# FSA/FSS risk management recommendation on one feed additive application for use in animal feed

## Summary

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## Document subject and purpose

In this document we publish the Food Standards Agency (FSA)/Food Standards Scotland (FSS) risk management recommendations on one application for a feed additive.

Since the end of the EU exit transition period, the FSA/FSS have adopted technical guidance and quality assurance processes used by the European Food Safety Authority (EFSA) to be able to undertake GB risk assessments for regulated product applications. Further information is available on our website: Regulated products application guidance.

Our risk assessors deliver the science behind our advice and publish their safety assessments. The link is available under Annex A.  Risk assessors are responsible for identifying and characterising hazards and risks to health and assessing levels of exposure.

The risk management recommendations consider the safety assessment (which represent the opinion of the FSA and FSS for the application) as well as potential impacts that may result from the authorisation of this feed additive. They also consider other legitimate factors that ministers may want to consider before making a decision on authorisation of this application.

The final FSA/FSS proposed risk management recommendations that are made to ministers in England, Wales and Scotland and shared with the Northern Ireland Minister are published under Annex A and will also consider stakeholders' views received from this consultation.

# Annex A: RP16 Chromium chelate of DL-methionine as a feed additive for dairy cows (Availa®Cr) (Zinpro Animal Nutrition (Europe), Inc.) (new)

## Safety assessment conclusion

The FSS/FSA has undertaken a safety assessment of application RP16 for the authorisation of use of Chromium chelate of DL-methionine (Availa® Cr) as a feed additive for dairy cows.

The FSS/FSA updated safety assessment was published on 22 May 2024 and can be found here: Safety Assessment RP16 Chromium Chelate of DL-Methionine | Food Standards Agency

The assessment of Chromium chelate of DL-methionine (Availa® Cr) shows that the conditions for authorisation in Article 5 of assimilated Regulation (EC) 1831/2003 are satisfied.

The FSA/FSS conclusion on chromium chelate of DL-methionine (Availa® Cr) is that:

- The additive is safe for dairy cows at a maximum of 0.5 mg/kg chromium in complete feed with a moisture content of 12%.
- The additive has the potential to be efficacious for increasing milk yield in dairy cows at the proposed dose of 0.2-0.5 mg/kg of complete feed with a moisture content of 12%.

- The additive is safe for consumers up to the maximum level of chromium in feed and for the environment.
- On worker safety, the feed additive is not a skin or eye irritant but is considered a skin sensitiser. Given the uncertainties and the high dusting potential of the additive, measures should be taken to minimise exposure to users and workers through inhalation.
- There is no need for specific requirements for a post-market monitoring plan.

## Any relevant provisions of assimilated law

Under the requirements of assimilated Regulation (EC) 1831/2003 ('the Regulation') for feed additives:

1. Article 4 and 7: Authorisation for a new or new use of a feed additive.
2. Article 6: Categories of feed additives.
3. Article 16 and Annex III: Labelling and packaging requirements apply, if authorised.
4. Article 21: Analytical methods have been verified by the European Reference Laboratory as used for the control of chromium chelate of DL-methionine in animal feed as detailed in the EURL analytical method evaluation report (FAD-2018-0021). Valid analytical methods exist for:
    - the quantification of chromium in the feed additive
    - the quantification of methionine in the feed additive
    - proving the chelated structure of the feed additive.
5. Annex IV: The general conditions of use must be complied with, where applicable, for the individual feed additive authorisation.

### FSA/FSS risk management recommendation

The FSA/FSS risk management recommendation is that chromium chelate of DL-methionine (Availa®Cr), as described in this application, is safe and is not liable to have an adverse effect on the target species, environmental safety and human health under the proposed conditions of use. The FSA/FSS conclusion is that we are in favour of authorising the feed additive as per Article 8 of assimilated Regulation (EC) 1831/2003. The proposed terms of authorisation are set out below.

## Proposed terms of authorisation RP16

| Proposed terms of authorisation | RP16 |
|---|---|
| Additive | Chromium chelate of DL-methionine |
| Identification number | TBC |
| Authorisation holder | Zinpro Animal Nutrition (Europe), Inc |
| Additive category | Zootechnical additives |
| Functional group | Other zootechnical |
| Additive composition | Solid preparation of chelates of chromium (Cr) with DL-methionine with the below components:<br>Calcium carbonate: 95.6%<br>Chromium-DL-Methionine: 3.4%<br>Vegetable oil:1.0%<br>A powder consisting of particles with a diameter <50µm: 7.5% |
| Characterisation of the active substance(s) | Chromium chelate of DL-methionine ($[CH_3S(CH_2)_2CH(NH_2)COO]_3$ Cr) |

| Proposed terms of authorisation | RP16 |
|---|---|
| Analytical method[1] | For the quantification of chromium in the feed additive:<br><br>inductively coupled plasma-mass spectrometry (ICP-MS) in accordance with European standard BS EN 17053:2018[2]<br><br>For the quantification of methionine in the feed additive:<br><br>ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS) in accordance with BS EN ISO 13903:2005[3]<br><br>For proving the chelated structure of the feed additive:<br><br>mid-infrared (IR) spectrometry together with the determination of the content of chromium and methionine in the feed additive |

[1] Details of the analytical methods set out in the document referenced "JRC F.5/CvH/ZE/AS/Ares" and last updated on 18 October 2019 are available at: European Commission Joint Research Centre.

[2] BS EN 17053:2018 "*Animal feeding stuffs: Methods of sampling and analysis. Determination of trace elements, heavy metals and other elements in feed by ICP-MS*". Published by the British Standards Institution on 28 February 2018 (ISBN 978 0 580 94471 0). Available from the British Standards Institution .

[3] BS EN ISO 13903:2005 *"Animal feeding stuffs – Determination of amino acids content"*. Published by the British Standards Institution on 24 October 2005 (ISBN 0 580 46218 8). Available from the British Standards Institution.

| Proposed terms of authorisation | RP16 |
|---|---|
| Species or category of animal | Dairy cows |
| Maximum age | Not applicable |
| Minimum content of chromium in complete feed with a moisture content of 12% | 0.2 mg/kg |
| Maximum content of chromium in complete feed with a moisture content of 12% | 0.5 mg/kg |
| Other provisions | The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. |

## Supplementary information

- Feed additives are subject to UK health and safety legislation. The safety assessment identified that particular consideration should be given to hazards as a:
    - Skin sensitiser
    - Risk by inhalation
- Main animal species and their subgroups are defined in Annex IV of assimilated Regulation (EC) 429/2008.
- The FSA/FSS consider there is no basis to propose specific requirements for a post-market monitoring plan other than those established in assimilated Regulation (EC) 183/2005 laying down requirements for feed hygiene and good manufacturing practice.

## Recommendations of use

- The recommended use level is 0.2-0.5 mg/kg of complete feed with a moisture content of 12%.

## Other legitimate factors

In developing the risk management recommendation, the FSA/FSS have had regard to other legitimate factors (including Consumer Interests, Political, Environmental, Societal and Technical Feasibility) that ministers will consider as part of their decision on authorisation.

The FSA/FSS have not identified any other legitimate factors to date that would prevent authorisation or affect the conditions of authorisation of this animal feed additive. As noted above, stakeholders and the broader public are equally invited to consider and provide their views on any relevant other legitimate factors as part of the consultation process.

## Impacts

As part of the risk analysis process, FSA/FSS have assessed the potential impacts that would result from the authorisation of this animal feed additive, should ministers decide to authorise. No significant impacts were identified. The impacts considered included those most frequently identified as potential impacts when introducing or amending food and feed law (i.e. environmental, trade, and consumer interests). The authorisation of these products should generally result in greater market competition, supporting growth and innovation in the sector.