

26 February 2016

Dear Interested Parties

A Consultation Exercise by the Food Standards Agency and Food Standards Scotland on the Adulteration of Food - Setting Thresholds for Action and for Reporting

The Food Standards Agency (FSA) and Food Standards Scotland (FSS) are launching a joint consultation exercise across the UK to seek views on our proposed approach to dealing with incidents involving adulterated food.

BACKGROUND

This issue has its origins in the 2013 horsemeat incident, when the FSA set a threshold of 1% on a weight for weight basis of horsemeat in beef as a pragmatic and interim means of distinguishing adventitious contamination from gross adulteration.

The FSA subsequently gathered evidence, in terms of (i) what was technically achievable in terms of good manufacturing practice, (ii) what could be robustly measured analytically, and (iii) what was acceptable to the majority of consumers, to allow us to assess whether we should move from that position. These principles have subsequently been applied together with robust scientific risk assessment when dealing with other instances of food adulteration, such as recent concerns over nut proteins in cumin and paprika. In these cases we have worked closely with industry to rapidly share information to inform risk assessments and establish clear thresholds for reporting and action. This has led to a better understanding of: incident protocols, testing methodologies and capabilities and traceability within supply chains.

The FSA and FSS have agreed to support delivery of the right of consumers to be protected from unacceptable risks, we should develop and implement a

principles-based approach to thresholds for action and reporting of instances of adulteration¹ of food that takes into account:

- our assessment of the risks associated with that adulteration, including but not limited to chemical and microbiological risks and the risk of allergy, as well as potential or actual economic and social risk factors;
- any available evidence on the acceptability of that adulteration to consumers, including but not limited to grounds of religious observance and ethical considerations (but excluding those safety risks that the consumer reasonably relies on the FSA and FSS to appraise and deal with appropriately);
- the availability of 'fit for purpose' analytical methods to detect reliably and quantify that adulteration, their sensitivity and robustness; and
- the anticipated maximum level of any adventitious contamination with that adulterant (unintentional or coincidental, as opposed to fraudulent or negligent adulteration) that would be consistent with good agricultural or manufacturing practice.

Our proposals for this principles-based approach are outlined in the attached paper. Please refer to the consultation webpage for information on how to make a submission. Thank you for taking the time to contribute your views.



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¹ In a limited number of specific areas, limits or thresholds for adulterants are set in law. This principles-based approach would be applied in areas where there were no pre-existing statutory limits or thresholds.

A proposed approach to the Setting Thresholds for Action and for Reporting the Adulteration of Food

DEFINITIONS AND SCOPE

Adulteration for these purposes is defined as changing the nature, quality or substance of a food by the addition or substitution of undeclared inferior or extraneous substances, whether intentionally or through negligence.

In each such case we would identify:

- a threshold for action, above which food businesses must conduct an investigation aimed at reducing the level of adulteration below the threshold, and;
- a threshold for reporting; above which we would consider the level of adulteration to be always unacceptable and would expect the food business operator to report the issue to the enforcement authority and the FSA or FSS as appropriate and conduct a withdrawal or recall.

General food law applicable in the UK (for example the provisions of the General Food Regulations 2004, Regulation, (EC) 178/2002 and the Food Safety Act 1990) places responsibilities on food businesses to immediately withdraw or recall from the market food or animal feed that is unsafe, i.e. injurious to health or unfit for human consumption, and to notify the competent authorities. In Scotland the duty to notify FSS extends additionally where a food business operator is or has been, in charge of any food that contravenes the food information law Regulation (EU) No 1169/2011. Food law also makes it an offence to sell any food which is not of the nature or substance or quality demanded by the purchaser. We know many businesses have in place appropriate safeguards to secure their supply chains, including testing where appropriate, but the expectation is that all businesses can do so. Although food businesses are not obliged under (EC) 178/2002 to notify the competent authority of instances of adulterated food or feed where food safety requirements are not breached, we still expect them to inform either FSA or FSS without delay where such instances are identified, notwithstanding the specific legal obligation in Scotland for food businesses to notify FSS of contraventions of food information law.

In setting any thresholds for reporting and action, we recognise that even traces of an adulterant may lead to food safety risks for allergic consumers or be unacceptable for some consumers on religious observance or moral grounds. We also recognise that the current guidance to local authorities in the Food Law Code of Practice requires officers to consider action, where appropriate, against food business operators who, for example, sell mis-

described Halal foods, in the same way as they would for any contravention of food law in food premises generally. However, we would make it clear that assessment against food safety and statutory food standards criteria are our primary consideration. Enforcement of other non-food related commercial activity, ethical or faith-based standards where these criteria are not present is for the relevant certification bodies and would not ordinarily be a matter for direct intervention by the competent central authorities where there is no contravention of food law. Our intention is to work with certification bodies in these instances to assist them with their implementation of standards.

Setting thresholds levels for reporting and action will be dependent on the availability of reliable and validated analytical methods for the particular sample matrix under investigation, which have suitable performance characteristics as defined in EU Regulation 882/2004 (accuracy, applicability, Level of Detection, precision, recovery, sensitivity, selectivity, and linearity). Ideally laboratories implementing these methods should be accredited to ISO 17025, the standard laboratories should hold to be deemed technically competent.

Both the FSA and FSS are clear that it is the responsibility of people producing and supplying food to ensure that it is safe and what it says it is. We also recognise that the vast majority of businesses readily accept that responsibility. This means that businesses secure their supply chains, employ appropriate analysis and other methods to ensure the authenticity of the foods they use in production or that they supply to others.

A PRINCIPLES-BASED APPROACH

Our overriding principle remains putting the consumer first. The setting of thresholds will therefore aim above all to safeguard consumer interests, while having due regard to the balance of risks, costs and benefits to consumers and to other stakeholders. When faced with an incident of adulterated food we will consider the evidence relating to four factors which will inform a judgement on what an 'acceptable' level might be:

- our assessment of any food safety risks relating to the adulterant;
- what level(s) can be verified reliably in the affected foodstuff by appropriately accredited labs using available test methods or other means;
- what level(s) and types of cross-contamination might be expected where good practice and due diligence in different contexts has taken place; and
- what level(s) and types of cross-contamination are likely to be acceptable to different consumers in different contexts.

The extent to which evidence is available to address these questions will vary from case to case. Where significant gaps exist we will make a judgement on what level of further evidence-gathering and analysis is merited. In doing this we will consider the expected importance of new evidence in the overall decision, and also the evidence on the scale and nature of the potential risk (or other detriment) to consumers and the importance of the issue relative to other priorities. However, the scale and extent (and the cost and timescale) of the work carried out on these issues in relation to horse in beef is unlikely to be feasible or proportionate for the majority of adulteration incidents.

Based on our assessment of the four factors above, we will set and publicise an action level for each adulteration incident, above which an investigation of the source of adulteration must be conducted by food businesses with the aim of reducing the level of adulteration below that action level.

We will also set and publicise a reporting level (which is above the action level) for each adulteration event, above which we consider the level of adulteration to be always unacceptable. We will expect each instance of adulteration above this level to be reported without delay to the relevant enforcement authority (usually the local authority for the food business) and to the FSA and/or FSS as appropriate.

Where we are notified of an adulteration incident that has an actual or potential impact on food safety or statutory food standards criteria, we will expect the relevant enforcement authority to consider whether enforcement action is proportionate, regardless of the level of adulteration, and in each case weighing, amongst other things:

- the degree of risk to public health and consumers' other interests;
- the attitude and competence of the food business operator;
- any history of other incidents or breaches including previous enforcement action;
- the application of better regulation principles.

When we are notified of an adulteration incident and determine that it has an actual or potential impact on a non-statutory food or feed standard (such as those that are ethically or faith-based) we will share relevant information with certification bodies so that they may discharge their primary responsibilities for the assurance of products which carry their certification mark. This notification process will take place regardless of whether or not statutory or safety standards have also been breached. However, where the incident has an impact only on a non-statutory food or feed standard, the competent authority would not ordinarily have a role in setting and enforcing thresholds.

Where a food or animal feed contains a level of adulterant above the reporting level, and has subsequently been used as an ingredient in a composite food, we will set action and reporting levels for those composite foods based on the same factors.