

MICROVAL's FIRST CERTIFICATE PRESENTED

MicroVal Symposium March 2007, Amsterdam

The MicroVal Symposium was held in the Victoria hotel in Amsterdam. The atmosphere was festive as the first certificate was handed out, highlighting the operational status of the organization. Speakers and attendees from all sectors of the food industry and from both the United States and Europe were in attendance. The presentations and discussions were varied and the day was seen as productive and successful by all.

MicroVal is a European certification organisation for the validation and approval of alternative methods for the microbiological analysis of food and beverages. MicroVal validates and certifies alternative methods in order to show that such proprietary methods perform as well as internationally standardised methods.

Opening by chairman

The MicroVal symposium in which this first certificate was handed out was held in March 2007. At this symposium the experiences and points of view of the various stakeholders were shared and discussed. The symposium was opened by Prof. Dr. Mike van Schothorst, one of the managers of the Eureka project, who chaired the symposium. He mentioned the deliverables of the MicroVal project which focused on quality control and led to development of the MicroVal Rules & Certification scheme and formed the basis of EN ISO 16140.

MicroVal benefits for end users

Hereafter the chairman of MicroVal, Dr. Peter McClure, Unilever Research, outlined the role of Microbiological testing in the food production and manufacturing chain. He gave as an example a case where a third party laboratory incorrectly identified *Salmonella* contamination, due to their use of a non-validated method. The results were incorrect and forced an expensive and unnecessary recall. He emphasized the need for accurate validated methods available across different regions. AOAC and EN ISO 16140 (MicroVal) would appear to be the best international routes forward.

First certificate

Peter McClure congratulated Dr. Stephan Speidel (HyServe GmbH. & Co.) with this MicroVal milestone. He then presented him with the certificate for the Compact Dry TC method, manufactured by Nissui Pharmaceutical Co. Ltd. Stephan Speidel was happy to receive the first MicroVal certificate.

Experience of a MicroVal Certification Body

Mr. Hans van Rijn opened his presentation with a brief history of Lloyds Register Quality Assurance (LRQA) and proceeded to give an overview of the MicroVal organization and its procedures. He showed that the market for microbiological methods is rapidly growing a predicated a bright future for MicroVal. Six validations will be performed this year with new contracts expected soon.

Experience of an Expert Laboratory validation Compact Dry TC

Dr. Chris Bayliss, Campden & Chorleywood Foods Research Association,(CCFRA) focused his presentation on the interpretation of EN ISO 16140 and the resulting statistical complications and data analysis. As a result of his work with the standard, he presented a number of points that could be considered for improvement including layout, descriptions/explanations and the clarity of the statistics (application and interpretation). He concluded that test kit manufacturers wanted fewer schemes not more and that MicroVal provides a European scheme for certification and validation of alternative methods. For MicroVal to be successful, the scheme must provide a fast and efficient service for kit manufacturers and laboratories validating the methods. CCFRA fully

support MicroVal as the European Certification Scheme.

Importance of validation for Food Businesses

Dr. John Marugg, Nestlé Research, described the importance of rapid methods for Food Businesses. He showed that the food industry needs alternative methods but that there is a wide choice of methods but often no means of reliably choosing between them. He outlined the structure Nestlé uses for evaluating traditional and alternative methods (NesVal) and the requirements it places on testkits, as a user.

Importance European validation/certification for manufacturer

Dr Jörg Siekmöller, 3M Deutschland GmbH Neuss/Germany, opened his presentation with a brief history of 3M and its organisation. Following this he outlined the procedures used by 3M in selecting validated methods. His presentation clearly expressed the problems faced by companies when presented with a multitude of certification bodies. Mike van Schothorst indicated that hopefully in the future this process would be simplified and allow for an easier way to share validation results across regions.

Regulation (EC) 2073 on microbiological criteria for foodstuffs

Mrs Maija Hattaka, DVM PhD, of the European Commission DG SANCO (a MicroVal Observer), gave a presentation on EC Regulation 2073/2005, microbiological criteria for foodstuffs. After listing the goals of the regulation, she proceeded to detail various cases where rapid methods provide an advantage over traditional ones. For these methods to be used there are a number of items risk managers require before making a choice. These include having taken European Community legislation into account, a single validation protocol and a transparent discussion across all bodies of food microbiology.

Mike van Schothorst pointed out that one of the most important aspects of the new regulation criteria is the emphasis on process hygiene criteria, which are separate from the food safety (end product) criteria. This is a breakthrough in HACCP relying on data obtained during processing rather than data obtained on the analysis of end products.

Belgian point of view on validation/certification

Ir G. De Poorter, Director General Laboratories, Belgian Federal Food Safety gave a presentation on behalf of FLEP (Food Law Enforcement Practitioners). He outlined the structure of the Belgian food safety legislation and discussed the changes it would undergo over the next few years. He outlined the process for MicroVal approved testkits to be accepted within Belgium. He also presented for discussion the idea that Certification Bodies would opt for accreditation via EA according to ISO Guide 43, 62 or 45012 to create a more transparent environment for legislators. Mr. De Poorter is of the opinion that this would ensure that an independent third party has assessed the certification scheme, allowing it to be automatically accepted by all national bodies.

Short statement FLEP

Erik Dahm, representative of FLEP, explained that FLEP is an informal group of European food law enforcement practitioners. He explained that FLEP is a member of MicroVal, because it is an independent platform and actively seeks cooperation with other certification bodies to provide a single validation system and aiming at harmonized interpretation of EN ISO 16140 and a mutual recognition of validated methods. This prevents a wasteful duplication of effort and money. Furthermore the interest of FLEP is served by promoting a diverse market, preventing a monopoly on test kit production and validation as well as securing a transparent validation process.

View of a national (UK) view on Regulation

Mrs Melody Greenwood presented on behalf of the UK Health Protection Agency. Her presentation covered the implementation of Regulation 2073/2005 in the UK and the role that alternative microbiological methods have in this. She covered the perspectives of all stakeholders in this process, including the official control laboratories, the competent authority, the local authorities and the food business operators.

A recurring element was the lack of routine testing requirements in 2073/2005 (except for fresh meat and meat preparations), giving greater weight to the evaluation of procedures and using testing where concerns are raised.

Future changes EN ISO 16140

Dr. Paul in 't Veld presented on behalf of the Dutch Food and Consumer Safety Authority, concerning the current status and future changes of EN/ISO 16140. He gave an overview of the different project groups. Concerning the topics for proprietary methods discussed so far are, Inclusion IDF 161 (Bactoscan), Natural versus artificially contaminated samples, Outline collaborative study, Statistics for the evaluation for quantitative data and Determination of the relative accuracy. It is expected that 2- 3 years will be needed before all parts of the revised standard will be available for comments by ISO and CEN. Also acceptance of standards will take a further 2-3 years.

Global harmonization perspective

Mr Philip Feldsine of BioControl Systems, represented AOAC International at the symposium. His presentation focused on the harmonization of international validation for analytical methods. He briefly reflected on the history of validation developments. Hereafter he pointed out that the AOAC Micro guidelines and EN/ISO 16140 have similar requirements and that the technical requirements of both are virtually identical. This provides the key to harmonization. He discussed all key elements required to achieve this and detailed the work that remains to be done.

Mrs. Deborah McKenzie, Manager Technical Programs, AOAC Research Institute presented on the status of international microbiology method validation. In particular she detailed the efforts of AOAC to work together with other organizations in coordinating the International Data Collection program (IDC) and present value to all parties concerned. She emphasized the ongoing harmonization work between AOAC and MicroVal. She concluded the presentation by congratulating both HyServe and MicroVal with the certificate.

Discussion

Dr. McClure, as chairman of MicroVal, led the discussion. Dr. Uyttendaele from Ghent University started the discussion and mentioned that there exists some confusion concerning validation schemes and procedures in Belgium and wondered how MicroVal fitted in this and if the Belgian validation method list would be updated to include the MicroVal certifications.

Mr. De Poorter reiterated his position on accreditation and mentioned that without that each certification by each party would be examined by the Belgian National Reference Lab individually.

Dr. Uyttendaele then questioned the extent to which the Belgian national list of approved validation schemes applies to companies operating across borders and performing the tests in a different country. Mr. De Poorter replied that all imported goods are subject to monitoring programs, which use the Belgian approved methods. The extent of the applicability of these programs to trans-national entities, however, was not a subject for national authorities but the European Commission.

Dr. McClure took this opportunity to point out that a reference had been made to MicroVal as a commercial entity, but that this was incorrect as MicroVal is a not-for-profit organization and that some of the components are commercial entities.

The discussion continued on the subject of imported foods. Dr. Greenwood mentioned that this regulation only allows the safety criteria to be allied to food imports, not hygiene criteria. However, hygiene criteria play an important role in determining both the quality of the food as well as predicting the presence of pathogens.

In reply to a question of asking for a perspective from the EC, Mrs. Hattaka said that Food Safety Criteria apply to imported products, while process hygiene criteria only apply during the production process; they cannot be used for the evaluation of imported products that are already

on the market. When there exists doubt about health risks, then other regulations have to be applied.

Prof. van Schothorst mentioned that he was puzzled by the discussion on accreditation and asked Mr van Rijn for some clarification on the relevance.

Mr van Rijn explained that the MicroVal organization has many provisions in place to safeguard the impartiality and the independence of the decisions taken. These provisions satisfy the demands of all members. The EU regulations do not contain acceptance criteria for validation organizations. For an audit to have any relevance, these criteria would first have to be formalized.

Mr de Poorter mentioned that he was in favour of discussing a European answer to further the goal of harmonization. Mr Van Rijn mentioned that the EU requires only compliance with EN/ISO 16140, which MicroVal does. Mr de Poorter referred to the ISO Guide 43, 62 or 45012 and that he would prefer to see all parties comply with that. Dr Peter McClure suggested that this discussion be continued with other people in the sector over the coming period to raise a consensus.

Mr Clark from Microgen questioned the effectiveness of using a single validation methodology for varied testkit technologies at different stages of development and whether or not different levels of validation would be taken into account. Dr .Paul in't Veld pointed out that the EN/ISO 16140 aims to validate all types of alternative methods, in as far as this is possible. However it would in his opinion be difficult to prescribe different validation levels for different methods, apart from the differences being taking into account for qualitative and quantitative methods.

Mr. Clark gave an example where the level of validation for a particular method as required by EN/ISO 16140 was too extensive and time consuming. He mentioned that these procedures are required for screening methods, which is a big market, but that many rapid methods are used simply for culture confirmation and he presented clinical examples. He asked if it was not also possible to outline general principle guidelines for alternative methods. Dr McClure of Unilever restated his example of a false positive on salmonella in the field by a third-party due to the use of a non-validated method. Both Dr. McClure and Mr. Hart agreed that the validation levels of a method should fit the purpose for which it is used.

Dr Bayliss spoke from his experience with biochemical test systems and took on the point that Mr Hart had raised and that the difficulty in validation is often specifying the order, range and strains for which to use for validation. A possible limitation on the scope of the validation could be for expert labs to verify the results of the research done by the manufacturer instead of duplicating the entire test range or to limit the tests to only a select number of organisms. He suggested that in the future other aspects of microbiological testing be taken into account.

Mr. Feldsine was asked if AOAC had any experience validating such testkits. He replied that they had and that the expert review committee handled such cases where the scope was narrowly defined and where necessary refined on a per-protocol basis. Dr. In 't Veld pointed out that a part of EN/ISO 16140 deals with inclusivity and exclusivity and that parts of this might be used for a more general validation foundation.

Dr. McClure closed the discussion and thanked for the contributions to the discussion and the speakers, who collectively covered a range of different aspects of validation of methods. Each had its own unique contribution and with the mix of presentations there was hardly an overlap.

Prof. van Schothorst, as day chair, closed the meeting with a summary of the day and thanked the participants for their contributions and involvement.