

LEGAL POINTS TO WATCH: New US food regulations will need careful consideration.

New US food controls create additional issues for Australian food exporters

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THE LEVEL of food safety regulation in the US has risen over recent years as its governments have sought to protect the safety of food consumed in the country.

According to the US Food & Drug Administration (FDA), about 48m people (one in six Americans) get ill, 128,000 are hospitalised and 3000 die each year from food-borne diseases.

The regulation not only applies to food produced in the US but extends to those producing food which is produced outside of the US and imported into the US. As a result, the regulations impose obligations on Australian producers and exporters of food to the US. That regulation has included the US Biosecurity Act which, among other things, requires registration of premises at which food is produced.

Background

The current level of regulation is about to increase as part of a broader suite of food safety provisions contained in the US Food Safety Modernisation Act of 2010 (Act). The Act is considered to provide the most significant increase in food safety requirements since the original passage of the Food, Drug and Cosmetic Act (FDCA) which increased the powers of the FDA with respect to food.

Scope of the Act

It is relevant that the Act applies both to food produced in the US as well as food imported into the US. In terms of imported food, the Act does not apply to food from any specific country even though there have been some substantial issues associated with food imported into the US from particular countries of origin.

Exception for certain food

The Act does not generally apply to food such as meat, poultry or egg products which are already administered by the US Department of Agriculture (USDA). Even so, those involved with those products need to monitor developments as there are anecdotal reports that the USDA is considering adopting a regime similar to that found in the Act.

Basic elements of the Act

According to the FDA website, the major elements of law can be divided into five key areas:

- Preventative controls – For the first time, FDA has a legislative mandate to require comprehensive, prevention-based controls across the food supply.

- Inspection and compliance – The legislation recognises that inspection is an important means of holding industry accountable for its responsibility to produce safe food; thus, the law specifies how often FDA should inspect food producers. FDA is committed to applying its inspection resources in a risk-based manner and adopting innovative inspection approaches.

- Imported food safety – FDA has new tools to ensure that those imported foods meet US standards and are safe for our consumers. For example, for the first time, importers must verify that their foreign suppliers have adequate preventative controls in place to ensure safety, and FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with US food safety standards.

- Response – For the first time, FDA will have mandatory recall authority for all food products. FDA expects it will only need to invoke the authority infrequently since the food industry largely honours requests for voluntary recall.

- Enhanced partnerships – The legislation recognises the importance of strengthening existing collaboration

among all food safety agencies – US federal, state, local, territorial, tribal and foreign – to achieve our public health goals. For example, it directs FDA to “improve training of state, local, territorial and tribal food safety officials”.

Impact on imported foods – who is affected?

Sections 301 to 309 of the Act are the basic provisions relating to the importation of food.

Basically, the intent appears to be to ensure that food which is produced overseas is produced in the same way and under the same regulatory regime as applies to the production of food in the US. In relation to imported food, the significant obligations are placed on the “importer” of food.

In the most part, the term is defined to be the US “owner” or “consignee” of the article of food at the time of entry into the US or if there is no US owner or consignee, the US agent or representative of a foreign owner or consignee at the time of entry into the US.

Accordingly, on one limited reading, Australian food producers may believe they are not affected as they are not shown as the owner or consignee of food at the time it is imported into the US (which would generally be the purchaser of the food from the Australian exporter or producer).

At the same time, it is possible that some Australian producers or exporters (as required by their trading

arrangements) will be shown as the importer or owner or consignee on US import documentation.

However, in a broader sense, once the obligations contained in the Act are imposed on importers in the US, then those importers will be similarly imposing those obligations on the Australian producers or exporters from whom they purchase the food to ensure that they can warrant that they have complied with obligations under the Act.

As usual, once an obligation is imposed on the final party in a supply chain, then that party will ensure that the obligations and risks are passed to all those who are also involved in the supply chain. This will mean that the obligations can be contractually imposed on Australian producers or exporters and even their freight forwarders or transport companies.

Obligations on importers

Again, according to the FDA website, new provisions under the Act relating to importers include:

- Importer accountability – Importers must verify that their foreign suppliers have adequate preventative controls in place to ensure safety.
- Third party certification – FDA will be able to accredit qualified third party auditors to certify that foreign food facilities are complying with US food safety standards.
- High risk foods – FDA now has the authority to require that high-risk

imported foods be accompanied by a credible third-party certification as a condition of admission to this country.

- Additional resources are directed towards foreign inspections – FDA now has the authority to refuse entry into the US of a food that has refused US inspection.

These provisions have the effect of “extending” the US regulation to Australian producers and exporters of food.

The aims described above raise a series of related issues including a new provision requiring every US importer to perform risk-based foreign supply verification activities to verify that the imported food has been produced in accordance with hazard analysis and preventative control requirements, produce standards and is not adulterated or misbranded. It also raises the possibility of direct inspection of Australian food production facilities by the certified third-party auditors or representatives of the FDA.

A related concept (and one which is already being adopted in Australia for our food importers) is the creation of the Voluntary Qualified Importer Program. This will establish a scheme for US importers to become “approved” importers due to the level of safety in food production and supply chain.

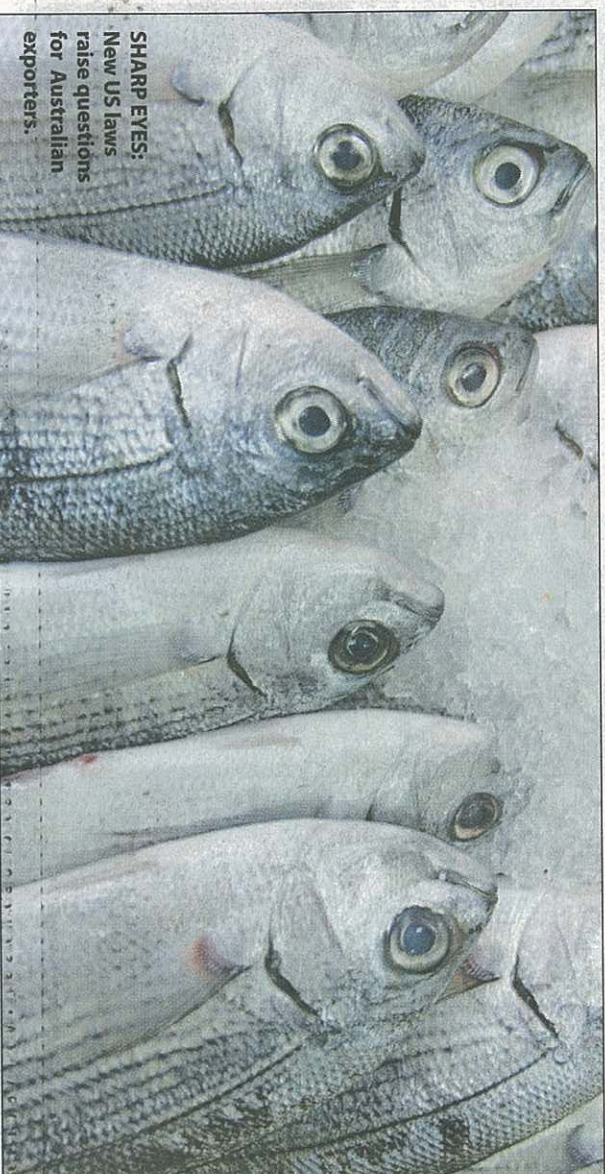
The aim is for such parties to receive more rapid passage through the import process if they have been registered in the program.

Timing of the provisions

It is important to note that the Act has passed. Its implementation is likely to take some time given that the Act requires the FDA to undertake preparation of various rules and regulations over prescribed periods to give effect to the various instructions.

However, Australian food producers and exporters involved in the sale of food into the US should be aware of the provisions both in terms of their own obligations and in terms of those obligations which will be imposed upon them by their US customers.

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SHARP EYES: New US laws raise questions for Australian exporters.