

ADVISORY COMMITTEE ON THE MICROBIOLOGICAL SAFETY OF FOOD
DISCUSSION PAPER
THE MICROBIOLOGICAL SAFETY OF SPROUTED SEEDS

Purpose

1. The purpose of this paper is to draw the Committee's attention to a number of recent developments in relation to the microbiological safety of sprouted seeds.
2. The Committee are asked to note the actions taken following the Shiga toxin-producing *Escherichia coli* (STEC) O104 outbreaks and to comment on the risks associated with the production of sprouted seeds. In particular:
 - to advise whether, in light of the actions taken, there remains a residual risk of outbreaks of illness associated with consumption of sprouted seeds and, if so, to comment on the magnitude of this risk.
 - to advise whether some groups of consumers may be particularly vulnerable to the risk of illness from sprouted seeds.

Introduction

3. In recent years, consumption of sprouted seeds has been associated with significant outbreaks of foodborne infection in the UK and other EU member states.
 - In 2010, there was a large outbreak of foodborne *Salmonella* Bareilly infection across the UK, with a total of 241 outbreak cases including one death.¹ Epidemiological and microbiological investigations implicated bean sprouts as a vehicle for transmission and it was concluded that the seeds were likely to have been contaminated at source prior to importation.
 - In May 2011 in Germany, a major outbreak of Shiga toxin-producing *Escherichia coli* (STEC) occurred involving over 3,000 cases and over 40 deaths. A second, much smaller, outbreak caused by the same O104 strain occurred in France in June 2011. Based on the results of a trace-back exercise fenugreek seeds from Egypt were considered the probable initial source of both the outbreaks.²

¹ http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1315372088636

² <http://www.efsa.europa.eu/en/supporting/doc/176e.pdf>

Advice to producers, caterers and consumers

4. Public health interventions resulting from the investigation of the S. Bareilly outbreak focused mainly on communications to consumers and to food business operators and environmental health professionals, advising on the correct preparation of bean sprouts and on improving information on food labels where this was ambiguous.^{3 4}
5. Following the German and French outbreaks, interim advice for seed and sprouted seed producers and enforcement officials was issued by FSA on the Agency's website⁵. This provided information in relation to the outbreaks and outlined current controls and best practice for producers. Current Agency advice to consumers and caterers is that sprouted seeds can be eaten raw if they are labeled 'ready to eat' or 'ready to wash'. All other sprouted seeds should be cooked thoroughly until steaming hot throughout.
6. Advice to consumers on sprouting seeds at home is to follow the manufacturer's instructions. Equipment that has been used for sprouting seeds should be cleaned thoroughly using hot soapy water before and after use. People should always wash their hands before and after handling seeds intended for planting or sprouting as well as when preparing food.
7. Advice to consumers in Germany is similar but the German Federal Institute for Risk Assessment (BfR) advises that those with a weak immune system should only eat sprouted seeds which have been cooked.⁶

Local Authority Enforcement

8. Local authorities, who have enforcement responsibility for seed sprouters, importers and traders within the UK have been advised to ensure that these establishments have good controls throughout the growing cycle. This should include seed, equipment, water, packaging materials and staff hygiene and training and therefore implement appropriate GAP, GMP, GHP⁷ and robust HACCP-based controls, including setting an appropriate shelf-life for the product, with particular emphasis on:

³ <http://www.food.gov.uk/multimedia/pdfs/publication/annualreportofincidents2010.pdf>

⁴ <http://www.food.gov.uk/news/newsarchive/2010/sep/sprouts2>

⁵ <http://www.food.gov.uk/foodindustry/guidancenotes/hygguid/sproutingseedproducers/>

⁶

http://www.bfr.bund.de/en/press_information/2011/41/ehec_outbreak_2011__recommendations_on_the_handling_of_sprouts-127982.html

⁷ Good Agricultural Practice (GAP), Good Manufacturing Practice (GMP), Good Hygienic Practice (GHP),

- Ensuring that producers demonstrate they have permanent procedures based on HACCP principles in place and that those procedures are fully effective through appropriate verification checks, such as microbiological testing.
 - Where the legal requirements are breached, the appropriate enforcement options available should be applied, following the hierarchy of enforcement.
9. The primary growers of the seeds who supply the sprouters, importers and traders generally exist outside of the UK and are not under the control of the local authority regulators. The Agency, in discussion with the industry, has highlighted the need for the sourcing of seeds to be carefully controlled, with full traceability, and the industry itself should apply pressure on primary producers outside of the UK to meet the necessary standards.

EFSA opinion

10. A European Food Safety Authority (EFSA) scientific opinion on the public health risk of STEC and other pathogenic bacteria that may contaminate seeds and sprouted seeds was published on 15 November 2011⁸. The EFSA scientific opinion concludes that ready to eat sprouted seeds are a microbiological food safety concern due to the potential for contamination with pathogenic organisms, subsequent growth of the organisms and consumption of the product raw or minimally cooked. A number of risk factors along the whole production chain are identified including risks to the effective identification and management of outbreaks. Potential risk mitigation options offered focus on application of HACCP principles, GAP, GMP, and GHP along relevant stages of the production chain. Potential seed decontamination treatments are also considered.
11. The opinion gives consideration to the establishment of additional microbiological criteria for seeds and sprouted seeds. It notes that microbiological criteria, including the design of sampling plans for pathogenic bacteria, should be considered as one of the components of food safety management systems for the sprouted seed production chain. Data collection and quantitative risk assessment are needed before it is possible to evaluate the extent of public health protection provided by specific microcriteria for seeds and sprouted seeds. Annex 1 details the terms of reference of the EFSA opinion and summarises key conclusions.

European Commission

12. A European Commission meeting of Chief Veterinary Officers, Chief Medical Officers and food authorities was held on 18th November 2011 to discuss lessons learnt from the *E. coli* outbreaks. In addition to proposals for improving responses to outbreaks in general, the Commission proposed a number of potential control options for sprouted seed production based on the EFSA recommendations. The proposals appear to build on existing work in progress rather than additional legislation, with the EFSA risk assessment being used to underpin measures. The Commission has prepared a discussion paper on which

⁸ <http://www.efsa.europa.eu/en/efsajournal/pub/2424.htm>

it will be seeking Member States' views over the coming months. An initial discussion of the proposals was held at the Commission Hygiene Working Group on 5th December 2011 and written comments were invited. The UK is broadly supportive of the proposed measures and, informed by ACMSF advice, will follow this work closely to ensure that they are sufficiently strong to protect consumers. Further discussions will take place at the Standing Committee on the Food Chain and Animal Health (SCOFCAH) on 18th January 2012.

Industry guidance

13. The Fresh Produce Consortium has established a small working group of stakeholders, including importers, sprouters and retailers, to take forward development of guidance on the hygienic sourcing, production and safe handling of sprouted seeds. The guidance will be an industry owned/branded document but the FSA is participating in the working group and assisting or advising where required. The group have met three times to date and are taking the EFSA scientific opinion into consideration.

ACMSF action:

14. The Committee are asked to note the actions taken following the STEC O104 outbreaks and to comment on the risks associated with the production of sprouted seeds. In particular:

- to advise whether, in light of the actions taken, there remains a residual risk of outbreaks of illness associated with consumption of sprouted seeds and, if so, to comment on the magnitude of this risk.
- to advise whether some groups of consumers may be particularly vulnerable to the risk of illness from sprouted seeds.

15. Members may also wish to note that a paper on internalisation of pathogens in fresh produce is planned to be presented at the May 2012 meeting.

Secretariat

January 2012

Annex 1

EFSA Scientific Opinion

Following the Shiga-toxin producing *E. coli* (STEC) outbreaks in Germany and France in May and June 2011 the Commission asked EFSA to issue a scientific opinion on the public health risk of STEC and other pathogenic bacteria that may contaminate seeds and sprouted seeds. The Commission requested that the opinion:

- 1) Assess the public health risk from STEC and other bacteria that may contaminate seeds and sprouted seeds for direct human consumption.
- 2) Identify risk factors contributing to contamination of these products with STEC and other pathogenic bacteria.
- 3) Recommend possible risk mitigation options across all parts of the seed and sprouted seed food chain and assess their effectiveness to reduce risks from STEC and other pathogenic bacteria.
- 4) Recommend, if appropriate, microbiological criteria for seeds and sprouted seeds and other materials used throughout their production chain.

The opinion was issued on 15 November 2011. The main conclusions are summarised below.

Assessment of public health risks

- Ready-to-eat sprouted seeds are a microbiological food safety concern given the potential for pathogenic bacteria to contaminate seeds and grow during germination and sprouting coupled with the fact that the product is eaten raw or minimally processed.
- The risk of contamination and growth of pathogens may vary with different types of seeds (i.e. sprouts, shoots, cress), most data is available on the risks from sprouts, there is little data on cress and shoots.
- Alfalfa and mung bean sprouts are most commonly consumed and have been implicated most frequently in outbreaks. *Salmonella* and *E. coli* are the most commonly reported pathogens. Very low levels of contamination can cause sprout-associated outbreaks, for example 4 *Salmonella*/kg of dried seed.
- *Bacillus cereus*, *Staphylococcus aureus*, *Listeria monocytogenes* and *Yersinia enterocolitica* have also been implicated in outbreaks but very rarely.
- Contaminated seed lots may be used by several plants in different countries causing widespread related outbreaks. The recent Germany outbreak demonstrated the potential for contaminated products to cause major public

health emergencies in healthy people i.e. illness was not limited to individuals generally considered vulnerable to infection.

Identification of risk factors

- Pathogenic bacteria may contaminate seeds in the field and throughout the production chain. Potential sources of contamination are:
 - Irrigation water
 - Manure
 - Birds and rodents in storage facilities
 - Dust and soil particles
 - Asymptomatic carriers
- The temperature and humidity employed during germination and sprouting of seeds is considered a major risk factor as this favours the growth and dissemination of pathogenic bacteria.
- Other risk factors include:
 - The widespread distribution of seed lots which can increase the size and spread of the outbreak.
 - Poor traceability which can present difficulties for producers in assessing the hygienic quality of seed lots and can delay action to control outbreaks.
 - A lack of methods to detect emerging pathogens in seeds and sprouted seeds which presents challenges in identifying the source of outbreaks.
- Given the above risk factors hygienic control of the production process for sprouted seeds has to date been difficult.

Risk mitigation options

- FBOs producing sprouted seeds should apply HACCP principles in their food safety management including Good Agricultural Practice (GAP), Good Hygienic Practice (GHP) and Good Manufacturing Practice (GMP) along the entire production process. Hazard analysis should include risk classification of commodities, origin and suppliers of seeds. The difficulties in defining Critical Control Points (CCP) including hazard control measures, critical limits and monitoring are recognised.
- Preventing seed contamination is key given the long survival time of pathogens on seeds and their multiplication during production. This is relevant to both home sprouting and industrial sprouting.
- GAP and GHP in primary production, storage and harvesting should be applied with a high level of stringency, as with fresh-produce primary production, to minimise contamination risks. This includes:

- Identifying seed crops for planting before use
 - Minimising contamination with soil during harvest
 - Safe use of fertilizers and irrigation water
 - Ensuring hygiene and health requirements are followed for workers handling seeds
 - Transporting, processing and storing seeds under conditions that will minimise contamination
 - Removing damaged seeds/avoiding lot with damaged seeds
 - Improving traceability of seed lots and minimising mixing of lots
- GMP, GHP and HACCP principles should be applied during sprouting as for other ready-to-eat foods.
 - Washing of seeds prior to sprouting is recommended. Some Members States employ decontamination treatments and harmonised evaluation at EU level of the safety and efficacy of different decontamination treatments for seeds is also recommended. It is noted that no decontamination method eliminates pathogens in all seed types without affecting germination or sprout yields.
 - A chill chain for sprouts and shoots from end of production to consumption is necessary to limit growth of pathogens.
 - Stakeholders, including consumers and those practicing home-sprouting should be informed of the food safety risks posed by sprouted seeds.

Microbiological criteria

- Microbiological criteria, including the design of sampling plans for pathogenic bacteria, should be considered as one of the components of food safety management systems for the sprouted seed production chain. However, microbiological testing alone may give a false sense of security due to the statistical limitations of sampling plans. It is not currently possible to evaluate the extent of public health protection provided by specific microcriteria for seeds and sprouted seeds. Data collection and quantitative risk assessment are needed.
- As a ready-to-eat food there are already food safety criteria applicable to sprouted seeds for *Salmonella* and *Listeria monocytogenes* in Regulation (EC)2073/2005. There is also a process hygiene criterion for *E. coli* that applies to harvested cress and shoots only. As there is no cutting step in sprouted seed production, this criterion does not apply under this legislation to sprouted seeds. Consideration should be given to development of new or a revision of existing criteria for the pathogens most frequently associated with

outbreaks (*Salmonella* and pathogenic *E. coli*), giving consideration to serotypes of human health significance.

- Criteria for all stages of the production chain should be considered i.e. before the start of the production process, during sprouting and in the final product, to maximise the chance of detecting contamination that can occur at any stage and recognising that detection techniques may not be fast enough to allow withdrawal of products with a short shelf-life.
- Low levels of *Salmonella* (4 bacteria/kg in dried seeds) have been sufficient to cause outbreaks and therefore sampling plans may require pooling of seed lots to maximise the chances of detecting contamination. Pooling strategies would need to be validated and standardised taking into account the possible low levels of contamination. Sampling protocols should also apply to seeds for home sprouting.
- Other possibilities include testing dust and debris from seed storage areas, testing spent irrigation water and undertaking total *E. coli* counts to provide evidence of faecal contamination.
- There are currently no indicator organisms that can effectively substitute for the testing of pathogens in seeds, sprouted seeds or irrigation waters although testing for *E. coli*, *Enterobacteriaceae* and *Listeria* spp can inform process hygiene control.
- Use of standard testing methods, developed for analysing micro-organisms in seeds, spent water and sprouts would be preferable and rapid methods validated to EN/ISO standards would be advantageous given the short shelf-life of sprouted seeds.