The Brewers of Europe

Confédération Européenne
des Producteurs de Spiritueux

cev

Comité Européen des Entreprises Vins

To the attention of:
Dockets Management Branch (HFA-305)
Food and Drug Administration
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Rockville
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COMBINED THE BREWERS OF EUROPE / CEPS / CEV POSITION PAPER

US BIOTERRORISM ACT AND ASSOCIATED PROPOSED REGULATIONS

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CEPS is the representative body for EU producers of spirits drinks. Its membership comprises 38 national associations representing the industry in 21 countries – all EU Member States, the Czech Republic, Hungary, Norway, Russia, the Slovak Republic and Switzerland – as well as a group of leading spirits producing companies.

CEV is the representative body of the European wine industry, encompassing trade in still wines, aromatised wines, sparkling wines and fortified wines. Its membership comprises 16 national associations in EU Member States and 2 other associations from Switzerland and Hungary.
The three organisations are grateful to the Food and Drug Administration to be able to comment on the Notice of proposed rulemaking (Docket No. 02N-0277) in regard to the provision for the Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Act).

02N-0277

EMC 48

US BIOTERRORISM ACT of 2002

Docket No 02N-0277 – Establishment and Maintenance of Records

Listing of Ingredients

Alcoholic beverage producers are indeed concerned about the need to list the ingredients in their product. There is no requirement to list ingredients on the labels of alcoholic beverages in either the EU or the US. In any event, in the event of a health risk situation, producers would readily cooperate in providing from their own records information on the source(s) of their ingredients.

As far as distilled spirits are concerned, there is a question of interpretation as to what is meant by ingredients. The distilling process changes substantially the character and chemical composition of the raw materials and some of them may even be absent from the final product. This is one reason why an ingredient list on a bottle label would be misleading.

It has been assumed for the purpose of traceability that this is not necessarily what the proposed regulation intends ingredients to mean. For instance, a blended whisky consists of various whiskies blended together to produce the final whisky, although in turn those individual whiskies have been distilled from cereals, water, yeast.

There are potentially innumerable sources of 'ingredients' to be recorded for an alcoholic beverage product, the actual number being dependent on the category and particular brand. Under the proposed regulation, although it is not entirely clear, it appears that all of these would require to be identified.

In the event that the precise ingredients of a particular brand of alcoholic beverage requires to be known, the most efficient and acceptable way of establishing this is to locate the importer and/or producer. This is most easily achieved through the TTB's existing database.

Duplication of Records

Alcoholic beverages are 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). The particular regulations for the maintenance of records of imported spirits, wine and beer are

contained in 27 CFR Part 251, Subpart I. The importer's records enable a product to be traced from the point of importation on to its destination as well as back to the producer/supplier.

It has recently been announced that the FDA and US Customs will work together in order to enable the supply of a single set of information, based on the information requirements of the FDA, by the importer (exporter) to satisfy both the existing US Customs '24-hour rule' and the FDA Prior Notice of shipment requirement under the Bioterrorism Act. The EU alcoholic beverage industry welcomes this simplification and logical solution to a duplication of requirements.

However, a duplication of requirements occurs once again by virtue of the existing and soon to be amplified information that is/will be required by US Customs/FDA under their respective advance notice requirement(s) for shipments arriving in US ports and the FDA proposed regulation to require a further set of records on the immediate previous source of imported products.

EU alcoholic beverage producers hold comprehensive records that enable full traceability for all components of their products. Many of them also hold records for tracing key 'dry material' components, such as bottles, capsules etc.

The FDA is aware that there may be existing requirements for record keeping and appears flexible in regard to the manner in which records are maintained. This begs the question why it is necessary for the FDA to formulate at all another raft of recorded data requirements, most of which is already on record in some form or another.

Time frame for Accessing Records

The FDA requires records to be accessible within a time-frame of not more than 4 to 8 hours, depending on the day and time. Naturally, companies would endeavour to supply what may be requested as fast as possible.

This time-frame is totally unrealistic for records that are held 'beyond' the US. Local time requires to be taken into consideration, eg a request made at 2.00pm Washington time is received at 8.00pm in France when no-one would be present at a distillery or even in an administrative building. A delay of 24 hours would be essential and this would not cover the eventuality of a request being made during a weekend.
If the request takes place during a week end (using local times - 4 PM Washington time on Friday afternoon is already the week-end in Europe), we would be ready to respond within 72 hours.

Records, particularly older as opposed to recent, may be stored 'off site'. In such circumstances, more than 24-hours would be needed in order to retrieve such records.

The provision of 24-hour cover to assist with emergency access to records, whether on or off site, would be extremely costly to businesses.

Costs Entailed

In order to comply fully with the record-keeping proposals, it is estimated that a large company would have to employ 1-2 extra full time persons and that this would cost some € 85,000-100,000 per year.

Disclosure of Food Recipes

The FDA bases its definition of a 'recipe' as the notification of the actual quantity of each ingredient used in the manufacture of a product and, accordingly, assumes that it is not requesting 'recipe' information because it does not require to know the relative individual quantities.

The industry is very concerned by the risk of disclosure of sensitive commercial information through having to provide a 'one-up' source nontransporter record for each of the ingredients in a product. The complete formula may not be disclosed but, for instance, listing the source of each one of as many as 50 individual Scotch Malt and Scotch Grain Whiskies in a blended Scotch Whisky is not only extremely burdensome but would essentially reveal the trade secret 'recipe' for that brand. This is often not even known by more than a few within the company itself.

This leads to the serious question of how such commercially sensitive information would be handled and by whom once the 'recipe' has passed out of the producing company's control.

Modification of existing records in order to comply

Documentation which records purchases (eg purchase orders and invoices) and shipping, details (eg bills of lading and invoices) may be inadequate for the possible addition of information under the proposed record keeping requirements. Consequently, the format of a company's documentation system may need to be modified to accommodate the extra data, although the shipping company would be responsible for the bill of lading. As a corollary to this, a company

may require to obtain additional information from suppliers in order to ensure that it has the necessary data relating to what they receive from them. This all involves extra time and administration for both purchaser and supplier.

Small and Medium-sized Companies

A longer time-scale for compliance with the proposed regulation would be permitted for companies with 10-500 employees and for those with up to 10 employees. This is appreciated.

The burden of record-keeping and ensuring accessibility to records within the specified time-frame is considered totally impractical. Exceptional expense, which it has not been possible to realistically guesstimate, would be entailed.

Application of the Requirements 'beyond' the importer

It is significant that the record keeping requirements of the TTB for alcoholic beverages do not go 'beyond' the importer. This is as it should be given that the TTB, together with the Bureau of Alcohol, Tobacco, Firearms & Explosives (ATFE), its companion law enforcement agency, have no jurisdiction 'beyond' the US border.

It has been acknowledged in the context of recent US Customs initiatives that US Customs has no jurisdiction outwith US territory. Mutual agreements on cooperation between US Customs and, for example, the EU Commission have been reached in order to address responsibly together their shared Customs security objective.

The proposed regulation for the establishment and maintenance of records as drafted 'would require the establishment ... by certain domestic persons who ...' but then makes an assumption that 'these requirements apply to certain foreign facilities that ...'. This is unacceptably open-ended, and reflects the FDA's uncertainty on the extent of its jurisdictional remit.

The questions that must be asked are Why? and How? does the FDA justify the application of its record keeping requirement 'beyond' its Federal jurisdiction?

Another Raft of Data

This new proposed raft of data, records for most of which are already held in one form or another as the FDA has indicated would be acceptable, appears to require two sets of data covering the (1) 'one-up' source and (2) 'one-down' recipient to be maintained by a foreign

nontransporter. (It is however, in contrast, quite clear that similar records do not require to be maintained by foreign transporters.)

One-up Nontransporter	One-down nontransporter	One-up/one-down Transporter
1.name, address, phone of immediate previous source	Same of immediate subsequent recipient	1.name, address, phone of immediate previous source + date of receipt
2. type of food	Type of food	2.name, address, phone of immediate subsequent recipient + date of delivery
3. date received	Date delivered	3.type of food
4. lot number /other ID	Lot number/other ID	4.lot number/other ID
5. quantity	Quantity	5.quantity
6.name, address, phone of transporter to you	Name, address, phone of transporter from you	6.ID of each & every transport mode used from transporter's receipt to delivery

The 'one-up' nontransporter data required by an importer of alcoholic beverages is already available for US Customs and the TTB. An importer of a shipment of a brand of, for example, blended Scotch Whisky should have only one 'one-up' list to cover (although he may have several 'one-down' lists for that shipment).

However, when applied to a foreign facility which produces, for example, that same shipment of blended Scotch Whisky, the foreign producer may have as many as 50 'one-up' lists to cover because as many different Scotch malt and grain whiskies alone may be contained in a final blended product. This serves as just one instance of the potentially endless quantity of 'lists' of data that the FDA requires foreign facilities 'beyond' its legal jurisdiction to maintain. Nonetheless, production records for alcoholic beverage producers are a sine qua non.

Storage Facilities

The proposed regulation requires a record of all information reasonably available to identify the specific source of each ingredient used in every lot of finished product.

Some ingredients may not be held in common storage.

Retention of Records

The FDA proposes that records are retained for a period of 2 years.

From the point of view of alcoholic beverage production and distilled spirits in particular, retention of records for a period of only 2 years

would be inadequate to trace a matured product right back to source. This suggests reliance should be placed upon alcoholic beverage producers' own record systems to enable traceability.

Traceability and Security 'Beyond' the US

The import of alcoholic beverages is prohibited unless the importer holds a Federal Basic Permit to import and an alcoholic beverage cannot be imported for sale in the US domestic market without first having obtained a Certification/Exemption of Label/Bottle Approval (COLA) from the TTB. Substantial information about a product imported legally into the US is therefore already held in the TTB database.

In any event, EU spirits producers hold comprehensive records that enable full traceability for all components of their products, as well as records for tracing key 'dry material' components, such as bottles, capsules etc. In addition, EU legislation requires the inclusion of lot codes on the labels for the purpose of traceability; US regulations require tamper-proof closures on spirits and wine products; and containers are security sealed.

The traceability and security of EU spirits and wine products is already provided for under EU and, in some cases, national legislation and also in standard industry practice. For example, in the UK, a licence is required to operate a distillery; the production of Scotch Whisky and other UK spirits is carried out under HM Customs & Excise control; the entire production process is subject to strict quality controls including chemical analysis and profiling to safeguard against, inter alia, contamination.

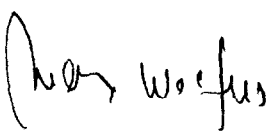
Emergency procedures are also in place in the event of a 'food safety' emergency. A Rapid Alert System is in place, which has been set up to deal with a scenario involving illness, microbiological contamination, contamination of a product by a foreign body or malicious contamination.

In the same way as the US Customs and EU Commission have reached an agreement to cooperate on security initiatives within the EU, it is believed that the US FDA should trust the EU Commission to assist quickly, efficiently and vigilantly in tracing the source of a suspect element which is discovered in the US and traced back to the EU, through the procedures that are already in place. The alternative would potentially result in two parallel but separate tracking exercises being undertaken, wasting both time and manpower.

Inconsistency of application of the 'Requirement'

As stated in the EU alcoholic beverage industry's previous submissions on the proposed Registration and Prior Notice requirements under the Act, notwithstanding that all alcoholic beverages are tightly regulated in the US under the jurisdiction of the US Department of Treasury (TTB) and the Department of Justice (ATFE), the scope of the regulations under the Bioterrorism Act apply to them. Meanwhile, meat, poultry and egg products under the jurisdiction of another agency, the US Department of Agriculture, are specifically exempt from the scope of the Act.

Another contrasting feature of the FDA legislation is that, despite the exemption of some food products that are regulated by another US agency, the FDA expects facilities 'beyond' the US border to comply with the demands of its Bioterrorism legislation.



Marion Wolfers
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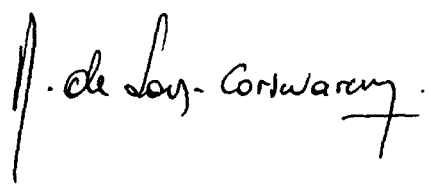
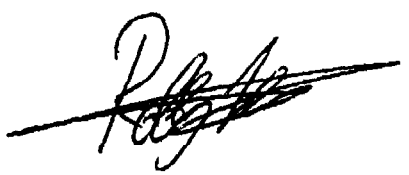


Rodolphe de Looz-Corswarem
The Brewers of Europe



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US BIOTERRORISM ACT of 2002

Docket No 02N-0275 – Administrative Detention

Discrimination and 24-hour hold for Imports

Companies are concerned that imported products are more likely to be subject to precautionary action and therefore detention.

In this connection, it is felt that the proposed provision for the temporary holding of imports for 24 hours is open to abuse. Not only is there no comparable provision for domestic products but there is 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.

Period for Administrative Detention

A reasonable period of 20 days, which could be extended to 30 calendar days, means in practical terms that all perishable foods/drinks, including those "commercially" perishable, are no longer suitable for sale.

This means that, if a 'fast-track' appeal for perishable food does not allow a 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 will be cleared and therefore finally released. This reflects a high margin of 'safety precautions'. Despite the major commercial and financial implications for food and drink companies associated with this high margin for erroneous detention, the FDA makes no provision for compensation for a food/drink product that is finally released from detention on being found safe but which has undergone alteration as a result of the period of its detention.

Detention should not result in loss of or reduction in quality of any food product or of its presentation. Given that detention would in any event incur delay, cost, reduced efficiency and customer concern/dissatisfaction, it is necessary to understand what the US authorities intend to achieve during a 30 day detention period and what determines its duration. Would, for instance, availability of FDA resources be a factor?

Definition of a perishable food

The definition of a perishable food only refers to products physical and/or biological properties may be affected by detention. It does not take into account the perishable nature of a product by virtue of the way it is marketed. For instance, "nouveau" wines are released for consumption on a specific date. If such a product is detained, it would not qualify as a perishable product according to the FDA proposed definition. Nevertheless, it would be severely affected by such detention because, if such a product is not actually available for sale at the optimum date, D-day, it loses its annual sales which are completed within a brief two-three week period.

It is therefore necessary that the FDA takes into account the specific vulnerability of such a product in order that it is not effectively prohibited access to the US market.

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, one might question 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.

The exclusion of the TTB, which has longstanding expertise in the alcoholic beverage field, from active involvement in the FDA decision making process on whether a shipment of alcoholic beverages merits detention for further investigation does not make sense. It is wasteful of informed resources and denigrates the valuable work of a fellow Federal agency that is entrusted with specific responsibilities.

It is therefore vital that, in order for FDA officers to fully understand the alcoholic beverage sector, they work alongside TTB officers and, further, that it is the TTB officers who are responsible for ordering any necessary detention of an alcoholic beverage shipment.

Definition of 'serious adverse health consequences'

FDA proposes that detention may be ordered if there is credible evidence or information that a food offers 'serious adverse health consequences'.

No apparent safeguards or parameters are set to contain the scope for detention being implemented. For example, are there any procedures in place to corroborate the evidence or information before the order is made or is it totally discretionary/subjective?

Erroneous Detention

The FDA estimates that up to 48% of the food that is administratively detained may be done so erroneously.

The costs of erroneous detention may include transport, storage, marking and labelling, loss of product, loss of product value and appeal. Such costs immediately hurt small and medium-sized companies more than large or multinational companies. The impact of the detention regulation is therefore potentially significant, underlining the necessity for the objective basis on which detention is ordered to be thoroughly well set out.

The question could be raised whether the FDA would consider compensation for costs resulting from erroneous detention, even if on a contributory percentage basis only. Such compensation could act as a restraint to consignments being detained without real demonstrable cause and because there is an appeal process.

Classified National Security Information

FDA mentions that it will not release classified information relating 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*".

How much of the information that is withheld from the party (eg importer) concerned, due to the classified nature of the information, requires to be assessed on an individual case by case basis. According to the FDA's own estimate, 48% of shipments will eventually be released; therefore bona fide parties who comply with requirements under the Bioterrorism Act should be afforded the best information possible to facilitate preparing their case for release of their shipment. Besides, more questions could be clarified if not answered sooner, failing which there is a problem.

Consolidated Shipments

It has been reported that a single container which holds consolidated small shipments of different products or origins may no longer be permitted entry into the US. If, however, this is not confirmed, there

is concern about what would happen if one part of a shipment/container is regarded as providing a threat of serious adverse health consequences or death to humans or animal while the rest is not. Consideration and clarification of the consequences in this event for the safe elements within the container are requested.

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