

# Impact of the development of microbiological rapid methods on Food Safety implementation in the European Union

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During the past decades, due to the emergence of different crisis incriminating Food, the consideration of problems related to Food Safety has taken an increasing importance all around the world.

In order to answer to consumers' fears, a lot of initiatives have been taken; as it appeared necessary to evaluate the risks for the consumers, Food Safety Agencies have been created at a national then at the European level; the risk's monitoring has led to the setting up of new regulations ...

Of course, all measures which are recommended must be implemented; different aspects have to be considered: among them, the impact of rapid methods in Food microbiology.

In order to get a comprehensive understanding of that impact, I would like to share with you a few data: at first, they will concern the evolution of the place of Food Safety in Europe, then we shall have a look at the development of rapid methods during the past decades; then we'll try to answer to the question: Which is the impact of the development of rapid methods on Food Safety implementation in the European Union?

## I - Evolution of the place of Food Safety in Europe during the past decades

In fact, the concept of Food Quality from the point of view of consumers has somewhat changed according to the periods. In a book published about ten years ago, Pierre Feillet indicated different periods:

- 1945-1955: efforts to improve the shelf life of food products.
- 1965-1985: development of the concept of Food Science
- 1975-1995: the years of biotechnologies.
- 1990-1995 and later: priority is given to Food Hygiene.

Then, during a long time, the relationship between Food and the consumer's health has been somewhat underestimated; then, around the nineties, it may have been overestimated, due to the BSE crisis, to the increase of the knowledge on listeriosis as being mostly a foodborne disease and, generally speaking, to the development of molecular tools allowing to trace the contaminants (a lot of examples may be taken ..)

Whichever the reasons, Food Safety has become a very important topic and, in different countries, people in charge of the consumer's health had to reorganize the expertise which, in fact, did exist, but necessitated a reorganization. As an example, in France, different groups of people were in charge of Food Safety but the coordination between those groups was far to be perfect; the creation of the French Food Safety Agency including the existing groups and organisms in charge of consumers' protection has been considered in a short time as a noticeable progress ..

An important date has now to be mentioned: on January 12<sup>th</sup> 2000, David Byrne, nominated to the European Commission in 1999 and serving as a Commissioner with responsibility to Health and Consumer Protection, presented what has been called the "White Paper". It originated from the "Green Paper" published in 1997; its purpose was to reach the highest level of Food Safety in Europe. In order to do so, it was considered as necessary to set up an important program of new regulations taking the "New Approach", from farm to fork into account in order to harmonise the expertise of the European scientific community. As we shall examine later, the impact of those recommendations would be far more important it was possible to imagine at first, especially in the field of rapid methods whose development has been spectacular during the past decades.

## II - Development of rapid methods in Food microbiology from the end of the sixties till now

From many decades, in the field of Food Microbiology, industrials and, consequently research laboratories have been seeking for methods which may be used as alternatives of reference methods, in order to detect and/enumerate microorganisms; in fact, reference methods are usually somewhat expensive and many days are necessary to obtain a result; alternative methods should give a quicker result, allow to examine a lot of samples simultaneously, win of the place

...

During a long period, that looked like a dream ..; now, the situation has changed for different reasons:

In fact, along the past years, the question of Food Safety has taken an increased importance in the consumers' mind, in all countries worldwide. Different measures have been taken at different stages from food's production till distribution to the consumers in order to improve Food Safety whose responsibility now belongs to industrials; in that context, implementation of the HACCP method (Hazard Analysis Critical Control Point) is mostly important when it is applied to raw materials and foods examined at different stages "from farm to fork". The results of those controls must be available, accepted by all concerned groups, including, of course, official controls. That means the validation of two steps: sampling as the sample must be representative of the population to be examined; the conditions of sampling must be perfectly defined and be founded on statistic considerations; the nature of samples must be defined and known; then, the method used for the analysis must be the good one and practiced in a competent laboratory; if those two conditions are not respected, the results can't be taken under consideration.

The advantages of alternative methods have often been described.

The laps of time necessary for implementing the whole method must be significantly less than which is used for traditional methods (including the time for sample preparation and eventually for pre-enrichment), be cheap ..

Their use in epidemiological studies which necessitates the examination of a high number of samples appears necessary if one wants to examine a sufficient number of samples. Presently, as we shall see in a few minutes, the introduction of principles of Risk Analysis seem to have made the use of alternative methods unavoidable.

During a very long period, traditional methods have been the only ones registered in regulations in all countries worldwide; however, different improvements have been observed along the years:

for example, official methods concerning milk and dairy products have been revised regularly during the annual meetings of National Reference Laboratories organized by the Community Reference Laboratory. In priority, methods standardized by CEN, ISO or IDF have been taken under consideration which, most of them, are considered as reference methods. However, from many years, at a European level, alternative methods have been allowed to be used, subject to a validation (presently, according to the recommendations of the standard EN/ISO 16140 which defines the conditions of validation and certification).

- One of the resolutions taken at Parma (It), on April 23<sup>rd</sup> 2004 during a joined meeting of ISO/TC34/SC9 and CEN/TC275/WG6 has to be mentioned; it indicates that, each time a reference method is being revised, the possibility of using new technologies, including PCR, must be examined by comparing results with those obtained when using the conventional method (based on the use of culture media).
- For a given microorganism, in order to complete the existing method, the development of standardized methods based on new technologies can be proposed when the purpose to be obtained (for example the pathogenicity level makes it necessary)
- When new technologies, including PCR are used as alternative methods, they must be validated against the reference method.

Those two examples show an important progress in the acceptance of alternative methods.

Finally, in the EC new regulation, alternative methods are now accepted as we can read in the EC regulation (2073/15 December 2005):

“Test results are dependent on the analytical method used , and therefore a given reference method should be associated with each microbiological criterion. However, food business operators should have the possibility to use analytical methods other than the reference methods in particular more rapid methods , as long as the use of these alternative methods provide equivalent results . Moreover, a sampling plan needs to be defined for each criterion in order to ensure harmonized implementation. It is nevertheless necessary to allow the use of other sampling and testing schemes including the use of alternative indicator organisms on condition that these schemes provide equivalent guarantees of food safety”.

The dream becomes a reality ...

### III - Impact of the development of rapid methods on Food Safety implementation in the European Union

As we have said previously ,from a long time the necessity of implementing the HACCP method has led a lot of industrials and research laboratories to be conscious of the necessity of rapid methods to be used in Food microbiology ; the eldest of us have been able to follow the progress of the first kits presented of the market , many of them concerning Salmonella ( I remember some of them “forgot” to include the time of pre-enrichment, and sometimes enrichment in the time necessary to get a result!) ; later, the request of trying to reach the highest level of Food Safety in Europe has led to a package of new regulations called the “ Hygiene Package” including general rules for all types of foods , specific regulations for foods of animal origin ; in addition, specific regulations for animal feeds; other regulations have been set up which concern official controls and inspections .....

It seems easy to understand that the implementation of regulations represents a huge work in terms of laboratory work .

In order to make the situation more complicated, a lot of problems of harmonization did exist , especially for microbiological criteria; in the new context, as a consequence of those regulations and in order to evaluate the acceptability of the process as well as the safety of food products , it has been necessary to set up microbiological criteria; the result of that important work was published ( Regulation EC n° 20073/2005 of the Commission) . It must be mentioned that harmonisation is a verydifficult topic to be implemented ...

Criteria include the sampling plan, the number of samples to be tested, the microbiological limits and, of course, the microbiological methods Harmonisation of microbiological methods is prepared by working groups of ISO ( TC34 /SC9) and CEN( TC275/WG6) .From many years( many decades for ISO), an important work of methods harmonization has been undertaken ; recently, EC has given a mandate to CEN and finance collaborative studies to fully validate reference methods. Moreover alternative methods are now allowed to be used, on approval of validation according to the standard EN/ISO 16140.

What to say as a **conclusion** ?

Many people do not know the idea of miniaturized and rapid methods have germinated about 40 years ago in the brain of a very young and enthusiastic microbiologist, American Chinese ,who is present in the room and will teach you the whole week ( I don't know if you can imagine how much you, we are lucky ..)

So, the idea has been the beginning of a long story : rapid methods have been developed; in the beginnings, they were not always well accepted ; there were a lot of obstacles; now, the situation has changed ; Food Safety has become a priority; in order to be able to examine samples representative of the populations , the need of rapid methods has become more and more obvious ; the improvements in the field of standardization have made the use of rapid methods at a large scale possible and realistic . What was only a concept at the beginnings has become a very important reality and I am sure that, during the week , you will appreciate the efforts realized , enjoy yourselves and go back home with a lot of ideas to develop .

Now, I would like to wish you a very nice and fruitful week and I thank you very much for your attention .

If you have any question, I shall be pleased to try to answer .

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and automation in microbiology .  
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**IMPACT OF THE DEVELOPMENT  
OF FOOD MICROBIOLOGICAL  
RAPID METHODS ON FOOD  
SAFETY IMPLEMENTATION IN THE  
EUROPEAN UNION**

Cécile Labellet ( F )

## INTRODUCTION

- Emergence of different crisis incriminating food
- Necessity to evaluate risks for consumers: creation of Food Safety Agencies
- Setting up new regulations
- Impact on the development of microbiological rapid methods

## PLAN

- INTRODUCTION
- I- EVOLUTION OF THE PLACE OF FOOD SAFETY IN EUROPE DURING THE PAST DECADES
- II- DEVELOPMENT OF RAPID METHODS IN MICROBIOLOGY
- III- IMPACT OF THE DEVELOPMENT OF RAPID METHODS ON FOOD SAFETY IMPLEMENTATION IN THE EUROPEAN UNION
- CONCLUSIONS

## EVOLUTION OF THE PLACE OF FOOD SAFETY IN EUROPE DURING THE PAST DECADES

- The concept of « Food Quality » from the point of view of consumers ( P.Feillet, 1998 )
- 1945-1955: efforts to improve the shelflife of products.
- 1965-1985 : development of the concept of « Food Science »
- 1975-1995: the years of biotechnologies.
- 1990-1995 and later: priority is given to Food Hygiene .

## Evolution of the relationship between Food and the consumer's health .

- Underestimation , then overestimation of this relationship.
- Creation of National Food Safety Agencies.
- The « White Paper » . The « New Approach » and the creation of the European Food Safety Authority.
- Setting up of new regulations .

## II- The development of rapid methods in Food microbiology

- From a long time, industrials as well as research laboratories were interested in methods which may be used as alternatives to reference ones.
- In fact, new methods have been developed from the end of the sixties.
- Presently, the number of kits available on the market is impressive ....

### The development of rapid methods in Food microbiology

Food safety has taken an increasing importance in the consumers' mind.

At the same time and in order to improve Food safety whose responsibility now belongs to professionals, different measures have been taken at different stages « from farm to fork ».

### The development of rapid methods in Food microbiology

- Implementation of the HACCP method
- The results of the controls must be available  
accepted by all parties,  
including people in charge of official controls

### The development of rapid methods in Food microbiology

To be accepted, two steps have to be validated:

sampling, as the sample must be representative of the population to be examined :

the conditions of sampling must be perfectly defined and founded on statistical considerations

### The development of rapid methods in Food microbiology

- The nature of the sample must be defined and known
- The method used for the analysis must be the good one and practiced by a competent laboratory .

### The development of rapid methods in Food microbiology

IF THOSE CONDITIONS ARE NOT RESPECTED, THE RESULTS CAN'T BE TAKEN UNDER CONSIDERATION

### The development of rapid methods in Food microbiology

- Advantages of rapid methods , often been described ..
- Their use is unavoidable for the analysis of high numbers of samples (for example in epidemiological studies)

However, during a long period of time, traditional methods have been the only ones accepted officially .

### The development of rapid methods in Food microbiology

- Different improvements may have been observed along the years

For example, alternative methods have been allowed to be used for milk and dairy products, subject to a validation (presently, according to the recommendations of the standard EN/ISO 16140).

### The development of rapid methods in Food microbiology

- Parma (It) - April 23rd 2004 ( joined meeting of ISO/TC34/SC9 and CEN/TC275/WG6)

- 1- Each time a standard method is being revised, the possibility of using new technologies , including PCR, must be examined by comparing results with those obtained when using the official conventional method .

### The development of rapid methods in Food microbiology

Parma meeting ( following)

- 2- For a given microorganism, in order to complete the existing method , the development of standardised methods based on new technologies can be proposed when the purpose to be obtained ( for example pathogenicity level) makes it necessary .

### The development of rapid methods in Food microbiology

Parma meeting (following)

- 3- When new technologies , including PCR, are used as alternative methods, they must be validated against the reference method

### The development of rapid methods in Food microbiology

- FINALLY, in EC regulation 2073/15 December 2005 ( microbiological criteria) « Test results are dependent on the analytical method used, and therefore a given reference method should be associated with each microbiological criterion . However, Food business operators should have the possibility to use analytical methods other than the reference methods in particular more rapid methods , as long as the use of these alternative methods provide equivalent results »

When a dream becomes reality ..

### III- IMPACT OF THE DEVELOPMENT OF RAPID METHODS ON FOOD SAFETY IMPLEMENTATION

- WE HAVE SEEN THAT , FROM A LONG TIME APPEARED THE NECESSITY OF IMPLEMENTING THE DIFFERENT ASPECTS OF THE HACCP METHOD
- IN FACT, THAT APPEARED DIFFICULT WITHOUT RAPID/ AUTOMATED METHODS .

### IMPACT OF THE DEVELOPMENT OF RAPID METHODS ON FOOD SAFETY IMPLEMENTATION

NEW REGULATIONS HAVE BEEN SET UP : cf « THE HYGIENE PACKAGE » , INCLUDING GENERAL RULES FOR ALL TYPES OF FOODS, WHILE OTHER REGULATIONS CONCERN OFFICIAL CONTROLS AND INSPECTIONS..

### Impact of the development of rapid methods on Food Safety implementation in the European Union

The implementation of regulations represents a huge work in terms of laboratory

### Impact of the development of rapid methods on Food Safety in the European Union

- Harmonisation of microbiological methods includes their validation and an important piece of work has been undertaken in order to fully validate reference methods
- But alternative methods are now allowed to be used on approval of their validation according to the standard EN/ISO 16140

### CONCLUSIONS

- The idea of miniaturized and rapid methods germinated about 40 years ago (Dr D.Y.C. FUNG)
- That was the beginning of a long story ....

### Conclusions (following)

- Rapid methods were developed but have not been well accepted during a long time
- THEN, the need of rapid methods has become more and more obvious ; happily, the improvements in the field of standardization have made the use of those techniques possible and realistic at a large scale .
- What was only a concept at the beginnings has become an important reality .