Guidance on the application of Commission Recommendation 2013/165/EU on the presence of T-2 and HT-2 toxin in cereals and cereal products

UK Stakeholder Group

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Presented by Susan MacDonald / Derek Croucher

Background & Organisation

- UK Stakeholder Group set up January 2013
- Guidance drafting group set up by FSA involving experts in agronomic factors, analysis, cereal supply chains and cereal processing
- Meetings held at UK Food Standards Agency [FSA] with FSA Chairing and providing Secretariat support
- Aim to draft UK Guidance but with wider objective of potential for extension across EU after appropriate scrutiny / comment
- Document is dynamic, and we welcome comments and suggestions

Key Objectives

- Support consistent application of the Recommendation
- Suggest Responsibilities between Member States and Feed / Food Business Operators
- Provide Guidance on the two main requirements
  - **Monitoring of T-2 and HT-2 toxin in cereal / cereal products**
    - Ensure validity of data whilst maintaining the current level of data collection by Trade Associations / Non Governmental Organisations
    - Provide practical guidance on sampling and analysis
  - **Investigations where repetitive findings above the indicative level are found**
    - Define “Repetitive Findings”
    - Clarify “Investigations”
- Provide Guidance on Data Submission

Guiding Principles

- Ensure proportionality – the indicative levels are not feed or food safety levels or maximum / enforcement limits
- Ensure appropriate and focussed involvement of both Member States and Feed / Food Business Operators
- Maintain or increase the current levels of monitoring
- Designed to increase understanding of:
  - year-to-year variability
  - any effects of feed / food processing
  - Accepts that in many cases it may be difficult to establish agronomic factors unless specific testing (as part of a focussed agronomic study) is carried out at the farm or at bulk store intake

Sampling and Analysis – General Note

- Recommendation requires sampling and analysis to be carried out in accordance with (EC) 401/2006 [Food] or (EC) 152/2009 [Feed], but accepts that procedures applied by food / feed business operators **may deviate from these requirements as long as they are representative for the lot sampled**
- The Guidance recognises that there are a number of existing data collection schemes in place for T-2/HT-2 coordinated by Trade Associations or Non-Governmental Organisations [TA/NGO schemes].
  - commonly use “Industry Standard” sampling / analysis regimes;
  - Individual data not typically in full accordance with EFSA data requirements;
  - The value of such schemes is the large quantity of data that is generated; the mass of data produced offsets many of the concerns relating to sampling / analysis;
  - **The continuation of such schemes is encouraged by the Draft Guidance**

Analysis – General Requirements

- Specific sampling and analysis requirements are given in recital 3 & 4 of the Recommendation
- Re-iterates that, where possible, samples should also be tested for deoxynivalenol and zearalenone (maize samples should additionally be tested for fumonisins B_1 and B_2)
- The Guidance expands on the Recommendation as follows:
  - Methods of Analysis should comply with provisions of Items 1 & 2 of Annex III to Commission Regulation (EC) No 882/2004, in as far as possible any laboratory used should be accredited to ISO17025 (but this is not an absolute requirement)
  - Methods used should be at least in-house validated by a recognised protocol. The Guidance gives a non-exhaustive list of examples of appropriate protocols
  - Lack of accreditation should not be a barrier to producing and submitting data especially in the case of TA/NGO monitoring schemes, as long as the minimum quality parameters and method performance criteria are met

Analysis – Performance Criteria

- Performance criteria from Regulation (EC) 401/2006 are applicable for deoxynivalenol, zearalenone and fumonisins B_1 and B_2. The performance criteria in Regulation (EC) 401/2006 do not currently cover the range of levels for T-2 / HT-2 toxin stipulated in the Recommendation. Regulation (EC) 401/2006 is currently under revision and performance criteria are being established. Suggested values are:

Level µg/kg	T-2 and HT-2 toxin		
	RSD_r %	RSD_R %	Recovery %
15-250	≤ 40	≤ 60	60 to 130
> 250	≤ 30	≤ 50	60 to 130

Precision values are calculated from the Horwitz equation

Analysis – Screening Methods

- Where possible fully quantitative methods that determine T-2 and HT-2 toxin levels should be used – however screening methods that produce a result as the sum of T-2 and HT-2 toxin may be used.
- Screening methods are any method that may not provide a fully quantitative or confirmed result. Examples are:
  - Commercial test kits – ELISA, Lateral Flow etc
  - Instrumental methods designed for rapid throughput e.g. LC-MS/MS methods with single point calibration
- Any exceedance of the indicative level should however be verified by a confirmatory method.
  - In case of test kits results should be verified by an alternative confirmatory method
  - In case of instrumental screening verification may use the same technique provided a fully quantitative measurement is made.

Data Collection – General Notes

- Member States should identify responsibilities for sampling, testing and reporting in accordance with the categories detailed within the Annex to the Recommendation in conjunction with Feed & Food Business Operators and / or relevant sector stakeholders (including Trade Associations / Non Governmental Organisations [TA/NGO])
- These should be reviewed and agreed per crop year to ensure data are representative and complete
- Where relevant existing TA/NGO monitoring plans may be included (typically these will report annually)
  - Consideration must be given that where TA/NGO monitoring operates on a European level (i.e. across Member States) that data are submitted only once (i.e. not at both European and National level)
- Data should be submitted to the Member State according to the agreed reporting schedule using an agreed template

Data Collection – Reporting to the Commission

- In the case of TA/NGO schemes, where data is submitted to the Commission (as opposed to EFSA), reporting should include the following:
  - Product / Crop Type
  - Intended Use (e.g. food / feed)
  - Crop Year
  - Region of Production (if available)
  - Sampling Plan Used
  - Mycotoxins Tested
  - Analysis Details
  - Results; including units and expressed on a dry matter basis

Data Collection – Note on the Annex

The Annex to the Recommendation is not completely clear with regards to the categorisation of oats and oat products. To ensure a consistent approach across Member States the following categorisation is suggested

	Category	Description
1.	Unprocessed cereals	
1.2	Oats (with husk)	Oats with husk
2.	Cereal grains for direct human consumption	
2.1	Oats	Oat groats (i.e. oats without husk)
3.	Cereal products for human consumption	
3.1	Oat bran and flaked oats	Oat bran, flaked oats, whole rolled oats, wholegrain oatmeal, wholegrain oat flour
3.2	Cereal bran except oat bran, oat milling products other than oat bran and flaked oats and maize milling products	Oatflour with bran removed
4.	Cereal products for feed and compound feed	
4.1	Oat milling products (husks)	Animal feed: oat milling products (husks)

Repetitive Findings

- **Where any individual result** exceeds the relevant indicative level further samples should be tested
- Depending on the nature of product (e.g. raw cereal grain; processed cereal or retail product sample) the **further samples should be taken from different lots representing different production lots representing different production batches of the same product** (unless this has already been done as part of the original sampling regime e.g. in the case of TA/NGO schemes, and where no additional results exceed the indicative level)

Repetitive Findings & Investigations

- Whilst an appropriate level of additional testing will be dependent upon a number of factors (e.g. number of batches available; frequency of production) **typically a minimum of four additional samples would be expected**.
- Responsibility for the additional testing would typically rest with whoever carried out the original tests
- If none of the additional samples exceeds the indicative level no investigation is required, and the data may simply form part of the overall data submission
- **If any one of the additional samples exceeds the indicative level this would be deemed a "Repetitive Finding" triggering an Investigation**

Investigations

In case of a Repetitive Finding an Investigation should be carried out as so
as is practicable

As part of the Investigation it may be appropriate to study similar product
with T-2/HT-2 toxin results significantly lower than the indicative level – th
may help identify approaches to reduce or avoid the presence of T-2/HT-2

Investigations may be carried out by Member States, by Feed/Food Busine
Operators [FFBO], or in partnership. The Guidance suggests however that
typically Investigations will be carried out by the FFBO.

Investigations should seek to identify possible factors resulting in repeated
exceedance of the indicative level and should be shared with the Member
State

Results of the investigation may be documented using an agreed checklist

Investigations – Summary Checklist

s to be addressed	Guidance
tify the product	Depending on the point in the chain this may be field number, storage b batch or lot number
tify intended use	Is the product concerned intended for use in the food or feed chains. Is t intended market a specific sub-sector e.g. infant food, ruminant or no ruminant feed
tify processes carried out	Is the product unprocessed grain or has it been subject to processing (r including drying and cleaning). Include details of processing tim temperature
il raw material information	What percentage of the product in stock has high levels, is this isolated to particular raw material – if so then identify the supply chain including (whe possible) country of origin and crop year.
il storage	Record details of storage including (where available) length of storag temperature and moisture levels of product in store, relative humidity levels
ord other relevant quality meters	Depending on the position in the chain, including level of processing, det other relevant quality information (e.g. fibre, pH, protein etc.)
il available agronomic detail	Record available information on variety, previous cropping, region production, year of production, details of crop establishment and cr management

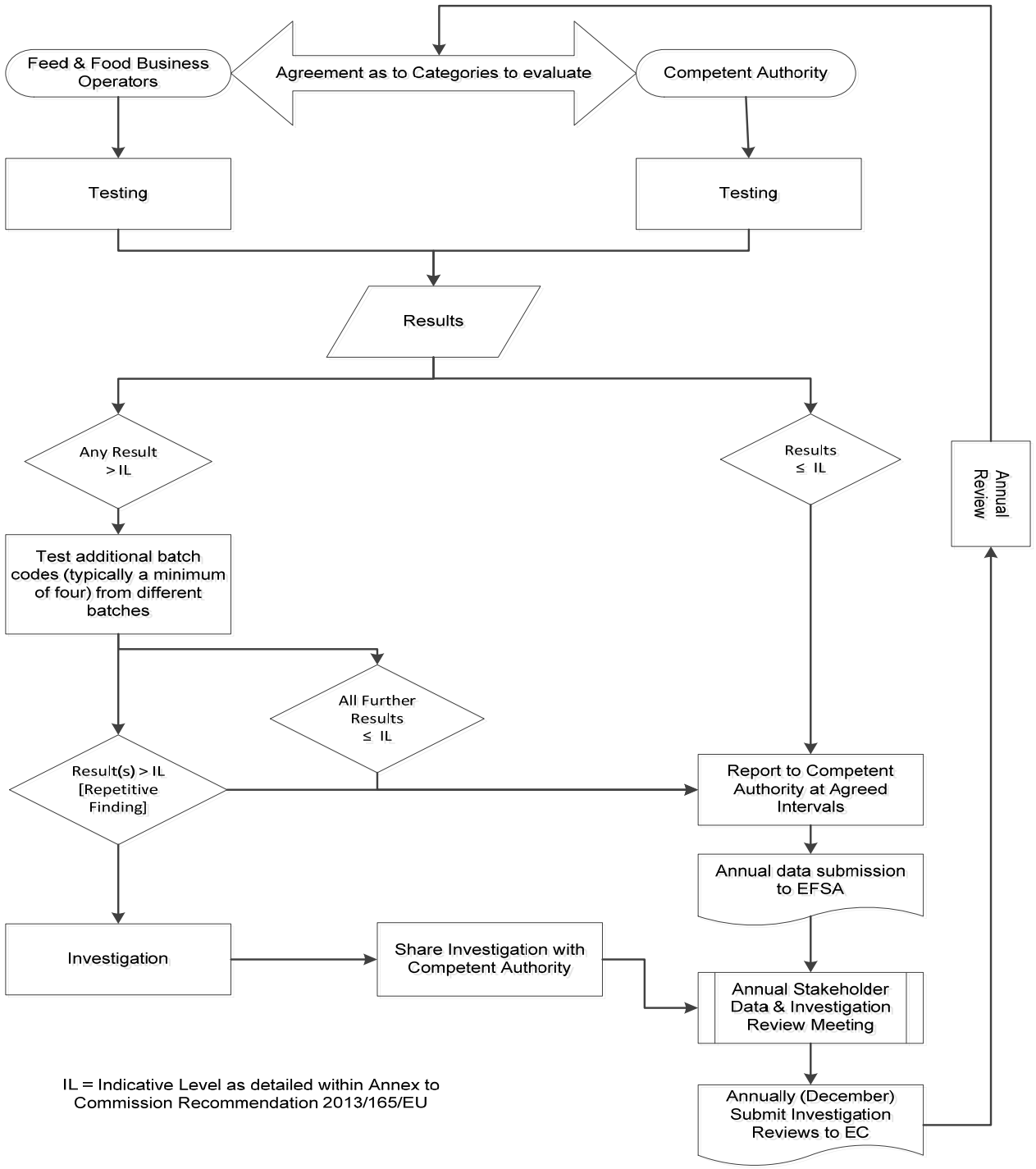
Data Submission

- As indicated earlier – two types of data may be generated:
  - Information from rapid, basic methods of analysis which generate extensive data useful to Member States and the European Commission (e.g. as part of TA/NGO monitoring schemes)
    - Within the UK a database is being developed to capture results from rapid, basic methods and TA/NGO schemes
  - Data from sampling / analysis carried out in compliance with legislation
    - Results from compliant testing should be submitted through the EFSA database (annually as a minimum)
  - Recommendation requires first submissions of both data and details of Investigations to EFSA / European Commission by December 2013

Review of Data / Investigations

- **Data**
  - At the end of each crop year the Member State competent authorities, together with relevant stakeholders, should review the data collected and assess where there are gaps or areas that require greater emphasis in following years.
- **Investigations**
  - On an annual basis (as a minimum) there should be a review of all investigations per crop year to identify any consistent factors or trends. Results of Investigations must be submitted to the Commission. If consistent factors / trends are identified this may warrant:
    - Further monitoring over subsequent years (including additional monitoring in other Member States if relevant)
    - Detailed research to identify and quantify the impact of an agronomic factor or food process on the level of T-2/HT-2 in cereals and cereal products

Summary Flow Chart



IL = Indicative Level as detailed within Annex to Commission Recommendation 2013/165/EU

Summary

- UK Guidance has been developed
- Some final work on data submission system to be finalised
- Wider objective of adoption across EU after appropriate scrutiny / comment
- **Document is dynamic, and we welcome comments and suggestions**

Guidance Drafting Group

e	Representing	Email
evin Hargin	Food Standards Agency	kevin.hargin@foodstandards.gsi.gov.uk
hristina Baskaran	Food Standards Agency	christina.baskaran@foodstandards.gsi.gov.uk
n Bramley	Food Standards Agency	gillian.bramley@foodstandards.gsi.gov.uk
n MacDonald	Food & Environment Research Agency	susan.macdonald@fera.gsi.gov.uk
essor Simon Edwards	Harper Adams University	sedwards@harper-adams.ac.uk
Rooke	Agricultural Industries Confederation	paul.rooke@agindustries.org.uk
West	Maltsters' Association of Great Britain	colin@magb.org.uk
atalia Douek	British Oats & Barley Milling Association	natalia.douek@pepsico.com
k Croucher	British Oats & Barley Milling Association	derek.croucher@morningfoods.com

Food Standards Agency food.gov.uk

Harper Adams University

fera The Food and Environment Research Agency

aic agricultural industries confederation

magb

BOBM The British Oat and Barley Millers' Asso