
FSA 23-12-07 Annex A

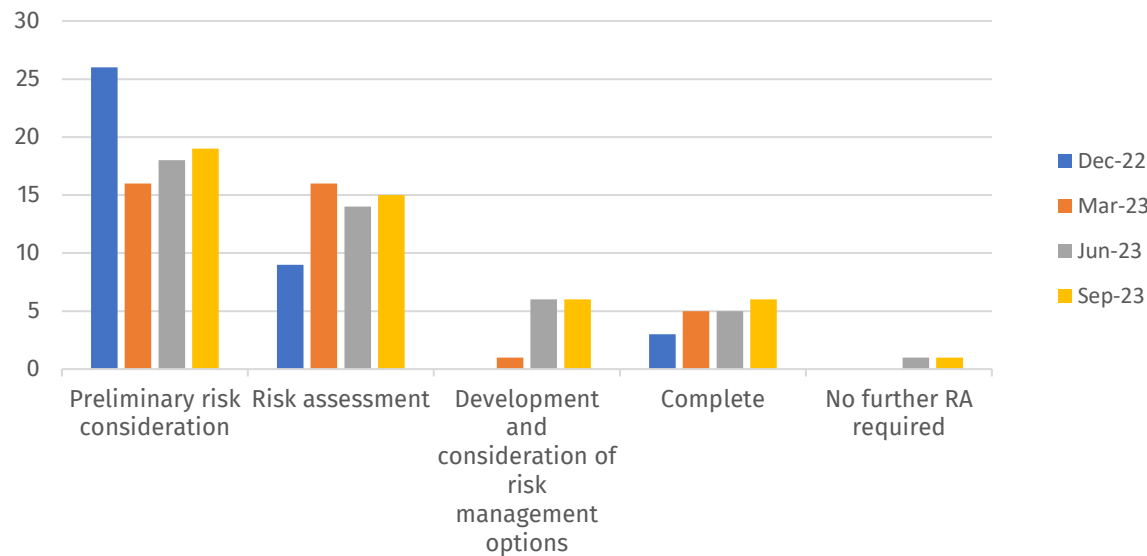
**Risk Analysis and
Regulated Products Service
Report**

Risk Analysis updates

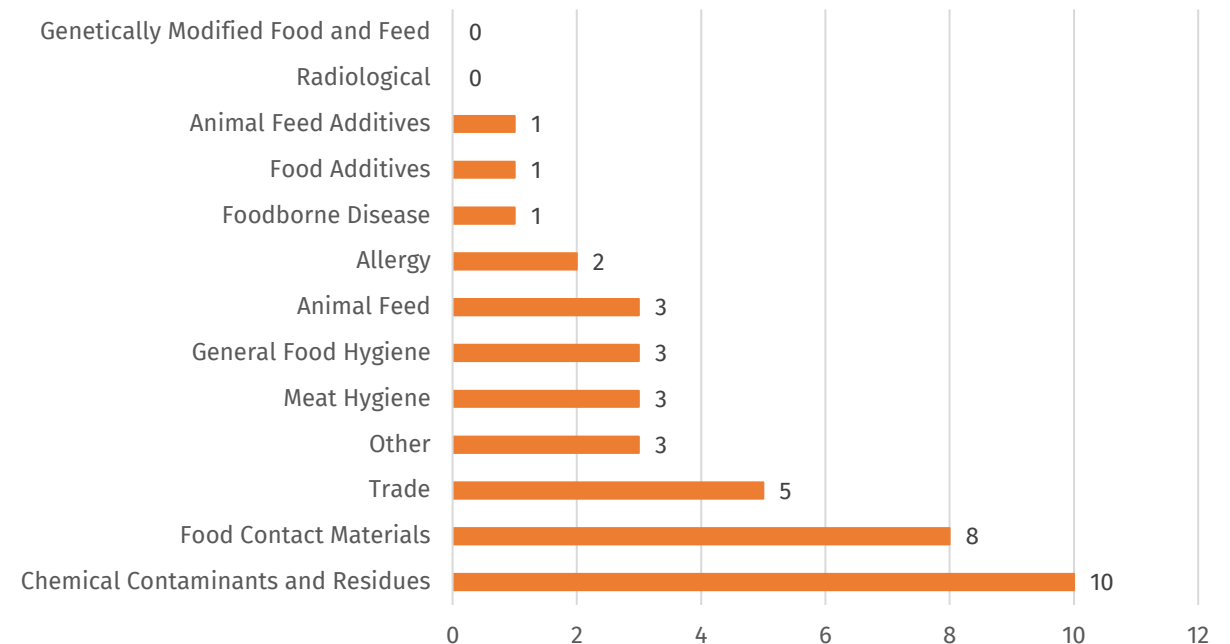
Overview

Issues in risk analysis internal system*	
Total active issues	40
Issues flagged for additional board scrutiny	8

Issues per Risk Analysis Stage



Active Issues by Policy Area



- Issues that are at risk assessment and beyond are published to an online [register](#) on a quarterly basis.
- One issue has been marked complete and three have been added to the register since the last report (listed in later slide).

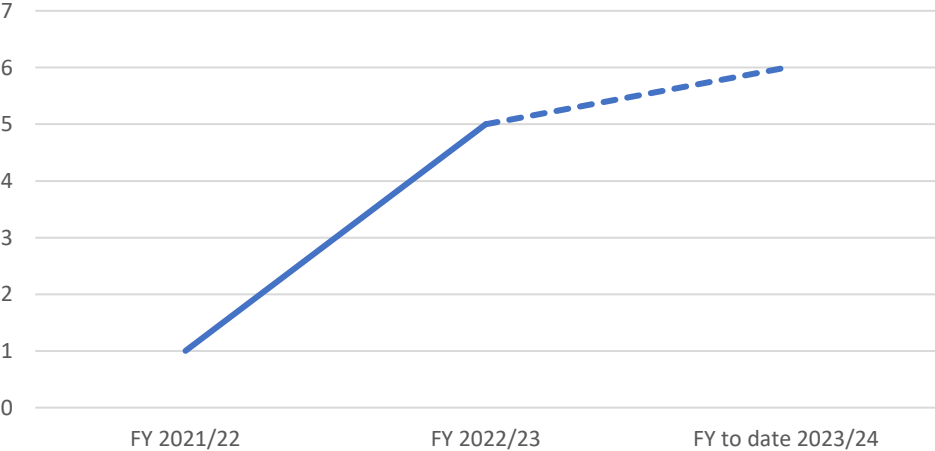
*Active issues are those progressing and logged in FSA internal system. These are published to the online register when they reach the risk assessment and evidence gathering stage. Data correct as of 29 September 2023.

Performance measures



Compliance indicators (risk analysis principles)* <i>Please note, figures for FY 2023/24 are year to date.</i>								
Evidence-based**			Open and transparent			Four country working		
Issues with sufficient evidence package and sign-off			Completed issues recorded in public register with full information pack published***			Active issues where dispute mechanism triggered		
2021/22:	2022/23:	2023/24:	2021/22:	2022/23:	2023/24:	2021/22:	2022/23:	2023/24:
100%	100%	100%	100%	100%	100%	0	0	0

Completed issues (cumulative)



Monitoring indicators
Issues completed (financial year to date): 1
Issues completed (total): 6

* 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 – 1 complete (end of March 22)
 - 2022/23 – 5 complete (end of March 23)
 - 2023/24 – 6 complete (2023/24 FY to 29th September 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 – 40 active (2023/24 FY to 29th September 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 September

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
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.	Previously in register – moved to Complete

New risk analysis register additions since last Board meeting in September

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*
Titanium dioxide as a feed additive	On 16 June 2021 the European Food Safety Authority (EFSA) published an opinion on the safety of titanium dioxide (E171) as a FEED additive (EFSA No.6630). The Panel concluded that E171 can no longer be considered safe when used as a feed additive. This was followed by the publication of Regulation (EU) 2021/2090 of 25 November 2021 concerning the denial of authorisation of titanium dioxide as a feed additive for all animal species, which came into force in the EU on 20th December 2021, with sequential transition periods of up to 6 months (to 20 June 2022). A parallel safety assessment of titanium dioxide as a FOOD additive (G10000050) is ongoing. The safety risk assessment for titanium dioxide as a feed additive will consider the conclusions from the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) on the food additive prior to finalising the feed additive assessment.	Added to register – risk assessment and evidence gathering	The risk assessment will not be available until April 2024 at the earliest.
Assessment of Bisphenol A (BPA)	Review of latest evidence relating to the safety of BPA in food. The European Food Safety Authority (EFSA) published its updated Opinion in April 2023 and recommended that the tolerable daily intake (TDI) be reduced to 0.2 ng/kg per body weight per day.	Added to register – risk assessment and evidence gathering	A risk assessment will not be available until 2024 at the earliest.
Assessment of the risk of allergic reaction from fortification of non-wholemeal wheat flour with folic acid	UK Health Departments are pursuing a public health intervention to require the fortification of non-wholemeal wheat flour with folic acid at a level of 250 µg per 100 g of flour in order to prevent an estimated 200 babies being born each year with neural tube defects (e.g. spina bifida and anencephaly). This work will assess the risk of allergic reaction arising from the fortification of non-wholemeal flour with folic acid at 250 µg / 100g of flour should this not be reflected on labelling or provided to consumers by other means to inform consideration of whether a limited transitional period may be provided.	Added to register – risk assessment and evidence gathering	The risk assessment was published in October 2023 [^] . This will inform other government department risk management decisions. [^] This update falls outside the performance window for this report.
*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 27 September 2023, incorporating updates to the end of August. The next update will incorporate updates to the end of November and will be published by the end of December at the earliest.

**Regulated Products
Service Update**

Cohorts by Quarter

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

	Total Contacts	Incomplete Applications	Applications Progressing	Pre-Validation	Risk Assessment	Risk Management	Completed
Jan-Mar 2021	993	790	177	54	68	13	26
Apr-June 2021	183	135	36	4	19	2	12
Jul-Sept 2021	105	82	19	3	9	6	4
Oct-Dec 2021	111	73	34	4	26	3	4
Jan-Mar 2022	108	83	22	3	15		3
Apr-June 2022	123	97	26	6	9		0
Jul-Sept 2022	113	90	23	16	3	1	0
Oct-Dec 2022	129	86	42	33	6		1
Jan-Mar 2023	128	105	23	21			0
Apr-June 2023	70	48	22	21	1		0
Jul-Sept 2023	27	1	26	3			
Total	2090	1590	450	168	156	25	50
Stop the Clock				61	40		

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

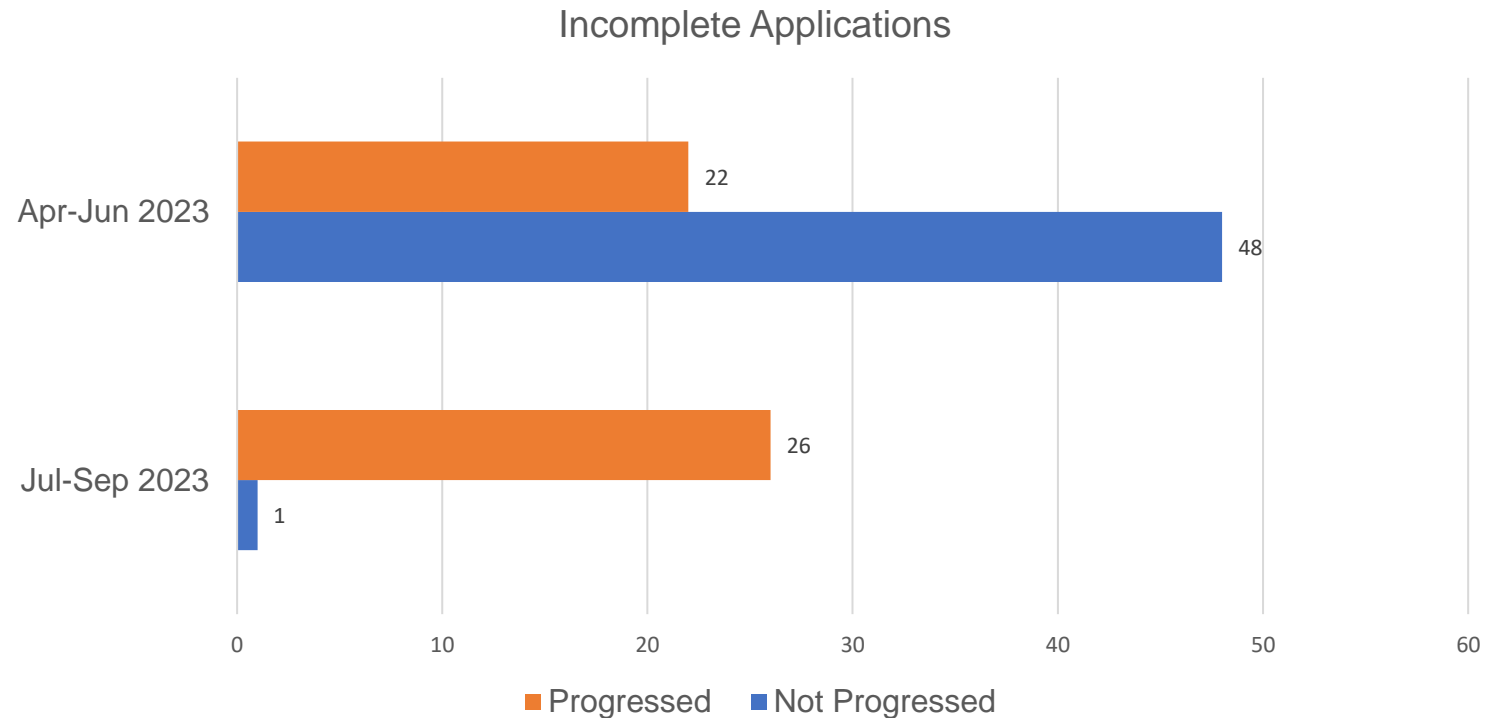
This slide presents blended data from the legacy Application Service and CMS (launched in June 2023).

Incomplete Applications

Incomplete applications describe any communications submitted through the approvals process that are not taken forward. This can include questions and comments as well as applications that do not contain sufficient information to proceed. With the implementation of CMS, the number of incomplete applications has decreased substantially.

**Total number of contacts:
April – June 2023 = 70**

**Total number of contacts:
July – September 2023 = 27**



This slide presents blended data from the legacy Application Service and CMS (launched in June 2023).

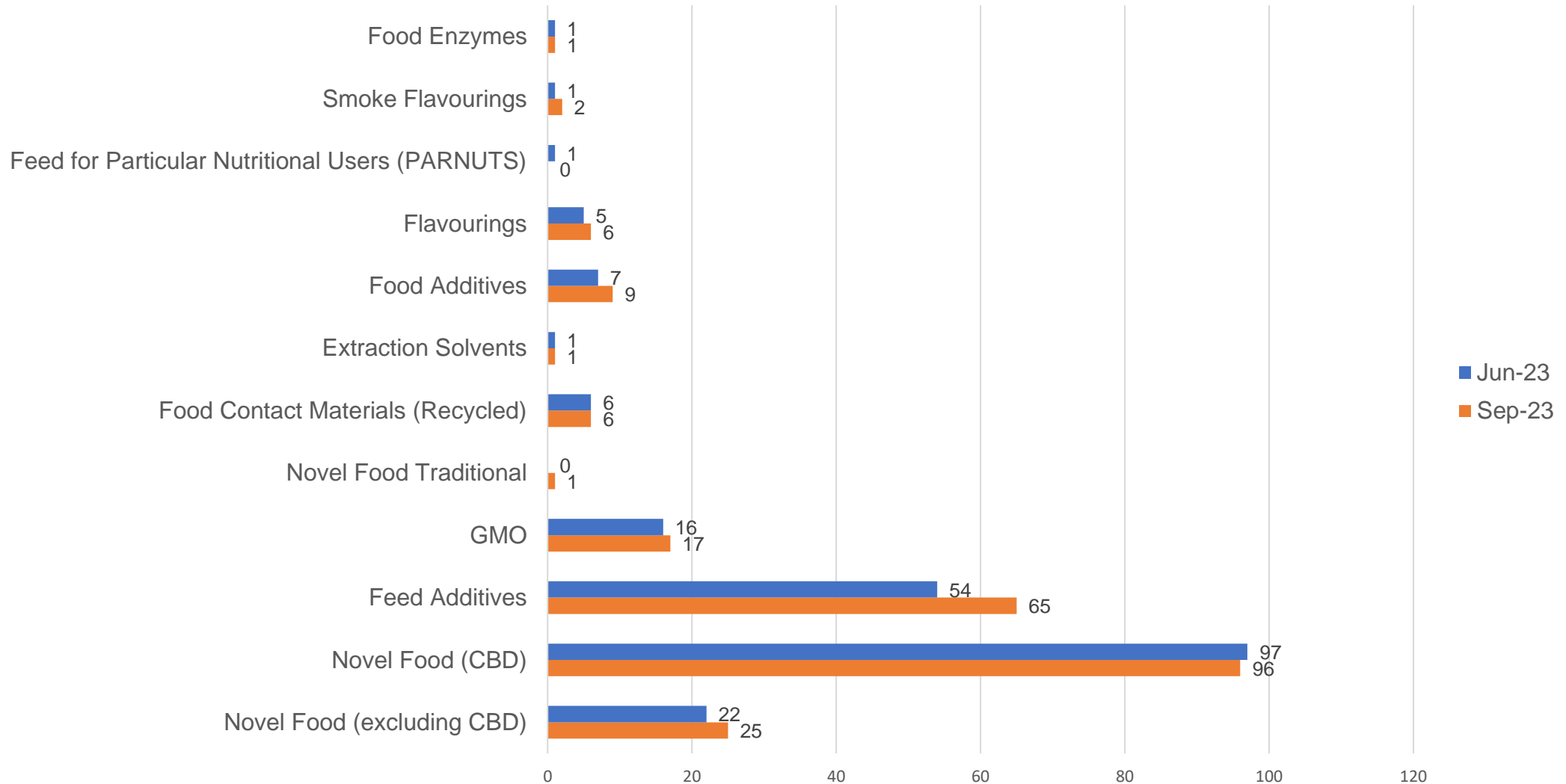
This table breaks down the applications by regime at different stages in the Regulated Products Service: **June 2023 v Sept 2023**

Regime	Applications progressing		Applications at Pre-Validation		Applications at Risk Assessment		Applications at Risk Management		Applications at Authorisation		Applications completed	
	June 23	Sept 23	June 23	Sept 23	June 23	Sept 23	June 23	Sept 23	June 23	Sept 23	June 23	Sept 23
Novel Food (excluding CBD)	52	59	22	25	30	30	-	4	-	-	8	8
Novel Food (CBD)	122	122	97	96	25	26	-	-	-	-	-	-
Feed Additives	166	177	54	65	92	92	20	20	-	-	11	11
GMO	29	30	16	17	13	13	-	-	-	-	21	21
Novel Food Traditional	-	1	-	1	-	-	-	-	-	-	3	3
Food Contact Materials (Recycled)	12	12	6	6	6	6	-	-	-	-	-	-
Food Contact Materials (Plastics)	3	3	-	-	3	3	-	-	-	-	-	-
Extraction Solvents	1	1	1	1	-	-	-	-	-	-	-	-
Food Additives	19	21	7	9	12	12	-	-	-	-	1	1
Flavourings	9	10	5	6	3	3	1	1	-	-	1	1
Feed for Particular Nutritional Users (PARNUTS)	3	3	1	0	2	3	-	-	-	-	-	-
Novel Food Status	-	-	-	-	-	-	-	-	-	-	2	2
Smoke Flavourings	9	10	1	2	8	8	-	-	-	-	3	3
Food Enzymes	1	1	1	1	-	-	-	-	-	-	-	-
Feed Detoxification Processes	-	-	-	-	-	-	-	-	-	-	-	-
Other Applicant has not selected the regime (mainly enquiries checking whether application is required). If these applications progress, the appropriate regime will be assigned.	-	-	-	-	-	-	-	-	-	-	-	-
Total	426	450	211	229	194	196	21	25	0	0	50	50

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Pre-Validation

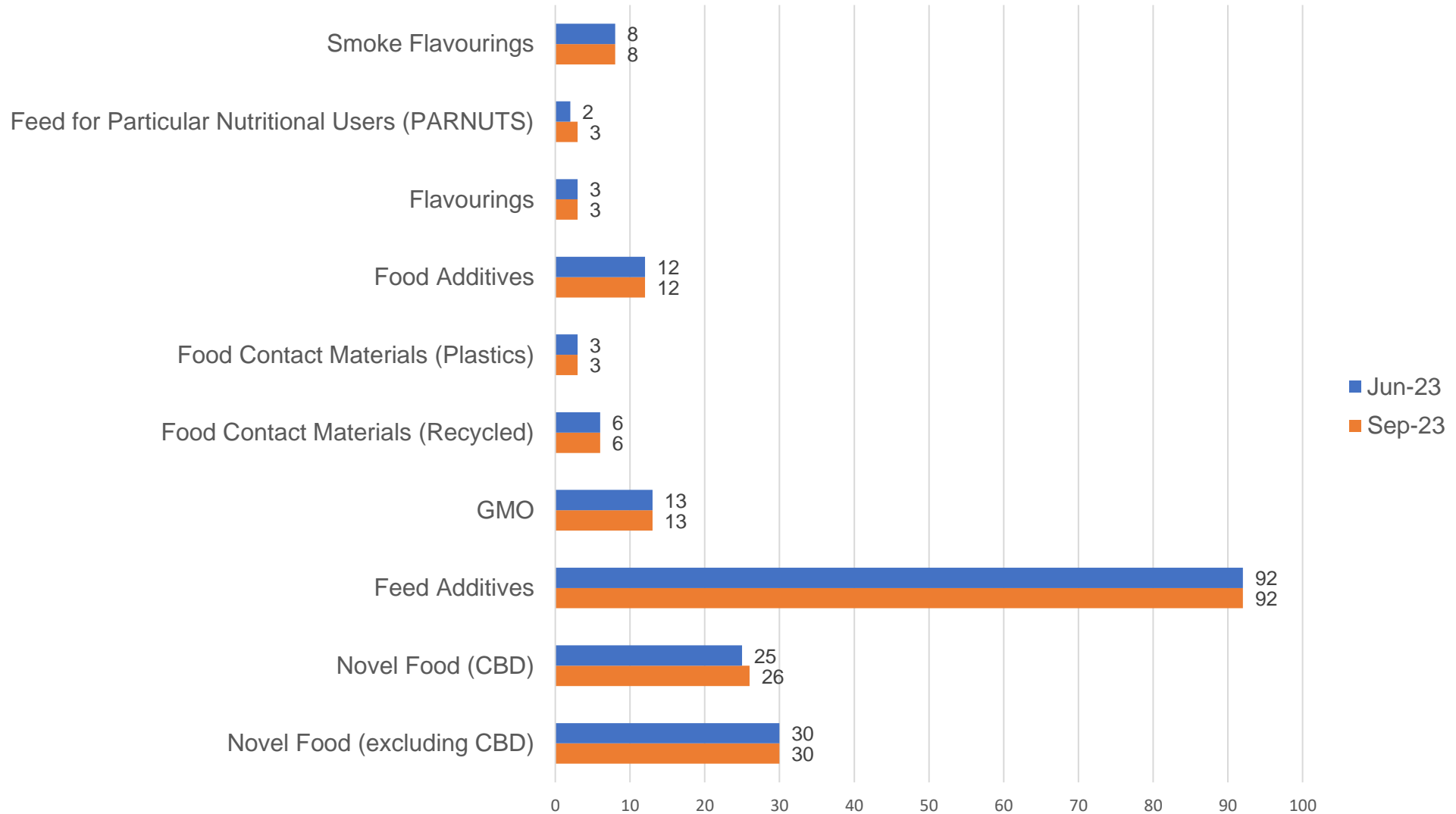
51% of all applications are at the Pre-Validation stage. CBD applications make up 42% and are being actively managed. As of 30 September 2023, there were **229** applications at this stage, compared to 211 at June 2023. The regime distribution is shown in the below graph.



This slide presents blended data from the legacy Application Service and CMS (launched in June 2023).

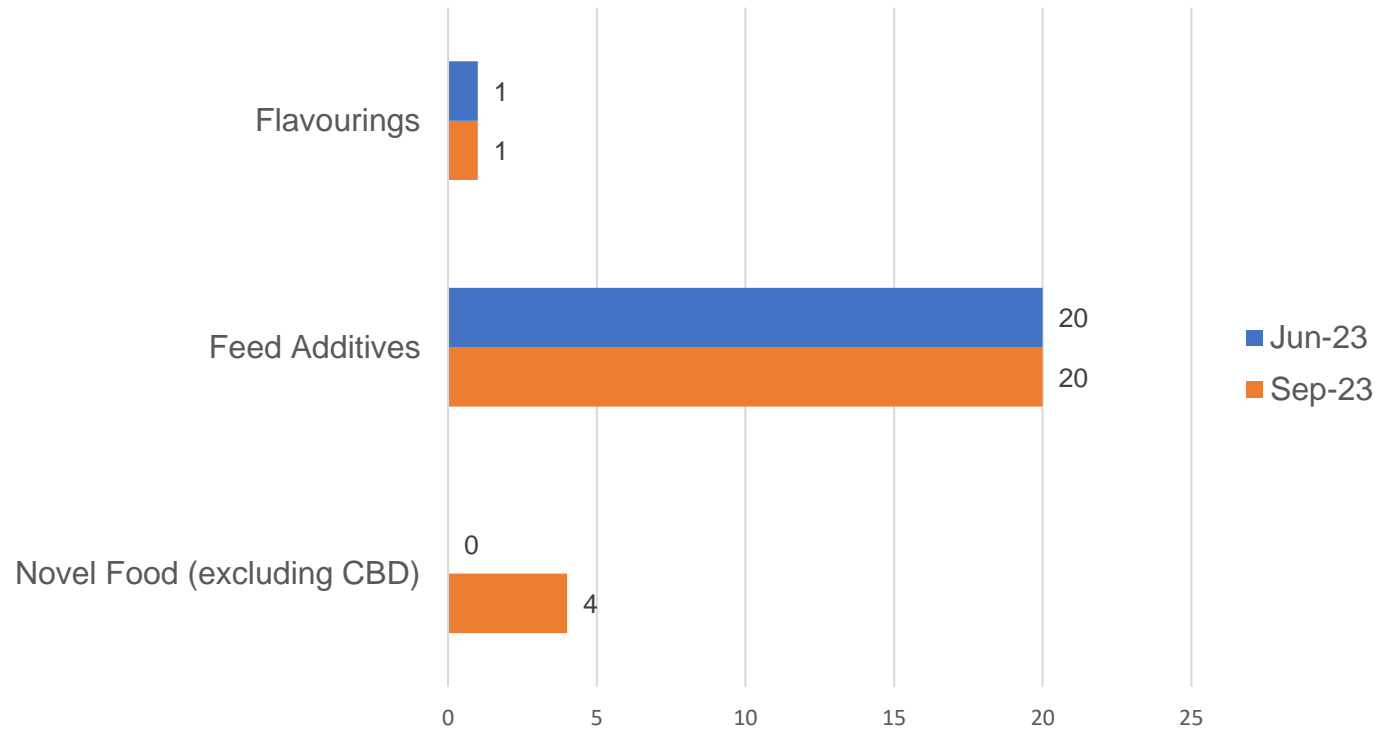
Risk Assessment

44% of all applications are currently at the Risk Assessment stage. As of 30 September 2023, there were **196** applications, compared to 194 in June 2023. The regime distribution is shown in the below graph:



Risk Management

6% of all applications are at the Risk Management stage. As of 30 September 2023, there were **25** applications at this stage, compared to 21 in June 2023. The regime distribution is shown in the below graph:



Completed Applications

As of 30 September 2023, the Regulated Products Service has **completed 50 applications**. The regime distribution is shown in the below graph:

