 1938, and we might have expected Congress, in 2002, to have relied on more specific terminology – particularly in light of the significant burdens imposed upon both the public and the agency by the Act's requirements. Not only are tableware and other food contact articles not "food" in the ordinary sense of the term, but it is hard to imagine how terrorists would regard china or crystal as effective targets for acts of bioterrorism. Certainly, nothing in the terms of the Bioterrorism Act itself suggests such a broad scope.

It was, therefore, with some surprise that we read in the definitions sections of both regulations (*see* proposed Sections 1.227 and 1.277) that FDA proposes to give the term "food" as used in the Bioterrorism Act an expansive interpretation, including not only such obvious foods as "fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or components of food; animal feed, including pet food; and food and feed ingredients and additives," but also "substances that migrate into food from food packaging and other articles that contact food." *See* 68 Fed. Reg. at 5382, 5430. Further evidence that FDA believes that the Bioterrorism Act requires the registration and prior notice requirements to extend beyond food itself to any article that contacts food can be found buried in the analysis of economic impacts of the proposed registration regulation, where the agency estimates that over 22,000 firms engaged in the manufacture and distribution of not only chemicals and food packaging materials, but such housewares as ceramic tableware, glassware, pots and pans, and eating utensils, would be subject to the registration requirement. *See id.* at 5391. Unfortunately, this suggests all too clearly that FDA construes the statutorily-mandated requirements as extending beyond "food" (in the ordinary sense of that term) to the very limits of FDA's regulatory authority. At the same time, it demonstrates the significant burdens that the regulation would pose on industry.

Because the terms of the Bioterrorism Act, its legislative history, and strong logical and practical considerations support limiting application of both the registration and prior notice requirements only to food *per se* (a term which includes *direct* food additives, but not indirect food additives), food contact articles should be covered by the registration and prior notice requirements only to the extent that they have actually been used to package foods (and thereby become indissolubly associated with the food (or direct food additive) itself). Packaging materials that have not yet been packed with food and other food contact articles that are not typically distributed in commerce with or containing food – including not only ceramic and lead crystal tableware, but a broad range of housewares such as ordinary glassware, kitchen utensils,

stainless and silver flatware, and pots and pans, all of which may contain *indirect* food additives – should not be covered by the registration and prior notice requirements.

I. THE COALITION'S AND FEDERATION'S INTEREST

In suggesting that the registration and prior notice requirements should not be applied to tableware articles, the CSC and ICF should not be misunderstood. Both associations support appropriate FDA oversight over the safety of their respective products; indeed, the associations were founded in 1989 and 1991, respectively, in direct response to FDA's concerns about the use of lead as a component of ceramic glazes and decorations and lead crystal glass. Following the submission of detailed safety assessments to the agency in order to respond to those concerns, both associations embarked upon a number of initiatives designed to limit leachable lead levels in their products. In the CSC's case, these included adoption of a quality assurance program to ensure members' consistent compliance with the reduced regulatory limits on leachable lead in ceramicware issued by the agency in 1992 and the joint promulgation (with the Society of Glass and Ceramic Decorators) of a voluntary standard for leachable lead in external decorations in the "lip-rim" area (*i.e.*, top 20 mm) of the external surface of glass and ceramic drinking vessels. The ICF's most important initiative was to adopt (and on several subsequent occasions, reduce) voluntary standards for leachable lead in lead crystal tableware articles after it became clear that FDA was not inclined to promulgate regulatory guidelines for lead crystal tableware as it has for ceramicware. Members' compliance with the ICFs' voluntary standards is addressed in a quality assurance program similar to that adopted by the CSC. In addition, the Federation has sought to reduce leachable lead levels throughout the industry by sponsoring a series of 14 "technical exchange conferences" that have focused on (among other things) state-of-the-art techniques for reducing leachable lead levels in crystal glass.

Given the background of the two associations, it should go without saying that they are sensitive to concerns about the safety of their products and have, throughout their history, worked closely with FDA to respond to such concerns. Both associations recognize that FDA properly has the authority to take enforcement action under the FD&C Act in those cases where it deems leachable lead levels in ceramic or crystal tableware to constitute a threat to public health. FDA has traditionally done so by invoking § 402(a) of the FD&C Act, which expressly provides that a *food* may be deemed adulterated "[i]f it bears or contains any poisonous or deleterious substance which may render it injurious to health . . . or . . . if it is or if it bears or contains any food additive that is unsafe within the meaning of section [409]." 21 U.S.C. § 342(a)(1), (a)(2)(C)(i). Because the agency's real interest is in removing tableware articles containing excessive levels of leachable lead from the market before they can adulterate food within the meaning of § 402(a), the agency has historically engaged in the legal fiction of treating the tableware article itself as "food" that is adulterated under § 402(a) if it contains leachable lead levels deemed excessive. *See, e.g., United States v. Articles of Food . . . Pottery . . . Contemporary Ironstone (Cathy Rose)*, 370 F. Supp. 371 (E.D. Mich. 1974).

Having said this, however, the fact is that the agency has chosen to regulate ceramic and lead crystal tableware in only an informal and *ad hoc* manner. Neither is subject to the rigorous premarket approval/notification process. In the case of ceramicware, FDA has established informal regulatory limits for leachable lead and cadmium (in Compliance Policy Guide Sections 545.400 and 545.450).[1] And FDA's regulation of lead crystal is so informal that it would be better termed theoretical only: the agency has never promulgated even informal regulatory guidelines for leachable lead in crystal glass, and indeed, to our knowledge, has never taken enforcement action against lead crystal tableware articles. For all practical purposes, then, it is fair to say that lead crystal tableware is not actively regulated by FDA.

It is precisely this sort of nebulous regulation of ceramic and crystal tableware – not to mention a host of other "housewares" discussed below – that inspires these comments on the proposed registration and prior notice regulations. It is one thing for FDA to assert a right to take enforcement action against food contact articles when they are deemed to pose a risk of adulterating food. It is quite another thing, however, for FDA to assert that the Bioterrorism Act requires that all domestic and foreign facilities that manufacture, process, pack, or hold these tableware items register with FDA as if they were manufacturing, processing, packing, or holding *food for human or animal consumption.* Clearly, it is threats of bioterrorism directed at food *per se* that must be given the highest priority. If the prior notice regulations are applied to ceramic and crystal tableware, U.S. purchasers and importers will be required to submit prior notices of literally hundreds of thousands of individual import transactions each year despite the fact that few (if any) of those products would, in the normal course, ever receive regulatory scrutiny by the agency. The burdens placed on both the agency and the industries by these requirements – particularly, the prior notice requirement – are wholly out of balance with the agency's very informal regulatory approach to date. This significant imbalance is a reflection of the overbreadth of the scope of the regulations, and suggests that the registration and prior notice requirements should be applied only to products at the core of the FDA's regulatory regime – that is, to "food" and direct food additives.

Of the two statutory/regulatory requirements, it is the prior notice requirement that is of most concern to the CSC and the ICF. To be sure, the registration requirement, as currently framed, would impose significant (and in the view of the Coalition and Federation, unwarranted) burdens on the industry by requiring not only the producer of the tableware article, but all facilities "holding" that nominal "food" article (other than retail establishments) to register – which would ostensibly require every firm engaged in the process of distributing ceramic and lead crystal tableware in the United States to register with the agency. But the burdens imposed on individual importers by the prior notice requirement would be considerably greater, given the sheer volume of international trade in tableware articles. The majority of ceramic and lead crystal tableware consumed in the United States is imported, with literally hundreds of thousands

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[1] Indeed, the only formal regulatory provision directly applicable to ceramic tableware is a regulation specifying methods for identifying ornamental and decorative ceramicware from the agency's informal regulatory guidelines applicable to ceramic tableware intended for food use. *See* 21 C.F.R. § 109.16.

of individual transactions made each year. Moreover, because any individual shipment is likely to consist of numerous tableware articles of varying descriptions, each required report could very well be voluminous. The CSC and ICF believe, therefore, that application of these rules – particularly the prior notice requirement – to ceramic and lead crystal tableware articles would be unreasonably burdensome, especially since registration of tableware facilities and prior notice from tableware importers would provide little or no benefit to public safety.

II. THE REGISTRATION AND PRIOR NOTICE REQUIREMENTS SHOULD BE APPLIED ONLY TO FOOD WITHIN ITS ORDINARY MEANING (INCLUDING PACKAGED FOOD), BUT NOT TO TABLEWARE AND OTHER FOOD CONTACT ARTICLES

In the Bioterrorism Act, Congress left little doubt that it intended FDA to require the registration of food facilities and prior notice of food importations in order to improve FDA's ability to inspect and interdict contaminated shipments of food. It is, however, clear from the language of the statute that Congress did not necessarily intend these requirements to apply with regard to anything other than "food" in the ordinary sense of the term – such as those food contact articles that FDA has treated as "food" for certain purposes. Indeed, the legislative history clearly indicates that the only food contact articles subject to the prior notice requirement are those holding food at the time of importation (*i.e.*, packaging). The same limitation should likewise apply to the requirement that "food" facilities be registered. This limitation is consistent with both logic and practical considerations.

A. The Statute Does Not Require That the Registration and Prior Notice Requirements Extend to Food Contact Articles

Nowhere in the Bioterrorism Act is the term "food" expressly defined. Rather, since all of its substantive provisions are styled as amendments to the FD&C Act, the general definition of "food" already contained in the Act is presumably applicable. This does not mean, however, that the agency must give the term "food" as used in the registration and prior notice provisions of the Bioterrorism Act the same broad construction that the term is given in other provisions of the FD&C Act. Rather, these particular contexts warrant interpreting "food" narrowly, in accordance with the literal definition of the term in the FD&C Act.

"Food" is expressly defined in Section 201(f) of the FD&C Act 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." 21 C.F.R. § 321(f). The last of these – "articles used for components of any such article" – describes food ingredients, including any substance directly and intentionally added to food (*i.e.*, a direct food additive). The term "food additive" is separately defined in Section 201(s) of the FD&C Act as meaning (in relevant part) "any substance the intended use of which results or may be reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food . . .) ." *Id.* § 321(s). While substances that are directly

added to food can be considered both "food" (*i.e.*, "articles used for components of any [food] article") and a "food additive" (or more precisely, a direct food additive), substances that become components of food only through unintentional (albeit unavoidable) migration are, strictly speaking, "food additives" (or more precisely, indirect food additives), rather than "food."

Although the "food additive" definition was added to the FD&C Act in 1958 to describe the products subject to the newly-instituted premarket approval process, it has always been understood that not all substances meeting the indirect food additive definition are subject to the premarket approval process. The legislative history of the 1958 amendments makes clear that Congress did not intend FDA to have premarket clearance authority over "housewares" – that is, articles used by consumers to hold, prepare, or serve food – when it authorized the agency to regulate food additives. During Congressional hearings that preceded passage of the amendments, Rep. John Bell Williams, Chairman of the House Subcommittee on Health and Science and the floor manager of the bill, expressly stated that the legislation was "not intended to give the Food & Drug Administration authority to regulate the use of components in dinnerware or ordinary eating utensils." 104 Cong. Rec. 17417 (Aug. 13, 1958).

That housewares are exempt from the premarket approval process does not, of course, mean that they are not regulated by FDA. The agency retains authority to take enforcement action against housewares that it believes may adulterate food pursuant to Section 402(a)(1) of the FD&C Act. While invocation of that authority against the food contact article itself necessitates entertaining the fiction that the food contact article itself is "food" subject to the agency's enforcement authority, food contact articles are certainly not "food" as it is expressly defined in the FD&C Act – or by extension, in the Bioterrorism Act.

Put differently, FDA should not mindlessly adopt the definition of "food" which has arisen out of FDA's administration of the FD&C Act because the FD&C Act and the Bioterrorism Act are directed at different problems, at least as far as dangers to public health arising from the use of tableware and other housewares are concerned. Thus, from a statutory construction standpoint, FDA is not required to adopt the FD&C Act's definition of "food" in administering the Bioterrorism Act because the two statutes are directed at different public health problems. Rather, the agency should construe "food" more narrowly for purposes of the Bioterrorism Act, so that the purpose of that legislation – protection of the public from the deliberate contamination of foods intended for direct consumption – can be more effectively achieved.

B. The Legislative History Indicates That the Prior Notice Requirement Does Not Apply to Packaging and Other Food Contact Substances Unless They Are Imported With Food

Recognizing that FDA's longstanding practice has been to treat food contact articles as "food" under the FD&C Act even though such articles and the indirect food additives contained in them are not consistent with the express definition of "food" in Section 201(f) of the FD&C Act, the managers of the House-Senate Conference on the Bioterrorism Act took pains to make

clear in the Conference Report on the legislation that they did not intend the prior notice requirement to apply to packaging or other food contact substances unless they were actually used for, or in contact with, food at the time of importation. The Conference Report states:

> The Managers intend that the requirements of this Section [307] should not be construed to apply to packaging materials if, at the time of importation, such materials will not be used for, or in contact with, food as defined under Section 201 of the FFDCA. Nothing in this Section shall be construed to alter or amend the regulatory treatment of food packaging materials or food contact substances under the FFDCA.

H. Conf. Rep. 107-481 at 137. Although this statement expressly references only packaging materials, its operative concept – that is, that such materials are covered by the prior notice provision only to the extent that they are "used for, or in contact with, food as defined under Section 201 of the FFDCA" – applies equally to tableware articles and other housewares. The conference managers clearly indicated that the prior notice provision was to be applied only to "food" as expressly defined in the FD&C Act. The managers further stated that this narrow construction of "food" for purposes of the prior notice provision was not intended to affect the longstanding regulatory treatment of food packaging and food contact substances under the FD&C Act (based on a more expansive interpretation of the term "food"). Accordingly, even though these food contact articles are not themselves subject to the prior notice requirement, the agency retains full authority to take enforcement action against them when they are deemed to pose a risk of adulterating food.

During floor consideration of the Conference Report on the Bioterrorism Act, Rep. Shimkus, one of the bill's sponsors, reiterated that "Section 307 dealing with prior notice of imported food shipments should not be construed to apply to food packaging materials or other food contact substances if, at the time of importation, they are not used in food." 107 Cong. Rep. E916 (May 22, 2002). Together, these excerpts from the legislative history indicate clearly that Congress intended packaging materials and other food contact articles to be subjected to the prior notice requirement for imports only to the extent that food was packaged in them at the time of importation. This is only sensible, after all, since the food product itself would be subject to the prior notice requirement, and no additional burden would be imposed on food importers.

To be sure, the legislative history only speaks of this narrow interpretation of the term "food" in the context of the prior notice requirement in Section 307 of the Bioterrorism Act: the Conference Report's discussion of the registration requirement for "food" facilities contains no comparable discussion. Despite this silence, however, it would be reasonable for FDA to construe "food" narrowly for purposes of the registration provision as well – particularly considering that Congress used the same terminology ("food") in both contexts. Since Congress clearly did not intend the prior notice requirement – at the very least – to extend to food contact articles except to the extent that they were imported with food (*i.e.*, as part of a packaged food

article), FDA should interpret the companion registration requirement in the same limited manner.

C. Logical and Practical Considerations Support Limiting the Scope of the Regulations to Products Meeting the Ordinary Definition of "Food"

Although the brief passages in the legislative history addressing the intended scope of the prior notice provision provide no detailed explanation for why the requirement should be extended to food contact articles only to the extent that they are used for, or in contact with, food at the time of importation, there are strong logical and practical reasons supporting this construction.

One such consideration is the nature of FDA regulation of food contact articles. As noted above, the agency's regulation of these products is essentially *ad hoc* – which is to say that the agency asserts regulatory authority of products on a case-by-case basis, applying (at most) an informal regulatory guideline in making a discretionary judgment that a particular article risks "adulterating" food. This is in sharp contrast to the comprehensive premarket approval/notification regime to which direct food additives and food packaging materials (and their indirect food additives) have long been subjected.

Indeed, ceramic tableware probably represents the most highly regulated houseware product, by virtue of FDA's longstanding regulatory guidelines for leachable lead. Most other housewares – including glassware (including lead crystal), stainless flatware, kitchen utensils (of wood, plastic, and metal), metal servingware, and pots and pans – are, for all practical purposes, not regulated by FDA at all. The materials utilized in these housewares are generally recognized as safe ("GRAS"), and as far as we are aware, are not even subjected to sporadic inspections and testing. It necessarily follows that the incidence of enforcement activity against these products – again, based on the legal fiction that they are themselves "food" within the meaning of the FD&C Act – is nil.

Given this dearth of regulatory action with respect to housewares, it hardly seems reasonable for FDA to suddenly assert that these and all other food contact articles should be subject to the new registration and prior notice requirements along with food *per se*. If there is any logic and purpose to doing so, it is not apparent: the new requirements are designed to facilitate increased inspections, and it is impossible to see how FDA could devote greater attention where it belongs – that is, to inspections of food – if it is going to give greater scrutiny to such low-risk bioterrorism targets as houseware articles.

Given the nature of FDA's regulation of housewares and other food contact articles, one wonders how manufacturers and importers are to make a reasoned judgment as to whether they need to comply with the registration and/or prior notice requirements. The agency appears to suggest in the preambles that both regulatory requirements apply to absolutely all articles that contact food. Does this mean (for example) that a shop that fabricates a variety of furniture and other wooden articles – including cutting boards and wooden spoons – must register with FDA

as a "food" establishment? Must an importer of ordinary soda lime glassware provide FDA with prior notice of all of its inbound shipments? Does the agency really want to know every time a consignment of stainless steel cutlery arrives in the United States? In short, if food contact articles are to be treated as "food" for purposes of both the registration and prior notice provisions, large numbers of firms are likely to remain unsure whether their particular products are covered. Given the sanctions available to the agency for non-compliance, this state of inherent ambiguity is intolerable.

For the procedures established by the Bioterrorism Act to have their intended effect of protecting the American public from adulteration of the food supply, it is important that FDA focus its inspection efforts on those food products that present the greatest opportunity for tampering and the greatest inherent risk to the public. Expanding the scope of inspections to products that nominally fall within FDA jurisdiction, but which would be an unlikely and ineffective target of bioterrorism – such as tableware and other housewares – is directly antithetical to the purposes of the Act, as it risks distracting FDA inspectors and straining available resources.

Even accepting that food contact articles can be considered "food" for purposes of applying the FD&C Act's prohibition against adulteration, the fact remains that they meet this standard only to the extent that they actually come into contact with food. While this point may seem self evident, it exposes the fundamental difference between food contact articles and food *per se*. Contaminated food products present an immediate risk to public health; adulterated food contact articles present a risk only once they contact food, and only if the poisonous or deleterious substance actually migrates into the food. This lack of immediacy means that there is significant potential for intervening actions – for example, the washing of purchased tableware items before using them for the first time – to reduce or eliminate any risks posed by a bioterrorist act aimed at food contact articles. This reduced risk warrants not treating food contact articles as "food" for purposes of the registration and prior notice requirements.

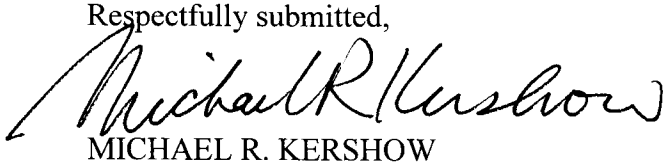
More fundamentally, it is hard to see how tableware articles and other housewares would be a likely target for bioterrorists. It takes little imagination to appreciate how even a small amount of a toxic chemical, dispersed through a silo of wheat or a tanker full of milk, could kill or injure thousands before the sabotage was discovered. Indeed, it was precisely the obviousness of such threats that inspired Congress to include strong measures to protect the food supply in the Bioterrorism Act. But it is much harder to imagine how a toxin could be applied to the surface of large amounts of tableware articles or other housewares and not be detected or removed from the article in the normal course (*e.g.*, by washing after purchase), before harm could be done to consumers. Moreover, because tableware is not itself consumed, the effectiveness of any tampering directed at tableware items ultimately depends on the extent to which the toxic chemical would migrate into food – which is likely to vary greatly, depending on the type of food, its temperature, etc. In short, terrorists intending to do harm to large amounts of people could find myriad ways to wreak their havoc that would be far more efficient and effective than tampering with china or glassware.

A final practical consideration is that the proposed prior notice requirement would be largely duplicative of the advance notification program already implemented by the U.S. Customs Service. While it appears that Congress determined that more direct and immediate notifications should be given to FDA in the case of food products, its decision to exempt food contact articles from that additional reporting requirement only means that FDA will have to depend on receiving pre-arrival information from importers via Customs, rather than directly. This is, we submit, sufficient to allow FDA to achieve the purposes of the Bioterrorism Act without imposing additional, unnecessary burdens on importers of tableware products.

III. CONCLUSION

For the reasons detailed above, the final regulations should be amended to clarify that the definition of "food" for purposes of the registration and prior notice provisions does not include food contact articles except to the extent that they are actually used for, or in contact with, food when imported or otherwise distributed in commerce. In particular, subjecting tableware and other housewares to the new registration and prior notice requirements would place unreasonable burdens on industry without contributing significantly to Congress' objective of reducing the threat of bioterrorist attack on the food supply.

Respectfully submitted,



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