

THE SCOTCH WHISKY ASSOCIATION

3 April, 2003
Ref: TWJ/EL/us-bio (BY EMAIL & POST)

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

177
REGISTERED OFFICE
20 ATHOLL CRESCENT
EDINBURGH EH3 8HF
TEL: 0131 - 222 9200
Web: www.scotch-whisky.org.uk
INTERNATIONAL AFFAIRS
TEL: 0131 - 222 9229
FAX: 0131 - 229 1989
EMail: int@swa.org.uk

Dear Sirs,

ATTN: Docket No. 02N-0276 – Registration under the Bioterrorism Act of 2002

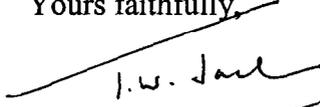
The Scotch Whisky Association, which is the representative body of the United Kingdom's Scotch Whisky Industry, appreciates the opportunity to comment on the Food and Drug Administration's Notice of proposed rulemaking (Docket No. 02N-0276) in regard to the 'Registration' provision under the Public Health 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 provides the assurances and the clarification requested therein, and gives due consideration to its proposed solution.

You will wish to be aware that, as a member of the European Confederation of Spirits Producers (CEPS), the Association endorses the common 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).

Many of the Association's members are also members of the Distilled Spirits Council of the United States (DISCUS) and the National Association of Beverage Importers Inc (NABI). In addition, therefore, the SWA expresses its full support for the individual submissions of these organizations on behalf of the alcoholic beverage industry within the US. Similarly, the Association strongly supports the collective position of the coalition of US trade associations, representing all tiers of the alcoholic beverage industry in the USA inclusive of DISCUS and NABI, which is set out in its submissions of 30 August 2002 and April 2003.

Yours faithfully,


T W JACKSON

Director of International Affairs

02N-0276

C 112

US BIOTERRORISM ACT AND ASSOCIATED PROPOSED REGULATIONS

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.

Background to the legislation

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 appropriate and proportionate to securing the desired objective. In particular, it believes it is essential that the measures are the least trade restrictive possible.

The Bioterrorism Act (Act)

It should be noted at the outset that Scotch Whisky, together with all other spirits and alcoholic beverages, remains subject to overall regulation under the Alcohol and Tobacco Tax and Trade Bureau (TTB) in accordance with Title 27 of the Code of Federal Regulations (CFR), while Scotch Whisky and all other imported alcoholic beverage products are also subject to the regulations of the US Customs Service (see below). Additionally, each US State has its own Alcoholic Beverage Control authority.

Despite the alcoholic beverage sector being thus highly regulated already, the FDA Act sets out new requirements in the following four areas:

- (1) Detention
- (2) Registration
- (3) Record Keeping
- (4) Prior Notice

To date only the proposed regulations for implementation of (2) Registration and (4) Prior Notice have been published. Accordingly, as invited, the SWA submits its comments on these specific Dockets as separate Annexes attached herewith (see **Annexes A** and **B** respectively). Closely related comments on the relevance and application of the overall legislation to Scotch Whisky (and all other alcoholic beverages) follow immediately.

Overall Comments

1. The SWA is concerned that the scope of the legislation extends beyond the boundaries of the USA, thereby requiring the extra-territorial application of US domestic legislation outwith the country. It believes this sets a troublesome precedent for the regulation of international trade.

2. There appears to be a real risk of a proliferation of separate but connected initiatives within the US designed to meet objectives similar to that of the Bioterrorism Act, all of which impinge on each other. For example, the processing of shipments in regard to the mandatory requirements of the Container Security Initiative (CSI), with its accompanying 24-hour Rule, varies in 'depth' and speed if the voluntary provisions of the Customs-Trade Partnership Against Terrorism (C-TPAT) are met as well.

The SWA has no difficulty with the thorough efforts of US agencies to establish the desired degree of security in international and domestic trading channels. However, it has considerable difficulty with the uncoordinated and inconsistent manner in which such measures are being introduced, to the extent that it has the potential to impact in a confusing and adverse manner on both public and private sectors in countries outside the US. For example, it is understood that the US Customs Service has already engaged the UK (and certain other EU Member States) individually in the CSI while the EU Commission is concerned that US Customs has not approached the EU as a Customs region, a matter which, reportedly, is to be addressed; it is unclear what will happen in the intervening period.

At the same time, on the European regional front, it is believed that the EU is working on its own security initiatives and that, in the international arena, bodies such as the International Maritime Organisation (IMO) and World Customs Organisation (WCO) also have potential action in hand. The SWA is unsighted of the details of all the various initiatives, but is concerned to ensure that the FDA Bioterrorism legislation does not lead to the creation of confusing, conflicting and/or duplicative requirements.

3. The Scotch Whisky industry also notes that 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 question could be asked why the exception has been granted to USDA products and not to alcoholic beverages given that the latter are already TTB-regulated under the US Treasury.
4. The traceability and security of Scotch Whisky and other EU spirits (and wine) products are already provided for under a combination of EU and US legislation and standard industry practice. For example, EU legislation requires the inclusion of lot codes on their labels for the purpose of traceability; containers are security sealed; US regulations require tamper-proof closures on spirits (and wine) products and a health warning (albeit against abuse of the product, not against contamination) on the innermost container of all alcoholic beverages.
5. The FDA Registration and Prior notice requirements under the Act will entail the storage in one place of a huge amount of information on the US food supply. The Scotch Whisky industry is concerned that adequate measures are taken to protect this information.
6. While acknowledging the validity of the policy objective of the Act, the SWA is obliged, on behalf of those of its respective members wishing to export to the US, to conclude that the detailed measures adopted by the FDA fail to meet the WTO requirement of being no more trade restrictive than necessary to meet the stated objective.
7. It is understood that the FDA intends to publish in the Federal Register proposed regulations for mandatory records to be created and maintained by all involved in the

production and supply of food for human consumption on a 'one up', 'one down' basis. The Scotch Whisky industry will submit comments on the relevant Docket, once published, but wishes to take this opportunity to comment generally in advance of its publication.

Under the TTB's existing regulations as set out in 27 CFR, the alcoholic beverage industry is required, to maintain records of production and importation. Given that this system, which establishes the immediate previous source and immediate subsequent recipient, is already in place and may even exceed the FDA's future requirements, little purpose would be served by introducing duplicative new regulations in this area. Again, the Scotch Whisky industry believes that any US agencies which impose similar requirements with the same motive, as in this case, should coordinate their responsibilities so that neither the duplication of government resources, manpower and regulations nor overlapping, conflicting or duplicative requirements for businesses becomes an issue.

Overall Conclusions

The SWA, representing the Scotch Whisky industry, recognises the need and desire in the current international climate for the US government to take proportionate measures to enhance the security and safety of the food supply chain in the US. Nevertheless, it wishes to draw attention to the fact that spirits, wine and other alcoholic beverages are already highly regulated by the TTB, to the extent that many of the existing requirements imposed by the TTB upon the alcoholic beverage industry and likewise by US Customs are now being required separately under the Bioterrorism legislation for Scotch Whisky and all other alcoholic beverages.

The Scotch Whisky industry is therefore concerned that the US Government is failing to consider how the administration/responsibility for the existing TTB regulations and Customs requirements can be harmonised with, or incorporated into, the FDA requirements under the Act. It seems only reasonable that alcoholic beverages should not be subject to heavier demands than other foods in terms of registration, record keeping and prior notice. In this regard it should be noted that the TTB response to the FDA highlights the need to 'avoid duplication of efforts and undue burden upon the alcohol industry'¹.

Against the existing regulatory background for all alcoholic beverages, the SWA believes that the scope of the Bioterrorism Act and its associated regulations has the potential to cause disruption to trade flows and that its impact might turn out to be disproportionate to its stated objective. It would therefore be grateful if the FDA would give consideration to how it may effectively resolve the issues raised in this submission without undermining the objective of its legislation.

Proposed Solution

In light of the foregoing, the SWA wishes to propose to the US authorities a solution along the following lines:

Given that all alcoholic beverages are tightly regulated by the Alcohol and Tobacco Tax and Trade Bureau under the US Treasury (27 CFR),

- **secure a legislative amendment to the Bioterrorism Act that exempts Scotch Whisky and other alcoholic beverages from its application, in the same way as meat, poultry and egg products under the jurisdiction of the USDA are excluded from its scope;**

¹ www.fda.gov/Bioterrorism/Act/section307/viewcomments : document ref C24 09/12/02 09/04/02 Dept of Treasury, ATF

failing which,

- **include express language in the final Registration rule (Docket No 02N-0276) under the Act which recognizes that a TTB alcoholic beverage registration or permit meets the FDA registration requirement under the Act, and**

given also that imported alcoholic beverages are already subject to US Customs notification requirements,

- **include express language in the final Prior Notice rule (Docket No 02N-0278) under the Act which recognizes that the US Customs Service existing notification requirements meet the FDA Prior notice requirement under the Act;**

failing which,

- **the TTB, US Customs and FDA accept and meet their respective and collective responsibilities to establish a co-ordinated system of information inter-change between US government agencies so that producers and exporters are not required to duplicate the information that is already being provided (in the case of Scotch Whisky and all other alcoholic beverages) to either the TTB or US Customs.**

The Scotch Whisky Association
20 Atholl Cresecent
Edinburgh EH3 8HF
Scotland, UK

3 April 2003

Annex A - Docket No 02N-0276

Annex B - Docket No 02N-0278

FDA Bioterrorism Act: Regulations

Annex A

Registration – Docket No 02N-0276

The FDA proposed regulations include the following provisions:

- Foreign facilities that manufacture, process, pack, or hold food for consumption must register with the FDA unless the food undergoes further processing or packaging by another before it is exported to the US. A *de minimis* packaging activity would thus require both the producer and packager to register.
- Electronic registration is not mandatory but clearly recommended by the FDA.
- A unique registration number will be assigned to each registered facility.
- A US agent may be designated to effect the registration, in which case FDA recommend a formal agreement between the relevant foreign and US parties.

Registration: Comments

The Scotch Whisky Association (SWA) wishes to comment as follows.

Although the information required by FDA for registration is extensive, registration of a foreign facility is not of itself problematic if it is only once. However, the SWA has reservations concerning the specific FDA registration requirements.

1. Principally, the FDA proposed registration regulations require the submission of a large amount of company information that is already submitted to the TTB under the latter agency's existing alcoholic beverage industry regulations, reference to which is made in the Scotch Whisky industry's main paper. There is therefore an unnecessary duplication and excessive overlap of these two US government agencies' requirements, the resolution of which could be achieved by any of the three proposed methods set out in the industry's conclusion to the main paper.
2. The SWA has a particular concern when the exporter is not one and the same as the producer because the registration requirements lead to a very burdensome situation, particularly in those instances when exporters bottle the product privately for labelling purposes. The requirement's potential impact would be to entail a far greater number of registrations for Scotch Whisky producers who may not know where their product will be shipped because they have sold it to a local company first. The consequent associated costs for those Scotch Whisky suppliers are much underestimated by the FDA.

Also, there is an added complexity stemming from this kind of commercial arrangement because the last foreign facility would be required to register as well; this means that, in the event that a local Scotch Whisky distiller sells his Scotch Whisky for bottling and sale by a different local company, not only will he have to register but so will each of the local bottlers who buy his Scotch Whisky and export it to the US. This will culminate in a plethora of foreign facilities having to register, a dimension which FDA does not appear to have foreseen.

3. Processing the registration applications of all the facilities subject to the Act is self-evidently a mammoth task for the FDA. Businesses may therefore be affected by delays in

this process during the relatively short period of 2 months during which registration must be effected, ie October to December 2003. The period in question is a peak time for the alcoholic beverage industry in the run up to Christmas and the New Year. Thus, any significant delay in the registration process could impact adversely on exports of Scotch Whisky (and all other alcoholic beverages) to the US.

In this regard, the Scotch Whisky industry would welcome the FDA's assurance that it has the capacity to handle the overwhelming number of facility registrations that will ensue from the legislation and, in particular, that hard copy registration applications will not receive second-class treatment by being placed at the bottom of the pile.

4. There must also be serious doubts about whether the time constraints of the registration process will allow thorough and meaningful examination of all the applications received by the FDA. It is not evident how the integrity of companies wishing to register will be audited or verified. Indeed, it is stated that assignment of a registration number does not denote FDA approval or endorsement of a facility or its products. It must therefore be open to question whether registration will materially enhance security of the food supply chain.
5. The industry agrees with the FDA recommendation that some kind of agreement or authorisation between a foreign facility and its designated US agent is desirable, but wishes to highlight the fact that, under TTB regulations, the importer is already charged with this responsibility.
6. Given that the FDA is proposing to require registration information to be kept updated, it is not clear whether historic registration information will be retained. This would appear to be essential if the process of tracing is to be effective.
7. The SWA shares with other EU alcoholic beverage interests certain specific concerns relating to the UK/EU spirits industries which, in order of importance, are outlined as follows:
 - Since the requirement for a foreign facility to appoint a single agent does not always match business practice, where two or more importers may handle a foreign company's different products within the same region, it is neither practicable nor commercially acceptable.
 - Consideration and clarification of the requirements for limited quantities of samples (e.g. for market testing, tasting or analysis purposes as opposed to sale) is requested since any requirement to comply with the registration provision before their importation could create a serious impediment to the introduction of new products or the promotion of products already in the market.
 - The FDA's claim that, in most cases, importers or business partners will act as agents with their foreign principals is disputed on the grounds that this could be difficult for some importers who might not wish to run any risk of legal consequences. This means that many small exporters may be compelled to face the additional cost of appointing an agent for the sole purpose of meeting the FDA requirements.
 - The non-discriminatory status of the legislation is challenged since it appears that foreign facilities will bear most related costs (Table 42 refers), which are in any event underestimated.

Registration: Conclusion

As set out in the main paper, the SWA proposes a solution along the following lines:

Given that all alcoholic beverages are tightly regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB) under the US Treasury (27 CFR),

- secure a legislative amendment to the Bioterrorism Act that exempts Scotch Whisky and other alcoholic beverages from its scope, in the same way as meat, poultry and egg products under the jurisdiction of the USDA are excluded from it;

failing which,

- include express language in the final Registration rule (Docket No 02N-0276) under the Act which recognizes that a TTB alcoholic beverage registration or permit meets the FDA registration requirements under the Act;

failing which,

- the TTB, US Customs Service and FDA accept and meet their respective and collective responsibilities to establish a coordinated system of information interchange between US government agencies so that producers and exporters are not required to duplicate the information that is already being provided (in the case of Scotch Whisky and all other alcoholic beverages) to either the TTB or US Customs.

The Scotch Whisky Association
20 Atholl Cresecent
Edinburgh EH3 8HF
Scotland, UK

3 April 2003

FDA Bioterrorism Act: Regulations Annex B

Prior Notice – Docket No 02N-0278

The FDA proposed regulations include the following provisions:

- The FDA requires the immediate prior notification to it of every single food shipment, on an article-by-article basis, by the US importer within a tight timescale. Only one 'Amended' notice to the 'Initial' information notice is permitted, other than 'Updated' arrival details all within a minimum timescale, and, if notice is not provided, the article of food will be refused admission.
- Notifications may be submitted by an importer or US agent but, whether 'Initial', 'Amended' or 'Updated', they must all be submitted electronically. This may be problematic for some smaller traders.
- It is instructive that the FDA considers it necessary to specify notification by means of an agent in order to limit the sources of notifications, degree of information, and number of delays that are likely to arise from the requirement.
- The information that must be supplied in the prior notice is excessively burdensome. A prior notice that is deemed 'inadequate' for e.g. untimeliness, inaccuracy or incompleteness, will result in the shipment not being admitted and possibly having to be removed by the US agent to temporary secure storage at his expense.

Prior notice: Comments

The Scotch Whisky Association (SWA) wishes to comment as follows.

1. The Prior Notice requirement is considered the most burdensome feature of the Bioterrorism legislation. Principally once again, the consequent duplication and overlap of existing requirements is the issue. Most of the information to be provided in the Prior Notice about the contents and the logistics of the shipment is already included in the commercial invoice data usually supplied for US Customs by importers when goods arrive in the US. The FDA is now requiring that it receives such information in advance on shipments to the US.

In this connection, at a meeting with FDA on 5 March, representatives of the EU spirits (and wine) industries were informed that the FDA Prior Notice requirement will not be integrated with US Customs current requirements and, further, that the US Customs existing system (ACS) cannot be modified to accommodate the FDA Prior Notice data requirements in time to meet the FDA statutory deadline of December 12, 2003.

Notwithstanding, it is understood that US Customs is in the process of developing a new system to replace the ACS but that, regrettably, this new Customs system will not be implemented until 2005; also, that the FDA will discontinue its Prior Notice system when the new all encompassing Customs system comes on line in 2005. However, in the meantime, the alcoholic beverage industry will be compelled to bear the burden and associated costs arising from the US Administration's internal software problems which result in a double, but unnecessary and unconnected, notification requirement to two different US authorities – Customs and FDA - for shipments to the US over a period of at least 2 years. Ensuring the requisite data flows should be the concern of the US authorities and not of US importers on behalf of third-country producers/exporters.

2. The Scotch Whisky industry wishes to be assured that the FDA will have the administrative/logistical capability to handle a constant and vast quantity of 'Initial', 'Amended' and 'Updated' Prior notices. Further, it would seem that, if they are to provide any measure of increased security, all these notices will have to be effectively scrutinised. In fact, there is no indication of how the excessive detail in the notices will be checked/verified.

Given the variables and imponderables associated with any form of transportation, particularly by ship, the FDA expectation for accurate notification of arrival time, within minor margins, is unrealistic. The Scotch Whisky industry wishes to be assured that arrival in port at a time inconsistent with that notified and/or at a different port would not entail a shipment being refused clearance without there being further cause for its detention, since such action would incur unjustifiable expense for the importer due to temporary storage costs and delay in the goods reaching the market.

3. So far as Scotch Whisky and other imported spirits are concerned, much of the information required in the Prior Notice, together with certain additional details, is already provided to the US authorities under existing regulations, viz:
 - (a) The TTB has to approve and register labels (including bottle sizes) for all alcoholic beverages imported into the US. The process involves the submission of substantial information relating to the company and its products.
 - (b) The US Customs Service receives advance notice of a ship's arrival and of its manifest well ahead of its actual arrival. Its Container Security Initiative (CSI) requires the presentation of cargo details 24 hours before loading onto the vessel. The checklist covers a total of 15 items of information that exceed the detail required under the Act.

Apart from burdensomeness in terms of labour, time and cost, such duplication could lead to errors and omissions due to slight inconsistencies between the sets of requirements and so defeat the purpose of strengthening security and safety. A solution to this potential problem might be for the US Government to:

- ensure consistency between the various legislative requirements;
 - require all US government agencies that have regulations and jurisdictions addressing the same objectives to coordinate their responsibilities in order to avoid a duplication of government resources, manpower and regulations; and,
 - ensure that businesses are not subject to overlapping, conflicting or duplicative requirements.
4. The Scotch Whisky industry notes that there are domestic exemptions to the Prior Notice procedures, eg individual travellers, and can recognise that, at a practical level, these are justifiable. However, these exemptions merely serve to underline the need to ensure that the imposition of new regulatory requirements to the food supply chain must be as reasonable as possible.
 5. Again, the SWA is concerned about the treatment of samples under the Prior Notice regulations. Clarification is requested on whether shipments of small quantities for market testing, tasting or analysis purposes (as opposed to sale) will be permitted without being subject to Prior Notice requirements.

6. Joining the Customs-Trade Partnership Against Terrorism (C-TPAT) is likely to become increasingly attractive for many traders because a potential consequence of membership is the speedier handling by Customs of a member's shipments. However, this initiative has the potential to create another unavoidable layer of bureaucracy and add to the growing complexity of trading with the US.
7. The FDA claims that advance information of a food shipment will allow the FDA to target arrival inspections more effectively before products enter domestic commerce. However, the CSI involves *inter alia* the possible inspection of shipments destined for the US by US Customs personnel based overseas. It is unclear to what extent these inspections will be coordinated.

Prior notice: Conclusion

In sum, the Scotch Whisky industry believes that it is unnecessary and potentially confusing for broadly parallel (but not identical) information concerning shipments to the US to be notified separately to different government departments/agencies.

As set out in the main paper, the SWA proposes a solution along the following lines:

Given that all alcoholic beverages are tightly regulated by the Alcohol and Tobacco Tax and Trade Bureau (TTB) under the US Treasury (27 CFR),

- secure a legislative amendment to the Bioterrorism Act that exempts Scotch Whisky and other alcoholic beverages from its scope, in the same way as meat, poultry and egg products under the jurisdiction of the USDA are excluded from it;

failing which,

given also that imported alcoholic beverages are already subject to US Customs notification requirements,

- include express language in the final Prior Notice rule (Docket No 02N-0278) under the Act which recognizes that the US Customs Service existing notification requirements meet the FDA Prior notice requirements under the Act;

failing which,

- the TTB, US Customs Service and FDA accept and meet their respective and collective responsibilities to establish a coordinated system of information interchange between US government agencies so that producers and exporters are not required to duplicate the information that is already being provided (in the case of Scotch Whisky and all other alcoholic beverages) to either the TTB or US Customs.

The Scotch Whisky Association
20 Atholl Cresecent
Edinburgh EH3 8HF
Scotland, UK

3 April 2003