FSA 23-03-08 – ANNEX 2 Risk Analysis and Regulated Products Service Report to Board March 2023



## Overview



| Issues in risk analysis internal system* |    |  |  |
|--|----|--|--|
| Total active issues                      | 35 |  |  |



0

2

6

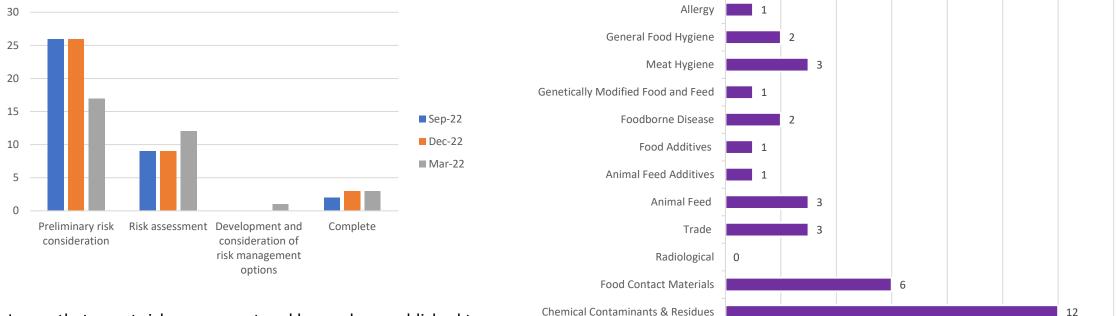
4

8

10

12

14



Issues that are at risk assessment and beyond are published to an online <u>register</u> on a quarterly basis. Four issues have progressed to risk assessment and no new

issues have 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 (3)

## 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<br>public register with full<br>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        |  |  |



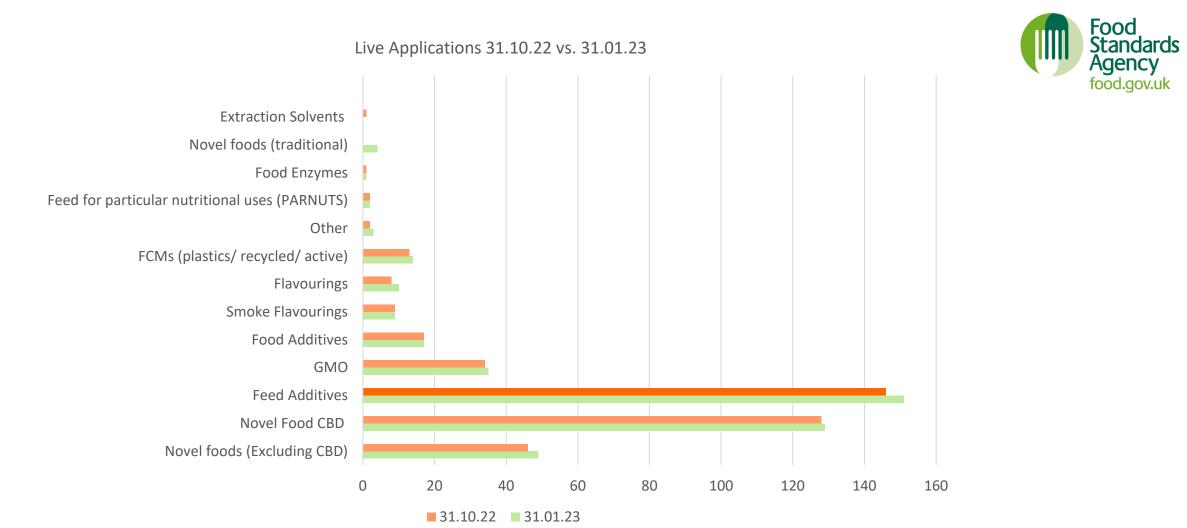
\*Our proposed evidence-based indicator ensures that the correct level of assurance took place during evidence generation.

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









We are receiving a steady flow of applications each month. As of 31 January, we have 424 applications progressing through our application service. This includes the peak of applications we received in Year 1 comprising applications already progressing in the EU and an influx of CBD applications. Over the next two years the number of authorisations will continue to increase and the peak of applications from Year 1 is expected to reduce.

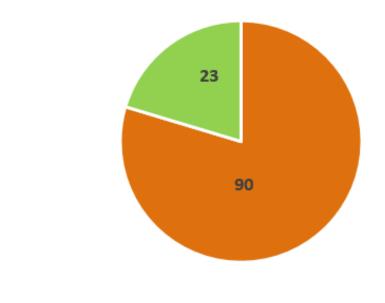
We are still receiving a large number of **incomplete applications**. These are usually sifted out of the service within a few days. The new application system, to be launched in Spring 2023, together with the user guidance, will help reduce this number.



Total contacts Oct-Dec 2022

86

Total contacts July-Sept 2022

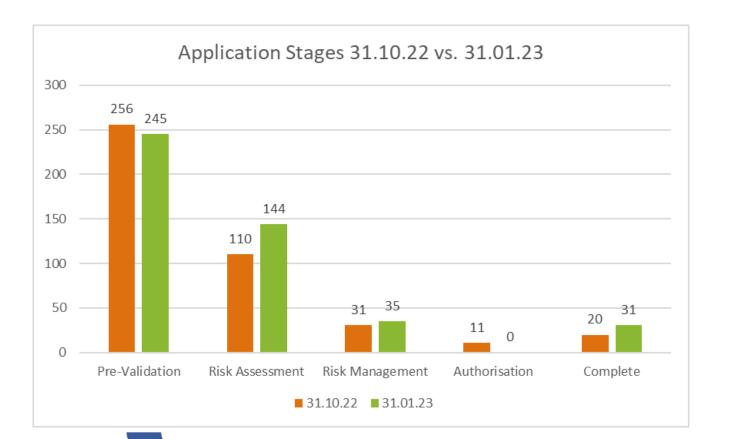


Incomplete Aplications Progressing Applications

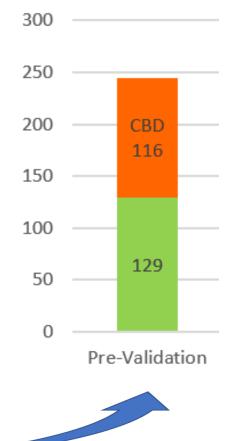
43

Progressing Applications

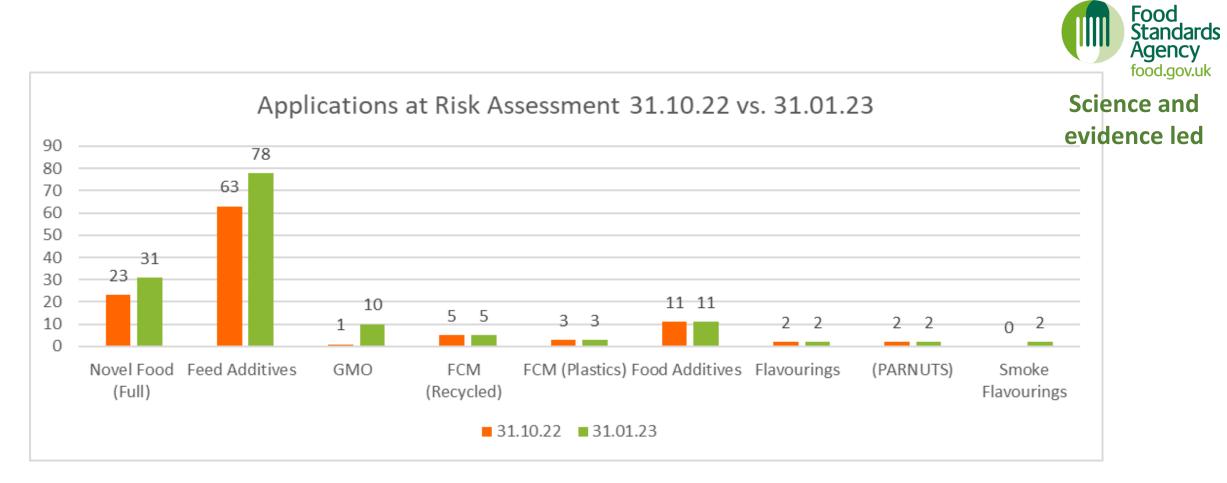
We have 255 applications at the **pre-validation** stage. 45% of those are CBD applications, for the majority of which we are awaiting further information before we can validate.



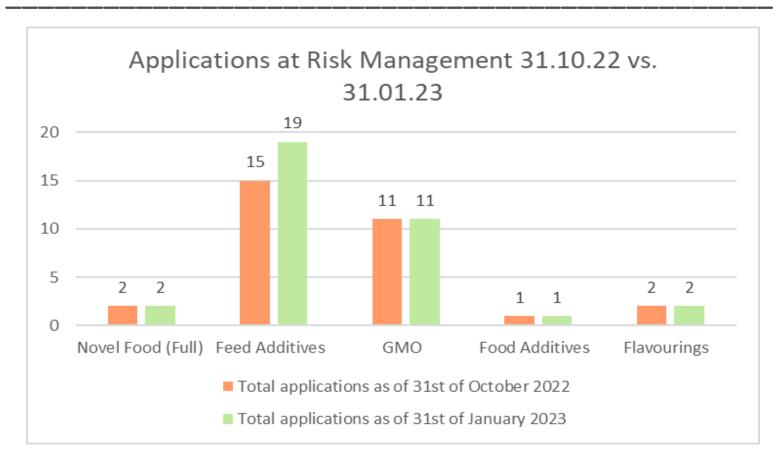
## Number of applications in pre-validation 31.01.23 that are CBD applications



Food



We have 144 applications going through the risk assessment stage, where they are being considered by the relevant expert groups or advisory committees.





The number of applications in Risk Management increased by 4 Feed Additive applications.

16 applications are in the final stages of authorisation. Recommendations were made to Ministers on those applications which include the GMO, Novel Foods, Flavourings and Food Additive applications. Following Ministerial agreement, Statutory Instruments authorising those applications will be laid in March. The legislation will come into force in April for the GMO authorisations and in May for the Novel Foods, Flavourings and Food Additive authorisations.

We will launch consultations on 12 Feed Additive applications in Q2 2023/24.