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Review of Referee Cases

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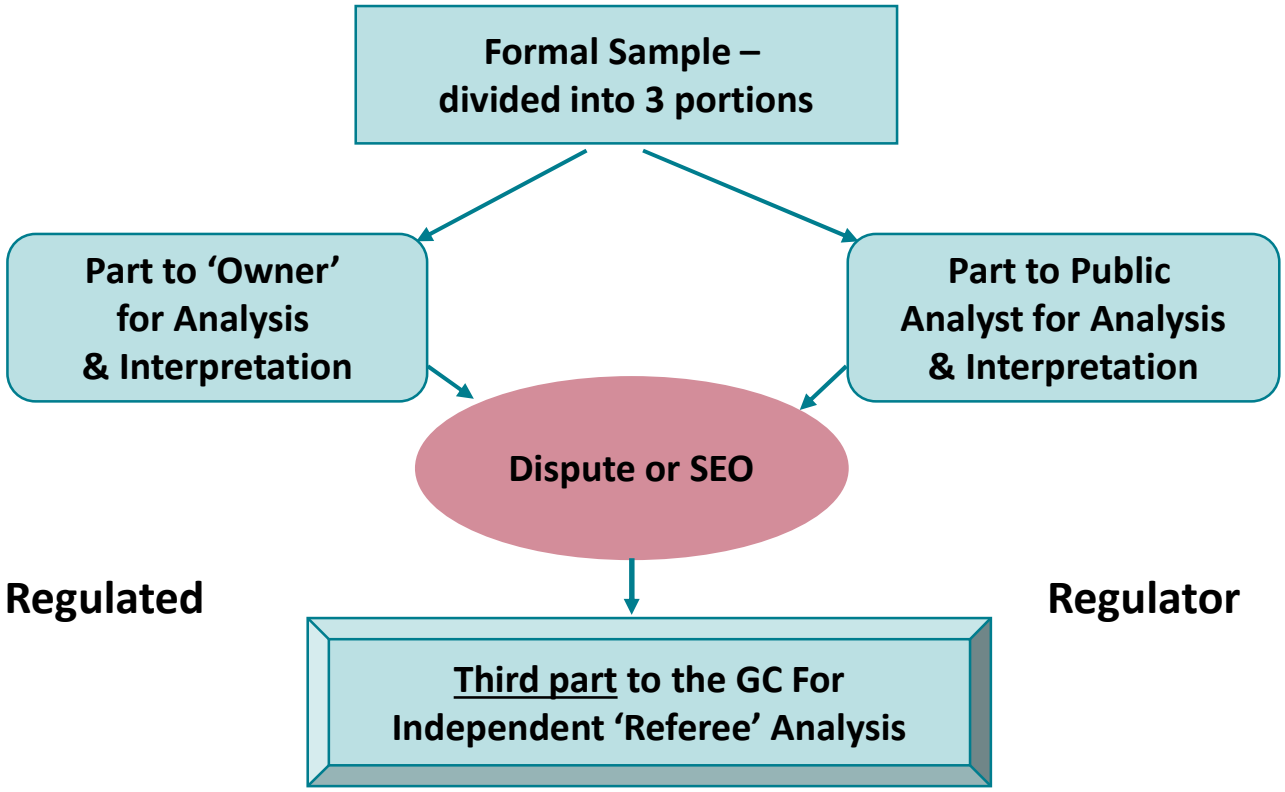
Review of referee cases

- **Introduction**
  - How a case arises
  - Steps in a case
- **Cases**
  - Reported cases
  - Current cases
- **Summary**

How a case arises:



Typical steps in a referee case

- **Decision to accept (is there a dispute?)**
- **Funding**
- **Schedule work**
- **Check legislation**
- **Identify appropriate methodology**
- **Method trialled**
- **Experimental design:**
  - Replicates 3 x 3
  - CRM's, RM's, spikes
  - Witnessed
- **More than one technique**
- **Transcriptions checked**
- **Results reviewed**
  - Interpretation
  - Statistical analysis
- **More analysis?**
- **Certificate**
  - Initial draft
  - Reviewed and independently checked
  - Issued to all parties

Case resource

Cases

- GMO in rice products from China (4 cases)
- Antibiotics in honey
- Novel food supplement
- Opinion on chemical form of a food supplement (on-going)
- Honey authenticity (on-going)

GMO's in rice products from China

- **China (Restriction on First Placing on the Market) (England) Regulations 2008**
  - Implement in England Commission Implementing Decision 2011/884/EU
- **Define specified rice products**
- **Permit the placing on the market such products only if they are compliant with EU law**
- **Non-compliant if a genetically modified element is detectable**
  - Target CaMV 35S, t-NOS and Cry 1Ab/Ac
- **Specified methods of analysis supported by EURL guidance**

Typical analysis plan for a rice product

- 10 retail packs (250g each) received, each with 3 bundles of noodles
- Packs randomly divided into 3
- For each sub-sample all packs opened and bundles mixed.
  - Air dry if necessary
- 2 bundles randomly selected (~160g) and homogenised
- 2 x 100mg taken from each sub-sample
- DNA extracted on different days
- Subjected to PCR
- QC to include BT11 maize, MON 810 maize, LL rice (LL 62), and wild type rice

Summary outcome of GMO cases

Case	PA result	FBO lab result	GC result	Outcome
1720-32	CaMV 35S detected	GMO ND*	CaMV 35S ND Cry1Ab/Ac detected	Non-compliant
2023-1	Cry1Ab/Ac detected	Case withdrawn at request of FBO		
2023-3 (i)	Cry1Ab/Ac detected	GMO ND	GMO ND	Compliant
2023-3 (ii)	Cry1Ab/Ac detected	GMO ND	GMO ND	Compliant
2023-5	t-NOS detected	GMO ND	GMO ND	Compliant

*ND = CaMV 35S, t-NOS or Cry1Ab/Ac not detected

Antibiotics in honey

- **Sample of Manuka Honey, consignment detained at POE**
- **PA found:**
  - Streptomycin 10±5 µg/kg
  - Dihydrostreptomycin 18±9 µg/kg
- **FBO lab reported <5 µg/kg for both analytes.**

Antibiotics in honey

- **Legislative background:**
  - The Animal and Animal Products (Examination for Residues and Maximum Residue Limits)(England and Scotland) Regulations 2015
  - EC Regulation 470/2009 with Commission Regulation 37/2010
  - EC Regulation 396/2005 on maximum residue limits of pesticides in or on food of animal origin.

Methodology

- **Literature review**
  - SPE clean-up followed by HILIC-MSMS
  - Selective and sensitive
  - No isotopically labelled analogues available as IS
  - No structurally similar antibiotic compounds viable
  - Therefore use added streptomycin as IS for dihydrostreptomycin and vice versa.
  - Matrix standards used to address matrix issues
  - Data subject to prescribed acceptance criteria, including retention time window, S/N ratio and transition ratio tolerances.

Results

- **Limits of detection and quantification**
  - Streptomycin 0.1 µg/kg and 0.47 µg/kg
  - Dihydrstreptomycin 0.26 µg/kg and 1.1 µg/kg

- **10 replicates for each analyte (20 data points)**
  - Dihydrostreptomycin all <0.26µg/kg
  - Streptomycin 9 results <0.1µg/kg,1 positive result at 1.7 µg/kg
  - No technical reason for positive result – treated as an unexplained artefact.

- **Outcome: Sample deemed compliant with relevant Regulations.**

Novel food supplement

- **A technical dispute around the composition and labelling of a niacin (vitamin B3) food supplement.**
  - The crux of the issue being the use of nicotinamide riboside chloride (NRC) as the source of niacin in the supplement.
- **The PA had commented on:**
  - Nicotinamide riboside chloride not being a permitted form of niacin
  - The form of expression for niacin was incorrect
  - The nutrient reference value (NRV) was not expressed correctly
  - The health claims marked on the label, although authorised, related to niacin and not NRC

Novel food supplement

- **GC opinion on the sample**
  - The structural form was confirmed and the amount confirmed using both NMR and HPLC
  - NRC had been approved as a novel food by Commission Implementing Regulation 2020/16 for use in food supplements, which also confirmed NRC as a source of niacin in the human body.
  - NRC had not been incorporated into the closed list of permitted forms of niacin, therefore:
    - The nutrition information was not correct
    - The health claims were not authorised
  - Notwithstanding the promulgation of the draft Regulation:
    - The use of the brand name in the nutrition information is not permitted
    - There was no express warning that the product was not suitable for pregnant or lactating women on safety considerations.

Current case

- **Case revolves around the structural form of a food supplement.**
- **Referred to the GC by another (non-scientific) regulatory organisation**
- **Opinion sought on:**
  - Appropriateness of science employed to support claims
  - Application of techniques
  - Interpretations of data generated.

Current case

- **Revolves around honey authenticity**
- **Critical assessment of analytical methods used to determine adulteration**
  - Application of the methods
  - Robustness of the background to each method.
  - Interpretation of large and complex data sets.

Summary

- Number of cases reduced – Covid
- Nature of cases diverse
- Less analysis and more advisory / interpretive
- Referee case analysis continues to resolve disputes in the food and feed sectors outside of the court system.

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