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RISK ANALYSIS

Chief Scientific Adviser's Science Report

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Chief Scientific Adviser's Foreword

"A strong, scientific, evidence-based approach has been, and will always be, integral to the Food Standards Agency's (FSA) mission to ensure food is safe, is what it says it is, and to empower consumers to make informed choices in relation to food.

Central to both the FSA's work and how it works is risk analysis. The FSA has been preparing for changes since the June 2016 EU referendum. However, since 2018, we stepped-up our preparations, conducting a detailed review of our whole risk analysis process: how we conduct human health risk assessment, build evidence of 'other' influencing factors, formulate an informed position and our advice, and communicate this with others.

This, my 9th and final Chief Scientific Adviser (CSA) science report, provides a summary of the FSA's strengthened risk analysis process and explains how science lies at its heart. It does so at a time when we will be putting more national emphasis on it, than ever before. We believe this process is world-leading in food safety regulation, particularly in ensuring transparency, public understanding and trust in the advice we provide.

The FSA is fundamentally committed to the principles of inclusive, rigorous and accessible evidence generation, evidence use and risk communication. As CSA, my job is to provide independent assurance of the rigour of FSA science and the appropriate use of scientific evidence. However, it's important to recognise that science and the evidence it produces are continuously developing, and that for a range of reasons, we must often formulate a position in the face of uncertainties. Our risk analysis process makes clear the existence of such uncertainties and will be reviewed when new evidence makes this possible.

The benefits of our principles, and the transparency of our public health messaging is further emphasised against the current backdrop of COVID-19 and growing public interest in the use of science to inform government policy.

Given the critical nature of science and evidence in driving the FSA's policy-making, the review of the FSA risk analysis process was conducted in parallel with a range of other associated efforts, designed to reinforce the FSA's scientific and analytical capability and capacity. This included doubling the size of its Risk Assessment Unit, expanding the independent Scientific Advisory Committees (SACs) and creating new specialist Joint Expert Groups (JEGs), that increased the combined capacity of our SACs and JEGs to more than 100 independent advisory experts. Through this action and in collaboration with the devolved administrations, the FSA is in a position of strength.

Our risk analysis process seeks to maintain public confidence in a robust regulatory regime that upholds high standards of food and feed safety across the whole of the United Kingdom, and supports our international reputation as an excellent, science-led and accountable regulator."

Professor Guy Poppy,
FSA Chief Scientific Adviser

INTRODUCTION

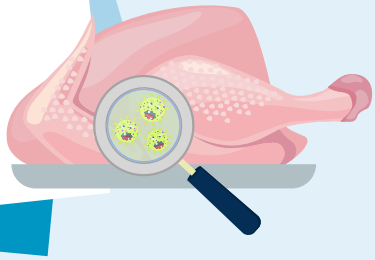
Currently, all home-produced and imported food and feed products sold in the UK have to comply with EU regulations. EU food and feed safety regulations are governed by the risk management decisions of the European Commission, taking into consideration risk assessments of the European Food Safety Authority (EFSA).

From 1 January 2021, European legislation on food and feed safety will move into UK law[1], providing a continuation of rules. However, leaving the EU means that the FSA, alongside colleagues from Food Standards Scotland (FSS), is responsible for many of the combined risk analysis functions previously carried out by EFSA and the European Commission.

DEFINING RISK

Hazard: Something that has the potential to cause harm. For example, Campylobacter (a type of bacteria that can be found on chicken) is a hazard.

Risk: The likelihood that a hazard will cause harm and how severe the effects could be. For example, eating undercooked chicken or poor hygiene practices during preparation make it much more likely that Campylobacter will make you ill[2]



The FSA's top priority is to ensure that UK food is safe and what it says it is, and we work hard to ensure that the high standard of food safety and consumer protection we enjoy in this country is maintained. If rules need to change or we need to act to protect consumers in the UK, we'll provide independent advice and recommendations to consumers, Ministers and others to do so, like we have done on the consumption of 'runny' eggs.

The delivery of an effective and trustworthy regulatory regime for food and feed safety outside the EU has required careful preparation, steered by the planning and leadership of the FSA Board. This has been particularly important given the expectation of an increased volume and scrutiny of our risk analysis advice and recommendations [3,4,5,6,7].

This report introduces the principles and processes we have established so that our risk analysis is robust and transparent, and based on the best and most up-to-date science and evidence available. Delivering an effective approach to risk analysis underpins everything we do and our ambition to be recognised as an excellent, accountable, modern regulator.

We have worked closely and collaboratively with government departments across England, Scotland, Wales and Northern Ireland to develop our risk analysis process. We are proud of our four-country approach to deliver a regulatory regime that is effective for the whole of the UK.

WHAT IS RISK ANALYSIS?

Risk analysis is the process of estimating risks to human and/or animal health, identifying and implementing measures to control the risks, and communicating these risks and measures to relevant parties. It has three components: **risk assessment**, led by science and evidence; **risk management**, the consideration of management options available by policy officials; and **risk communication**.

COMPONENTS OF RISK ANALYSIS

Risk assessment involves using a scientific approach to identify and define hazards, and to estimate potential risk to human and/or animal health. This includes evaluating the likely exposure to risks from food and other sources.

Risk management is the consideration of potential measures to either prevent or control the risk. It takes into account risk assessment and consumers' wider interests in food to formulate a response.

Risk communication is the exchange of information and opinions throughout the risk analysis process. This can be between risk assessors, risk managers, consumers, industry, the academic community and any other interested parties. It includes understanding consumers' concerns, publishing risk assessment findings, and distributing advice.

Food, food production/manufacturing and supply chain processes can expose consumers to a variety of risks. Risks include chemical, microbiological, radiological and food hypersensitivity issues including from things such as additives, flavourings, genetically modified (GM) foods, chemical contaminants and food contact materials[8].

Our risk analysis process is consistent and structured, but also agile and flexible in response, allowing us to provide robust risk management recommendations which protect public health in relation to food.

The outputs of the risk analysis process include advising on:

- Developing food and feed safety standards and controls based on scientific evidence; e.g. policies, guidance, controls and enforcement
- Pre-market approvals and post-market reviews of regulated food and feed products;
- Risk-based import controls;
- Handling incidents and food crime.

STRENGTHENING THE FSA RISK ANALYSIS PROCESS

The FSA's risk analysis has always aligned with international guidance, including that from Codex Alimentarius[9,10,11]. In reviewing our process, we have further drawn on the independent advice of our Science Council, with additional input and development by our Advisory Committee for Social Science (ACSS). We have considered their advice regarding establishing and communicating risk and uncertainty[12], accessing scientific capability and gaining assurance from this[13], and detecting future risks better[14].

We began our risk analysis review already in a position of experience and strength, and our revised process sets an international standard in transparent risk management advice. We are confident that our process is world leading.

The new elements we have added are:

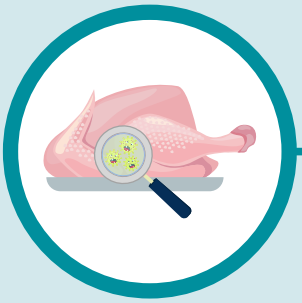
1. **A clearer separation between our risk assessment and risk management** to ensure the scientific integrity of risk assessment

2. **An expanded role for our Scientific Advisory Committees (SACs),** strengthened by recruiting additional experts and by establishing three new Joint Expert Groups (JEGs)

3. **A new UK process for authorising regulated products** such as food and feed additives, enzymes, flavourings, novel foods, GM food and feed

THE USE OF SCIENCE AND EVIDENCE IN RISK ANALYSIS

Scientific evidence, independent expert advice and assurance on the interpretation and use of science are integral to our risk analysis process and responsibilities as an excellent, accountable and transparent regulator. Our risk analysis process has three primary elements: risk assessment, risk management and risk communication.



Hazard identification

RISK ASSESSMENT

Risk assessors and other specialists deliver the science behind our advice. They are responsible for identifying and characterising hazards, assessing levels of exposure and characterising risks to health, or providing evidence on for example, potential economic impacts or consumer perceptions on an issue. The evidence collected by our scientists supports risk managers in developing the right advice.

We use the independent advice of scientific experts to help us ensure that our advice is based on the best and most recent scientific evidence. This includes our:

-Scientific Advisory Committees (SACs)
-Joint Expert Groups (JEGs)
-Register of Specialists

ROLE OF THE CHIEF SCIENTIFIC ADVISER (CSA)

Quality assurance for our science and evidence involves many people: internal reviewers, our SACs and external peer reviewers, but our CSA provides senior assurance on the integrity of our scientific evidence and its use.

RISK COMMUNICATION

Risk communication is embedded across our risk analysis framework, ensuring iterative exchange of opinions, understanding and options throughout the process.

We provide clear explanations of risk assessment findings and the basis of risk management decisions, using evidence-based and outcome focused methods to communicate with consumers, industry stakeholders and other interested parties.

To do this effectively, we use insights from social science to understand the attitudes, beliefs and behaviours of the people with whom we are communicating.

RISK MANAGEMENT

Risk managers consider which approaches could be implemented to manage and control risk. They will consult with interested parties and take into account factors relevant for the protection of consumers' health and their wider interests in relation to food.

Risk managers propose advice and recommendations.

Delivery of risk assessment and other scientific evidence from our risk assessors and analysts to risk managers

RISK ASSESSMENT

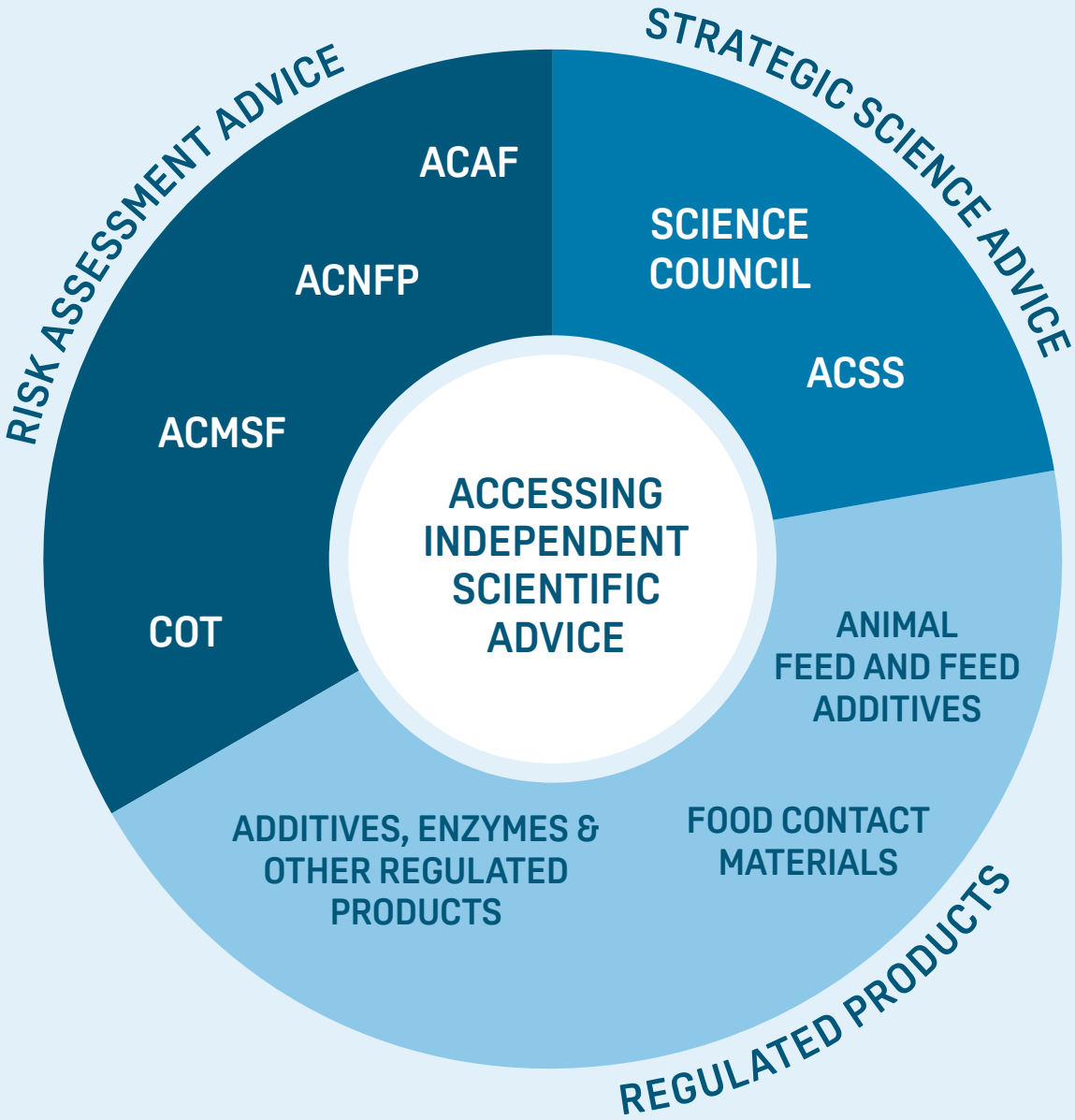
For the public to trust in our scientific rigour, we must establish confidence in our public health risk assessment. FSA risk assessors consider many factors in risk assessments, including what supporting tools and approaches are needed. These will vary depending on how new the hazard is, its complexity, and the food and feed production pathways involved.

FSA RISK ASSESSMENT CAPABILITY AND CAPACITY

DR AMIE ADKIN, HEAD OF FSA RISK ASSESSMENT UNIT

"Our role as risk assessors is to ensure that the best available scientific evidence is placed at the heart of decision making in a transparent and unbiased manner. Our strategic science plan[15] details our focus to build our scientific excellence together with our SACs, to be prepared for the future, and grow our influence and impact. To bring this into fruition and in response to growing expectations, the FSA Risk Assessment Unit has more than doubled in size since 2017. If you consider our statisticians, economists and social scientists as well, the FSA Science, Evidence and Research Division now constitutes a team of approximately 100 scientific experts and support staff, providing the capability, capacity and resilience needed as the competent food and feed safety authority."

In addition to our own dedicated FSA risk assessors, we work with four independent, expert SACs to assimilate scientific information and evaluate its relevance and influence, helping to ensure that our advice is based on the best and most recent scientific evidence. SAC members are appointed on a voluntary basis and are drawn from a wide, multidisciplinary field including specialist academics and experienced practitioners. The independent advice and support that SAC members (and our other advisory structures) provide, makes a real difference to public interests and health.



The four FSA SACs involved are:

- The Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT);
- Advisory Committee for the Microbiological Safety of Food (ACMSF);
- Advisory Committee for Novel Foods and Processes (ACNFP);
- Advisory Committee on Animal Feedingstuffs (ACAF).

To bolster the FSA's SACs outside the EU, we have appointed 35 supplementary committee members and created three new JEGs for regulated products, that work to the same principles as our SACs.

The four SACs will continue to provide risk assessment advice for risk-based standards and controls, while the JEGs will tackle most work required for regulated products. The three new JEGs focus on:

- Food Contact Materials
- Additives, Enzymes and Other Regulated Products
- Animal Feed and Feed Additives

Web pages further describing the risk analysis and regulated product authorisation processes are available for businesses on food.gov.

‘OTHER’ EVIDENCE CONSIDERED

When considering how to advise on risk management, there are a number of ‘other legitimate factors’ which need to be evaluated. The FSA is supported by other specialist analysts including our statisticians, economists and social scientists that provide ‘other’ evidence, further supporting clear, rational and justifiable risk management decisions.

Our social scientists also provide benefit in helping to create effective risk communication by understanding the attitudes, beliefs and behaviours of the people with whom we are communicating.

The additional factors we consider will vary according to the food or feed safety risk. In addition to human health risk assessment, they will generally include:

- Wider consumer interests like impact on the environment, animal welfare and food security
- Consumer habits, perceptions, acceptability and preferences, including likely consumer behaviours in response to risk and emerging trends
- Economic impact: impacts of the risk itself, the cost and benefit of implementing risk management options and consideration of who will bear these costs and who will benefit
- Technical and feasibility considerations i.e. capability and capacity to implement risk management options, the ability to enforce/verify controls, and consideration of scientific/ technological advances

These factors must be clearly identified and communicated to avoid misrepresentation of human health risk assessment evidence or uncertainty in why risk management recommendations have been made. In any given scenario, each factor will have a different weight and impact on the final risk management options advised. It is therefore important that we demonstrate all the factors risk managers should consider in their decision-making process.

HANDLING UNCERTAINTY AND CHIEF SCIENTIFIC ADVISER ASSURANCE

In risk management, each of the options must be individually considered, including the impact of any uncertainties.

There is virtually always an element of uncertainty in both science and food and feed safety decision-making, sometimes caused by missing data but also by natural variabilities. The ACMSF has helped us in applying consistent multidimensional representation of risks in risk assessment.

In many cases, we may have to announce a risk analysis position before waiting for more evidence to emerge in order to protect public health. Even when time is less of a restricting factor, uncertainty can either be irreducible or take disproportionate resources to reduce.

In circumstances where uncertainty remains about the nature or likelihood of the risk to public health, a precautionary principle may be used. In accordance with legal requirements, where this happens, the risk management action taken must be:

- Proportionate;
- No more restrictive to trade than necessary to achieve a high level of health protection;
- Feasible technically and economically;
- Reviewed within a reasonable period of time.

The precautionary principle is rooted in international trade law. It is applied where measures are needed to safeguard public health and there is insufficient scientific evidence to undertake a satisfactory risk assessment. In those circumstances, temporary risk management measures may be applied whilst further science is undertaken.

The transparency of our risk analysis process is important to ensure the integrity of our risk assessment science and evidence against decisions that may be motivated by other factors. This is one of the reasons why the FSA will publish the science and evidence underpinning its assessments and advice to health Ministers, who will be responsible for taking key risk management decisions.

The precautionary principle has been at the heart of much discourse in Europe. An example being the regulation of GM crops and the introduction of some 'new' plant breeding techniques. In this case, human health risk assessment evidence may suggest such products are safe to consume but uncertainties have been used to justify the adoption of the precautionary principle, alongside risk management decisions influenced by other factors.

By taking uncertainty and variability into account, we can make better, more transparent decisions about the control of risks. We can also weigh up risks and benefits in taking more time and resource to address sources of uncertainty.

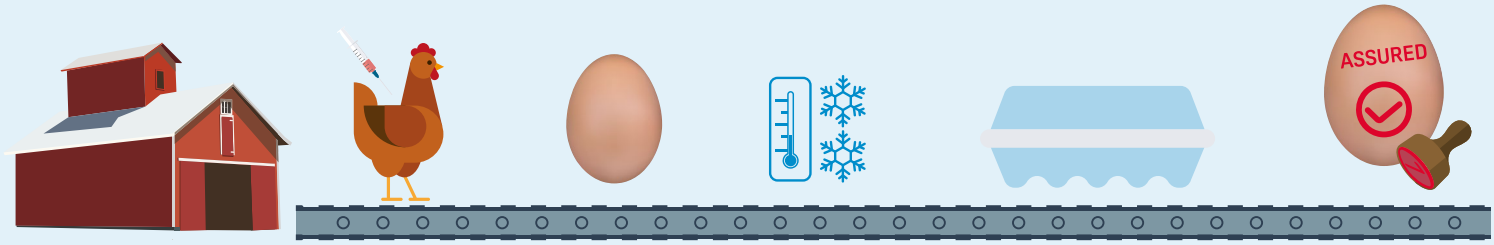
RISK ANALYSIS IS ITERATIVE

Risk analysis is iterative and can evolve/change over time. We continuously review our position as new evidence is made available and monitor the relevance, effectiveness and impact of risk management decisions. A good case example is FSA advice in relation to the consumption of 'runny' eggs.

In the late 1980s, *Salmonella enteritidis* caused the largest and most persistent epidemic of foodborne infection attributable to a single subtype of any pathogen. It is estimated that >525,000 people in England and Wales alone became ill as a result of this. As such, the FSA advised that vulnerable groups should not consume raw or lightly cooked eggs because of the risk of serious illness.

Throughout the '90s and '00s, a suite of control measures (notably poultry vaccinations) were introduced, backed by private assurance scheme codes of practice. This has dramatically reduced the number of cases of human infection.

In 2015, the ACMSF reviewed the scientific evidence. Based on the committee's recommendations[16], the FSA subsequently reviewed its advice, amending it to state that consumers – including vulnerable groups – can now safely eat raw or lightly cooked UK hen eggs or foods containing them. We will continue to assess the Salmonella evidence base and will further review our guidance as we believe necessary.



ROLE OF THE CHIEF SCIENTIFIC ADVISER (CSA)

The Chief Scientific Adviser provides senior assurance on the scientific rigour and integrity of FSA, SAC and JEG evidence and its use. This includes oversight of our processes, for example: internal and external peer review; identifying, considering and communicating uncertainties and their impacts; and weighting different pieces of evidence appropriately. Weighting can vary depending on the balance of all the factors within the completed 'evidence package'. This senior scientific assurance helps others take confidence in the use of science and evidence in FSA risk analysis.

RISK MANAGEMENT ADVICE

The 'evidence package' containing the human health risk assessment and evidence reports on other legitimate factors will be presented to FSA risk managers. Having this clear separation between the roles and responsibilities of our risk assessors, other analysts, and risk managers is important to ensure the scientific integrity of risk assessment.

Risk managers will use this evidence to develop risk management options and recommendations. This may include consideration of options in consultation with other government departments, the devolved administrations and stakeholders.

Ultimately, the FSA Board has oversight of the risk analysis process. When believed necessary for substantial or contentious risk management issues, the Board will consider the risk management options and finalise advice and recommendations provided to Ministers and others. For such issues, the Board may engage in initial scoping discussions at earlier stages of the risk management process, before any decisions are made. This will allow it to derive confidence that an appropriately broad set of impacts is being used when framing risk management advice.

The CSA will be involved in the consultation process and Board discussions to provide assurance on the interpretation and weighting of the scientific evidence.

RISK COMMUNICATION

Frequent interaction between risk assessors, risk managers and risk communicators is essential at all stages of the analysis process. It ensures shared understanding, which is especially important in relation to uncertainties.

There are three principles involved in our risk communication, which we aim to adhere to regardless of whether an issue is urgent, high profile, or simply one that we wish to raise awareness of:

1. **Communicate openly.** Both internally and externally, we provide clear explanation of risk assessment findings and the other legitimate factors forming the basis of risk management decisions. We consult with others on our draft risk management options and review as necessary, and we publish our evidence so stakeholders can make an informed judgement on our processes and decisions. This is consistent with the FSA Code of Practice on Openness[17].

2. **Maintain the FSA's national and international trustworthiness.** We work across England, Wales and Northern Ireland, and closely with our FSS counterparts in Scotland to develop joined up communication that is consistent across the UK. At the same time, we recognise where each country has specific needs and tailor our approach accordingly.

3. **Understand the audience's point of view.** We understand that people process risk and respond to uncertainty in different ways. We listen to the communities that we hope to communicate with and involve them in the creation of messages to make it as understandable as possible. The approach may be different for different stakeholders.

We regularly seek the support of the ACSS and communication professionals in:

- Understanding perceptions, beliefs, knowledge, attitudes and behaviours
- Balancing clarity and exactness
- Applying behavioural science principles
- Involving communities in creating messages and evaluating the effectiveness of our communication

CASE STUDY - FSA EVIDENCE PACKAGE FOR NHS HOSPITAL FOOD REVIEW

The FSA has been supporting on the NHS Hospital Food Review of the food provided in NHS facilities for patients, visitors and staff. This follows a recent incident where meat in pre-packed sandwiches was linked to *Listeria* infections in hospital patients and six people sadly died.

The FSA has presented a risk analysis evidence package to the reviewers. It presents evidence from a range of sources and draws on experiences and lessons from food safety incidents associated with hospitals. This is one of the first use cases that has helped test our clearer separation of risk assessment and risk management, utilising the tools/structures put in place to facilitate consistent evidence package exchange between risk assessors and risk managers.

A comprehensive assessment of the risks posed by *Listeria* to patients in a hospital setting is challenging due to a number of evidence gaps and uncertainties. A 'risk profile' was compiled, which includes steps such as hazard identification, exposure assessment (i.e. how likely is the hazard to occur and to whom), and hazard characterisation (i.e. what are the consequences)?

We compared the hypothetical food safety risks for the production of foods on-site (within hospitals) vs sourcing food pre-packed from external suppliers. This involved considering factors such as consistency of supply and traceability; the nature of ingredients used (i.e. raw or pre-cooked); the amount of human contact and mechanisation; post production storage; distribution within hospital; and time to reach consumers. We also considered that food establishments which receive a higher food hygiene rating during inspections are less likely to be the source of foodborne disease outbreaks[18,19]. Food produced on-site using fresh ingredients may present more theoretical risk factors than food sourced pre-packed from external suppliers, but it is not possible to say which poses a higher overall risk.

Our ‘other legitimate factors’ highlighted how behavioural insights could improve compliance with food hygiene best practices and therefore reduce the risk of *Listeria*. This involves learning from successful behavioural interventions, like improving hand hygience in health care, then targetting the riskiest behaviours which can result in foodborne infection in hospitals.

FSA risk managers have advised that better acknowledgement of individual responsibilities throughout the supply chain to hospital wards alongside better adherence to existing FSA guidance would help reduce the risk of vulnerable groups contracting listeriosis.

Listeria is widespread in the environment and can contaminate a range of foods. Foodborne listeriosis is rare in comparison to other foodborne pathogens, with only 135 cases in England and Wales in 2017[20]. Listeria may cause illness in healthy adults but can be much more serious for those who have weakened immune systems, and also the elderly, pregnant women and infants. Further information can be found on the Listeria guidance page on our website.

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CSA REFLECTIONS: FUTURE CHALLENGES AND OPPORTUNITIES

“This, my 9th CSA Science Report, is my last as the FSA’s Chief Scientific Adviser. I have been proud and inspired to be part of the FSA’s work to keep consumers safe and to represent the breadth of its multidisciplinary scientists.

Thanks to the FSA’s risk analysis process, the UK is in a position of ‘prepared strength’ when it comes to food and feed safety. Clear, honest communication will continue to be central to consumers’ trust in the FSA, as it will be between risk managers and risk assessors to ensure the right questions are being asked and that evidence is used appropriately.

We have an ongoing commitment to the open and transparent use of evidence; being clear on what we do and do not know, where we need to seek further evidence on an issue, how evidence is used and why we think a course of action is correct. This is fundamental to the principles against which the FSA was created 20 years ago, in order to protect consumers, in the wake of the Bovine Spongiform Encephalopathy (BSE) crisis. It is this commitment to scientific integrity and rigour that makes our advice to Ministers and others authoritative.

It is reassuring to see the role that science and scientists are playing in the UK response to COVID-19 and very pleasing to see that experts are 'back in fashion', providing a common language across departments, to help address a complex and difficult situation. Throughout my time at the FSA and as a CSA, science is often the glue that brings professions together to tackle challenges, and I think the FSA has delivered on what it was established to do in ensuring UK citizens can have food that is safe and that they can trust. Lessons are being learnt across government from COVID-19, with respect to bringing science visibly to the fore of decision making, and how to deal with and communicate uncertainty.

As with all science, it is reasonable and encouraged for others to challenge our evidence and its use as new and emerging evidence comes to light, as was the case for consumption of runny eggs and the Salmonella risk to vulnerable groups. However, if the FSA is to be judged by its scientific 'excellence' then the FSA should be equally clear to others on what it considers 'quality' evidence and the quantity of evidence required to trigger new analysis, reducing the burden and potentially harmful impact of perhaps anecdotal challenge.

As the FSA reaches its 20th anniversary, many challenges and opportunities lay ahead for the resilience of UK food safety and authenticity. The past 20 years have brought many foreseeable changes and challenges to the food system but also many one could not have predicted in the late 1990's. As the food system continues to change, hopefully to one which will improve human and planetary health, the FSA must have the best risk analysis process to facilitate change and continue to protect public health.

The development of a National Food Strategy is welcomed to help address the multiple needs of our food system and I will continue to champion the significance of food and feed safety and the excellence of FSA science whilst leading the Strategic Priorities Fund Food Systems Programme to transform the UK food system for healthy people and a healthy environment."

ACKNOWLEDGEMENTS

With thanks for the contributions of Lisa Nelson, Beth Davies, Joanne Edge, Gwen Aherne, Michelle Patel, Vanna Nasser Aldin, Linden Jack and Ben Goodall.

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