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8 July 2003

Dear Sirs,

ATTN: Docket No. 02N-0275 – Administrative Detention under the Bioterrorism Act of 2002

The Scotch Whisky Association, which is the representative body of the United Kingdom's Scotch Whisky Industry, appreciates the opportunity to comment on the Food and Drug Administration's Notice of proposed rulemaking (Docket No. 02N-0275) in regard to the provision for the Administrative Detention of Food for Human or Animal Consumption under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act).

The Association duly submits its comments thereon in the attached paper and requests that the FDA gives due consideration to them with a view to adjusting the regulations so that these particular concerns are mitigated.

You will wish to be aware that, as a member of the European Confederation of Spirits Producers (CEPS), the Association endorses the position which is being submitted to the FDA by CEPS in association with the European Committee of Wine Companies (CEV) and the Brewers of Europe (CBMC).

Yours faithfully,

T W JACKSON
Director of International Affairs

Enc.

02N-0275

EMC51

US BIOTERRORISM ACT of 2002

Docket No 02N-0275 – Administrative Detention

Preamble

The Scotch Whisky Association (SWA) is the industry's officially recognised representative body. Its 57 member companies, all of whom are distillers, blenders, owners of proprietary brands, brokers and exporters of Scotch Whisky, together comprise over 95% of Scotland's distilling and blending capacity.

Each year the industry exports Scotch Whisky valued in excess of US$3.5 billion to over 200 world markets. In 2002, goods to the value of some US$476 million were exported to the United States, making it the industry's single most valuable export market.

General Background

On 3 April 2003, the SWA filed submissions with the Food and Drug Administration (FDA) on the proposed regulations for implementation of the Registration and Prior Notice requirements (Docket Nos 02N-0276 and 02N-0278 refer). It does not intend to re-state the Overall Comments and Conclusions on the Bioterrorism Act that it made therein other than to reiterate the following.

The SWA understands that the FDA objective in formulating a strategy to enhance the security of the US food supply is to protect US citizens from the threat of bioterrorism and other such emergencies. It is not opposed in principle to the imposition of new legislative requirements governing the shipment of food products to the US, whether for import into the US domestic market, for onward shipment outwith the US, or for re-export from the US, **provided** that the specific requirements are (a) appropriate and (b) proportionate to securing the desired objective. Furthermore, it is essential that the measures are the least trade restrictive possible.

Bearing these principles in mind, the SWA's specific comments on the proposed regulation for Administrative Detention (Docket No 02N-0275) are as follows.

Jurisdiction

The Act specifically excludes those foodstuffs under the jurisdiction of the US Department of Agriculture (USDA), i.e. meats and poultry products as well as eggs. In contrast, spirits, wines and other alcoholic beverages which fall within the jurisdiction of another US agency, viz TTB under the US Department of Treasury, have to comply in the same way as all other kinds of food products. This inconsistency does not appear to be founded on any objective criteria such as risk analysis. Indeed, the SWA is unclear why the exception has been granted to USDA products and not to alcoholic beverages given that they are already tightly regulated by the TTB under the US Treasury.

There is another, related, incongruity. By virtue of the alcoholic beverage industry's regulation by the TTB, it is incongruous and incomprehensible that the TTB, with its longstanding expertise in the alcoholic beverage field, is excluded from active involvement in the FDA decision making process on whether a shipment of alcoholic beverages merits detention for further investigation. This omission is not only wasteful of informed resources but also denigrates the valuable work undertaken by a companion Federal agency that is entrusted with special responsibilities within a specific field.

The SWA believes that, in order for FDA officers to fully understand the alcoholic beverage sector, it is essential for them to work alongside TTB officers and, furthermore, that it is the TTB officers who are effectively responsible for ordering any necessary detention of an alcoholic beverage shipment.

'Serious adverse health consequences'

The proposed regulation requires that detention may be ordered if there is credible evidence or information that a food offers 'serious adverse health consequences'.

However, the FDA does not proceed to define what it would consider representative of 'serious adverse health consequences'. For instance, it has not set any apparent safeguards or parameters in order to contain the scope for detention being implemented. In this regard, the SWA is concerned whether there are any procedures in place to enable the evidence for suspicion to be corroborated before an order for detention is made or whether such an order would be made on a totally discretionary/subjective basis.

Potential Discrimination

The proposed regulation provides for the temporary holding of imports for 24 hours.

SWA members feel that this proposed provision is open to abuse because not only is there no comparable provision for domestic products but there is also a real risk that the provision could amount to a 'holding bay' for import inspections while FDA resources are used to deal with alerts elsewhere.

Thus, the SWA is concerned that imported products will be more vulnerable to precautionary action entailing detention, and similarly to pragmatic detention for reasons of demands on FDA time.

Erroneous Detention

The FDA estimates that up to 48% of the food administratively detained may be in detention erroneously.

The consequences of erroneous detention are many but one of the most significant is 'cost'. The ensuing costs may refer to transport, storage, marking and labelling, loss of product, loss of product value, loss of product appeal, and loss of customer. Any of such costs immediately hurt small and medium-sized companies more than large or multinational companies. Accordingly, the impact of Administrative Detention must not be underestimated and it underlines the necessity for the FDA to set out a clear and objective basis on which detention may be ordered.

Given the margin provided for error among detentions, the SWA believes that the FDA is obliged to consider offering some form of compensation in these cases, even on a contributory percentage basis. If there was some system for FDA to pay compensation for erroneous detention, it could act as a brake on unrestrained detention of consignments ordered by FDA without real demonstrable cause or justification while relying on the appeal process to correct any mistakes.

Appeal Process Classified National Security Information

The FDA proposes that it would not release classified information which relates to a suspect food but that "*the presiding officer will give you notice of the general nature of the information and an opportunity to offer opposing evidence or information*".

According to the FDA's own estimate, 48% of shipments would be eventually released having been detained erroneously. This figure alone justifies the necessity for affected parties to be provided with the best 'classified' information available to facilitate timely preparation of their appeal for release of a shipment. Those who are bona fide and comply with requirements under the Act, such as registered importers, should not be penalised by information being withheld on account of their shipment being suspect due to illegal interference or terrorist activity somewhere along the chain of supply. Besides, if the questions posed by the 'classified national security information' cannot be answered sooner failing which at least clarified by the affected party, this would indicate there was some problem to be addressed.

In order to understand the implications for the appeal process, the SWA requests that the FDA clarifies those aspects of the information that it currently proposes would be withheld due to its 'classified' nature from the affected party (eg importer) and would require to be assessed on an individual case basis.

Consolidated Shipments

It has been reported that a single container which consolidates small shipments of different products or origins may no longer be permitted entry into the US. However,should this not be the case, the SWA is concerned about what would happen in a situation where one part of a shipment/container is regarded as providing a threat of serious adverse health consequences or death to humans or animals while the remainder of the consolidated shipment/container is not.

The SWA requests that the FDA clarifies the practical consequences of such an event for the safe elements within a consolidated shipment/container and what degree of compensation may be available.

Detention Period

The proposed regulation states that the detention period would be 'reasonable', not exceeding 20 days, but could be extended by an additional 10 days to be detained for a total maximum of 30 calendar days.

In practical terms, this 'reasonable' period of up to 20 days, which could be extended to up to 30 days, means that all perishable foods/drinks, including those which are perishable in a 'commercial' sense, would no longer be eligible for sale. Therefore, if a 'fast-track' appeal for perishable food does not allow quicker release of detained food when it is found to be safe, the value of such an appeal is questionable.

The FDA estimates that 48% of detained shipments would be cleared and therefore finally released. This figure reflects a high margin of 'safety precautions'. Despite the major commercial and financial implications for food/drink companies that are associated with this margin for erroneous detention, the FDA makes no provision for compensation for a food/drink product that is eventually released from detention on being found safe and has undergone alteration as a result of the period of its detention.

Detention should not result in loss of or reduction in the quality of any food/drink product or of its presentation. Since any detention would incur delay, cost, reduced efficiency and customer concern/dissatisfaction, the food/drink industry requires to understand what the US authorities intend to achieve during a 30 day detention period and what factors are used to determine the duration of a detention. There is concern, for example, that these factors may include availability of FDA resource.

Conclusions

The SWA requests that the FDA notes its concerns and amends the proposed regulation in accordance with the following:

- requires TTB officers to work with the FDA with the former being responsible for detentions
- provides clear procedures to substantiate the grounds for an order for detention being made
- protects imports against discrimination for excessive precautionary or pragmatic reasons
- recognizes the need and provides a means to compensate for erroneous detention
- provides an appellant against detention with as much 'classified' information as possible
- clarifies the information to be potentially withheld from an appellant in any individual case
- clarifies the full consequences if one shipment within a consolidated containerload is suspect
- clarifies what determines the duration of a detention and what the FDA would achieve during it.

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8 July 2003