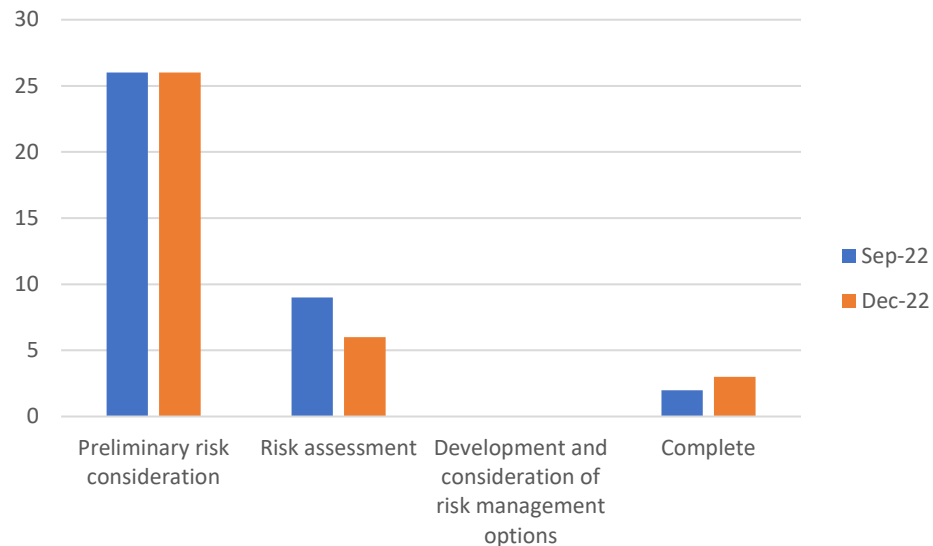**Risk Analysis and Regulated Products Service**
Report to
Business Committee
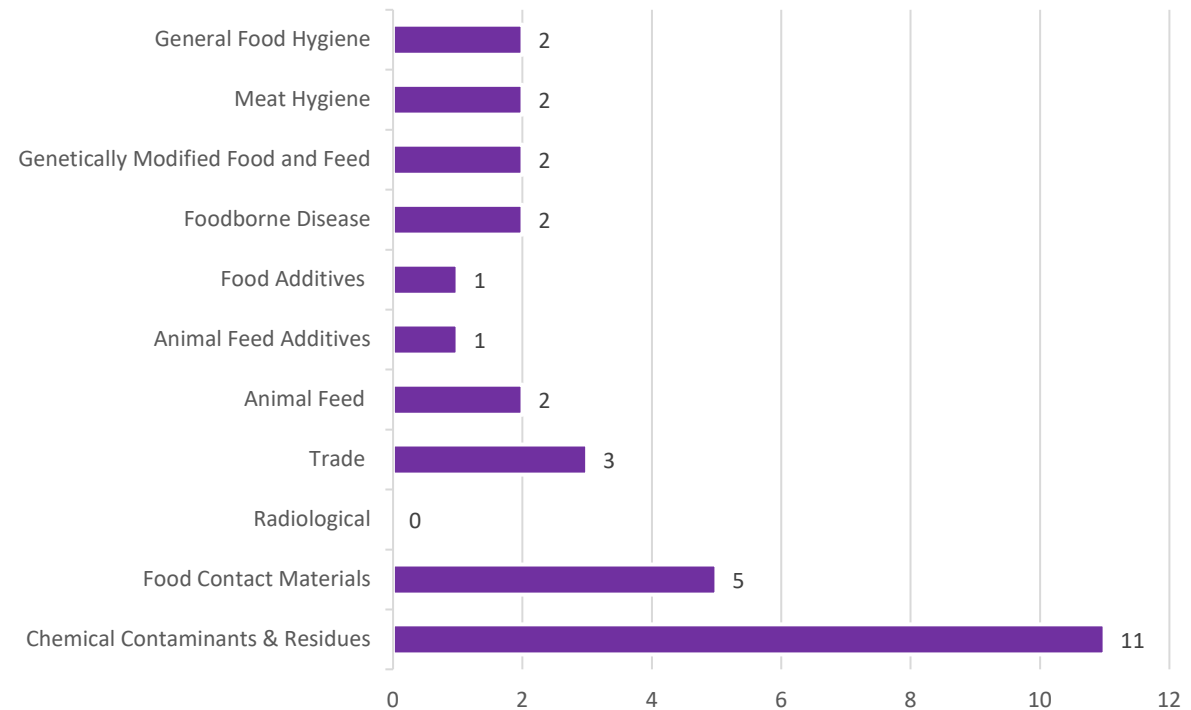**December 2022**

Risk Analysis updates

Overview

Issues in risk analysis internal system*	
Total active issues	35
Issues flagged for additional board scrutiny	8

Active risk analysis issues – policy areas


Issues that are at risk assessment and beyond are published to an online register on a quarterly basis.
Three issues have progressed to risk assessment and one has been classified as complete since the last report.

*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

Indicators

| Monitoring indicators					
Issues completed (financial year to date): 2					
Issues completed (total): 3					
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

Issues completed
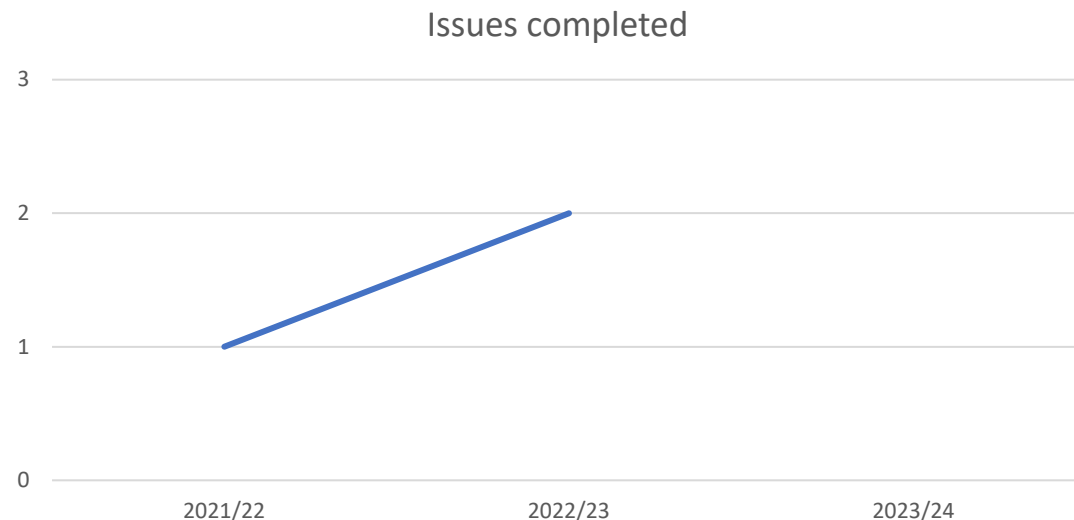
*Our proposed evidence-based indicator ensures that the correct level of assurance took place during evidence generation
**Publication of information in line with FSA Code of Practice on Openness

Regulated Products Service Updates

As of 31 October we have 407 applications progressing through our application service. 311 of these are applications for potential new authorisations of Regulated Products. The other 96 are for renewals of existing authorisations.

Food Standards Agency
food.gov.uk

Live Applications 31.07.22 vs. 31.10.22
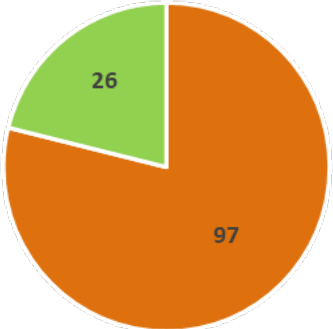
■ 31.07.22   ■ 31.10.22
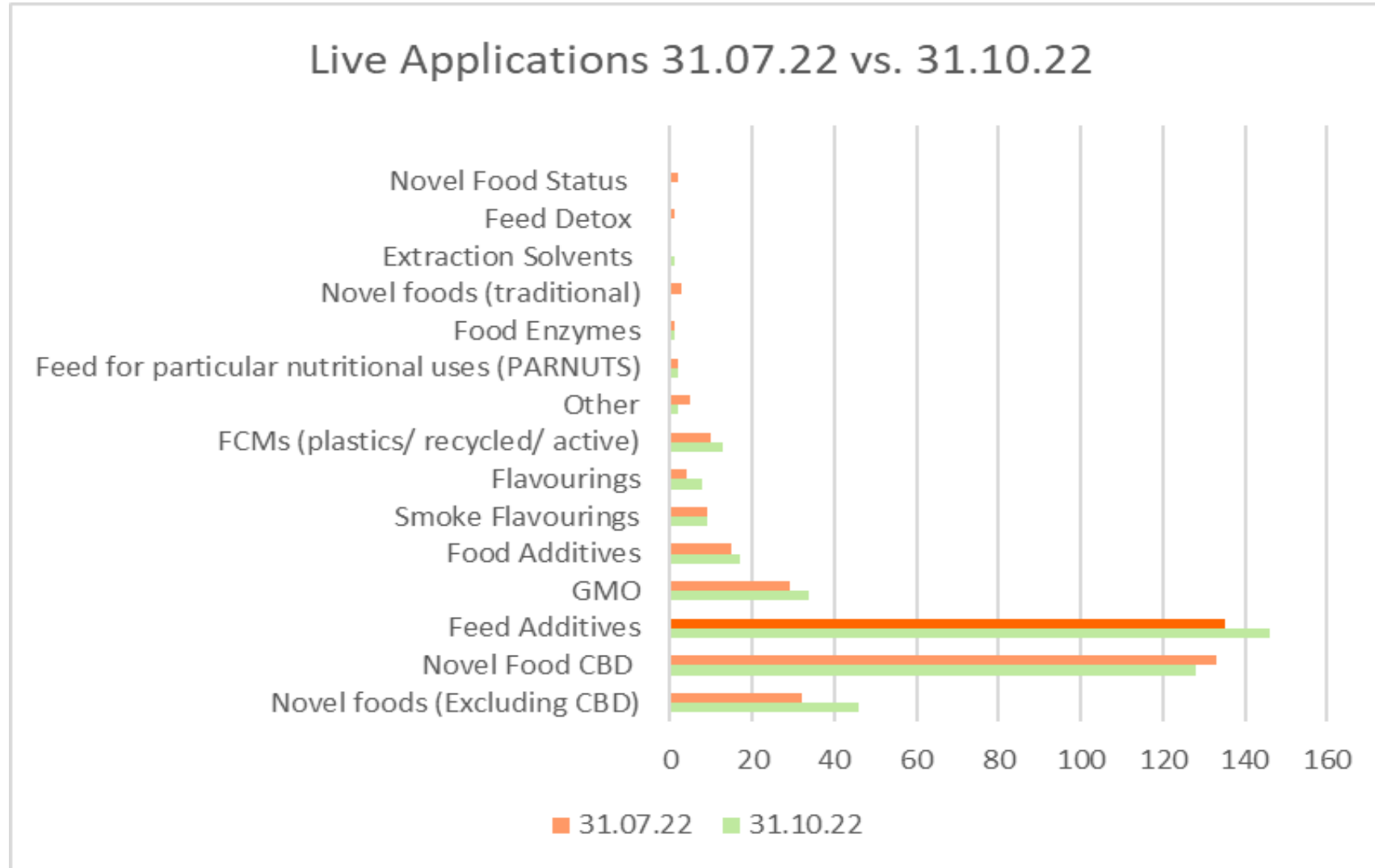
We are still receiving a large number of **incomplete applications**. These are usually sifted out of the service within a few days. The new application system, to be launched in early 2023, together with the user guidance will play a significant role in reducing this number.
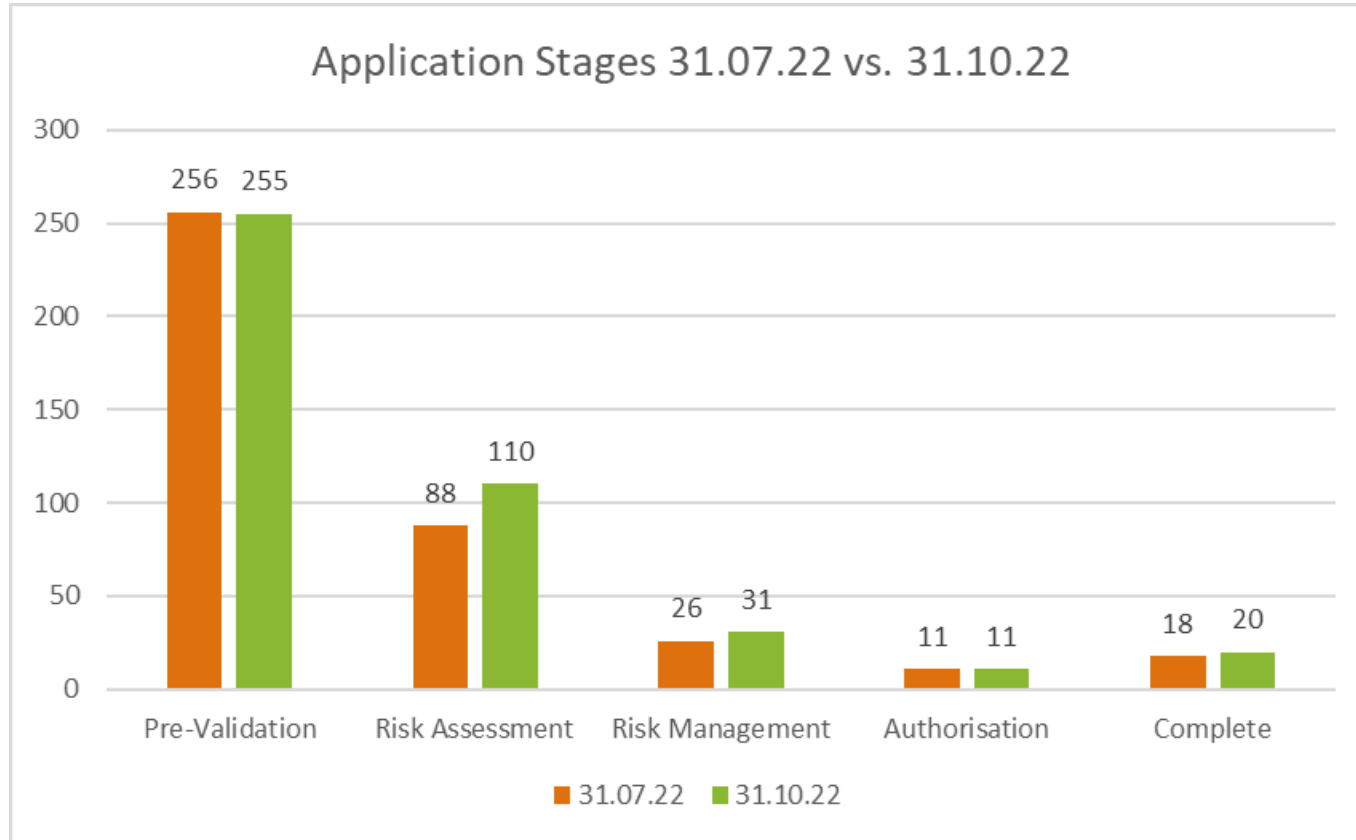

Total contacts July-Sept 2022

Total contacts April-June 2022
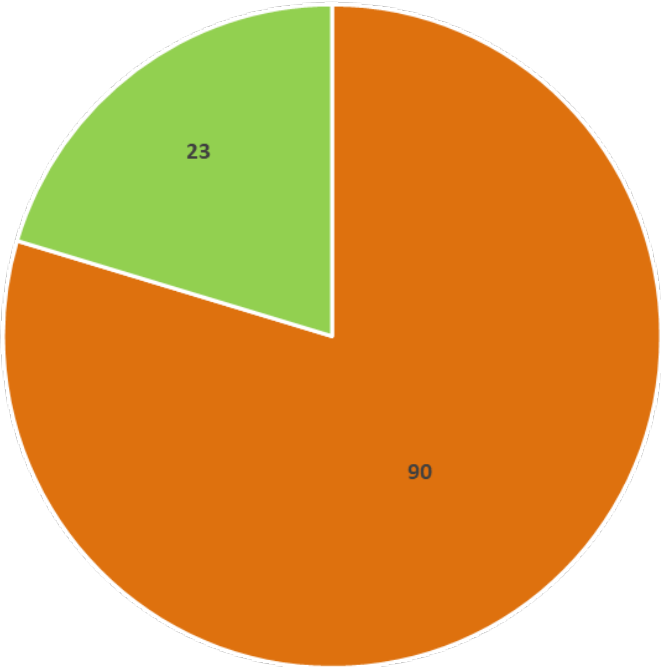
■ Incomplete Aplications   ■ Progressing Applications

We have 255 applications at the **pre-validation** stage. 45% of those are CBD applications, the majority of which we are awaiting further information before we can validate.


Application Stages 31.07.22 vs. 31.10.22

Number of applications in pre-validation 31.10.22 that are CBD applications

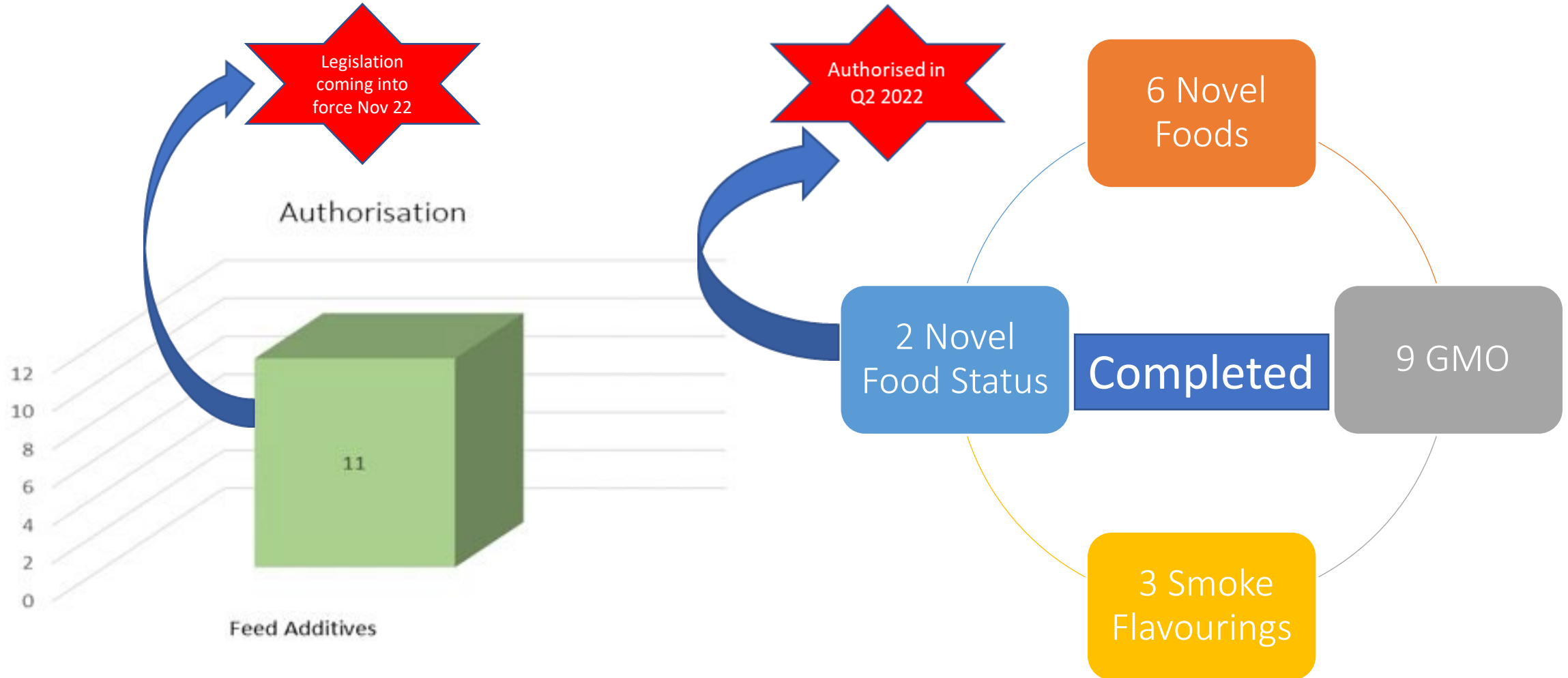Applications at Risk Assessment 31.07.22 vs. 31.10.22
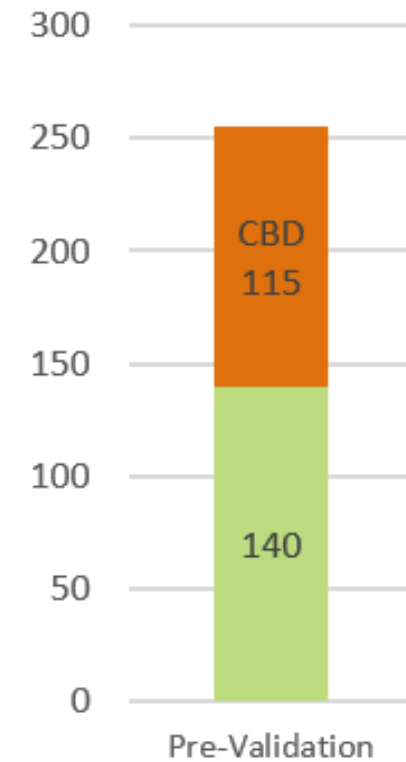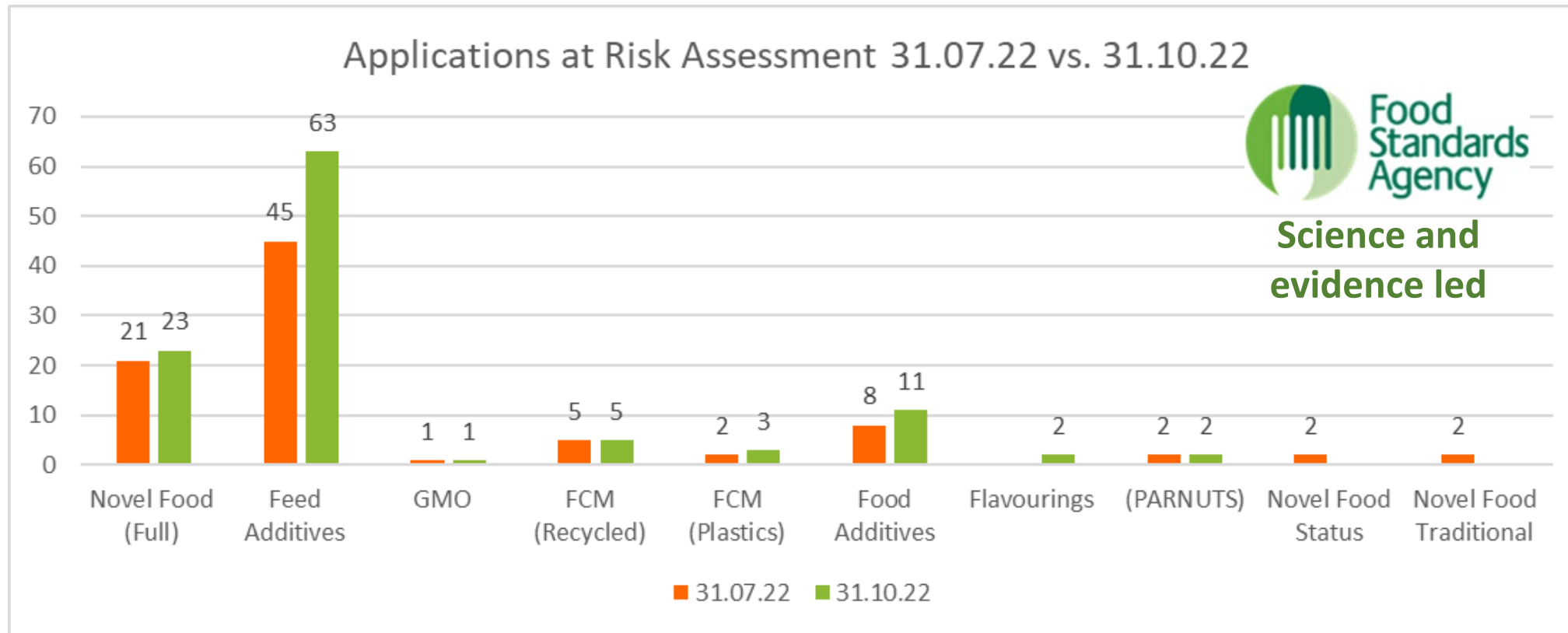
We have 110 applications going through risk assessment stage, where they are being considered by the relevant expert groups or advisory committees.

* 'Novel foods (full)' refers to an article 10 application, 'Novel Food status' refers to an article 4 application (to determine if it is novel or not), 'Novel Foods (Traditional)' refers to an article 14 application

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Applications at Risk Management 31.07.22vs. 31.10.22
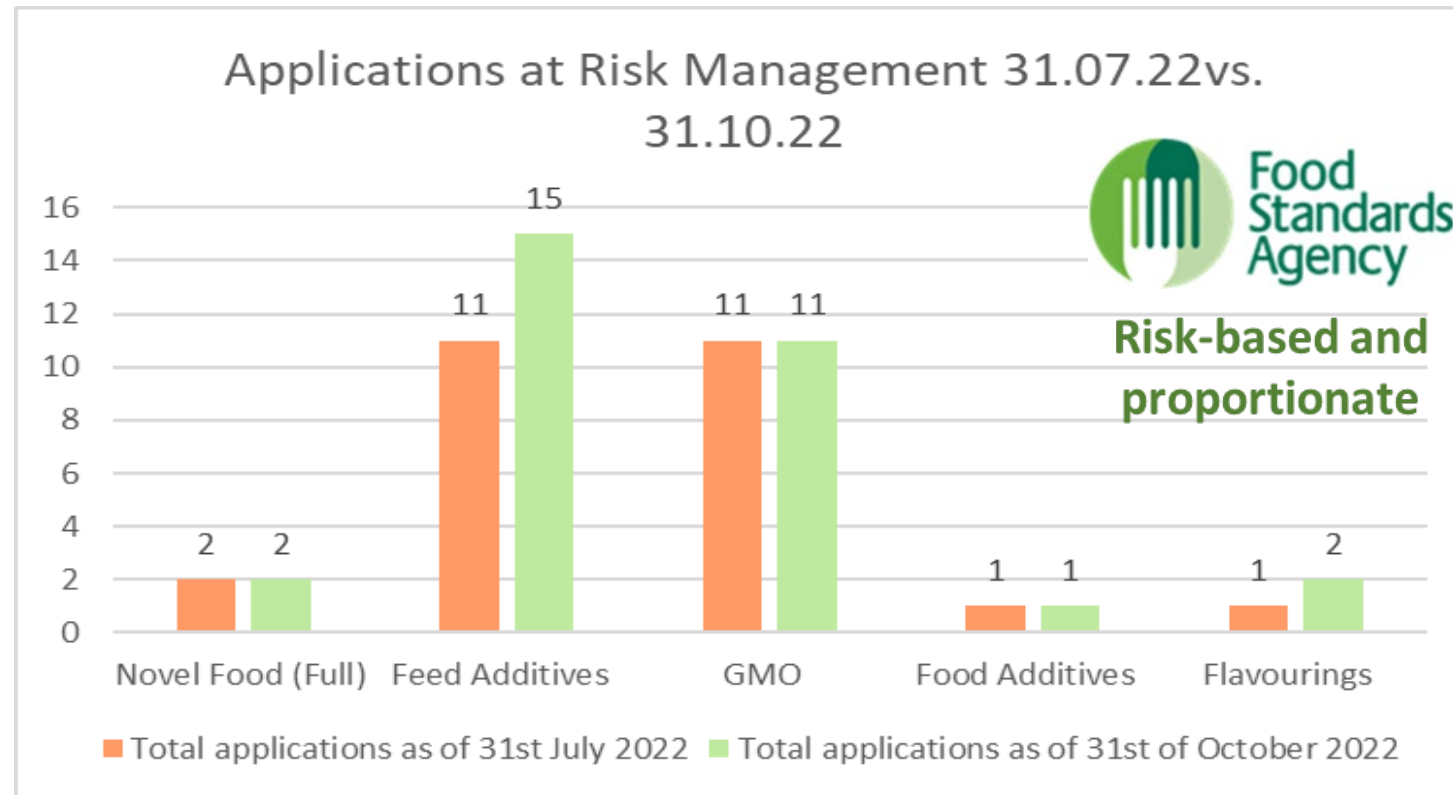
In October we launched consultations on 12 applications (eight GM, two novel food applications, a food additive and a flavouring). We are working towards launching consultations on 11 Feed Additive applications in January.

The Regulated Products Service has delivered [31] authorisations, including the required legislation.

Legislation coming into force Nov 22

Authorised in Q2 2022

Authorisation

6 Novel Foods

2 Novel Food Status

Completed

9 GMO

3 Smoke Flavourings

12
10
8
6
4
2
0

11

Feed Additives

Online Application System

- User testing has commenced internally on the front end of the new Case Management System, which will be used for future applications to be made on.

- We are working towards having a live system that we can test with users more widely by the end of the year, prior to the system being launched in early 2023.

Regulated Products: Key Performance Indicators

- In June 2022, we set out KPIs that we are currently working towards, including reducing the level of incomplete applications received and reducing the length of time it takes to validate an application.

- We are continuing to gather data on applications progressing through the service and increasing our baseline of applications that have moved through the whole of the authorisation process.

- We are also considering how our new application system can help us progress applications more smoothly and keep applicants informed of the progress.

Timeline per quarter of incomplete applications

% of incomplete apps per quarter
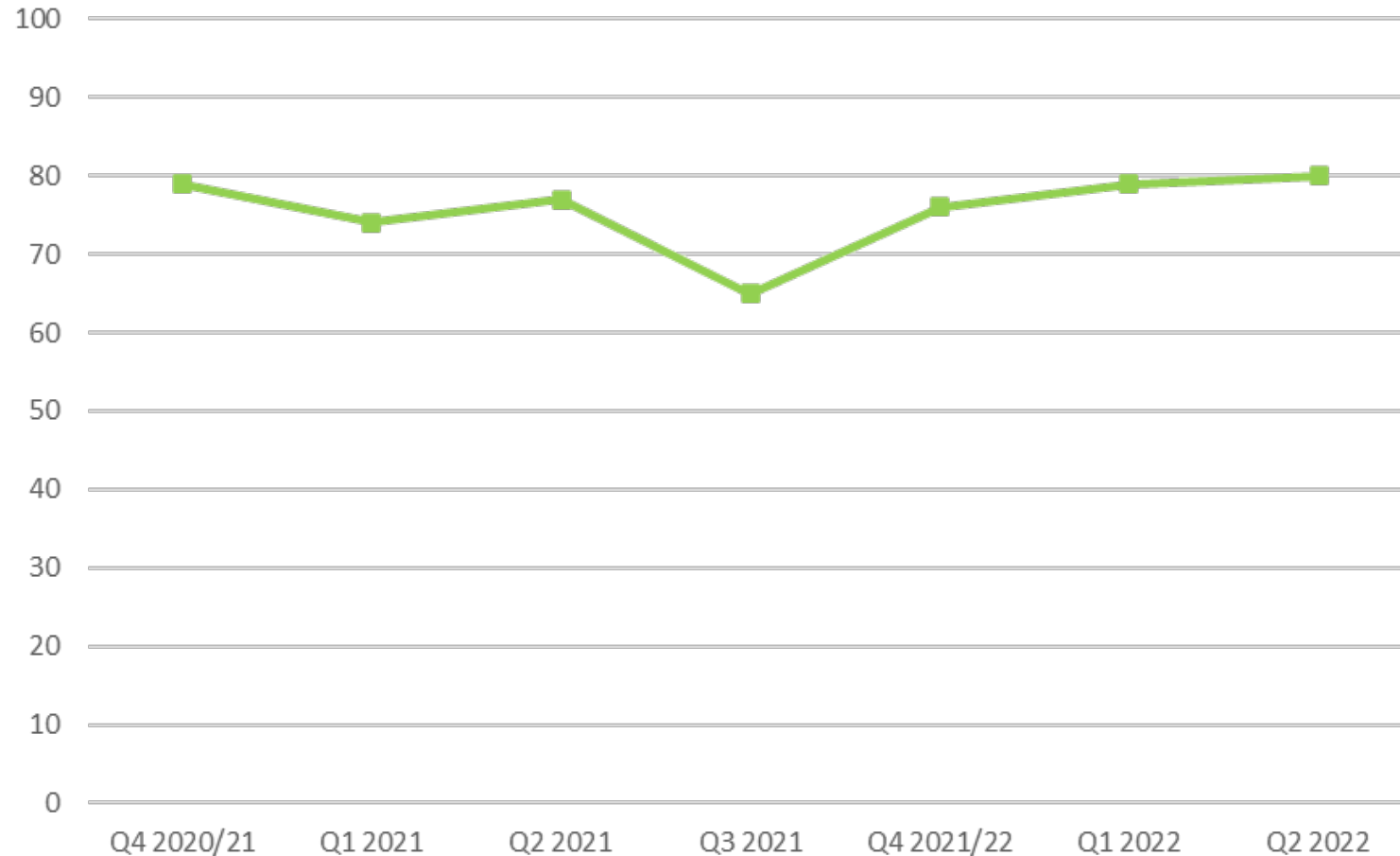
We continue to receive a high number of contacts on the application portal, that are not applications but are being counted as incomplete applications.

Our new Case Management System together with improved user guidance, will help to ensure applications are made at the correct time, and other queries that are not applications, are treated accordingly.

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