THE IMPORTANCE OF RAPID METHODS FOR FOOD SAFETY

Cécile Lahellec .

French Food Safety Agency.

During the past decades, the importance of food safety has been increasing all around the world . More and more , we are speaking of hazard, risk, uncertainty ; at the same time, and following the BSE crisis, food safety agencies have been created in quite all European countries ; the approach of food safety problems have been rationalized .

Presently, as everybody knows, a European Authority has been created and, among the different tasks of this Authority, the revision of microbiological criteria has appeared as a necessity . it is obvious that harmonized methods have to be connected with those criteria . In those conditions, which will be the place of rapid methods ? In which conditions will they be used ?

It is not in my intention to interfere with what will be presented on those days by very well known microbiologists, and especially with those of Pr D.Y.C. Fung, ; I would only like to share with you some part of my experience concerning that field .

-Why did setting up rapid methods in food microbiology appear as a necessity ?
-How and when those methods, commercial or not , were they introduced in France and different European countries ?
- The problem of validation of rapid methods . Past and present situation .

Then, I shall try to draw a conclusion : which can be the place of rapid methods in food safety ?

I- Why did setting up rapid methods appear, a long time ago, as a necessity , in different fields of food microbiology ?

We are on those days, a group of food microbiologists and we all have been studying the classical microbiology , as we have learnt from our "teacher" Louis Pasteur . We also know perfectly well that, in case of conflict, it is always necessary to use classical methods and, for example, to make the presence of pathogenic bacteria obvious .

However, food microbiology has different aspects : personally, I was involved very soon, at the beginning of the seventies, in what is called now the " new" approach , from fork to farm for the detection and monitoring *Salmonella* in the food chain, and especially for poultry meat products . In order to get a number of samples as much as possible, representative of the populations, we had to study a large number of samples and the cost was , of course very high ! at the same time, we had also to examine a large number of psychrotrophic strains in

order to better know those involved in shelf life of poultry sold as refrigerated ..and the lab work was very expensive !

I think I was really very lucky to be able to attend the meeting on rapid methods and automation in food microbiology, in September 1974 . during that meeting, there were a lot of presentations of rapid method for treating the samples (I saw a " stomacher" for the first time of my life) ; a lot of perspectives for the rapid detection of microorganisms did appear and, of course, I met Dr Fung who gave a wonderful and enthusiastic talk .... That was the beginning of the story ..

From that time, I had more and more the feeling that rapid methods were really very important for food safety ; the presentation of Dr Fung and the demonstrations he made in Ploufragan a few years later showing the interest of those methods led us to introduce them, at first in our laboratory, then in different places in French labs . In 1987, as I was the president of the section " food microbiology " of the French Society of Microbiology, we organized a colloquium on " rapid methods and automation in microbiology ". One can find in the proceedings a description of a lot of new methods and the same scientist who is here today, gave an important place ..

II- How and when those rapid methods, commercial or not, were introduced in France and in different European countries ?

From that period, but of course, the real beginnings were observed sooner , as the first international symposium on the theme was organized in Stockholm (Sweden) in 1973 , there was an intensive development of commercial rapid methods .and the question was to know in which context they could be used and recognized .

The development of rapid methods had appeared previously in the medical field and the interest in this sector was never controversed . Of course, different reasons may explain the delay for introducing rapid methods in the food microbiology sector : the number of samples to be examined , but also, among other reasons, the critical situation in which ill people are .. However, some large outbreaks, in which *Salmonella* or *Listeria monocytogenes* were involved , lead scientists and technicians, especially from food industries'labs, to give an increasing interest to rapid methods .
While there was no controversy for using rapid methods in the food industry, the same situation was not observed for official purposes : as an example, the question was raised during a meeting of the scientific veterinary committee, to know whether or not it would be possible to use a given rapid method for detection of *Salmonella*, in implementation of the Zoonoses directive .... But, at that time, there was no European recognized protocol for the validation of what is called " alternative" and only classical methods were adopted .

Of course, we have always to keep in mind that the situation may be different according to the sector of implementation : industry, official controls for monitoring, controls in case of conflict, in some cases, epidemiological surveys ...

III – The problem of validation of rapid methods . Past and present situation .

Following the development of alternative methods in microbiology, different systems of validation have been set up in different countries . (cf AFNOR, NMKL, ...) and different kits have been validated through different protocols .
There was obviously a need for a unique system ... but, there too, it is a long story . How to establish a standard and by whom has it to be established ?

It may be useful to mention some general considerations :

- a standard is a text of reference, established by a recognized body , which requests the consensus of all parties ; it is continuous, repetitive; their use is voluntary ; however, in case of conflict, it may become mandatory .
- The recognized bodies at the european level are CEN and ISO, the first created being ISO (International Organisation for Standardisation) , composed of standard bodiesof 138 countries ; the ISO standards are taken over optionally as national standards .
- CEN (Comité européen de normalization) has been created quite recently, in the 60's .

The members are standard bodies of Europe, at large . CEN standards have to be taken over as national standards and conflicting standards have to be withdrawn .

According to the " Vienna agreement", CEN takes, as often as possible, the ISO standards but can propose modifications to be introduced in the existing ones . *CEN can also be the leader for some topics, as it is the case for the reference protocol for the validation of alternative methods*

The advantages of alternative methods are obvious (quick answer, less preparation, less space....) and that is the reason why different systems of validation were developed all around the world .
The beginnings of the European validation can be found in a European Microval project . ; in 1996, the task of setting up the standard was transferred to CEN TC275/WG6 and a TAG (TAG2) was created in that purpose .
The aim of this standard (EN/ISO 16140) was to define as well the general principles and the technical protocol for the validation of alternative methods as the general principles for the certification of alternative methods .

The validation of an alternative method is the demonstration that the results obtained by the alternative method are comparable to those obtained using the reference method (comparable= at least equivalent)

The general principles of the validation protocols have two parts :
- a method comparison of the alternative method against the reference method (performed by one laboratory)

- the interlaboratory study of the two methods .

Technical rules for those two phases are applicable for qualitative and quantitative methods .

If the alternative method has been already validated, the results may be taken into account .

The general rules for the certification system concern :

- the organization to be defined by the certification body .
- the manufacturer to apply a quality system for the production line .
- a regular verification of the quality system .

The new standard EN/ISO 16140 has finally been accepted in may 2003 .

The outcome of that new standard can surely be accepted as an important progress in harmonization systems , even if not easily accepted by those countries having their own system of validation … In spite of different discussions, a resolution was recently taken by CEN/TC275/WG6 during the last meeting in Saint Denis (F) , saying that :
" *Possible amendment of the EN ISO 16140 will be considered only after implementation of the protocol and in connection with AOAC .* "

Even if different questions remain, for example " what is a reference method ?" , could PCR replace classical methods for the detection of some contaminants ? , it seems obvious that the new protocol for the validation of alternative methods can be considered as " historical" and should help a lot in the acceptance of different methods used in different purposes .

As a **conclusion** , I would like to emphasize the fact that the development of rapid methods has been somewhat slow . After this " latence" phase, there has been an exponential development of commercial kits based on the same systems as those used in the first beginnings ; the question was then " what to do with, in which purposes to use them ? Could rapid methods be , in some cases, used as references ?"

It seems that time has come for a rationalization of using rapid methods in food microbiology The discussions at a European level in different instances show clearly the evolution and, so, we can be optimistic concerning the future of rapid methods in food microbiology .But it will be more and more necessary in the future to have a reciprocal "enrichment " of technicians, scientists and people in charge of regulations and/or standardization, to see rapid methods take their right place on the European scene and play an important role in food safety .

Barcelona , 26/11/2003