ADULTERATION OF FOOD – THRESHOLDS FOR ACTION AND FOR REPORTING

Report by Steve Wearne, Director of Policy

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1 SUMMARY

1.1 This paper seeks to develop an approach to how we work with food businesses and enforcement agencies in response to food adulteration incidents, and in particular how we identify thresholds for action. This will be the first discussion of this issue by the FSA Board following publication of our strategy to 2020, and our intention is to then consult on implementation of the approach that the Board agrees.

1.2 The Board is asked to:

- Agree: that, to support the right of consumers to be protected from unacceptable risks, we should develop and implement a principles-based approach to thresholds for action of future instances of adulteration 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;
  - any available evidence on the acceptability of that adulteration to consumers, including but not limited to grounds of religious observance;
  - 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 that would be consistent with good agricultural or manufacturing practice.

- Agree: that in each such case we should identify:
  - a threshold for action; and
  - a threshold for reporting.

2 INTRODUCTION

2.1 This issue has its origins in the horsemeat incident, when we 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.

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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.
2.2 We 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. Based on that evidence, we recommended to the Board in January 2014 that our advice to the food industry and local authority enforcement officers should be based on the following principles:

- testing to determine the absence of carryover where good practice has been followed, whether such tests are part of industry own checks or part of official controls, should use a threshold of 0.1% undeclared meat species in comminuted meat on a weight for weight basis (w/w);
- where official control samples show a content of undeclared meat species in comminuted meat that is equivalent to between 0.1% and 1% w/w, enforcement officers should investigate the causes of this carryover and should ensure that corrective action is taken by the food producer; and
- where any test, whether conducted as part of industry own checks or as part of official controls, shows a content of undeclared meat species in comminuted meat that is equivalent to 1% or above w/w (once measurement uncertainty has been taken into account), the established procedure for reporting those findings to the Food Standards Agency, publishing details of the findings, and instigating a product recall should continue to be followed.

2.3 Having discussed, the Board provisionally accepted the recommendation and asked the executive to consider further the handling of those samples that show a content of an undeclared meat species of between 0.1% and 1%, clarifying what enforcement action would be expected in those circumstances and what communication would be made by whom to consumers.

2.4 Subsequent discussions lead us to conclude that the enforcement guidance on horsemeat in beef, as set out in the January 2014 paper, holds good. The 2014 guidance does not support a lack of enforcement action at levels below 1% horsemeat in beef. It identifies findings between 0.1% and 1% as a trigger for further investigation, which could lead to formal enforcement action if those further investigations do not provide assurance that appropriate controls are in place.

3 STRATEGIC AIMS

3.1 The strategic outcomes the Board has endorsed for the period to 2020 include:

- food is safe;
- food is what it says it is; and
- consumers can make informed choices about what to eat.

3.2 Our work with industry and enforcement partners to counter food adulteration contributes to all three of these outcomes. We recognise that communication-
based tools, such as providing greater transparency on business standards, can incentivise rapid and more comprehensive improvement than traditional legislative and enforcement approaches.

3.3 In setting any thresholds for reporting and action, we will 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.

4 EVIDENCE

4.1 In order to implement a principles-based approach, as discussed in this paper, we would need to consider the evidence relating to the three factors which would inform a judgement on what an ‘acceptable’ level of cross-contamination might be:

- what level(s) and types of cross-contamination are achievable by good practice and compatible with due diligence in different contexts;
- what level(s) can be verified reliably by available test methods or by other means; and
- what level(s) and types of cross-contamination are likely to be acceptable to different consumers in different contexts.

4.2 The extent to which evidence is available to address these questions will vary from case to case. Where significant gaps exist we would need to take a judgement on what level of further evidence-gathering and analysis is merited. In doing this we would need to 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. 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.

5 DISCUSSION

5.1 Since the previous Board discussion, risks such as adulteration of herbs and spices have come to the fore, although undeclared substitution of meat species remains a focus for targeted surveillance – see for example our report earlier this year on undeclared meat substitution and allergens in lamb-based takeaway meals.2

5.2 We have considered two alternative approaches to setting thresholds for reporting and action. We could extend the approach we took to horsemeat in comminuted beef products, setting thresholds for reporting and action of specified adulterants in specific foods. Alternatively, we could take a principles-based approach, setting out how for any future adulteration incident we would reach and then implement thresholds for action and reporting.

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5.3 Given the range of food products and commodities that may be at risk of adulteration, and the dynamic nature of our assessments of the threats of adulteration, we recommend the latter approach.

5.4 Our overriding principle remains putting the consumer first. The setting of thresholds will therefore aim above all to safeguard consumer interests, while having due regards to the balance of risks, costs and benefits to consumers and to other stakeholders. In considering appropriate thresholds, we will consider:

- our assessment of any food safety risks relating to the adulterant;
- the acceptability of the presence of the adulterant to consumers;
- the availability of analytical methods to reliably and robustly identify and quantify the adulterant;
- our expectation of the levels of adulterant that would be consistent with good agricultural practice and/or good manufacturing practice.

5.5 The assessment of possible risks to consumer health will address known and potential hazards associated with the adulterant and its components. This will include consideration of microbiological agents (e.g. pathogens and other microorganisms with characteristics of concern), and chemicals (e.g. present as residues of plant protection products, biocides or veterinary medicines, natural and environmental contaminants, and natural constituents of the adulterant). The allergenic properties of any adulterants will be evaluated. In some instances it might also be appropriate to consider prions or radiological hazards. The aim will be to quantify risks insofar as possible, taking into account the amount of the food that is likely to be consumed in order to assess exposure, the possible impact of food processing (such as cooking), handling and storage, and the quantity and distribution of the affected foodstuff, where appropriate. It is anticipated that initially few quantitative data will be available, and that the risk assessment will be refined as information emerges.

5.6 Understanding consumer acceptability of food adulteration is essential alongside the assessment of risk. Consumer acceptability may be contingent on religious, moral, ethical and other grounds and without consideration of these views, the application of a risk assessment may be undermined.

5.7 We would set an action level for each adulteration incident, above which an investigation of the source of adulteration would be conducted by the food business with the aim of reducing the level of adulteration below that action level.

5.8 We would set a reporting level for each adulteration event, above which we would consider the level of adulteration to be always unacceptable. We would expect each instance of adulteration above this level to be reported to the relevant enforcement authority (usually the local authority for the food business) and to the FSA as central competent authority. The FSA would
routinely publish this information and we would expect the food business to recall the food or commodity from its customers.

5.9 Where a food or commodity 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.

5.10 We would 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 on incidents or breaches including previous enforcement action.

6 IMPACT

6.1 Impacts on stakeholders, including food businesses, will be determined by how any principles agreed by the Board are applied on a case by case basis. We anticipate that the consultation exercise planned to follow the Board discussion will provide further information.

6.2 As set out in section 5.4 above, the thresholds set in any given case will aim to safeguard consumer interests, while having due regards to the balance of risks, costs and benefits to consumers, the food industry, the FSA itself and to other stakeholders. Any compliance costs for the food industry will contribute to government calculations of the “regulatory burden” associated with the FSA’s activities in consumer protection.

7 CONSULTATION

7.1 This is a pre-consultation discussion by the Board. Once the Board has agreed its preferred general approach, we will consult and engage with stakeholders on its further specification and implementation.

7.2 In parallel, we will seek advice from the Government’s Analytical Methods Working Group and the FSA’s scientific advisory committees.

8 LEGAL/RESOURCE/RISK/SUSTAINABILITY IMPLICATIONS

Legal considerations

8.1 The proposals in this paper exclude the areas where EU law already sets threshold levels for intervention. This relates to levels set in EU law that are intended to trigger further investigation, such as for dioxins in animal feed. It also relates to maximum permitted levels for contaminants and so on, where the risk assessment has in effect been done at EU level and marketing food containing substances in excess of those levels constitutes placing unsafe
food on the market, with consequent exposure to sanction for the food business operator responsible.

8.2 Article 14 of General Food Law (Regulation 178/2002) leaves space for judgements to be made by competent authorities in determining whether a particular food is unsafe. Paragraph 8 of that article gives competent authorities the discretion to take action on food which, despite conforming to specific relevant rules, is nonetheless considered to be unsafe. When considering whether a food is not of the nature, substance or quality demanded, there is again intentional scope for the relevant authorities, and ultimately the courts, to make judgements based on the particular facts of the case as to whether or not a line has been crossed.

In setting and applying principles as proposed in this paper, there are two risks to be considered. The first is the general principle in administrative law that a public authority should not “fetter its discretion” – in other words it should not take a decision or adopt a policy that artificially limits its range of reasonable responses to a future contingency. The proposals manage that risk by not setting thresholds as such, but instead facilitating the setting of thresholds through the application of agreed principles to different scenarios as they emerge.

8.3 The second risk to be considered is the relationship between EU law and domestic implementation, and the objective of avoiding gold plating on one hand, and under-implementation on the other. The proposed approach is a safeguard against gold plating, in that it seeks in a considered way to move away from zero tolerance in all circumstances towards an approach where the enforcement response is graduated in proportion to risk, and risk is in turn evaluated by a number of factors that include social as well as health-related considerations.

Other implications

8.4 These will be considered further in the light of consultation responses.

9 DEVOLUTION IMPLICATIONS

9.1 The recommendations from the executive relate to England, Wales and Northern Ireland.

10 CONCLUSION AND RECOMMENDATIONS

10.1 The Board is asked to:

- **Agree** that, 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 future instances of adulteration of food\textsuperscript{3} that takes into account:
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  \item our assessment of the risks associated with that adulteration, including but not limited to chemical and microbiological risks and the risk of allergy;
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  \item the availability of ‘fit for purpose’ analytical methods to detect reliably and quantify that adulteration, their sensitivity and robustness; and
  \item the anticipated maximum level of any adventitious contamination with that adulterant that would be consistent with good agricultural or manufacturing practice.
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