EU legislation on Low Level Presence (LLP); definition and application in practice

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laying down the methods of sampling and analysis for the official control of feed as regards the presence of genetically modified material for which an authorisation procedure is pending or the authorization of which has expired

Joint Research Centre

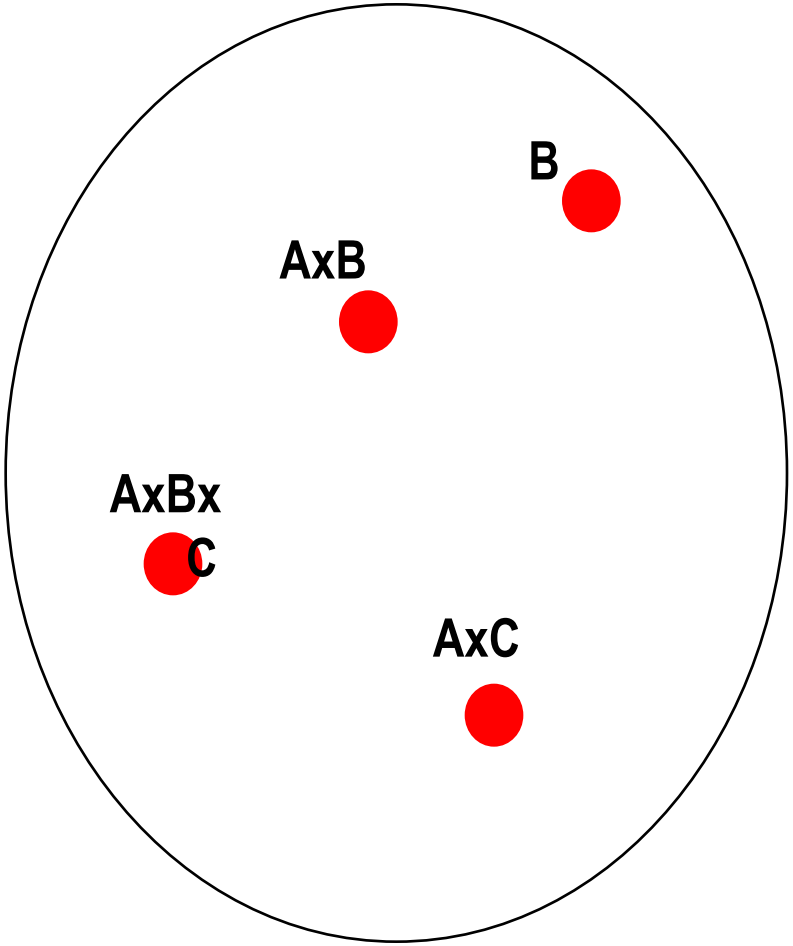
Whereas (9):

Accordingly, the scope of this Regulation should cover the detection in feed of GM material authorised for commercialisation in a third country and for which an authorisation procedure is pending for more than 3 months under Regulation (EC) No 1829/2003 where the event-specific quantitative methods of analysis submitted by the applicant have been validated by the EU-RL and provided that the certified reference material is available.

Whereas 14
It is appropriate to set as a Minimum Required Performance Limit (MRPL) the lowest level of GM material which is considered by the EU-RL for the validation of quantitative methods.
This level corresponds to 0.1% related to mass fraction of GM material in feed and is the lowest level where results are satisfactorily reproducible between official laboratories when appropriate sampling protocols and methods of analysis for measuring feed samples are applied.

Whereas (15):

The methods validated by the EU RL are specific to each transformation event irrespective of the fact that the transformation event is present in one or several GMOs containing one or several transformation events.



Assume A approved, B and C not approved:

If B or C are at or above the MRPL (as defined in accordance with the rules of interpretation), the feed shall be considered as non-compliant

Method of sampling:

Regulation (EC) No 152/2009 predominantly applies.

The EU-RL GMFF accepts only methods where the applicant proves that the RSDr at the level of 0.1 % related to mass fraction of GM material ≤ 25%; this value will be published in the validation reports

The EU-RL GMFF will determine in-house the RSDr at the level of 0.1 % related to mass fraction of GM material and will publish that data in the validation report.

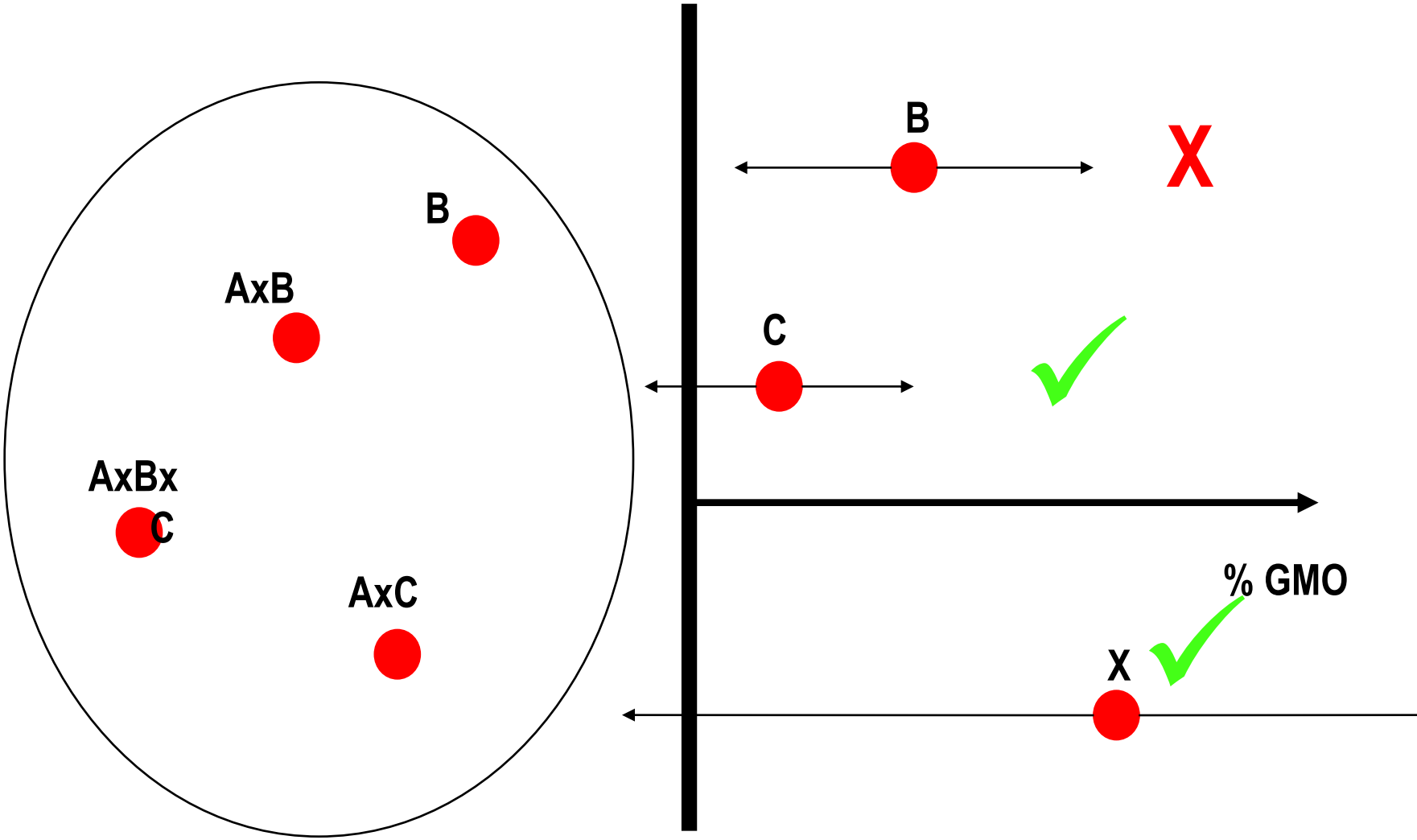
Following a ring-trial, the EU-RL GMFF calculates again the RSDr, this time according to ISO standard 5725. This value has been and will continue to be published in the validation reports.

In order to be fit for the purpose of meeting the requirements of the LLP regulation, all RSDr values mentioned above have to be below 25%.

According to the provisions of ISO 17025:2005 section 5.4.2, the official laboratory shall provide evidence that it can properly run a reference method by meeting the described performance parameters using actual laboratory data. In particular, the RSDr of the method shall not exceed 25% at the GMO concentration of 0.1% expressed.

To ensure a level of confidence of approximately 95 %, the outcome of the analysis shall be reported as x +/− *U* whereby x is the analytical result for one measured transformation event and *U* is the appropriate expanded measurement uncertainty.

MRPL



Expression of results in mass/mass % versus cp/cp %?

Unit of Measurement

Measurement results calibrated with a calibrant of a known mass fraction (e.g. a CRM), lead to measurement results expressed in mass fraction (likewise with a calibrant of a known copy number ratio and results in copy number ratios).

See Annex II: when results are expressed in DNA copy numbers they should be translated into mass fraction

Conversion between mass fraction and copy numbers is possible but includes an uncertainty. Proposed conversions:

For crops hemizygous for the GM insert (eg hybrid maize)

GM% in DNA copy = 0.5 GM% in mass

For crops homozygous for the GM insert (eg soya)

GM% in DNA copy = GM% in mass

Thank you!