Risk Analysis and Regulated Products Service Report to Board June 2023

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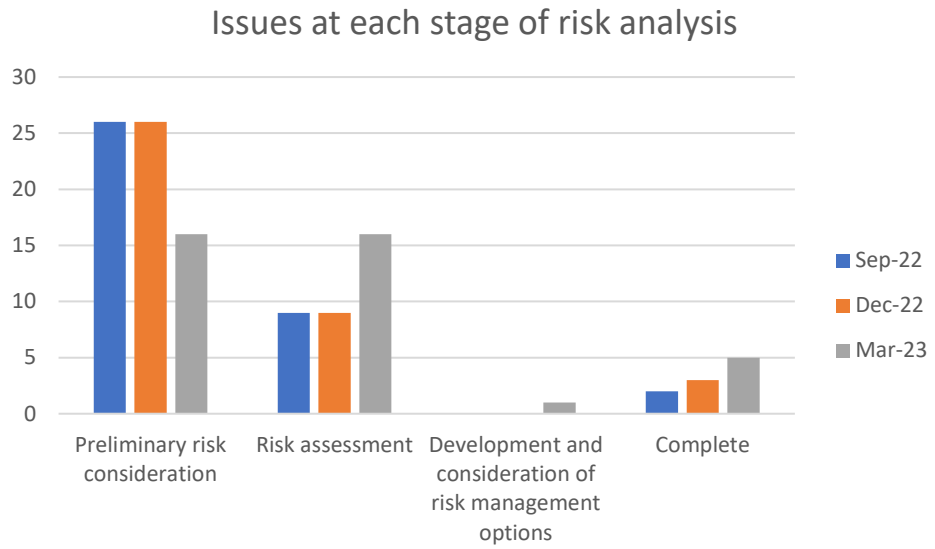
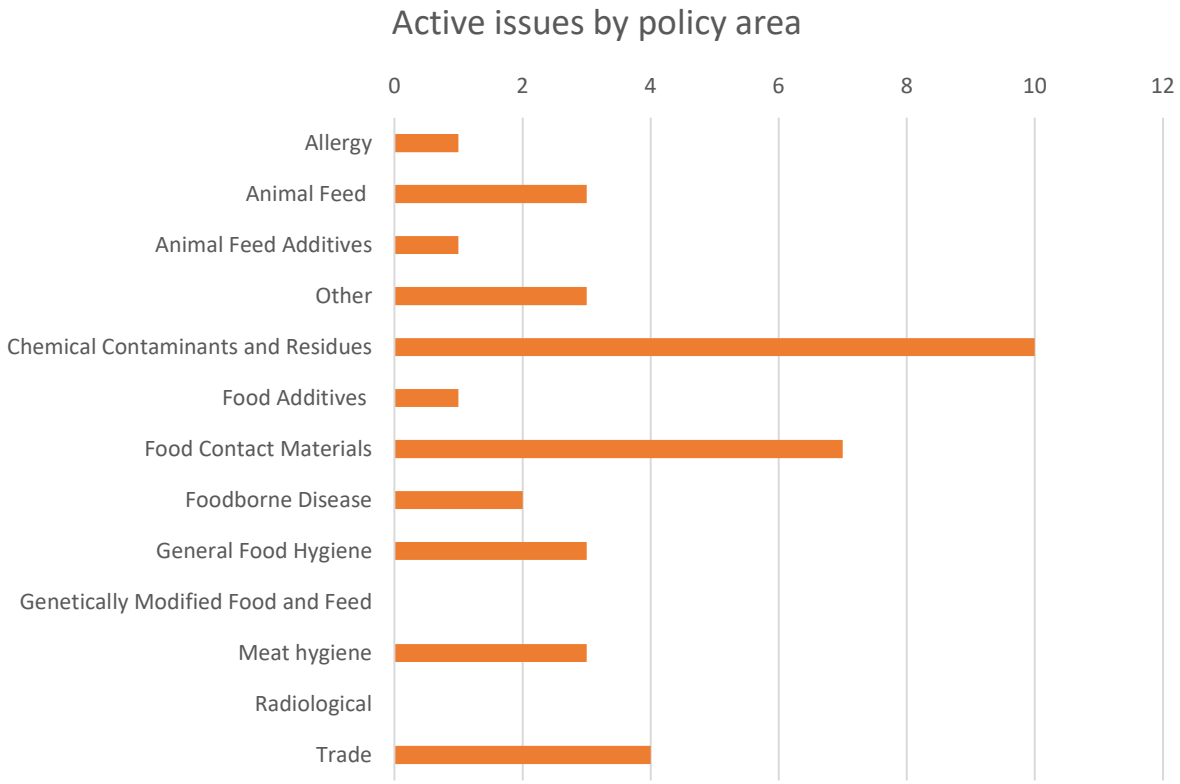
Risk Analysis updates

Overview

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



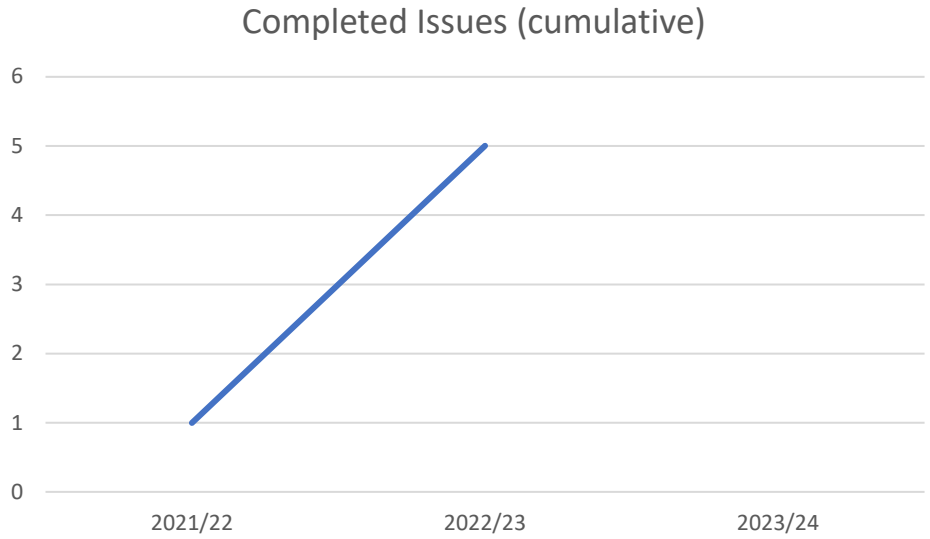


Issues that are at risk assessment and beyond are published to an online register on a quarterly basis.
Five issues have progressed to risk assessment and two have been classified as complete since the last report. (Listed in later slide).

*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 taken to the last register update in March 2023.

Performance measures

Monitoring indicators					
Issues completed (financial year to date): 4					
Issues completed (total): 5					
Compliance indicators (risk analysis principles)					
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:	2021/22:	2022/23:	2021/22:	2022/23:
100%	100%	100%	100%	0	0



*Our proposed 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 March

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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	Status	Description
Review of imported food and feed controls under Retained EU Commission Implementing Regulation 2019/1793	Previously in register – now complete	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
Extension of tolerance period for traces of Ms1×Rf1, Ms1×Rf2 and Topas 19/2 oilseed rape.	Added to register – now complete	Three GMO events that were formally withdrawn from the market (Ms1×Rf1, Ms1×Rf2 and Topas 19/2) are currently granted a tolerance in a proportion of no higher than 0,1% mass fraction in adventitious or technically unavoidable presence. This is outlined under REUL 2019/1562 with this tolerance period expiring after 31 December 2022, wherein it would return to zero. The authorisation holder informed the FSA that a technical zero presence would be unavoidable after the end of this tolerance period date and requested a review to extend the tolerance period to ensure its adventitious presence does not hinder the future trading of oilseed rape commodities.
Assessment of HPMA for use in can coatings	Added to register – risk assessment and evidence gathering	In 2012, EFSA assessed methacrylic acid, 2-hydroxypropyl ester (HPMA) for use in acrylic resin coatings for food cans at use levels up to 20%. The FSA will re-assess its suitability for use in coatings for placing onto the UK market.
Risk assessment of substrates used to rear insects for animal feed	Added to register – risk assessment and evidence gathering	The FSA has commissioned a comprehensive review of the safety of several currently non permitted substrates that could potentially be used to rear insect larvae for protein in animal feeds.
Review of the prevalence of certain mycotoxins in animal feed	Added to register – risk assessment and evidence gathering	Work to increase understanding of group A Trichothecenes; T2, HT2, Diacetoxyscirpenol (DAS) and Neosolaniol (NEO) and determine their prevalence in retail pet foods.
Assessment of plant based drinks	Added to register – risk assessment and evidence gathering	The SACN/COT working group on plant-based drinks is considering the benefits and risks of plant-based drinks in diets across all life stages. The outcome of this analysis will inform public health guidance on the suitability of these products for different sub-populations.
Vitamin D in infant and follow on formula	Added to register – risk assessment and evidence gathering	Review of the safety of vitamin D intakes from infant formula and follow on milks, in light of the updated regulations on the vitamin D content of these drinks and in the context of our existing advice for vitamin D supplementation in formula-fed babies.

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Regulated Products Service Updates

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

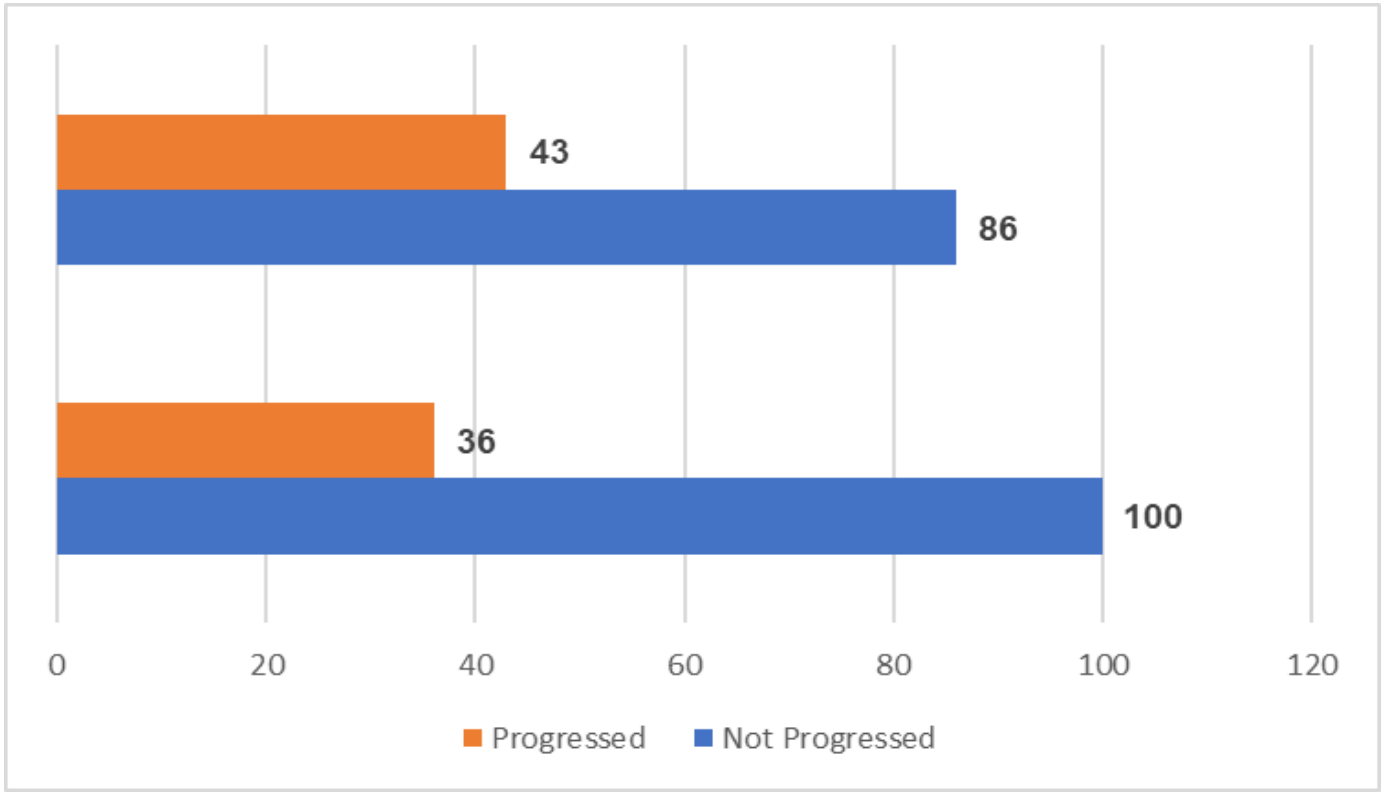
Regime	Applications progressing		Applications at Pre - Validation		Applications at Risk Assessment		Applications at Risk Management		Applications at Authorisation		Applications completed	
Date	Jan 23	Mar 23	Jan 23	Mar 23	Jan 23	Mar 23	Jan 23	Mar 23	Jan 23	Mar 23	Jan 23	Mar 23
Novel Food (Excluding CBD)	49	51	29	25	18	24	2	0	-	2	6	6
Novel Food CBD	129	130	116	113	13	17	-	-	-	-	-	-
Feed Additives	151	158	54	56	78	83	19	19	-	-	11	11
GMO	35	35	14	13	10	11	11	0	-	11	9	10
Novel Food Traditional	4	3	4	3	-	-	-	-	-	-	-	2
Food Contact Materials (Recycled)	11	12	6	7	5	5	-	-	-	-	-	-
Food Contact Materials (Plastics)	3	3	-	-	3	3	-	-	-	-	-	-
Extraction Solvents	-	1	-	1	-	-	-	-	-	-	-	-
Food Additives	17	18	5	5	11	12	1	0	-	1	-	-
Flavourings	10	10	6	5	2	3	2	1	-	1	-	-
Feed for Particular Nutritional Users (PARNUTS)	2	2	-	-	2	2	-	-	-	-	-	-
Novel Food Status	-	-	-	-	-	-	-	-	-	-	2	2
Smoke Flavourings	9	9	7	7	2	2	-	-	-	-	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)	3	5	3	5	-	-	-	-	-	-	-	-
Total	**424**	**438**	**245**	**241**	**144**	**162**	**35**	**20**	**0**	**15**	**31**	**34**

Incomplete applications

Incomplete applications describe any communication submitted through our online portal that is not taken forward. This can include questions and comments as well as applications that do not contain the information to proceed or are withdrawn. This quarter we have continued to receive a high number of incorrect, abandoned or incomplete applications **at 74%.** We expect this to begin to improve once our Case Management System is introduced in the summer.

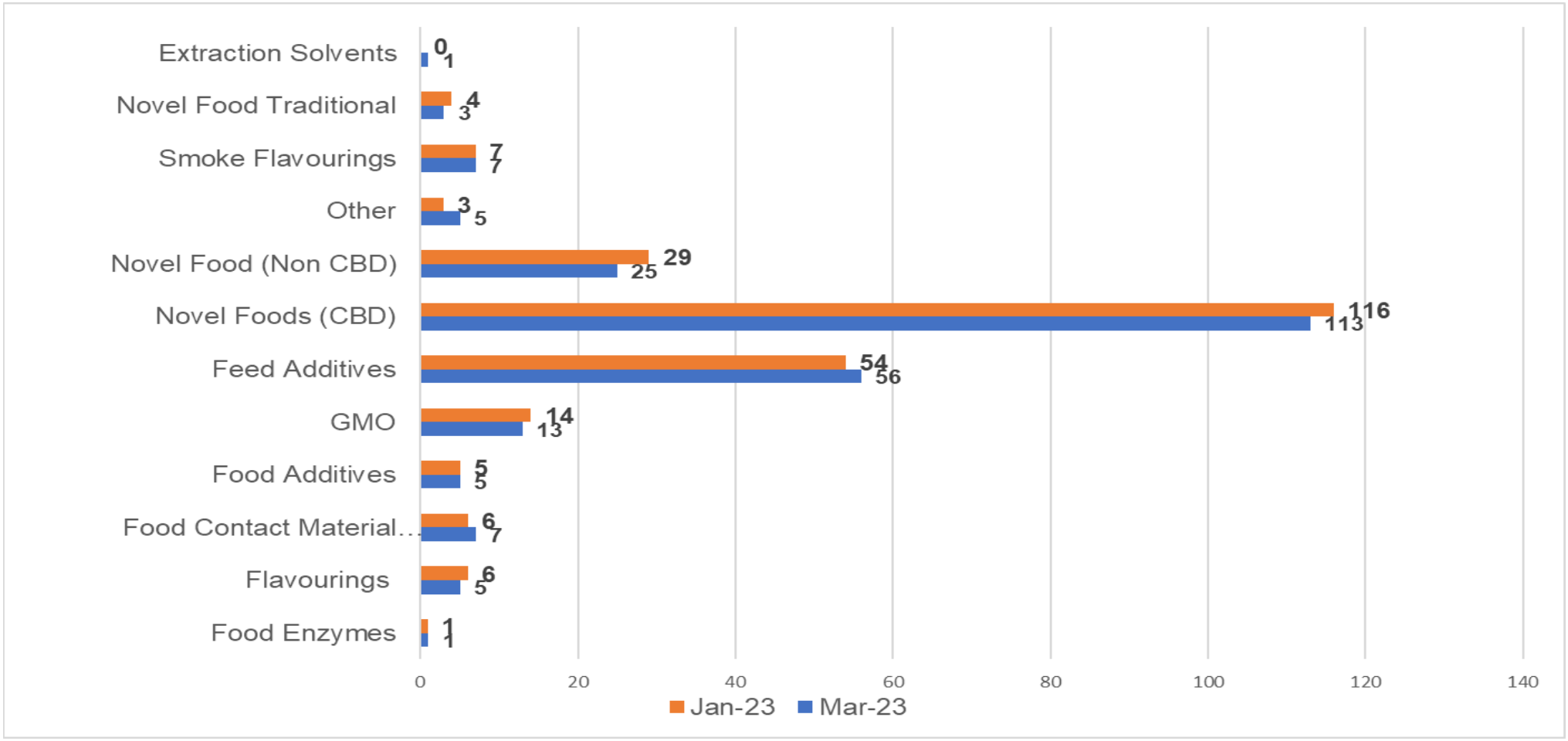
Total number of contacts October – December 2022 = 129

Total number of contacts January – March 2023 = 136



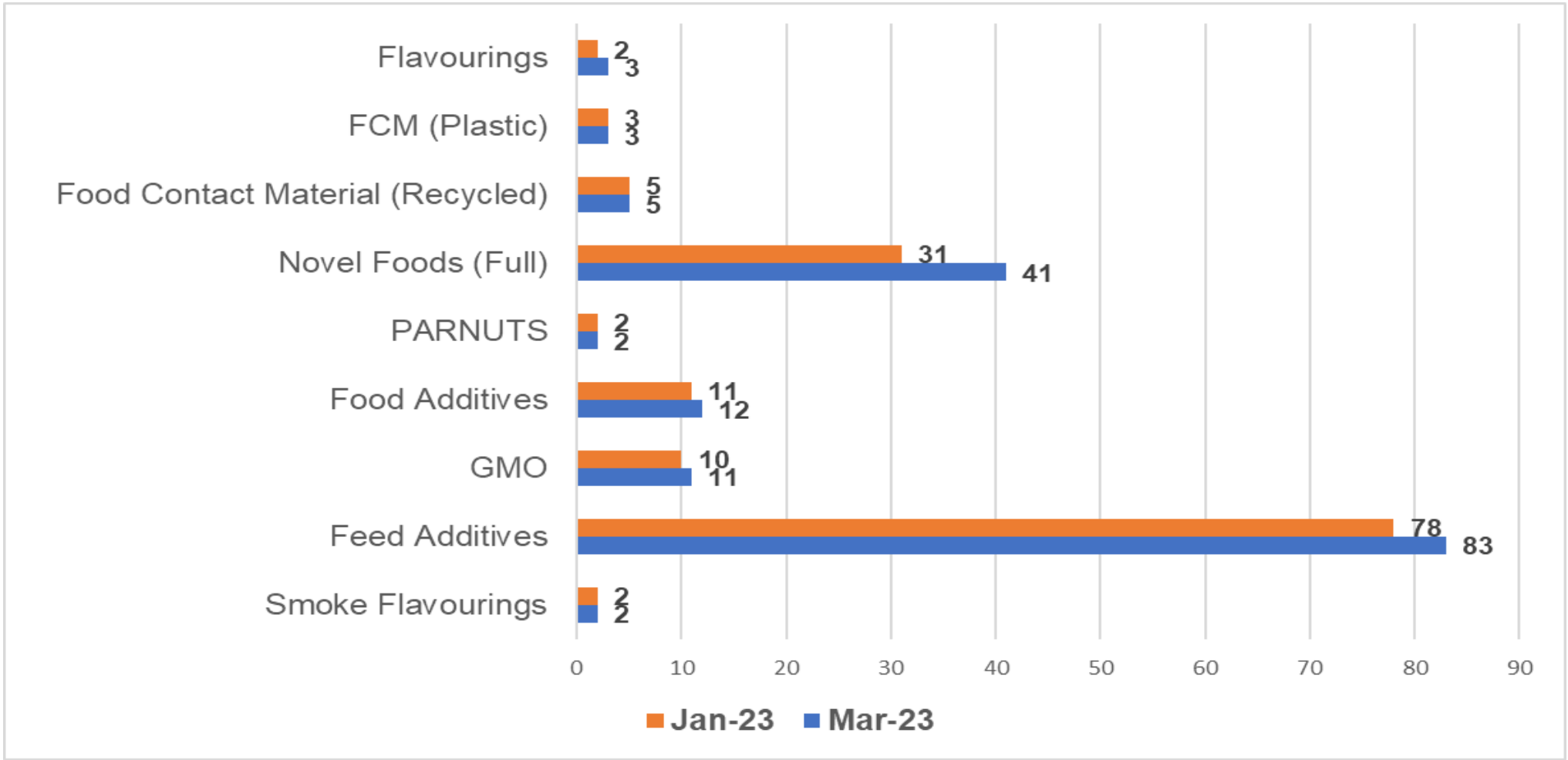
Pre - Validation

55% of all applications are at the Pre-Validation stage. This includes a large number of CBD applications 'awaiting evidence' which are being actively managed. As of 31 March 2023, there were **241** applications, compared to 245 in January 2023. The regime distribution is shown in the graph below:



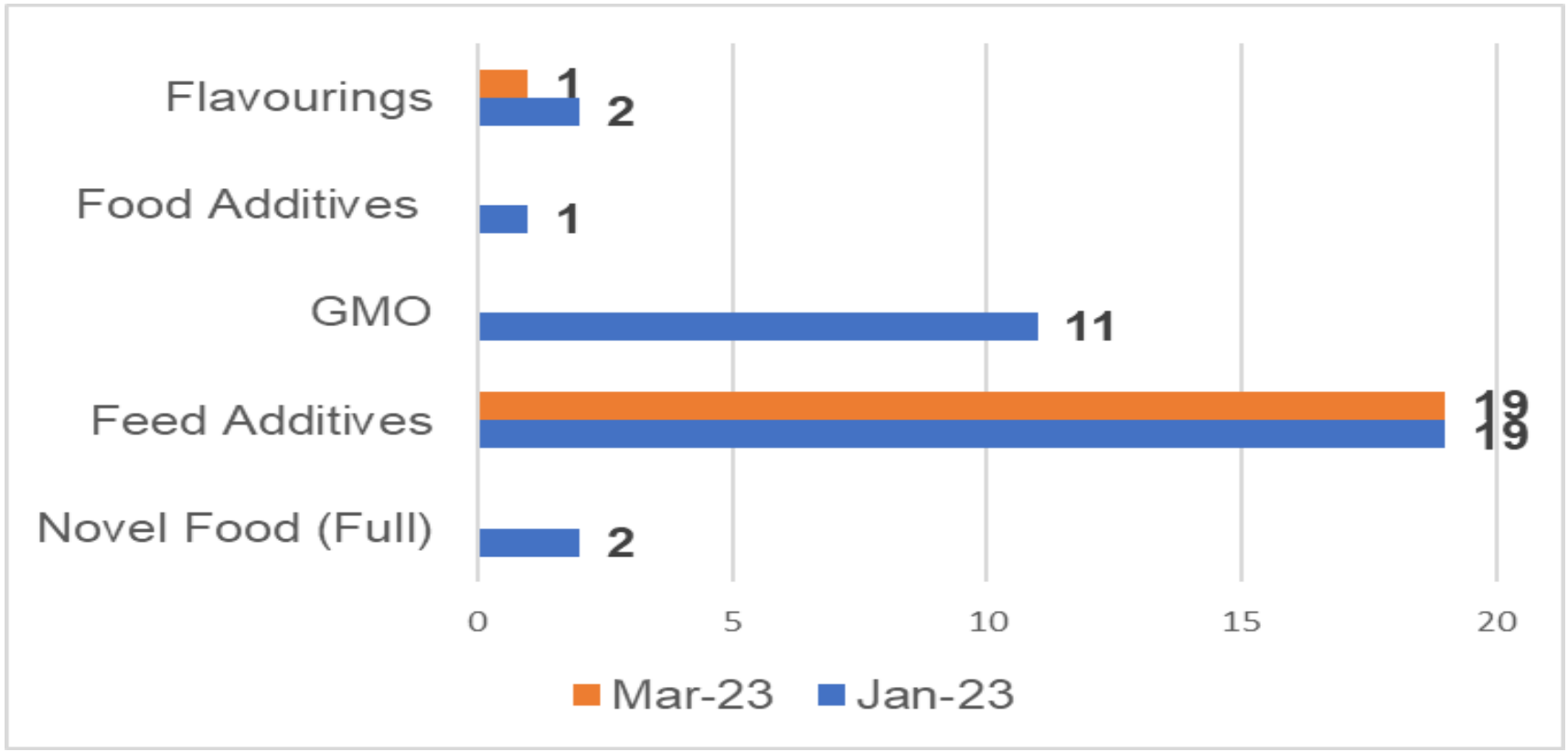
Risk Assessment

37% of all applications are at the Risk Assessment stage. As of 31 March 2023, there were **162** applications, compared to 144 in January 2023. The regime distribution is shown in the graph below:



Risk Management

5% of all applications are at the Risk Management stage. As of 31 March 2023, there were 20 applications, compared to 35 in January 2023. The regime distribution is shown in the graph below:



Completed Applications

As of 31 March 2023, the Regulated Products Service has **completed 34 applications,** the regime distribution is shown in the graph below**:**