

# Annex A: Risk Analysis and Regulated Products Service Report

FSA 23-09-08 Annex A Risk Analysis and Regulated Products Service Report gives updates on Risk Analysis and applications.

## Risk Analysis updates

### Overview

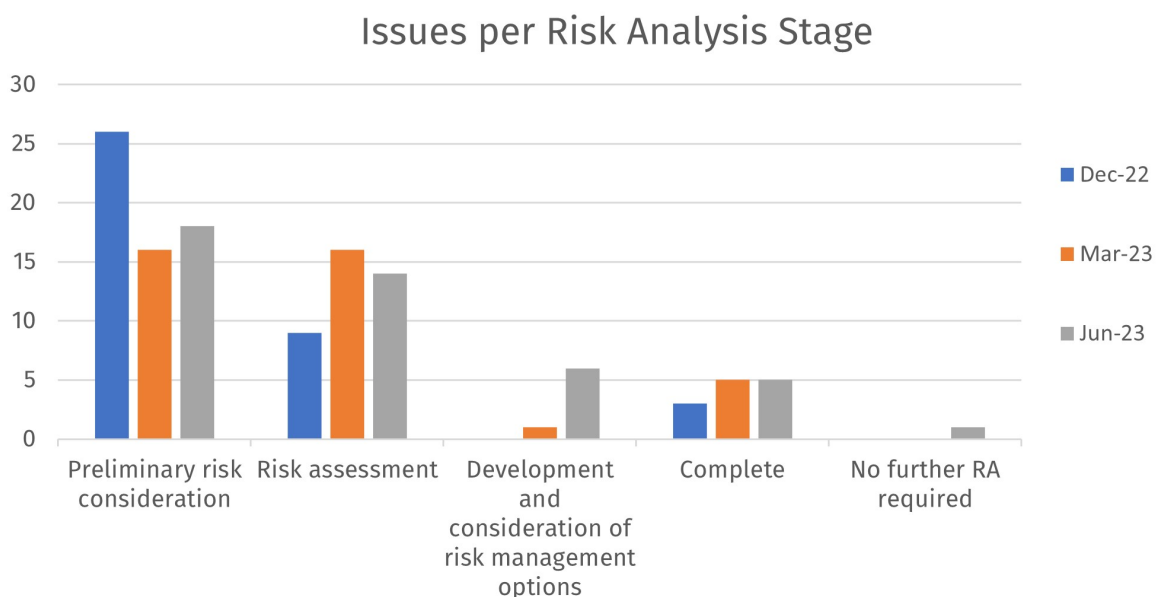
Issues in risks analysis internal system*	Totals
Total active issues	38
Issues flagged for additional board scrutiny	7

\*Active issues are those progressing and logged in FSA internal system. These are published to the online register when they reach the risk assessment and evidence gathering stage. Data correct as of 30 June 2023.

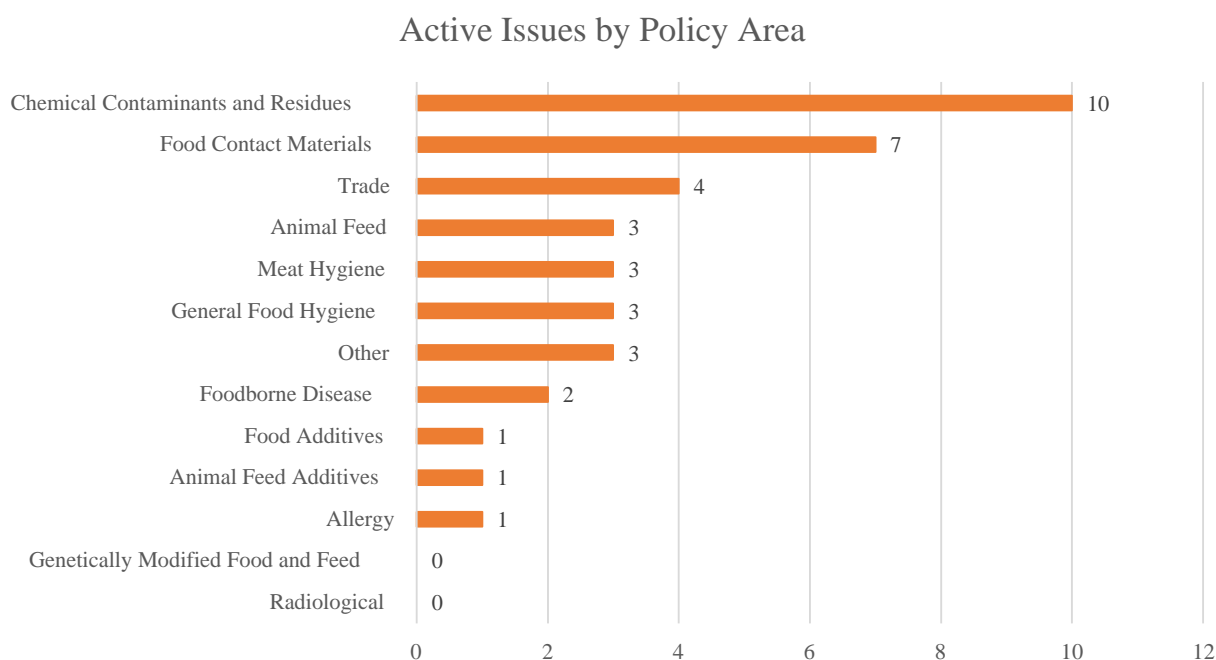
Issues that are at risk assessment and beyond are published to [an online register](#) on a quarterly basis.

Three issues have progressed to risk management and four have been added to the register since the last report. (listed in later slide).

### Issues per Risk Analysis Stage



## Active Issues by policy area



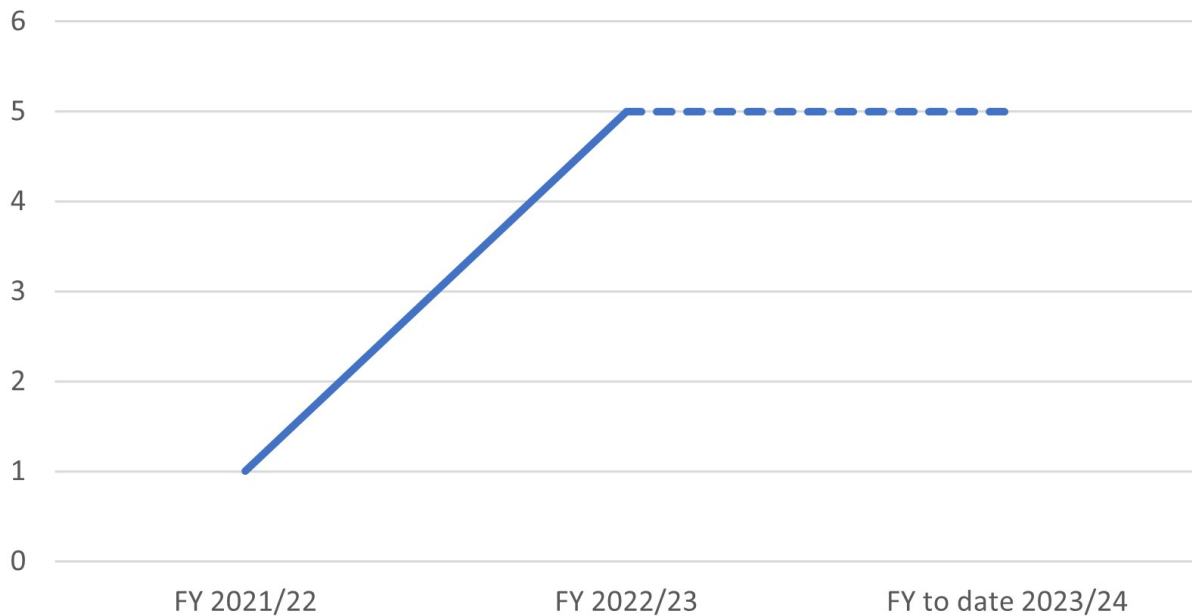
## Performance measures

**Compliance indicators (risk analysis principles)\*** (please note figures for financial year 2023/24 are year to date).

Compliance indicators	2021/22	2022/23	2023/24
Evidence based** Issues with sufficient evidence package and sign off	100%	100%	100%
Open and transparent: Completed issues recorded in public register with full information pack published***	100%	100%	100%
Four country working: Active issues where dispute mechanism triggered	0	0	0

## Completed issues (cumulative)

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Monitoring indicators	Total
Issues completed (financial year to date)	0
issues completed (total)	5

\* Compliance indicators relate to the following figures

Issues with sufficient evidence package and sign-off, and Completed issues recorded in public register with full information pack published:

- 2021/22 – one complete (end of March 22)
- 2022/23 – five complete (end of March 23)
- 2023/24 – five complete (2023/24 FY to 26th June 23)

Active issues where dispute mechanism triggered:

- 2021/22 – seven active (end of March 22)
- 2022/23 – 22 active (end of March 23)
- 2023/24 – 38 active (2023/24 FY to 26th June 23)

\*\*Our evidence-based indicator ensures that the correct level of assurance took place during evidence generation.

\*\*\*Publication of information in line with FSA Code of Practice on Openness

### Risk analysis register updates since last Board meeting in June

Details of issues undergoing risk analysis are published to an online register following initial consideration, once it is confirmed that risk assessment or other evidence is required, and the risk assessment phase of the process commences.

Issue	Description	Status
Country Profiles - Imported Food of Non-Animal Origin (FNAO) Phase 1	The FSA Market Access Assurance Team will support the FSA Trade Risk Assessment Team in the production of Country Profiles for trading partners exporting food of non-animal origin (FNAO) to the UK. These profiles will assist the Market Access Assurance Team in monitoring the risk associated with each country and to inform on the need for follow-up action.	Previously in register – Country profile not required. No evidence produced, and further risk analysis deemed unnecessary.
Risk assessment on Avian Influenza infection via food chain	Production of an updated risk assessment for Avian Influenza in food, triggered by changes to consumer advice regarding egg consumption and the geographically widespread nature of Avian Influenza generating over 100 confirmed cases in the 2021/22 Avian Influenza season. This work has been initiated to ensure risk management advice for the consumption of poultry, wild game and raw eggs remains appropriate and is supported by the latest evidence on risks associated with Avian Influenza, especially with respect to vulnerable groups, taking into account developments in the spread of Avian Influenza.	Progressed to development and consideration of risk management options.
Assessment of the risk to vulnerable consumers from Listeria monocytogenes in blue cheese	Assessment of the risk to vulnerable consumers from listeria monocytogenes in blue cheeses. There are inconsistencies in the advice provided by government partners to pregnant women on the consumption of blue cheese. A RA will assess the risk to vulnerable consumers. FSA and FSS are working together to present consistent RM advice underpinned by science and evidence.	Progressed to development and consideration of risk management options.

Issue	Description	Status
Assessment of the risk to vulnerable consumers from <i>Listeria monocytogenes</i> in smoked fish	Assessment of the risk to vulnerable consumers, including pregnant women and people with weakened immune systems, from <i>Listeria monocytogenes</i> in smoked fish. This follows confirmation there has been an increase over the period 2020-22 in the number of cases of listeriosis linked to the consumption of smoked salmon by vulnerable groups. FSA and FSS are working with other Government departments to present consistent RM advice underpinned by science and evidence.	Progressed to development and consideration of risk management options*  *Risk management advice has been published and this issue moved to complete. However, this occurred outside the performance window for this paper. This update will be incorporated in the next risk analysis register update.

[The register of risk analysis issues](#) was last updated on 26 June 2023, incorporating updates to the end of May. The next update will incorporate updates to the end of August and will be published by the end of September at the earliest.

### **New Risk analysis register additions since last Board meeting in June**

Details of issues undergoing risk analysis are published to an online register following initial consideration, once it is confirmed that risk assessment or other evidence is required, and the risk assessment phase of the process commences.

Issue	Description	Status	Earliest estimate of completion date*
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<p>Microbiological Risk Assessment to support development of advice and guidance to manage outbreaks of norovirus associated with consumption of raw oysters with respect to the amount of Norovirus contamination detected by real time reverse transcription polymerase chain reaction ISO 15216</p>	<p>The FSA is seeking to develop risk management advice in relation to Norovirus testing of oysters during outbreak situations, taking into account the amount of norovirus contamination detected and how this may lead to resumption of harvesting from oyster harvesting areas implicated in an outbreak.</p>	<p>Added to register – development and consideration of risk management options.</p>	<p>Risk management advice is expected to be completed by the end of October 2023.</p>
<p>2023 review of imported food and feed controls under Retained EU Commission Implementing Regulation 2019/1793</p>	<p>To ensure that the proposed changes to the list of certain controlled food and feed products not of animal origin (FNAO) in the annexes of Retained EU Commission Implementing Regulation 2019/1793 outlined are appropriate.</p>	<p>Added to register – development and consideration of risk management options.</p>	<p>Risk management advice is expected to be completed by Summer 2023 at the earliest.</p>
<p>Flexibility to increase the threshold for designation of low-capacity slaughterhouses</p>	<p>Flexibility under Article 7 (1) (b) of REUL 2019/624 to increase the threshold for the designation of low-capacity slaughterhouses. This will allow the post-mortem inspection in those eligible slaughterhouses to be performed by the official auxiliary without the official veterinarian (OV) being at the slaughterhouse when this is carried out.</p>	<p>Added to register – risk assessment and evidence gathering.</p>	<p>Risk assessment was completed in April 2023. No further information on risk management deadlines are available.</p>

Risk Profile - Live Bivalve Molluscs (LBMs): Oysters	FSA work with the UK Office for SPS Trade Assurance (in Defra) to identify and characterise the hazards associated with oysters from different global regions.	Added to register – risk assessment and evidence gathering.	The Risk Profile is expected to be completed by the end of August 2023 at the earliest .
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\*Earliest estimated completion dates are provisional at this stage and dependent on the progress of the RA phase and subsequent RM approach. Issues may be reprioritised if other issues emerge that take priority on public health grounds.

[The register of risk analysis issues](#) was last updated on 26 June 2023, incorporating updates to the end of May. The next update will incorporate updates to the end of August and will be published by the end of September at the earliest.

## Regulatory Products Service Update

### Key update

On 20 June 2023, CMS was launched as the new method to receive, track and progress applications to the FSA. Since implementation, there were no new applications between 20 and 30 June 2023. We believe this is due to additional information requested from applicants before a submission can be made.

The following reporting is based on applications received through the Application Service platform. Future reporting will include CMS data.

### Cohorts by quarter

The below table shows the breakdown and progress of applications in the Regulated Products Service by quarter.

Date	Total Contacts	Incomplete Applications	Applications progressing	Pre-Validation	Risk Assessment	Risk Management
Jan to March 2021	993	790	177	85	82	10
April to June 2021	183	135	36	5	29	2

Date	Total Contacts	Incomplete Applications	Applications progressing	Pre-Validation	Risk Assessment	Risk Manager
July to September 2021	105	82	19	3	11	5
October to December 2021	111	73	34	4	27	3
Jan to March 2022	108	82	23	5	18	-
April to June 2022	123	97	26	7	19	-
July to September 2022	113	90	23	16	6	1
October to December 2022	129	86	42	40	2	-
Jan to March 2023	128	105	23	23	-	-
April to June 2023	70	47	23	23	-	-
Total	2063	1587	425	211	194	21
Stop the clock	-	-	-	44	38	-

Note: 'Completed' refers to applications which have reached the final stage in the process and have been either approved or rejected.

This table breaks down the applications by regime at different stages in the Regulated Products Service: March 2023 v June 2023.



<b>Regime</b>	<b>Applications progressing</b>	<b>Applications at pre-validation</b>	<b>Applications at Risk assessment</b>	<b>Applications at Risk Management</b>	<b>Applications at authorisation</b>
Novel food (excluding CBD)	March: 51 June: 52	March:25 June: 22	March: 24 June: 30	-	March: 2 June: 0
Novel Food (CBD)	March: 130 June: 122	March: 113 June: 97	March: 17 June: 25	-	-
Feed Additives	March: 158 June: 166	March: 56 June: 54	March: 83 June: 92	March: 19 June: 20	March: - June: -
GMO	March: 35 June: 29	March: 13 June: 16	March: 11 June: 13	-	March: 11 June: 0
Novel Food Traditional	March: 3 June: 0	March: 3 June: 0	-	-	-
Food Contact Materials (Recycled)	March: 12 June: 12	March: 7 June: 6	March: 5 June: 6	-	-
Food Contact Materials (Plastics)	March: 3 June: 3	-	March: 3 June: 3	-	-

<b>Regime</b>	<b>Applications progressing</b>	<b>Applications at pre-validation</b>	<b>Applications at Risk assessment</b>	<b>Applications at Risk Management</b>	<b>Applications at authorisation</b>
Extraction Solvents	March: 1 June: 1	March: 1 June: 1	-	-	-
Food Additives	March: 18 June: 19	March: 5 June: 7	March: 12 June: 12	-	March: 1 June: 0
Flavourings	March: 10 June: 9	March: 5 June: 5	March: 3 June: 3	March: 1 June: 1	March: 1 June: 0
Feed for Particular Nutritional Users (PARNUTS)	March: 2 June: 3	March: - June: 1	March: 2 June: 2	-	-
Novel Food Status	-	-	-	-	-
Smoke Flavourings	March: 9 June: 9	March: 7 June: 1	March: 2 June: 8	-	-
Food Enzymes	March: 1 June: 1	March: 1 June: 1	-	-	-
Feed Detoxification Processes	-	-	-	-	-

Regime	Applications progressing	Applications at pre-validation	Applications at Risk assessment	Applications at Risk Management	Applications at authorisation
Other	March: 5 June: -	March: 5 June: -	-	-	-
Total	March: 438 June: 426	March: 241 June: 211	March: 162 June: 194	March: 20 June: 21	March: 15 June: 0

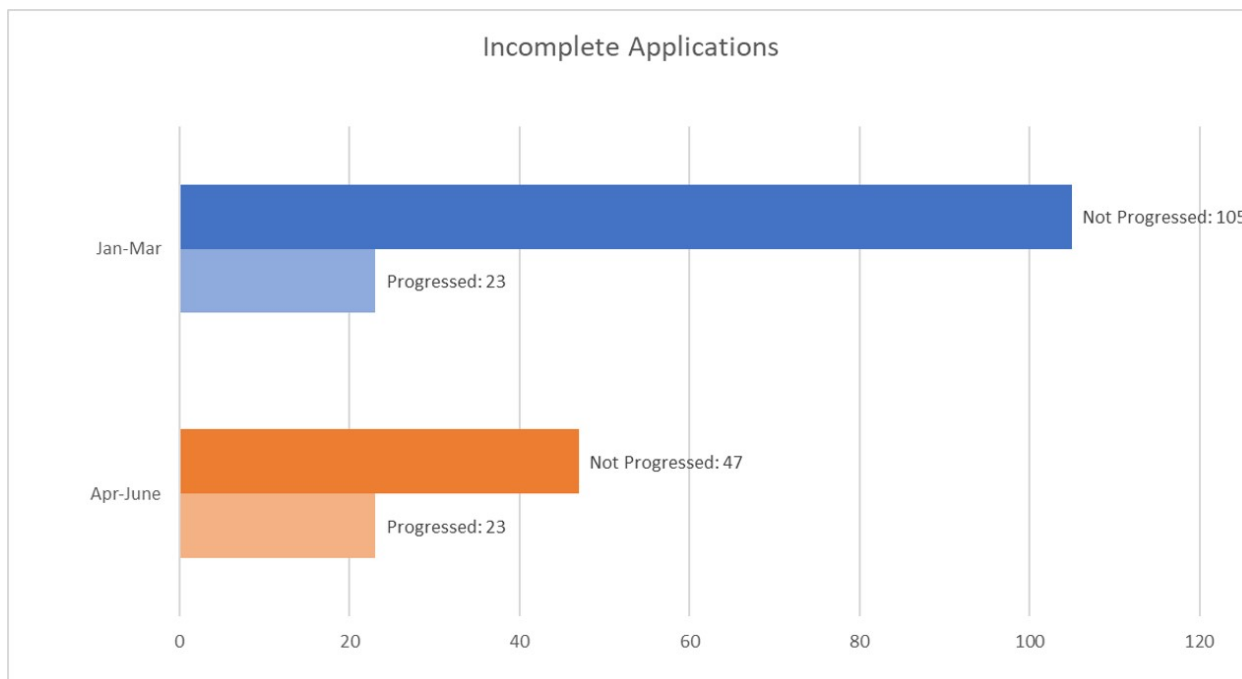
## Incomplete Applications

Incomplete applications describe any communication submitted through the online portal that is not taken forward. This can include questions and comments as well as applications that do not contain sufficient information to proceed. This quarter, we have continued to receive a high number of incorrect, abandoned or incomplete applications at 69%. As the new Case Management System has been introduced, we expect a significant reduction in incomplete applications.

Total number of contacts: January to March 2023 = 128

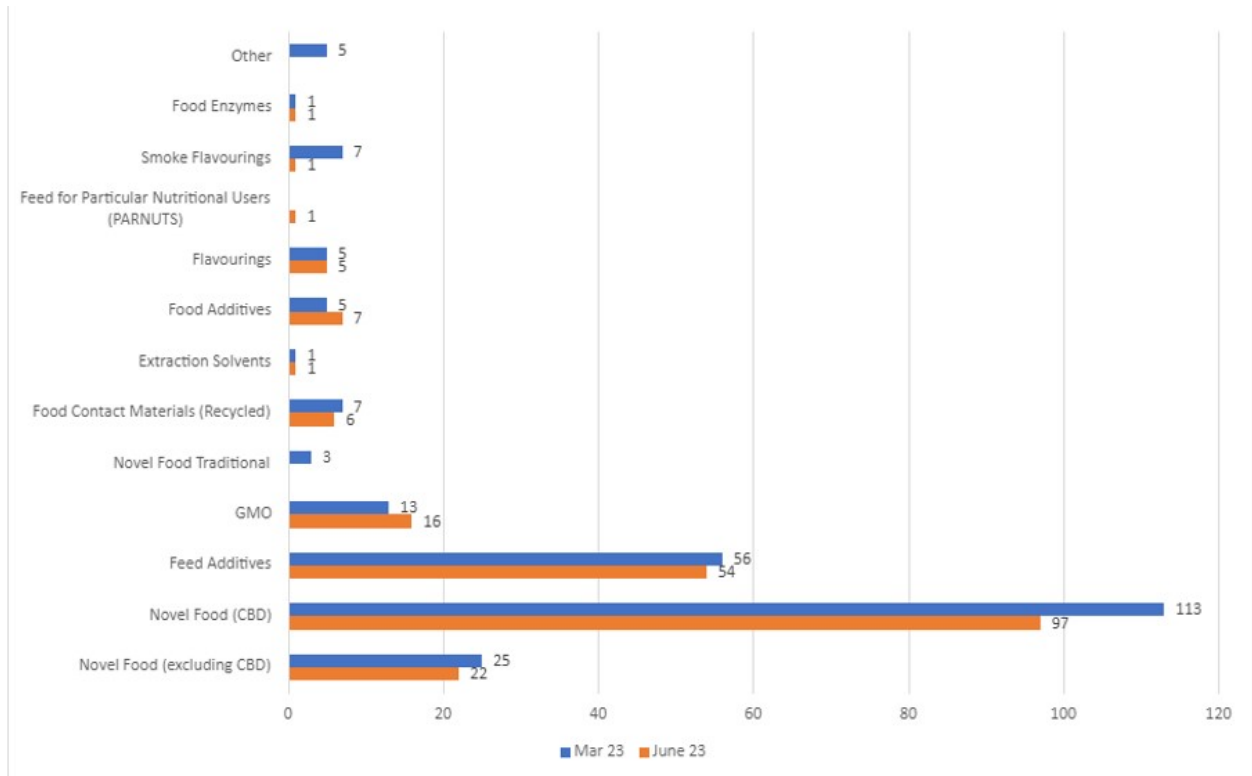
Total number of contacts: April to June 2023 = 70

### Incomplete applications



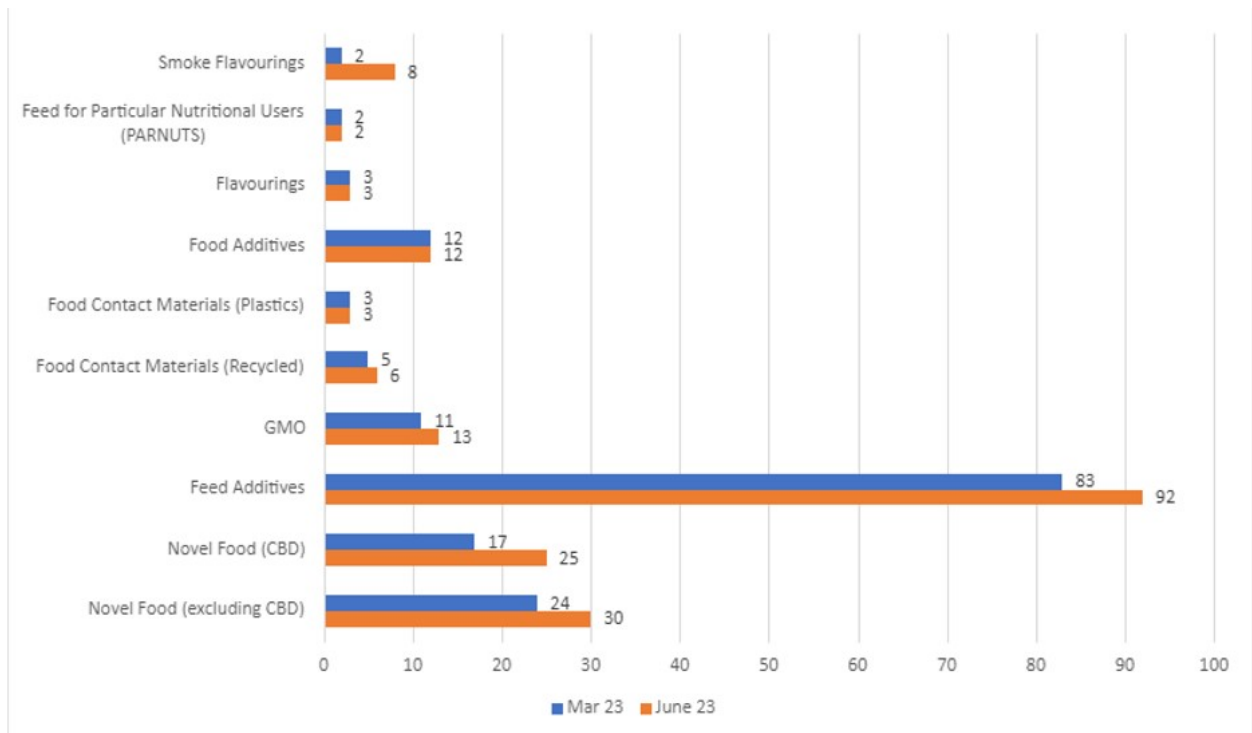
## Pre-Validation

49% of all applications are at the Pre-Validation stage. CBD applications make up 46% and are being actively managed. As of 30 June 2023, there were 211 applications at this stage, compared to 241 at March 2023. The regime distribution is shown in the below graph.



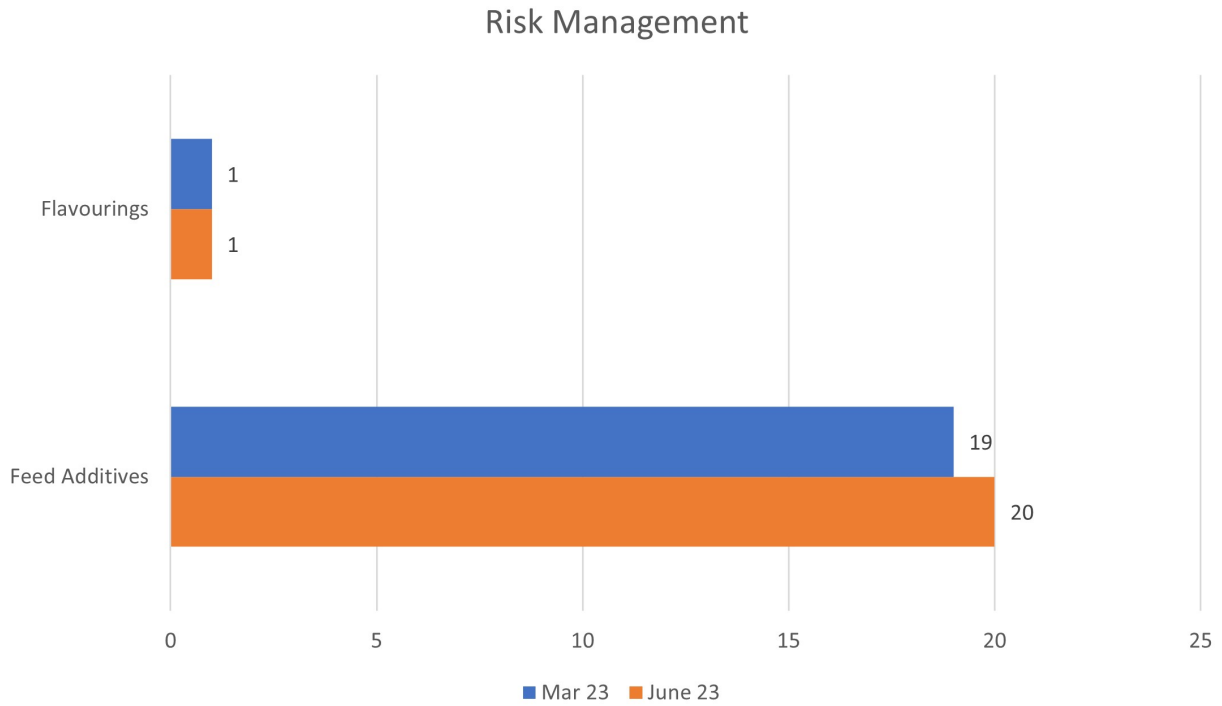
## Risk Assessment

46% of all applications are currently at the Risk Assessment stage. As of 30 June 2023, there were 194 applications, compared to 162 in March 2023. The regime distribution is shown in the below graph:



## Risk Management

5% of all applications are at the Risk Management stage. As of 30 June 2023, there were 21 applications at this stage, compared to 20 in March 2023. The regime distribution is shown in the below graph:



## Authorisation

As of 30 June 2023, there were 0 applications in the Authorisation stage, compared to 15 at March 2023 (which have now been completed). The regime distribution is shown in the below graph:



## Completed Applications

As of 30 June 2023, the Regulated Products Service has completed 50 applications, an increase of 16 from 31 March 2023. The regime distribution is shown in the below graph:

