Regulatory Sandbox for Cell-Cultivated Products (CCPs)

FSA BC 25/03/07 - Report by Tom Vincent, Deputy Director, Innovation Policy

1 Summary

1.1 This paper outlines the high-level delivery plan for the Cell-Cultivated Products (CCP) sandbox. The programme will be split into a series of six-month sprints. The Business Committee will be invited to review progress at the end of each sprint and discuss the forward look for the next sprint.

1.2 We invite the Committee to comment on the delivery plan and confirm it is content with the assurance mechanisms and schedule to keep the Board and Business Committee updated on programme progress.

2 Introduction

2.1 CCPs are a completely novel technology for the production of food, posing specific safety risks and complex regulatory questions. Furthermore, the CCP industry is in its infancy, and many companies do not have experience of working with regulators. Supporting innovation in food is a key part of the Government's Vision for Engineering Biology, and therefore the Department of Science, Innovation, and Technology (DSIT) have provided £1.6 million of additional funding to the FSA and Food Standards Scotland (FSS) to run a two-year regulatory sandbox.

2.2 A "sandbox" is typically considered an environment where firms can test innovations under the supervision of a regulator. The concept of a sandbox is defined by regulators in different ways, but all sandboxes facilitate extensive dialogue between industry and a regulator to inform regulatory actions that strike the right balance between facilitating innovation and risk management.

2.3 In this case, the FSA and FSS will work with a selected group of participants from business, academia and industry associations (outlined in **Annex A**) to deliver the following outcomes agreed with DSIT:

- **Regulatory approvals**: the FSA/FSS has a greater understanding about CCP hazards and production processes, leading to swifter, better-informed risk assessments and recommendations to ministers than are currently possible, reaching a typical timeframe for a routine, non-complex application of approximately 2.5 years.

- **Industry confidence**: the CCP industry has a much clearer understanding of what information they need to provide in their applications and how long this will take, reducing

delays and improving investor confidence in the ability of CCP applicants to meet required regulatory standards. Consequently, companies have more confidence in choosing the UK as the place to grow their business and submit CCP applications.

2.4 To achieve these post-programme outcomes, the sandbox will focus on producing tangible outputs (such as guidance) that will provide clarity in the following areas:

- **Hygiene:** food business operators must comply with the law around the hygiene of food, including elements such as how establishments are registered and approved and how products are labelled.

- **CCP production:** build understanding of how CCP products will be manufactured, and therefore the hazards that may be introduced and the regulatory requirements relating to production (e.g. HACCP requirements).

- **Labelling**: agreeing how these products will be labelled to ensure consumers know what they are eating and understand any associated risks, such as allergenicity and nutritional content.

- **Toxicological hazards**: outline suitable approaches to demonstrating the safety of products produced with various growth promoters and processing chemicals not usually found in the diet. Exploring how companies can demonstrate the safety of products using these compounds and if extensive toxicological studies are required.

- **Microbiological hazards**: build understanding of how the different production process for CCP products could mitigate the risk of many common foodborne pathogens but could introduce novel microbes to the final product that are rarely found in traditional agriculture but common contaminants in research cell cultures.

- **Allergenicity**: exploring the potential for different allergenic profiles compared to ‘traditional meat’ that may be introduced from different gene expression in cell culture, use of scaffolds in production or growth media residues.

- **Scale-up**: determining whether a product would have to be re-authorised if a company with an authorised application subsequently changes its processes as part of scaling production.

- **Consumer interests**: build industry understanding of consumer perceptions, the current state of the market and what information consumers want to make informed choices, including environmental or ethical considerations.

- **Enforcement**: ensure local authorities and business operators understand how enforcement to maintain market compliance will work, for example the inspection of production facilities.

- **Traceability & compliance**: requirements for supply-chain traceability of CCP products and business registration/approval requirements. Within this, we will explore business participation in quality assurance schemes.

- **Imports & exports**: determining what rules will be in place to facilitate import and export of these products, including what guidance or training will need to be offered to port health authorities.

- **Pet food & feed**: Although the primary focus is on food, the sandbox will also address priority questions about CCP feed and pet food, to ensure consistent and coherent regulation of the wider CCP industry.

3 Risk assessment of CCP applications

3.1 One of the KPIs for the programme agreed with DSIT is the completion of at least two CCP risk assessments within the sandbox period. The independence and robustness of the risk assessment process is critical for the FSA to deliver food consumers can trust. The existing checks and balances within the wider market authorisation service will ensure all CCP risk assessments, regardless of an applicant's participation in the sandbox or not, are conducted to the same high standard.

3.2 CCP applications will be treated the same as any other application for market authorisation, and the risk assessment of individual CCP applications will be governed independently of the sandbox programme itself. The work of the sandbox will play a vital role enabling CCP assessments to progress.

3.3 The integrity of the FSA/FSS risk assessment process is protected by a 'firewall' between **activities** conducted by the sandbox, and **decisions** on the progress of individual applications. Whilst sandbox-funded risk assessors will contribute to the progression of CCP risk assessments using the insights generated by the sandbox, quality assurance and sign-off on decisions to progress applications will be made independently of the sandbox through the existing FSA Risk Assessment Unit and our independent scientific advisory committees:

- Decisions relating to the scientific assessment of CCP applications sit with the existing, independent Advisory Committee on Novel Foods and Processes (ACNFP).

- Decisions relating to risk assessments and the progression of applications for consideration by the ACNFP sit with the existing Head of Novel Foods Risk Assessment, who is not part of the sandbox programme.

3.4 The Head of Regulated Products Risk Assessment, who is not directly involved in the sandbox programme, is responsible for overseeing this functional separation, and ensuring the risk assessment process remains robust.

3.5 New scientific and regulatory guidance published at regular intervals as part of the sandbox will be equally available to all applicants, regardless of sandbox participation.

4 Key workstreams

4.1 To enable the risk assessments, and to achieve the outcomes listed in paragraph 2.3, the FSA and FSS will deliver a set of key workstreams within the sandbox programme. The workstreams are interdependent and will each contribute to the overall development of regulatory positions on the issues outlined in Section 2.4 above.

4.2 **ACNFP subgroup:** we will set up a sub-group of the Advisory Committee of Novel Foods and Processes (ACNFP) to provide expert advice to the FSA on CCP products as food. This group, part-funded by the sandbox, will be providing expert advice to the FSA, informing the development of guidance for specific hazards associated with CCPs. This sub-group will not be involved in decisions on specific CCP applications. The subgroup will employ several ACNFP members (exact number to be confirmed) and will engage relevant Scientific Advisory Committees (SACs) and external expertise as appropriate for each topic. The first meeting of the subgroup is scheduled for June and these meetings are likely to run bi-monthly.

4.3 **Participant workshops:** we will hold monthly themed workshops with the sandbox participants to address the safety hazards associated with CCP production so the FSA can define the minimum levels of tests we will require businesses to carry out to demonstrate the safety of their products, as well as seeking contributions on regulatory issues relating to the safe production and sale of CCPs. The forward plan for the participant workshops is summarised at **Annex B.**

4.4 **Bespoke guidance**: CCP-specific guidance will be published in batches over the lifetime of the Sandbox programme. The guidance will be published in three waves, within sprints 2, 3 and 4. We have committed to publish the first wave of guidance by the end of 2025.

4.5 **Cross-Government Network**: we will establish a Cross-Government Network (CGN) comprising relevant UK government departments and devolved governments. This network will coordinate collective decisions about regulatory issues that sit within the remit of multiple UK government departments, such as labelling, to ensure a consistent approach is taken across Government on CCPs.

4.6 **International Regulators Network:** we will establish an International Regulators Network (IRN) comprising of regulators that already have conducted work to assess CCP applications. We will use the IRN to test our positions, learn what other regulators have done to identify and mitigate these hazards, and share learning from the sandbox internationally. In addition to providing valuable input to the sandbox, this will strengthen the FSA's reputation as an innovative, open regulator.

4.7 **Business Support Service:** we will provide tailored support to individual CCP companies planning to submit market authorisation applications in GB, helping them reduce delays and submit robust applications. This will be open to all CCP applicants, not just those who are participants in the Sandbox. It will include the option for 1:1 consultations with the FSA, both before an application is submitted, and whilst an application is within the market authorisation service. The delivery of this service will be kept under review once demand is clearer, to ensure the FSA/FSS can still provide an effective service whilst maintaining progress on the other key workstreams. As an entirely new service for GB, this will be a pilot for this kind of initiative, the lessons of which we can apply to wider market authorisation.

4.8 **Wider sector engagement:** we will share information and updates with the wider sector so that all relevant organisations can benefit from the work of the sandbox, even if not a direct participant. There will be a dedicated page on www.food.gov.uk for the CCP sandbox, where we will post FAQs, updates/news, video explainers and bespoke guidance as it is agreed. We will write regular gov.uk blogs to ensure transparency and to give further accessible information. In addition, we will issue regular news updates to the sector through a CCP-focussed newsletter and when relevant, use our social media channels to amplify our messages.

4.9 **Monitoring industry understanding and confidence:** as part of each six-monthly sprint, we will conduct periodic surveys of the CCP industry to understand how the work of the sandbox is impacting the industry and will make adjustments to our delivery plan if intelligence deems this necessary.

4.10 **Programme governance:** A Programme Board has been established consisting of FSA, FSS and DSIT senior officials that will meet six-weekly to review delivery progress, manage any issues arising, provide steers and relevant decision-making. This will include monitoring of Key Performance Indicators (KPIs) agreed with DSIT. As a tier one programme within the FSA's change portfolio, quarterly progress updates will also be provided to EMT in their role as Portfolio Board, and we will hold detailed checkpoint meetings with the Chief Executive Officer, and the Chair and Deputy Chair of the FSA Board. In addition, we propose providing Business Committee with updates every six months, at the end of each sprint. These updates will include both progress against the delivery plan, and monitoring of the KPIs.

5 Programme delivery

5.1 Whilst we have planned the activities that will be undertaken to deliver the defined outcomes for the programme, the pace at which we are able to work through the scientific hazards and regulatory questions will be dependent on the insights gained from the participant workshops (especially during the first six months).

5.2 This makes it challenging to plot out an exact timeline of deliverables from now until the end of the two-year programme. The sandbox will therefore need to be managed as an agile programme, composed of a series of six-month sprints. We have set out a plan for what we intend to deliver in the first six months in detail (see Section 6), but the way that we deliver the remainder of the programme will be highly dependent on the outcomes from the first six months. Running the programme in this manner will enable us to ensure that we deliver the outcomes required, while remaining flexible. Each sprint will be followed by a review stage at the Business Committee to review the outcomes of the previous sprint and set out the deliverables for the next one.

5.3 The timing for these sprints is:

- **Sprint 1: March 2025 – August 2025**. Review at September 2025 Business Committee.
- **Sprint 2: September 2025 – February 2026**. Review at March 2026 Business Committee.
- **Sprint 3: March 2026 – August 2026**. Review at September 2026 Business Committee.
- **Sprint 4: September 2026 – February 2027**. Review at March 2027 Business Committee.

6 Sprint 1 deliverables

6.1 For the sandbox programme, the planned deliverables for the first sprint between March 2025 and August 2025 for each of the key workstreams set out in Section 4 are provided below:

Sandbox Programme Deliverables (Mar 25 – Aug 25)

Number	Workstream	Deliverables
1	Running ACNFP sub-group	March 25: Establishing ACNFP CCP sub-group, identifying relevant external expertise and managing conflicts of interest ahead of the first sub-group meeting. Includes publication of the terms of reference for the sub-group. June 25: First meeting of the ACNFP sub-group to discuss nutrition and allergenicity. August 25: Second meeting of the ACNFP sub-group to discuss on CCP cell-line and production hazards.
2	Participant Workshops	March 2025: The programme launch event, attended by sandbox participants, will serve to introduce the role of the FSA, set the wider vision for the programme, and include preliminary information regarding the thematic workshops outlined below. April 2025: This workshop will focus on issues relating to hygiene (in relation to requirements for manufacturing premises) and relevant regulations, and will include discussions on POAO legislation, CCP terminology, and regulatory gaps. May 25: This workshop will focus on CCP production and will include a discussion of hazards in relation to how CCPs are made (e.g. the selection of cell-lines, use of different growth medias, and allergenicity). June 25: This workshop will focus on the issue of labelling and will include a discussion of questions relating to labelling requirements for CCPs (e.g. terminology and the inclusion of scientific, nutritional, and allergen information). July 25: This workshop will focus on toxicological (chemical) hazards within the CCP production process, including the potential for production scale-up (i.e. producing CCPs on a mass scale) to increase the presence of harmful chemicals in the final product. No workshop in August due to summer break.
3	Bespoke Guidance	March – Aug 25: Initial scoping of priority areas for guidance production based on participant workshops and ongoing risk assessments, ahead of first guidance publication by the end of 2025 (Sprint 2) August 25: Production of draft guidance on the status of CCPs within existing regulatory frameworks for meat and products of animal origin, ahead of publication in Sprint 2. August 25: Draft guidance on allergenicity and nutrition hazards, ahead of publication in Sprint 2.
4	Cross-Government Network	March 25: Agree terms of reference for the network and recruit members. April 25: Hold first meeting focused on agreeing the forward plan for the network, and how it its activities relate to the outputs of the participant workshops. Likely meetings in May 25 covering hygiene and CCP production, and July 25 covering labelling and toxicological hazards.
5	International Regulators Network	March 25: Agree terms of reference for the network and recruit members. May 25: Hold first meeting focused on agreeing the forward plan for the network, priorities of different members, and how its activities relate to the outputs of the participant workshops. Likely meeting in August 25 covering microbiological hazards, CCP production and hygiene.
6	Business Support Service	March 25: Agree scope of business support service April 25: Launch new business support service, including dedicated landing page on FSA website.

7	Wider Sector Engagement	April 25: Publish a dedicated page on www.food.gov.uk for the CCP sandbox, where we will post FAQs, updates/news, blog posts, video explainers and the bespoke guidance as it is agreed. April 25: Agree cadence and forward look for regular blog posts. Depending on agreed cadence, one blog post may be published within Sprint 1 April 25: Agree scope, content and cadence for the new CCP Newsletter, and publish our first edition.
8	Industry Monitoring	April 25: Undertake baseline industry survey to understand how the work of the sandbox is impacting the industry. The survey will be repeated every six months to track progress. April 25: Undertake baseline investor survey to understand how the work of the sandbox is influencing investor confidence in the UK CCP market. The survey will be repeated every six months to track progress The results from these tracking surveys will be reviewed by the Programme Board and will be included in the final CCP sandbox Review Report upon completion of the programme in 2027.
9	Governance	March 25: Business Committee (six monthly) April 25: Programme Board meeting 1 (inc. DSIT, six weekly) May 25: Portfolio Board (quarterly) April & July 25: CEO/Chair checkpoint (quarterly) June 25: Programme Board meeting 2 (inc. DSIT, six weekly) Aug 25: Portfolio Board (quarterly)

6.2 Whilst outside the scope of the sandbox activities, the programme will have a crucial role in tracking and scrutinising progress being made on individual CCP applications, to ensure we meet our KPIs (outlined below). The table below sets out the FSA's wider deliverables for CCP risk assessments during Sprint 1, enabled by the activities of the sandbox:

Risk assessment deliverables (Mar 25 – Aug 25)
April 25: Validation of at least two CCP applications will be completed by April provided applicants respond appropriately to outstanding RFIs.
July 25: Publication of report summarising the discussion of key hazards associated with CCPs from the open session of ACNFP held in February. This report will outline the key themes and questions that were raised in the open session and how these will be explored in the sandbox programme of work.

7 Assurance & Key Performance Indicators (KPIs)

7.1 We will put in place performance metrics that will be tracked throughout the duration of the programme to provide assurance to DSIT, EMT and the Board. These assurance tools will be reviewed on a six-weekly basis by the **Sandbox Programme Board**, and remedial action will be identified if there are concerns regarding pace of delivery.

7.2 The key performance indicators (KPIs) agreed with DSIT that will be measured against throughout the programme are outlined below, alongside the various assurance tools we will use to demonstrate progress against them.

KPIs	**Assurance Tool**

At least two CCP applications reviewed by the Advisory Committee of Novel Foods and Processes and risk assessment completed by the end of the programme	**CCP applications tracking:** Internal dashboard showing process stage of each live application
Industry understands and can use the guidance to inform their decisions about what data to include in safety dossiers; and, Enhanced engagement with prospective applicants and current applicants compared to pre-sandbox	**CCP application processing and feedback loop:** An internal dashboard showing the average time applications take to progress through each stage and reach completion. Application support service will allow for feedback loop over time from FSA, and resultant action to iterate CCP applications
Tranches of guidance published regularly about common safety hazards and tests companies need to conduct to generate data to prove mitigation	**Hazard guidance progression:** Internal dashboard showing stage of completion for each of hazard's areas that we need to analyse and produce guidance for
Published positions on key policy questions - considered and agreed on a four-nation basis	**Regulatory position guidance progression:** Internal dashboard showing stage of completion for each of the regulatory policy areas that we need to analyse and produce guidance for
Enhanced engagement with prospective applicants and current applicants compared to pre-sandbox	**Application support service tracking:** Internal dashboard tracking the number of requests we receive and service for application support service. Including feedback received from businesses, and resultant action to iterate the service
Industry understands and can use the guidance to inform their decisions about what data to include in safety dossiers	**Industry knowledge survey and tracker:** We will conduct six-monthly surveys of CCP industry to track improvements in industry understanding of information they need to provide in applications. A dashboard will track changes over time, compared to baseline
Increased clarity about regulatory process improves investor confidence	**Investor confidence survey and tracker:** We will conduct six-monthly surveys of CCP investors to track whether enhanced clarity of regulatory process has increased their confidence in the UK market A dashboard will track changes over time, compared to baseline

8 Next steps

8.1 We will launch the sandbox on 10 March 2025 at an external event hosted by Imperial College London. All sandbox participants are invited to attend, and we will use this meeting to set out the working arrangements for the programme, and how participants will work together to deliver the outcomes. We will also announce our agreed participants to the media as part of this launch.

8.2 We will work closely with the Board Secretariat to ensure the Committee, and the Board are kept informed as per the arrangements set out above. This is in addition to keeping both informed of any impacts on wider interdependencies with the market authorisation service that may arise as a result of delivering sandbox milestones and outputs.

8.3 We ask the Committee to comment on the high-level delivery plan and agree it is content with the proposed assurance mechanisms, including plans to update the Committee on future progress.

Annex A – sandbox participant list

Industry representatives:

- Gourmey - Paris, France (CCP duck foie gras producer)
- Vital Meat - Sèvremoine, France (CCP chicken producer)
- Mosa Meat - Maastricht, The Netherlands (CCP bovine cell producer)

- Roslin Technologies - Scotland, UK (Producer of bovine, porcine, and avian cells and cell media)
- Blue Nalu - California, USA (CCP tuna producer)
- Uncommon Bio - Cambridge, UK (CCP pork muscle producer/ includes plant-based ingredient)
- Vow – Australia (CCP quail cell producer)
- Hoxton Farm – London, UK (CCP pork fat producer)

Academic bodies:

- CARMA (Cellular Agriculture Manufacturing Hub (University of Bath)
- National Alternative Protein Innovation Centre (University of Leeds)
- Bezos Centre for Sustainable Protein (Imperial College London)

Trade bodies

- Alternative Proteins Association (APA)
- Good Food Institute (GFI)

Annex B – planned sandbox workshop schedule

The below sets out the provisional agenda for the participant workshops and has been designed to ensure each workshop can build off the next, tackling regulatory questions in the right order. We will revisit certain themes in multiple workshops to further refine and finalise regulatory positions based on previous feedback.

Hygiene (April & October 2025)

For industry to better understand the regulatory landscape on hygiene and regulated product requirements; and FSA to capture what industry best hygiene practices currently look like across different products and processes.

CCP production (May & December 2025)

For industry to better understand broader responsibilities in manufacturing CCP products (e.g. inspections, HACCP requirements) and FSA to capture granular detail in product manufacture, including scope of hazards from cell-lines and growth media etc.

Labelling (June & November 2025)

For industry to better understand labelling requirements, including on allergenicity and nutritional content. For FSA to gather information on labelling different CCP products and formulate a position on possible voluntary consumer information, including environmental or ethical considerations.

Toxicological hazards (July 2025 & February 2026)

For industry to outline sources and potential mitigation of possible toxicological hazards, including during production scale-up. FSA to better understand the scope of hazards to review whether sufficient information is available to undertake robust risk assessments.

Microbiological hazards and CCP production (September 2025 & March 2026)

For industry to outline sources and potential mitigation of possible microbiological hazards, including production during scale-up. FSA to better understand the scope of hazards to review whether sufficient information is available to undertake robust risk assessments.

Conditional approval (April 2026)

Working with industry, for FSA to formulate a framework to enable potential conditional market approval based on CCP product safety whilst setting defined boundaries for re-application.

Consumers (June 2026)

Industry share views on their observations of consumer perceptions of CCPs, the current state of the market and what information consumers want. FSA to gather and collate consumer views on CCP products placed on the market to feed into the scope of labelling requirements and desired consumer information.

Local Authorities (July 2026)

FSA to ensure that both business operators and local authorities have a competent understanding of any applicable requirements on production and enforcement to maintain market compliance. The details of those requirements will be developed through the course of the sandbox.

Traceability/compliance (September 2026)

Industry better understands current requirements for supply-chain traceability of their CCP products and business registration/approval requirements based on activities undertaken. FSA to also explore business participation in quality assurance schemes.

Imports/exports (October 2026)

For relevant stakeholders (i.e. manufacturers, distributors and Competent Authorities) to have a competent understanding of legal requirements to maintain international market compliance for individual CCP products.

Sandbox review (January 2027)

For all to reflect on the sandbox programme and looking forward, for the growing CCP sector to remain abreast of the developed CCP/Novel foods framework for application submission. FSA to better understand the future direction and product scope of the CCP sector and potential risk analysis considerations for future radical innovative products intended for market placement.