CHIEF EXECUTIVE'S REPORT TO THE BOARD

1. It is nearly 12 months since the UK formally left the EU's single market. It is also 21 months since the first lockdown in the UK. In 2020, I often used the metaphor of the FSA coming of age as we turned 20 and the UK left the EU. In 2021, the FSA does indeed have new freedoms and new responsibilities, in the context of a pandemic which itself has created pressures.

2. This time last year, the Trade and Cooperation Agreement was not yet finalised, and we did not know what exactly the import and export arrangements on 1 January would be. I told the Board in our meeting that we were as prepared as we could be for what we could foresee, but we would need to be agile. This year we have responded, in particular, to:

    - changes to arrangements for goods moving from Great Britain to Northern Ireland;
    - delays to the planned introduction of pre-notification of EU high risk food products, like products of animal origin;
    - a renewed focus on shellfish official controls, given changes in the EU's approach to shellfish imports;
    - continuing demands on local authority food officers because of Covid;
    - a shortage of vets in the UK exacerbated by more employment opportunities for vets as a consequence of certification requirements for GB products travelling to the EU or moving to NI. This was made worse by COVID and the return of many foreign nationals to their home countries;
    - a larger demand than forecast for our new regulated products responsibilities, though much of this was driven by CBD applications.

3. FSA staff have worked hard with businesses, governments, and officials, to address these matters. We have maintained 100% service delivery in official controls thus far; we have operated new arrangements for import controls; we reviewed all shellfish beds to ensure we were rating them appropriately; and we set out our local authority recovery plan in the Summer. Our scientists have completed the risk assessment stage on 27 regulated product applications, so these are now being considered by policy for risk management advice; 9 of these applications (relating to GMOs), are now out for consultation. Our data service to identify risk imports and provide intelligence to plan sampling is used by 936 users from 144 local and port heath authorities.

4. We have also made positive progress in other areas. We saw our first charge and guilty plea to a criminal prosecution entirely investigated and led by our National Food Crime Unit (see NFCU update paper). We did significant work to support businesses and local authorities as allergen labelling changes (also known as Natasha's Law) came into force on 1 October 2021; and we have consulted on the strategic work on the target operating model for our meat hygiene and other inspections. We secured a 7% increase to the FSA's Westminster budget in the Spending Round which will cover most of our EU

work and this will now provide more certainty over the next three years. These are all important steps forward.

5. Preparations for EU exit dominated the FSA's work for at least four years. EU exit, our new responsibilities, and our new ways of working within the UK, are now reality. We now need to bed this in and respond to the big challenges for the food system, particularly the climate crisis and the impact of food on long-term health. It is therefore right that we are refreshing our strategy and will launch that in Spring 2022.

6. In 2022 we will also increase attention on our reform programmes, particularly Achieving Business Compliance and Operational Transformation. In 2022 we will see our first ministerial decisions in response to FSA advice on regulated products. And the FSA's voice will be heard speaking in the consumer interest, not least with our forthcoming Annual Report on Food Standards, to be published jointly with Food Standards Scotland in the Summer.

7. The rest of this report focuses on updates on food hypersensitivity and regulated products, particularly on CBD. Other matters are picked up through the rest of the Board's agenda.

8. **Food hypersensitivity.** As mentioned above, the changes to allergen labelling of food products **pre-packed for direct sale, also known as "Natasha's Law",** came into force on 1 October. We delivered a communications campaign that targeted both FBOs and consumers to ensure preparedness. Defra provided £2m to local authorities to help them get familiar with the new law and for increased inspection time. Social media advertising reached approximately 900,000 people in the first two weeks of September, generating 45,000 clicks through to the FSA website.

9. **Precautionary Allergen Labelling: The "May Contain" Consultation.** We launched this consultation this week and it runs for fourteen weeks from 6 December 2021 to 14 March 2022. It consists of an online survey and twelve targeted workshops and will be gathering views on how to develop an approach that works for food businesses and keeps consumers safe, without limiting their food choice. The consultation seeks feedback in the following areas:

    - **Provision of Information to Consumers;** Consumer preferences in respect to the wording and format of precautionary allergen labelling, and the potential for the provision of additional information beyond the label, for example via an app or website.
    - **Advice and Training for Food Businesses;** Whether the current provision of advice and guidance to businesses on the application of precautionary allergen labelling could be improved.
    - **Ensuring Compliance;** The FSA's legal interpretation of current regulations and any need for further clarity.

- **Standards for Risk-Analysis;** To best to increase consistency in the assessment and management of the risk of allergen cross-contamination.

The feedback collected by the consultation will inform our future work.

10. The **UK Anaphylaxis** Register was launched at the Annual Conference of the British Society for Allergy and Clinical Immunology (BSACI) on 7 October 2021. The register is funded by the FSA with contributions from Food Standards Scotland and led by Imperial College London. The registry will enable healthcare professionals to record the details of serious, and potentially life-threatening, anaphylaxis reactions and collate data from across the UK to provide a better picture of the circumstances leading up to these reactions.

10. We are carrying out proof-of-concept (PoC) testing for a **Food Allergic Reaction Reporting Mechanism (FARRM)** to enable us to better understand the number and nature of food hypersensitivity and allergy reactions and near misses which do not result in hospitalisation. The PoC is now live on the FSA website and will run until February 2022.

11. **Risk analysis.** FSA and FSS are reviewing Retained Regulation 2016/6 on **enhanced controls for food and feed from Japan following the Fukushima nuclear accident** in 2011. In early November, I met the Japanese Vice Minister for International Affairs to discuss the review of import controls. We expect to launch a 9-week public consultation on the risk management options imminently. At the same time, we will publish our risk assessment and draft impact assessment.

12. The risk assessment has been independently peer reviewed by the Committee on Medical Aspects of Radiation in the Environment (COMARE), a scientific advisory committee of the Department of Health and Social Care. The conclusion is that removing the 100 becquerels per kilogram (Bq/kg) maximum level of radiocaesium for food imported from Japan to the UK would result in a negligible increase in dose and any associated risk to UK consumers. Following the consultation, we will make a final recommendation to you for a decision at the March 2022 FSA Board meeting, ahead of advising ministers.

13. **Food white paper.** The FSA continues to engage with other government departments on how to address the challenges set out in Henry Dimbleby's National Food Strategy in July. In particular, we are working closely with the team in Defra that will publish the Government's food white paper next year.

14. **Regulated products.** The regular regulated products update is at Annex A.

15. I wanted to give an update on the **CBD applications** in particular. As the Board know, the FSA has been concerned for some time about CBD food products which are on sale but have been concerned for some time about CBD food products which are on sale but have not yet been through the

formal novel foods market authorisation process. CBD products are unusual, in food regulatory terms, for three reasons:

- **Confirmed as a 'novel food' after many on sale**. After some time discussing the novel food status of CBD extracts, in January 2019, the European Commission confirmed that CBD is a novel food (i.e., with no significant history of consumption before May 1997). By that time, however, a substantial number of products had already been placed on the market. Our consumer research in 2020 told us that of the 60% who said they had heard of CBD, 13% said they had used it in the past year.
- **A food but could be a drug or a medicine**. CBD is in the nexus of regulatory regimes between drugs, medicines and food. Some CBD products are classed as medicines and are therefore regulated by the MHRA (Medicines and Healthcare products Regulatory Agency). CBD is widely associated with general health benefits; these claims have not been substantiated by the relevant bodies. Further, if there is THC (tetrahydrocannabinol, the psychoactive compound in cannabis) in the product – which is a risk as it is derived from the Cannabis plant - it becomes an illegal drug. A product cannot, legally, be both a food and an illegal drug.
- **A dearth of existing research**. There is little existing scientific evidence about the safety or effect of CBD on the body. The Committee on Toxicity (COT) identified in July 2019 that CBD can have a number of adverse side effects and that there were numerous data gaps and uncertainties. Further data are needed to fully assess its safety. It is a basic principle of food law that the food business which sells the product is responsible for making sure it is safe for the consumer.

16. Since 2020, the FSA has been taking a proactive and phased approach to bringing this part of the food industry into compliance with the law. The approach balances legal compliance, consumer safety, the interests of consumers who take CBD products, and the desire to support innovation in the food industry.

17. In the interests of consumer safety, in February 2020 we offered consumer advice, highlighting that none of the products currently for sale had been formally safety assessed. Further, if consumers were going to eat them, they should limit themselves to a maximum of 70mg a day, and we advised vulnerable consumers not to eat CBD products on a precautionary basis. We understand we were the first food regulatory agency in the world to do this.

18. To encourage the industry to become compliant, at the same time we set a deadline of 31 March 2021 for applications to be registered with the FSA so that CBD products could be taken through the usual novel foods assessment process. The responsibility for novel foods market authorisation assessments transferred from the EU to the FSA on 1 January 2021. We received a large number of enquiries and applications by our deadline but after filtering only

around 210 applications were viable for further consideration, connected to several thousands of products.

19. Since April 2021 we have therefore been working progressively to give more clarity to the market, local authorities and to consumers about the likelihood of those applications getting market authorisation. So far, we have looked at almost all of the applications to see if they have provided enough scientific data to enable us to do a scientific risk assessment for safety. The quality of applications was lower than we anticipated, so this work has taken longer than we thought it would. Where necessary, we have had to ask for additional scientific information from applicants. Once we are confident we have sufficient information, we 'validate' the application and it then goes formally into the scientific assessment process. Currently, four applications have passed through the validation stage. We have made this list public.

20. Over the next few months, we expect to:
    - reject some further applications which have insufficient information to be validated and no prospect of that information being provided;
    - add further applications to the published validation list and commence formal scientific assessment on them;
    - publish a list of the applications where work on studies was in train before our March 2021 deadline but where we are awaiting information and where there is a reasonable expectation that such scientific information will be provided in a timely manner in order that the application will be validated.

21. We will shortly have triaged all applications into the three categories above. After this time, only those products on the two lists should remain on the market. At that point we will remind stakeholders including retailers of this and will offer guidance to local authorities on the enforcement of novel food legislation.

22. For the products that are on the two lists, (see para 20) we need to be clear that these products are still not formally authorised for sale and neither have they yet been assessed for safety. But they are credible applications, and we are therefore proposing that products connected to them that are on sale should not be prioritised for enforcement action. Obviously this would change if they were subsequently rejected from the authorisation process, for example because information came to light about their safety, or about their status as a drug rather than a food. In the meantime, we continue to advise consumers to take account of our messaging, which is based on current knowledge.

23. Over the next 1-2 years we will then conclude our scientific assessments, our consultations with the public over the authorisation of these products and ultimately offer advice to ministers on which products should be formally authorised. This may seem slow, but I should note that the novel foods authorisation process is one guided by statutory timescales, and where the 'clock' can be stopped when additional information is awaited.

24. The CBD industry continues to grow. We hope that in taking this phased approach, we are acting in a reasonable way to support innovation while also protecting consumers and creating a level playing field for the CBD industry. Retailers and producers need to be responsible when marketing and selling these products, in relation to health claims and other aspects of food law. We will continue to work closely with the Advertising Standards Authority and DHSC where we become aware of unsubstantiated health claims being made on CBD food products. We continue to monitor the situation closely and will take other steps if we consider that consumer safety is at risk.

25. **My external engagements.** Since my last report, I have met the Secretary of State for Health to discuss PACE powers for the NFCU. I have also met Adam Memon, DHSC Special Adviser, representatives from GS1, the UK Safety Regulators' CEO Group, The Food Foundation, UK in a Changing Europe and the BMPA (British Meat Processors Association). I undertook a weeklong residential trip as part of the National Leadership Centre where I met a number of local public sector leaders; and I met several academics at the University of Cambridge as part of a Policy Leaders Fellowship.

26. I have accompanied Susan in meetings with the Natasha Allergy Research Foundation, Food Standards Scotland meetings with Chair and CEO, the Food to Go Group from the British Retail Consortium and several introductory meetings with senior leaders of some of the major supermarkets. I also joined her in a meeting with Lynne Neagle MS Deputy Minister for Mental Health and Wellbeing to discuss gene editing.

27. In October, Susan and I visited the FSA office in Northern Ireland. As well being able to meet colleagues there, we joined NIFAC and met Ministers Poots and Swann. We also met the Food Industry Liaison Group and Professors Chris Elliott and Tim Lang.

28. At the beginning of November, Susan and I undertook a local authority visit to Cheshire West and Chester Council.

29. I gave speeches at the CIEH (Chartered Institute of Environmental Health) and the Worshipful Company of Butchers and participated in a panel at the Institute of Grocery Distribution Technical Leaders working group. I also attended a meeting of technical directors convened by the British Retail Consortium.

30. Finally, I attended the Whitehall & Industry Group Event, the SOFHT (Society of Food Hygiene and Technology) Annual Lunch and Awards, the FDF (Food and Drink Federation) President's Reception and Christmas drinks hosted by the Agriculture Counselor of the Embassy of the United States.

Annex A Risk Analysis and Regulated Products Update

1. Following the end of the transition period, 31 December 2020, the FSA took the responsibility of managing risks in the food chain, from the EU. The FSA risk analysis process operates in line with the position agreed by the Board in previous meetings, most recently in September 2020. Where legislative change is required, such as to place a new regulated product on the market in England and Wales, our advice to ministers is underpinned by the risk analysis process. The process is run jointly with Food Standards Scotland, who advise Scottish ministers. FSA and FSS (Food Standards Scotland) have been receiving applications for food and feed products which require authorisation prior to entering the market. The approval process for applications has various stages prior to recommendations being made to Ministers in England, Scotland and Wales. Where Ministers decide to authorise, the authorisation must be set out in legislation before products may be placed on the market within the nations. In Northern Ireland regulated products continue to be assessed and authorised by the EU.

2. **Register of Regulated Product Applications**
   Once applications are validated, and the information within the dossiers is considered suitable for it to continue progressing through the authorisation process, information on the application is published on a register on the FSA website.
   The register details a short summary of the product being considered and the stage of the authorisation process that the application has reached. The register is updated monthly, and currently consists of 72 applications. Prior to this, we do not publicise details of individual applications we have received.

3. **Regulated Products applications received**
   A summary of the regulated products applications received is in the table below.

Total contacts made through application service	1,395
Non-applications (e.g., queries) and incomplete applications (where no documents or insufficient information was uploaded)	851
Applications withdrawn by applicant	53
Applications assessed as invalid	39
Live applications	416

1. For the live applications see below for a breakdown by regime of where applications are in the overall process.

Regime	Total live applications	Applications pre-validation	Applications at risk assessment	Applications at risk management
Novel Food	248	235	7	6
Feed Additives	101	64	26	11
GMO	31	21		9
Novel Food (Traditional)	6	5		1
Novel Food Status	2	2		
Food Contact Material (Recycled)	5	1	4	
Food Contact Material (Plastics)	3	2	1	
Food Additives	13	8	5	
Flavourings	2	2		
Food Enzymes	1	1		
Feed for Particular Nutritional Uses (PARNUTS)	2	1	1	
Other	2	2		
Total	**416**	**344**	**45**	**27**

2. **Progress towards regulated products authorisations**
The first group of potential GB authorisations consists of a combined total of 26 applications for Novel Food, GMO and Feed Additive authorisations. These applications have been previously evaluated by the European Food safety Authority (EFSA) and had EFSA risk assessment opinions adopted prior to the end of the EU exit transition period. For these applications we have taken a pragmatic approach; rather than undertake a full risk assessment, our risk assessors have reviewed, and quality checked the EFSA opinions, and where content, the applications progress to risk management. We launched a public consultation on nine GMO applications on 13 November, which runs until 25 January 2022. Once the consultation has closed, responses will be considered before finalising recommendations to Ministers on options for authorisation in early 2022. Consultation on six

novel food applications and 11 Feed Additives applications will be launching soon.

3. **Other applications to note**
The majority of applications progressing through the process are for new products to enter the GB market. An application for **3 Nitrooxypropanol** (3 NOP), which is a methane reducing feed additive, has recently been validated. This product has attracted some interest, given the environmental benefits it may have. The application is in the early stages of risk assessment and the relevant Joint Expert Group (JEG) is considering how it plans to assess the application.

We are also progressing applications requesting to **change conditions of use** for existing food additives, for example to allow their use in additional food categories. The Additive, Flavourings and Enzymes JEG is considering 5 such applications and considering the impact of any additional consumer intake of the additives but also if any additional food safety risks arise from such uses.

4. **Register of risk analysis issues**
In addition to regulated product applications, other issues relating to food and feed policy development, including requests from other government departments for food and feed safety advice, may require a risk assessment. Once preliminary steps have been completed and it has been confirmed that the identified issue should go through the risk analysis process these are published in our register of risk analysis issues.
There are currently 6 issues in the Register, which are summarised in the appendix. The Register is updated quarterly, and no new issues were added to the last update in October 2021.
Current issues in the Register include our review of retained EU Regulation 2016/6 placing controls on imports from Japan following the Fukushima nuclear accident as described previously.
In May, I updated you on the EFSA opinion that concluded Titanium Dioxide (E171) can no longer be considered safe when used as a food additive, despite uncertainty associated with some of the findings in its evaluation. UK Scientific Advisory Committees have scrutinised the EFSA opinion and the FSA and FSS are now taking the issue through the full risk analysis process. This will inform the future policy position and any risk management options to protect consumers, and a joint statement from the Committees is expected soon.

RA ID number	Type of issue	Title of issue	Summary	Phase of risk analysis
G10000047	Imports	Imported Products of Animal Origin (POAO) 2022 Controls Project	FSA work with Defra to consider the public health aspects of the Future Animal Imports Risk Review (2022). Our risk analysis input has been completed and has been sent to	Complete

			Defra to help with its policy development.	
G1000006	Radiological	Review of Controls on Imports from Japan following Fukushima Incident	Review of the controls in retained EU Regulation 2016/6 imposing special conditions governing the import of food from Japan following the Fukushima nuclear power station incident. Review will consider latest evidence on levels of contamination in food from Japan to determine whether controls should continue and, if so, whether any amendments to the controls are required.	Development and consideration of risk management options
G1000023	Chemical Contaminants and Residues	Dioxin & Polychlorinated Biphenyls (PCB) Risk Analysis	Consideration of the need for changes to risk management measures following a reduction in the Health Based Guidance Value for dioxins. This may include changes to existing regulatory limits in food and/or revised consumer advice.	Risk Assessment and Evidence
G1000028	Chemical Contaminants and Residues	Perfluorinated Alkyl Substances (PFAS) Risk Analysis	Consideration of risk management measures associated with Perfluorinated Alkyl Substances (PFAS), a broad range of often persistent industrial chemicals some of which have been reported in food.	Risk Assessment and Evidence
G10000050	Food Additives	Analysis of the safety of Titanium Dioxide (E 171) as a Food Additive	On 6 May 2021 the European Food Safety Authority (EFSA) published an opinion on the safety of titanium dioxide (E 171) as a food additive. The EFSA panel concluded that E 171 can no longer be considered safe when used as a food additive. UK Scientific Advisory Committees will assess the EFSA opinion and any associated studies alongside the existing scientific evidence to provide a view on the safety of this permitted food colour. This will help inform what appropriate risk management action	Risk Assessment and Evidence

			may be needed to safeguard consumers.	
G1000051	Imports	Risk Analysis of Minced Meat and Meat Preparations - Review of Prohibitions and Restrictions on Imported EU foods.	FSA work with Defra to consider the risk associated with imported chilled meat preparations (all species), chilled minced meat (bovine, porcine, ovine and caprine) and minced meat (poultry).	Risk Assessment and Evidence