SYMPOSIUM: LEGAL LIMITS ON THE ROAD TO FOOD SAFETY: ESTABLISHING SOUND CRITERIA FOR COMPLIANCE DECISIONS

COMPLIANCE DECISION CRITERIA – PROBLEMS ENCOUNTERED AND ACTIONS TAKEN IN THE EU AND CODEX

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May also be regarded as:

The relationship between the final analytical result and the sampling, the measurement uncertainty and the recovery factor used to obtain that result.

These factors affect the relationship between the final analytical result and the provisions in legislation

Decisions taken by those responsible for the enforcement of legislation directly affect decisions as to whether a lot is in compliance with that legislation.

SCIENTIFIC CO-OPERATION TASK 9.1

“PREPARATION OF A WORKING DOCUMENT IN SUPPORT OF THE UNIFORM INTERPRETATION OF LEGISLATIVE STANDARDS AND THE LABORATORY QUALITY STANDARDS PRESCRIBED UNDER DIRECTIVE 93/99/EEC”

was initiated to identify differences amongst Member States.

14 participated. Final Report is now published.

MAJOR ISSUES IDENTIFIED

The basic principles of the sampling procedures used by The Member States, the treatment of analytical variability (normally known as the measurement uncertainty) in the interpretation of an EU specification, and the use of recovery corrections when calculating and reporting analytical results.

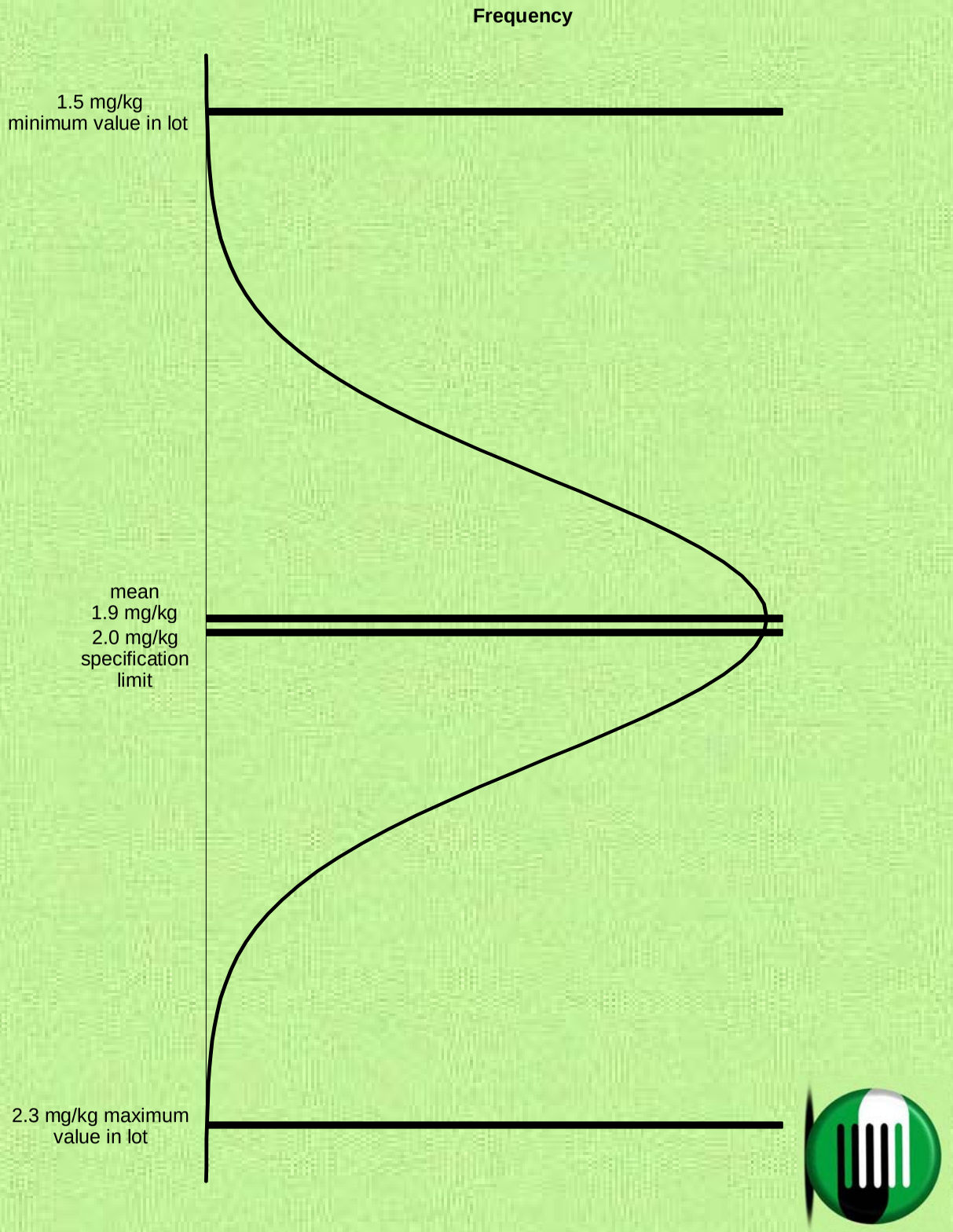
The effect of different countries taking different approaches for each of the issues identified are described. It must be appreciated that there may be other enforcement issues which have a similar effect.

At the present time there is no common interpretation of analytical results across the EU in the food sector so significantly different decisions may be taken after analysis of the "same sample". Material for which there is a statutory limit of, say, 4μg/kg for a contaminant (e.g. total aflatoxins) may be interpreted as containing 3μg/kg on analysis in one country but 8 μg/kg in another. This is because some countries correct analytical results for recovery, others do not; some countries use an "every-item-must-comply" sampling regime, others may use an "average of a lot" regime, some make an allowance for measurement uncertainty, others do not.

It is essential that interpretation of analytical results is similar if there is to be equivalence across the EU; without it there is no uniform interpretation of legislation.

Some of these points now explained.

It is stressed that this is not an analysis or sampling problem as such but an administrative problem which has been highlighted as the result of recent activities in the analytical sector, most notably the development of International Guidelines on the Use of Recovery Factors when Reporting Analytical Results, and various Guides prepared dealing with Measurement Uncertainty.


Frequency
1.5 mg/kg
minimum value in lot
mean
1.9 mg/kg
2.0 mg/kg
specification
limit
2.3 mg/kg maximum
value in lot

Two countries may have different national rules for the interpretation of results from lots.

Country A requires: that each and every item in the lot meets the specification. In this example it means that all 1,000 units, if analysed separately, would have to be less than 2.0 mg/kg. Here a significant number of units are greater than 2.0 mg/kg so the lot would be deemed to be in non-compliance with the legal specification and so would be rejected, but Country B requires: that the mean value of the characteristic in the lot is to be less than the legal specification. In this case the mean value is 1.9 mg/kg so the lot would be deemed to be in compliance with the legal specification.

Consequence: the two countries A and B will make different judgements as to compliance with a legal specification on essentially the same lot. This is unacceptable and can only be avoided if the sampling procedures are elaborated at the same time as the commodity standard is elaborated. In addition it should also be noted that the number of units to be analysed also influences the decision on compliance.

REPORTING OF RESULTS WITH RESPECT TO THEIR MEASUREMENT UNCERTAINTY

All analytical results should be reported in the form "a ± b" where "a" is the best estimate of the true value of the concentration of the measurand (the analytical result) and "b" is the range within which the true value is estimated, with a given probability, to fall. The value of "b" is known as the "measurement uncertainty" and may be estimated by the analyst in a number of different ways.

The estimation of the value of “a” is dependent on: the accuracy of the method of analysis used, how well the analyst uses that method, i.e. whether the analytical system is “in control”.

The value of the measurement uncertainty “b” is dependent on:

- **the inherent precision of the method of analysis used**
- **the number of analytical replicates that are carried out.**

The more replicates the less the value of the measurement uncertainty.

REPORTING OF RESULTS BY FOOD CONTROL ANALYSTS

The procedure adopted by some food control analysts is to report samples as containing “not less than “a” – “b”” in situations where the statutory limit is a maximum permissible concentration. Thus, in any enforcement situation the maximum benefit is given to the food producer. This is consistent with the requirement to prove ***beyond reasonable doubt*** that a limit has been exceeded, if the case should come to Court. This does mean that the effective enforcement limit is, in such countries, not identical to the numerical value given in legislation.

Other food analysts may report the value “a” without taking into account any measurement uncertainty considerations.

CONSEQUENCES OF REPORTING RESULTS IN DIFFERENT WAYS

There are potential problems with the reporting of result for which there is a legal specification. This is best explained by example:

Let us assume that there is an EU specification of 4 μg/kg for the analyte being analysed. It would be anticipated that the measurement uncertainty for the analysis will be of the order ± 45% of the analytical result, i.e. the analyst would determine for nominal concentrations of 3, 6 and 10 μg/kg, the following concentrations including their uncertainties:

a. 3.0 ± 1.3 μg/kg,

b. 6.0 ± 2.6 μg/kg, and

c. 10.0 ± 4.4 μg/kg

Situation a

Here the level reported is below the EU specification. All countries would take the same view and accept the material.

Situation b

Here the level reported is above the statutory limit but the true value lies in the range 3.4 to 8.6 μg/kg. The level and its uncertainty would be reported. Here some countries would report the sample as containing not less than 3.4 μg/kg of the analyte and because it is not beyond reasonable doubt that the limit has been exceeded, no action will be taken.

However, other countries may take action on the 6.0 μg/kg result, without taking uncertainty into account. For these countries, the material will be deemed to be non-compliant.

Situation c

Here the level reported is above the EU specification and the true value lies in the range 5.6 to 14.4 μg/kg. All countries will state that the material is non-compliant with the EU specification.

Conclusion

In situation b there is the possibility that different countries will take make opposite decisions as to whether the material conforms with the EU specification.

The SCOOP Task found this to be the situation.

Similar considerations identified in Codex Alimentations Commission

See: ALINORM 04/27/23, APPENDIX VII

“THE USE OF ANALYTICAL RESULTS: SAMPLING, RELATIONSHIP BETWEEN THE ANALYTICAL RESULTS, THE MEASUREMENT UNCERTAINTY, RECOVERY FACTORS AND THE PROVISIONS IN CODEX STANDARDS”

Codex Paper

THE USE OF ANALYTICAL RESULTS: SAMPLING PLANS, RELATIONSHIP BETWEEN THE ANALYTICAL RESULTS, THE MEASUREMENT UNCERTAINTY, RECOVERY FACTORS AND PROVISIONS IN CODEX STANDARDS

ISSUES INVOLVED

There are a number of analytical and sampling considerations which prevent the uniform implementation of legislative standards. In particular, different approaches may be taken regarding sampling procedures, the use of measurement uncertainty and recovery corrections.

At present there is no official guidance on how to interpret analytical results across the Codex Community. Significantly different decisions may be taken after analysis of the "same sample". For example some countries use an "every-item-must-comply" sampling regime, others use an "average of a lot" regime, some deduct the measurement uncertainty associated with the result, others do not, some countries correct analytical results for recovery, others do not. This interpretation may also be affected by the number of significant figures included in any commodity specification.

It is essential analytical results are interpreted in the same way if there is to be equivalence across the Codex Community.

It is stressed that this is not an analysis or sampling problem as such but an administrative problem which has been highlighted as the result of recent activities in the analytical sector, most notably the development of International Guidelines on the Use of Recovery Factors when Reporting Analytical Results and various Guides prepared dealing with Measurement Uncertainty.

RECOMMENDATIONS

It is recommended that when a Codex Commodity Committee discusses and agrees on a commodity specification and the analytical methods concerned, it states the following information in the Codex Standard:

1. Sampling Plans

The appropriate sampling plan to control conformity of products with the specification. This should state:

- whether the specification applies to every item in a lot, to the average in a lot or the proportion nonconforming;
- the appropriate acceptable quality level to be used;
- the acceptance conditions of a lot controlled, in relation to the qualitative/quantitative characteristic determined on the sample.

2. Measurement Uncertainty

That an allowance is to be made for the measurement uncertainty when deciding whether or not an analytical result falls within the specification. This requirement may not apply in situations when a direct health hazard is concerned, such as for food pathogens.

3. Recovery

[Where relevant and appropriate the analytical results are to be reported on a recovery corrected basis and that the recovery should be quoted in any analytical report.]

4. Significant Figures

The units in which the results are to be expressed and the number of significant figures to be included in the reported result.

REPORT TO THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

ON THE RELATIONSHIP BETWEEN ANALYTICAL RESULTS, THE MEASUREMENT UNCERTAINTY, RECOVERY FACTORS AND THE PROVISIONS IN EU FOOD AND FEED LEGISLATION WITH PARTICULAR FOCUS ON THE COMMUNITY LEGISLATION CONCERNING:

- **CONTAMINANTS IN FOOD (COUNCIL REGULATION (EEC) No 315/93 OF 8 FEBRUARY 1993 LAYING DOWN COMMUNITY PROCEDURES FOR CONTAMINANTS IN FOOD)**

[1] Official Journal of the European Communities, L37, 13.2.1993, p. 1

- **UNDESIRABLE SUBSTANCES IN FEED (DIRECTIVE 2002/32/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 7 MAY 2002 ON UNDESIRABLE SUBSTANCES IN ANIMAL FEED)**

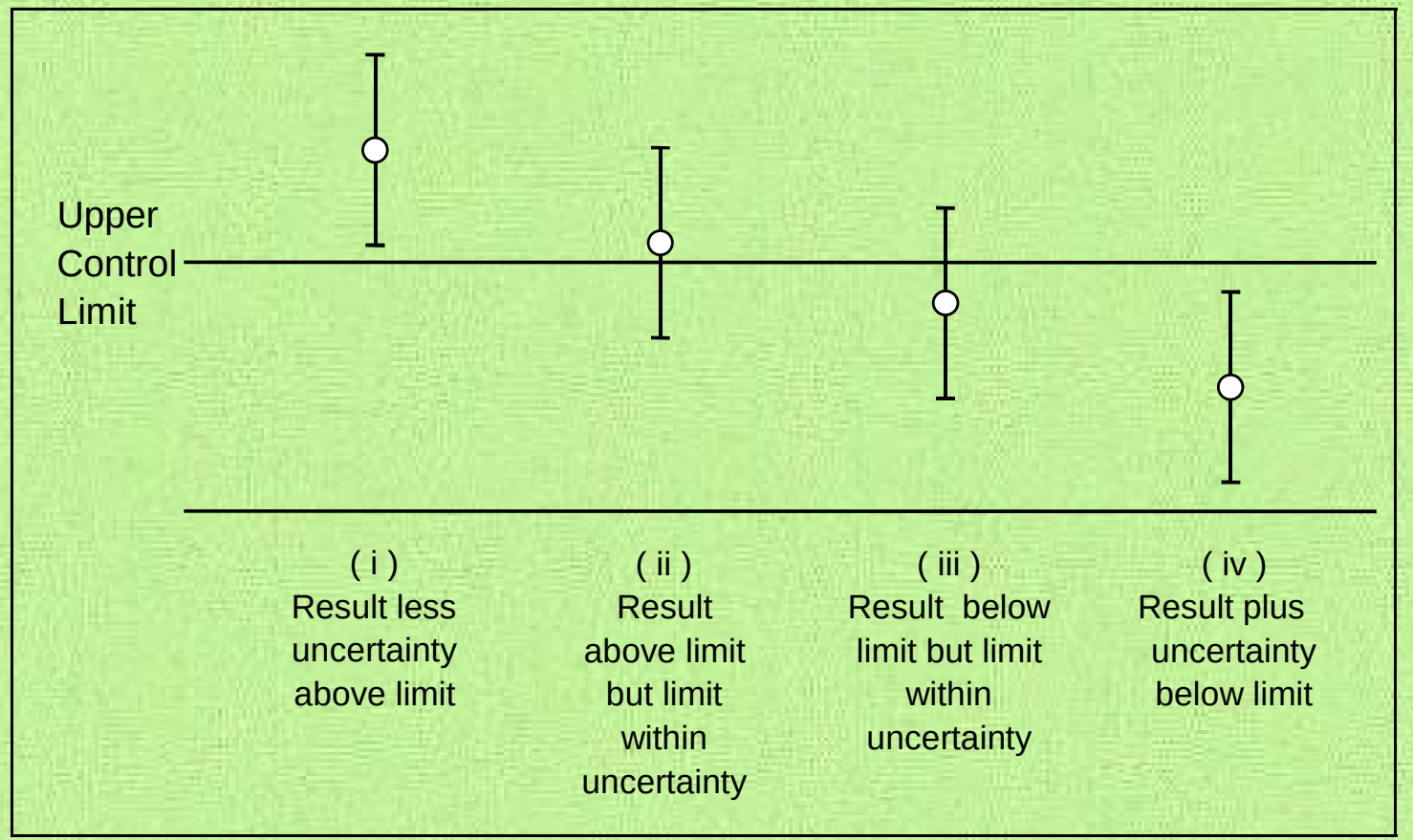
[2] Official Journal of the European Communities, L 140, 30.5.2002, p. 10

Website Address

http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/report-sampling_analysis_2004_en.pdf

and

http://europa.eu.int/comm/food/food/animalnutrition/sampling/index_en.htm


Upper
Control
Limit
(i)
Result less uncertainty above limit
(ii)
Result above limit but limit within uncertainty
(iii)
Result below limit but limit within uncertainty
(iv)
Result plus uncertainty below limit

This means that the legal specification and enforcement limit are different.

This should be appreciated when specification is being set.