

## Summary of substantive comments to the FSA consultation on The Animal Feed (Basic Safety Standards) (England) Regulations 2018

Further details on the consultation can be found at: [www.food.gov.uk/news-alerts/consultations/the-animal-feed-basic-safety-standards-england-regulations-2018](http://www.food.gov.uk/news-alerts/consultations/the-animal-feed-basic-safety-standards-england-regulations-2018)

Respondent	Comment	Response
<b>North East Trading Standards Association Feed Technical Group</b>	The concept of proving mens rea in relation to the main offence doesn't seem to be appropriate. The group would prefer an offence that does not include the word 'intentional' but does include a due diligence defence.	<p>This is intended to reflect the requirements of the Directive - which is that Member States shall prohibit the deliberate addition of radioactive substances in the production of foodstuffs, animal feeding stuffs, etc</p> <p>We recognise that the "normal" approach to feed law offences is to create a strict liability offence coupled with a due diligence defence, but here, the reference to intention is an express feature of the EU Directive. To take a different approach could be considered gold plating.</p>

<p><b>The Government Chemist</b></p>	<p>Agreed the likelihood of such addition is negligible compared with the risk from nuclear accidents such as Chernobyl and Fukushima, control of which is available by alternative food and feed law.</p> <p>However, having consulted colleagues in the International Atomic Energy Agency and the Association of Public Analysts, there are several issues that need to be considered:</p> <p>1. Potassium-40, 40K. 40K is a significant source of natural radioactivity in animals including humans, however levels are naturally maintained in equilibrium by excretion hence naturally occurring levels in feed should not trigger the provisions of the proposed regulations but should be borne in mind by enforcement authorities on foot of any sampling and analysis.</p> <p>2. Use of Security Devices There is a need to consider exemptions for inspection and security devices at ports of entry etc. especially those that rely on nuclear activation. Applied to feed this would give rise to very short-lived radionuclides. Such devices are exempted, subject to maximum applied doses, by Regulation 2 of the Food Irradiation (England) Regulations 2009.</p> <p>3. Fishmeal Fish tend to contain elevated levels of polonium; hence care is needed to avoid the application of the regulations preventing the use of fishmeal in feed which might be construed as intentionally adding polonium-210 which is naturally occurring.</p>	<p>The definition of “radioactive substance” is provided in the draft Regulations as:</p> <p>“radioactive substance” means any substance that contains one or more radionuclides the activity or activity concentration of which cannot be disregarded from a radiation protection point of view.</p> <p>Substances containing naturally occurring radionuclides (such as potassium-40 and polonium-210) would not be considered as being radioactive substances which cannot be disregarded from a radiation protection point of view unless the activity levels had been deliberately enhanced (e.g. by removing the non-radioactive materials in order to concentrate the radioactive content). The same would apply to trace levels of radionuclides which are incidentally present in feed materials as the result of regulated discharges or historic human activity. This principle is established and consistent with other legislation regarding radiological protection.</p> <p>With regard to the use of security devices, the process described does not constitute the addition of a radioactive substance. The product is exposed to radiation which leads to the generation of short lived radionuclides but at no point is a radioactive substance added. This practice would therefore not be prohibited by these regulations as no radioactive substance is</p>
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	<p>My recommendation is that the above exceptions are dealt with by way of guidance to the proposed regulations rather than incorporated in the regulations themselves.</p>	<p>deliberately added. It should also be noted that due to the short-lived nature of the radionuclides generated, there is no safety risk.</p>
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<p><b>London/ALEHM</b></p>	<p>Q1</p> <p>The need for the new legislation is outside the scope of my expertise, however it does seem odd that food has been deemed to be protected by ‘rendering injurious to health’ where as the Regulation 767 article 4.1 feed to be ‘safe’, or 4.2 requirement for feed to ‘sound, genuine, unadulterated, fit for its purpose and of merchantable quality is not sufficient. We believe the current legislation provides adequate legal protection and this interpretation would minimise the impact of these controls on local authorities.</p>	<p>The decision that the obligation in Regulation (EC) No 767/2009 was insufficient in this context was, effectively, that of the EU as it has chosen to bolster the protection by means of the Directive.</p> <p>In the case of food there is national legislation in the Food Safety Act. It is our opinion that sections in the Food Safety Act 1990 have the ability to cover aspects of article 21 of the BSSD for food. In particular in section 7 the words “injurious to health” and in section 14 “quality demanded”.</p> <p>It is our opinion that present national feed legislation in the form of section 72 in the Agriculture Act 1970 does not cover adding radioactivity to food due to the wording “suitable”. This is due to a range of substances being added to animal feed in the form of minerals.</p>
	<p>Q2</p> <p>Authorisation</p> <p>The Regulations are made under both the Agriculture Act 1970 and the EC Act 1972.</p> <p>It is not clear to me whether an officer/inspector requires additional authorisation to enforce this regulation. There is no definition or reference to an ‘authorised officer’ in the Regulation.</p> <p>I think that being Authorised under the Agriculture Act will be sufficient but am not sure. Can this be clarified?</p> <p>Offences</p> <p>The wording of the proposed offences seem reasonable although guidance will be necessary on ‘radioactive</p>	<p>The empowerment of the Authorised Officer is achieved by way of regulation 7.</p> <p>The definition is taken from the Directive. To take a different approach could be considered gold plating. Substances containing naturally occurring radionuclides would not be considered as being radioactive substances which cannot be disregarded from a radiation protection point of view unless the activity levels had been deliberately enhanced (e.g. by removing the non-</p>

	<p>substance which cannot be disregarded'. The definition of 'radioactive substances' is very vague. Guidance will need to be available for both enforcers and the trade to clearly demonstrate what levels are deemed acceptable to deal with background radiation issues.</p> <p>The penalty in the Agriculture Act (level 5 at first summary conviction) does not match those under the Animal Feed (Composition etc) Regulations for similar offences (summary includes potential 3 months for a first conviction). Given the potential seriousness of a feed being contaminated with a radioactive substance this seems odd that the penalty does not match or surpass those which would apply to feed containing undesirable substances (Dir 2002 32). Feed hygiene offences have higher penalties than either.</p> <p>The inclusion of these regulations in the list of specified feed law enables officers to use existing powers of entry and inspection from the Animal Feed (Hygiene etc.) Regulations to be used which includes sampling. The wording assumes that all officers intending to enforce the Animal Feed (Basic Safety Standards) Regulations will already be authorised under both the Animal Feed (Hygiene etc) and Animal Feed (Composition etc) Regulations.</p> <p>However guidance will need to be issued on how sampling will be required to be carried out in order to be admissible and what methods of testing/analysis will be needed to prove any offences.</p> <p>The current wording would permit officers also authorised under the Animal Feed (Hygiene etc.) Regulations to use the</p>	<p>radioactive materials in order to concentrate the radioactive content). The same would apply to trace levels of radionuclides which are incidentally present in feed materials as the result of regulated discharges or historic human activity. This principle is established and consistent with other legislation regarding radiological protection.</p> <p>This Regulation adopts a different approach to that used for the regulation on Animal Feed (Composition and Hygiene). The enforcement provisions are via section 74A of the Agriculture Act which provides:</p> <p>"Any person who contravenes any prohibition or restriction imposed by regulations under subsection (1) above, or fails to comply with any other provision of the regulations, shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale or to imprisonment for a term not exceeding three months, or to both."</p> <p>Therefore, the sanction could be either a fine or imprisonment or both. Note that there is legal impediment under Section 2.2 of the European Communities Act which means that the sanction cannot be more severe. In addition, we are not aware of any evidence that the feed industry currently adds radioactive material to feed and we do not anticipate prosecutions under this legislation.</p>
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	<p>seizure and detention powers of that legislation to deal with non-compliant product.</p> <p>The same would apply to the use of Improvement Notices/ Emergency Prohibition Notices.</p> <p>This adds complexity, but we believe it is unlikely that anyone enforcing these regulations will not also be authorised under other feed law.</p> <p>The amendment of the OFFC Regs 'Relevant Feed law' to include this legislation would not appear to impact on direct enforcement, as it seems to bring the (Basic Safety Standards) Regulations within the scope of FSA monitoring and control/audit of local enforcing bodies.</p>	<p>Please also note that in line with broader Government policy, the FSA has made a commitment to reduce reliance on criminal sanctions in the future, this includes introducing additional civil sanctions for the offences in this the legislation. We will be consulting on introducing new civil sanctions to existing regulations in due course.</p> <p>Noted – we do not consider there is a need to be specifically authorised under the Animal Feed (Composition etc.) Regulations 2015 as these regulations contain no powers.</p> <p>Noted – we believe that routine testing would be disproportionate. Testing would only be appropriate if there was evidence to show deliberate contamination was being undertaken.</p>
	<p>Q3</p> <p>Could these matters could be dealt with by introducing an amendment to existing legislation, for example within The Animal Feed (Composition, etc ) Regulations? These already deal with similar contamination issues for the Undesirable Substances Directive 2002 32.</p> <p>This would minimise the impact on Local Authorities as authorisations would not need to be reissued. All existing enforcement powers and provisions would be usable without question and no new separate legislation would be required.</p>	<p>Our view is that the aims and objectives of this Directive sit outside the mainstream of animal feed law. In addition, a standalone SI on this issue had the advantage of simplicity.</p> <p>Our view is that costs of familiarisation/training would be minimal given the phrasing of the offences being similar to offences LAs are already familiar with enforcing and investigating when breached. In terms of updating the procedures, as required by the Code of Practice, the work has been considered within the Feed Code and Practice Guidance review.</p>

	<p>In any case there will be some cost of implementation for the following:</p> <ul style="list-style-type: none"> <li>• Initial Training and maintenance of CPD (while small, it still impacts on enforcement teams)</li> <li>• Updating of procedures to ensure the legislation is incorporated into relevant policies and procedures as required by the Code of Practice</li> <li>• Potential additional monitoring at points of entry</li> <li>• There will be administrative costs if new authorisation is required as all officers enforcing the new regulations will need to have their documentation updated.</li> <li>• Are Authorities expected to test material for radioactivity? Will this require formal samples or will it simply be a test of evidence, as with unsafe? Local authorities are not currently equipped for this purpose. Guidance would be helpful.</li> </ul> <p>In order to use the full range of enforcement options it appears that officers will need to be Authorised under both sets of the 'Animal Feed' Regulations as well as these regulations. This may restrict the range of officers who are able to respond to issues should they arise.</p>	<p>In respect of additional monitoring at points of entry, our view is that there is no evidence to suggest that deliberate contamination of radioactive substances to animal feed is occurring and therefore any additional monitoring would be disproportionate to the risk. In addition, as there are natural levels of radioactivity in the environment that could be detected in most things if tested.</p> <p>The amendment makes it an offence to deliberately add radioactive materials to feed. So, if in the course of due diligence checks there is reason to suspect that radioactive materials are being deliberately added then testing may be appropriate and advice should be sought from an accredited laboratory. The FSA therefore does not envisage any sudden shift in additional work as monitoring is funded by the FSA in England through the feed delivery programme. There would simply, if felt appropriate, be a re-prioritisation of the current monitoring i.e. LAs would stop monitoring something else of a lesser priority.</p> <p>Our view is that LA authorisations would not need to be re-issued as the powers to enforce these new Regulations stem from the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 given the amendments proposed to Schedule 1 which will include the addition of the Animal Feed (Basic</p>
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		<p>Safety Standards) (England) Regulations 2018. LAs should already have the Animal Feed (Hygiene, Sampling etc. and Enforcement) (England) Regulations 2015 listed on their authorisations as advised in the current Feed Law Practice Guidance otherwise they are not currently authorised to use their powers to enforce the current list of legislation in schedule 1 'specified feed law'.</p>
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