

The ISO 16140 standard : a revision in progress to further improve the methods and labs involvement....

History in a nutshell!

The ISO 16140 (2003) standard describes the technical protocol for the validation of alternative methods within the framework of the microbiology of food and animal feeding stuffs. The standard project development was started during an European Eureka project. The first validation studies according to the ISO 16140 were certified in 2004. The standard is now fully recognised by the users, i.e. the certification bodies of course, and as well the routine labs, in the scope of the EU directive 2073/2005 which clearly mentioned three requirements for the alternative method validation:

1. comparison to ISO/CEN reference method,
2. validation according to the validation protocol stated in standard EN ISO 16140 (or similar),
3. certification by a third party.

But optimisation, and normalisation, are never ending stories : in 2006, the revision of the ISO 16140 was decided based upon remarks received, particularly on the reliability of the proposed statistical tests.

A revision to go further with method validation...

The ISO 16140 standard revision is ongoing in the ISO TC 275/SC9/WG3, in close collaboration with the WG2 which mainly focuses on statistics. If the standard was at first particularly dedicated to the proprietary method validation, the WG3 works at extending the scope by including procedures for (i) in house validation which corresponds to the single lab validation, (ii) intermediate validation which is useful when only a restricted number of labs are interested at least in the use of the studied method, (iii) standard method validation, (iv) method verification which describes the technical protocol to prove that the users apply the method correctly on the matrices analysed in the lab. If the protocol for proprietary method validation remains the core of the revision, the new ISO 16140 standard will also provide technical requirements adapted to the focus area and the application of the newly developed method, from a single lab use to a standard use. Furthermore, the foreseen inputs will also enhance new quality assurance procedures in the labs which apply the methods in the framework of the legislation.

But, designing statistical tests for microbiological purposes is a real challenge...and the revision is still in progress! Hopefully, many organisations are involved in the revision process, and the next ISO 16140 standard may become the worldwide recognised technical protocol for method performance assessment...?

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Member in the expert laboratory body at the AFNOR Certification and Microval certification committees

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