FSSC 22000 guidance on Appendix IA

The following provides additional information relating to questions arising from the revised requirements

Appendix 1A item 3 – Specific Regulatory Requirements

> *"Organizations seeking certification shall assure that specifications for ingredients and materials take account of any applicable regulatory requirements [e.g. control of prohibited substances]."*

This new requirement is essentially an extension of the requirements given in ISO22000 7.3.3.1, to assure that all applicable statutory and regulatory requirements are identified and incorporated into specifications.

ISO22000 7.3.3.1 states "All raw materials, ingredients and product contact materials shall be described in documents to the extent needed to conduct the hazard analysis" and goes on to say "The organization shall identify statutory and regulatory food safety requirements related to the above".

The difference between the ISO requirement and the revised FSSC 22000 scheme text is due to the limitations incorporated in the ISO text:

A] The ISO text is limited to information needed to carry out the hazard analysis, and it is therefore possible that some substances may be omitted, and

B] The ISO text is limited to identifying statutory and regulatory food safety requirements, not all statutory and regulatory requirements.

Requirements that need to be considered for inclusion in the specifications may include, but are not limited to: specific micro requirements, mycotoxin levels, glycoalkaloid levels, prohibited colours and/or flavours, maximum or minimum preservative levels and migration potential.

Appendix 1A item 4 – Announced but unscheduled Audits of Certified Organizations

> *"The certification body will participate in a risk-based programme of office audits and announced, but unscheduled audits of certified organizations. These audits shall be carried out in accordance to the GFSI requirements."*

The question arises as to what is meant by 'announced, but unscheduled audits of certified organizations'. The GFSI GD Section 2.5.6 gives no further explanation or guidance, but there is a definition given later in the GD that describes: Unscheduled Supplier Audits: Audits planned within a defined programme, but without the allocation of a specific programme date.

We have interpreted this as for a given year we will announce to CBs that we will "witness" audit an X number of certified organizations. The dates and locations for these audits will be chosen from the CBs audit schedule (list of audit dates, auditor names and client locations).

Appendix 1A item 5 – Management of inputs

> *"The organization shall implement a system to assure that analysis of inputs critical to the confirmation of product safety is undertaken. The analyses shall be performed to standards equivalent to those described in ISO 17025."*

Note: The requirement wording is very specific: it is not about the achievement or maintenance of product safety, but about the confirmation of product safety.

Inputs critical to the confirmation of product safety may include any material that is added to the product or used as a processing aid. What makes the input critical is the potential to introduce contamination such as pathogens, aflatoxins, pesticide residues, heavy metals etc. or a specific property that affects the product such as pH value or moisture content.

Raw and packaging materials will normally be subject to specified requirements and are tested to assure that they present no risk to the product or process. Where testing may not be the norm [for example in the case of water, steam or ice] the organization has to determine if there is potential risk to the safety of the product.

In cases where risk is identified [for example, by application of HACCP principles], an appropriate testing protocol must be put in place. The testing must be carried out to standards equivalent to those described in the laboratory accreditation standard ISO17025.

This does not mean that the testing has to be carried out by an accredited laboratory, but non-accredited laboratories must be able to demonstrate that they follow the principles of the standard. This will include, but is not limited to use of recognized, validated test methods, calibration of instruments, proficiency testing of analysts, traceability of samples and results etc.