Recent trends in Food microbiology at European level

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A long time ago (i.e more than 40 years), the European Community began to "re-model" its face. Brain storming meetings took the first place in order to reach harmonization in different fields.

Due to different factors , including the cultural diversities , existing regulations, that represented , of course , a big challenge and it was the case , especially in the field of Food Safety .

That is the reason why this morning , I would like to share with you a few data and comments concerning the changes which , during the past decade especially , re-modelled Food Safety at a European level . That is very important for us as Food microbiology and techniques are fundamental for the implementation of the new regulations .

In order to do so, we shall begin by a few historical data ; we shall remember the creation of the European Food Safety Authority , have a look at the main European regulations; then , before trying to draw some conclusions , we shall speak about the incidence of new regulations for the laboratories .

I – A few "historical" data

Probably , everybody remembers the creation of the Common Agricultural Policy ; it happened in 1962 and was the consequence of the obvious necessity to build a regulated frame in order to regulate the trade . It seems of interest to mention that , from 1964 to a recent period, there were 17 sectorial directives ; the differences in the approach of member states were not neglectible ! Concerning the expertise , it was carried on by different groups with different approaches, even in the same country

An important date has now to be mentioned :
12 January 2000, David BYRNE, nominated to the European Commission in 1999, serving as Commissioner with responsibility to Health and Consumer Protection, presented what has been called the ""White Paper". It was 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 and to create a Food Safety Authority , in order to harmonise the expertise of the European scientific community .

The publication of "The Food Law" (regulation (EC) n° 178/2002, applicable from January 2005) was the consequence of the presentation of " The White Paper".

The main objectives of the "Food law" were as follows :
- Improvement of the Community sectorial legislation
- Improvement of the control of their implementation
-Improvement of the consumer's information,
All those improvements should result in a large simplification

The general principles took into account :
-the "Risk Analysis" and precaution principle
-the duties resulting from the international trade
-the safety prescriptions
-the responsibility which is given to the professionals
-the traceability
-the existence of an "Alert system"
-the Emergency measures which have to be taken .

And reference was made to the European Food Safety Authority for a common expertise.

All steps had to be considered from the primary production , industry of animal feed, veterinary pharmacy till further processing plants, all types of foods and all places including importations, exportations..

II – The European Food Safety Authority (EFSA)

The main objective of the creation of EFSA presented in the " White Paper" was to reach the broadest acceptance of Risk Assessment which is essential to ensure that the action is appropriate and rapid, that may cancel the diversities in the approaches of different member states .
Presently , EFSA is located in Parma (It) . Of course, national agencies participate to the evaluation works carried out at the Community level but the collaboration between EFSA and national agencies is still under construction .

III – The main European new regulations

Following the" Food Law" publication, a set of new regulations has been prepared which is called " **Hygiene Package**", including:

- General hygiene rules for all types of foods
- Specific regulations for foods of animal origin

And , in addition, specific regulations for animal feed have been prepared .

- General hygiene rules are provided in the regulation (EC)n 852/2004

The main statement is surely represented by The Good Hygiene Practices .

The guides are written by professionals , for professionals , expertised and validated by the administrations . In fact , it is an excellent tool to justify the manufacturing hygiene practices taken by professionals

The regulation (EC)n°853/2004 gives the specific rules for foods of animal origin

It concerns : The approval of plants
-Safety marks; identification
-Information of the Food chain
And annexes concerning the sectorial activities (i.e bovine slaughtering, dairy products'processing..)

The regulation (EC) n°183/2005 concerns specific rules for animal feed

And gives procedures based on HACCP, rules of traceability and financial guarantees ; of course , it includes general and specific hygiene rules .

Moreover , some other regulations concern official controls, inspections
In that context, the regulation(EC) n°882/2004 is related to:

- Harmonisation of procedures and instructions
- Frequency of inspections based on Risk Analysis
- Approvals

While the regulation(EC) n°854/ 2004 gives :

- Specific rules for the organisation of official controls for foods of animal origin
- Practical conditions of the official controls in processing plants, further-processing plants, shelfish, seafood, raw milk and dairy products .

It introduces the notion of pilot progress in the context of national measures .

As **CONCLUSIONS** concerning the new regulations , we can say they show a simplification of European legislation an harmonisation between Member States

Moreover it is easier to read as there is a clear separation between the missions of professionals and those of official controls .

IV – The incidence of recent regulations for the laboratories

As a consequence of those mentioned regulations, and in order to evaluate the acceptability of the process as well as the safety of food products, it was necessary to set up **MICROBIOLOGICAL CRITERIA** .

Till recently, a lot of microbiological criteria did exist in the different European countries and most of them concerned food of animal origin .

NOW, HARMONISED CRITERIA HAVE BEEN SET UP AT A EUROPEAN LEVEL

(Regulation (EC)n°2073/2005 of the Commission 15 November 2005)

Objectives

The main objective of the new microbiological criteria is to validate and verify the procedures based on HACCP and other measures to control hygiene but

Microbiological criteria have also to define the acceptability of the products and also to set up microbiological safety criteria .

All operators of the food chain have to refer to those criteria which include :

- SAMPLING
- ANALYSIS
- CORRECTIVE MEASURES

Consequently, it is necessary to set up application measures which include :

The sampling plan, including the number of samples to be tested .
The microbiological limits .
The methods of analysis and eventually uncertainty measurement .

It is also necessary TO TAKE MEASURES CONCERNING FOODS AS WELL AS THE CRITICAL CONTROL POINTS TO WHICH THOSE CRITERIA HAVE TO BE APPLIED OR MEASURES TO BE TAKEN WHEN THOSE CRITERIA ARE NOT OBSERVED .

Those measures concern especially:

The control of raw materials
The control of hygiene
The control of temperature and shelf life of a given food

So , we can see that the changes are fundamental . In order to reach a good harmonisation, the regulation (EC) n° 882/2004 of the European Parliament requests from Member States OFFICIAL CONTROLS, regularly performed in connection with the RISK and with an APPROVED FREQUENCY .

THOSE CONTROLS MUST BE APPLIED AT APPROPRIATE POINTS OF PRODUCTION, FURTHER-PROCESSING AND DISTRIBUTION .

Even before the creation of EFSA , some recommendations had been proposed by the Scientific Committee which was preparing the new microbiological criteria :

23 September 1999, the Scientific Committee for veterinary measures in terms of Public Health has underlined the importance of setting microbiological criteria based on a formal RISK ASSESMENT .
They have to take PUBLIC HEALTH under consideration .

It was of course a great challenge to adopt common views among the Member States and the recommendations which are presented hereafter are , of course , the result of a consensus .

So,

A recommendation for *Listeria monocytogenes* (less than 100/g) has been approved on 22 June 2004 by the Scientific Committee for Human Nutrition .

The opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* of 19 and 20 September 2001 is that there is no justification to set up specific criteria .

On 30/31 January 2002, it was recognised that conventional indicators are not suitable to demonstrate the possible contamination by the Norwalk virus .

It was also recommended to use *E.coli* instead of fecal coliforms .

27 February 2002 : a special recommendation for gelatine says that a microbiological criteria must be mandatory for *Salmonella* only .

21/ 22 January 2003, foods in which the presence of VTEC represent a risk for Public Health have been identified .

26/ 27 March 2003 : criteria applicable to coagulase positive *Staphylococcus* and staphylococcal enterotoxins in cheese , raw milk Have to be revised .

14/15 April 2003 : recommendation for *Salmonella* : it is necessary to look for when a problem of Public Health does appear

9 September 2004: (group BIOLOGICAL HAZARD of EFSA) : most problems for baby foods concern *Salmonella* and *Enterobacter sakazakii*. However , routinely, Enterobacteriaceae can be used for monitoring

IN THAT CONTEXT , IT IS IMPORTANT TO KEEP IN MIND THE FACT THAT HARMONISATION OF CRITERIA INCLUDES HARMONISATION OF METHODS OF ANALYSIS .

In Food Microbiology, , European standards are set up by CEN (Comité Européen de Normalisation) which works in connection with ISO (International Standardisation Organisation) , according to what is called the "Vienna Agreement".

However , for a long time in Europe , standards were set up in different places by different groups and CEN standards were not always recognised ... But , something very important happened in 2006 , i.e A MANDATE FOR STANDARDISATION HAS BEEN ADDRESSED BY EC TO CEN IN THE FIELD OF METHODS OF ANALYSIS OF FOODSTUFFS CONCERNING HYGIENE .It will finance collaborative studies to fully validate the set of 15 CEN/ISO reference methods .

ONE OTHER IMPORTANT FACT CONCERNS THE COMMUNITY REFERNCE LABORATORIES WHICH HAVE TO USE THE STANDARDS RECOMMENDED BY CEN

Another decision seems also to be of most importance :

The Draft IDF/ISO , version 3, April 2006. THE PROTOCOL FOR THE ESTABLISHMENT OF PRECISION CHARACTERISTICS OF QUANTITATIVE METHODS BY INTER-LABORATORY STUDIES FOR THE EUROPEAN MANDATE IN MICROBIOLOGY , TOGETHER WITH EN ISO 16140 . Recently , a new working group (WG3) has been created under ISO TC34/SC9 : its purpose is to standardise the validation of microbiological methods , especially EN/ISO 16140 (for intra-laboratories validation, validation between 2 or 3 laboratories, verification of methods for accreditation , for reference laboratories)

CONCLUSIONS

A lot of work has been done from the day of the presentation of the "White Paper" by David BYRNE, 12 January 2000 .

The result may be considered as an important revolution in the field of Food Safety in order to afford the consumers the highest safety level .

The approach is complete , ambitious and should lead to a lot of improvements in different sectors , including the laboratories , their ways of thinking and working ..

However , a lot of work remains to be done in terms of harmonisation in different fields .

One more question :

There are so many Member States

May Europe be considered as a "laboratory for the world" ?

AT LEAST, THE CHANGES FROM 2000 ARE SPECTACULAR.

RECENT TRENDS IN FOOD MICROBIOLOGY AT A EUROPEAN LEVEL

Cécile LAHELLEC (F)

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Recent trends in Food microbiology at a European level

- INTRODUCTION

I -A few « historical » data

II- the creation of EFSA (European Food Safety Authority)

III- the new European regulations

IV- The incidence of the recent regulations for the laboratories

- CONCLUSION

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A few « historical »data

- Before January 2000
- Creation of the Common Agricultural Policy (1962) . Necessity to build a regulated frame in order to regulate the trade
- From 1964, 17 sectorial European directives. Everybody could observe the imperfection of the sectorial approach and the differences existing between Member States .
- Expertise performed by diferent groups , even in the same country .

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FROM JANUARY 2000 TILL NOW

- 12 January 2000, presentation of the « White Paper » by David Byrne, serving as Commissioner with responsibility for Health and Consumer Protection .

Purpose: reach the highest level of food safety set up an important program of new regulations taking into account the « new approach »

FROM FARM TO FORK .

create a European Food Safety Authority

NB: the « White Paper » is originating from the « Green Paper » 1997

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THE FOOD LAW: regulation (EC)n° 178/2002) applicable from January 2005 .

- Main objectives:
- Improvement of the Community sectorial legislation
- Improvement of the control of legislation implementation-
- Improvement of the consumer's information
- Simplification

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THE FOOD LAW (following)

- GENERAL PRINCIPLES
- Risk Analysis and precaution principle
- Duties of the international trade
- Safety prescriptions
- Responsibility given to professionals
- Traceability
- Reference to the European Food Safety Authority for expertise
- Alert system
- Emergency measures

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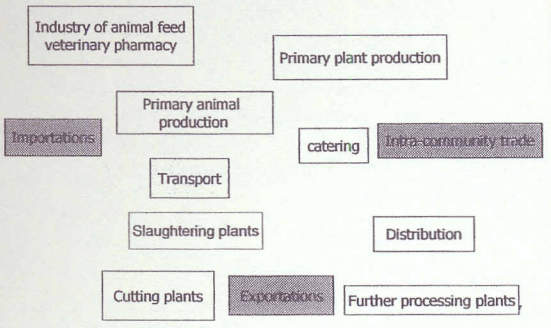
A lot of steps may be involved in Food Safety



Creation of the « EUROPEAN FOOD SAFETY AUTHORITY »

Main objective:

Reach the broadest acceptance of Risk Assesment which is essential to ensure that the action is effective , appropriate and rapid .

Present situation

The regulation 178/2002 gives orientations for the articulation between EFSA and national agencies .

From the creation of EFSA, national agencies participate to the evaluation works carried on at the community level but the collaboration between EFSA and national agencies is still under construction.

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The main European Food Safety Regulations

Following the Food Law publication, a set of new regulations has been prepared which is called the « HYGIENE PACKAGE », including:

- General hygiene rules for all types of foods
- Specific regulations for foods of animal origin

In addition, specific regulations for animal feed have been prepared .

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REGULATION EC N°852/2004 (general)

- Main statement: GOOD HYGIENE PRACTICES
- Written by professionals , for professionals, expertised and validated by administrations
- Excellent tool to justify the hygiene practices taken by professionals

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REGULATION (CE) N°853/2004

- Specific rules for food of animal origin

Approval of plants
Safety marks; identification
Information of the Food chain
Annexes concerning the sectorial activities (i.e: bovine slaughtering, dairy products'processing ...)

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REGULATION (EC) N°183/2005

- Specific rules for animal feed
- General and specific hygiene rules
- Procedures based on HACCP
- Traceability
- Financial guarantees

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REGULATION (CE) N°882/2004

- Harmonisation of procedures and instructions
- Frequency of inspections based on Risk Analysis
- Approvals

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REGULATION (EC) N°854/2004

- Specific rules for the organisation of official controls for foods of animal origin
- Practical conditions of the official controls in processing plants , further processing plants, shelfish, seafoods, raw milk and dairy products
- Notion of pilot progress in the context of national measures

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CONCLUSIONS ABOUT THE FOOD LAW

- HARMONISATION BETWEEN MEMBER STATES
- SIMPLIFICATION OF EUROPEAN LEGISLATION
- EASIER TO READ (CLEAR SEPARATIONIN THE MISSIONS OF PROFESSIONAL AND OFFICIAL CONTROLS)
- FINAL SETTING UP OF THE NEW APPROACH FOR PROFESSIONALS

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CONSEQUENCE OF THE NEW REGULATIONS

- NECESSITY TO SET UP MICROBIOLOGICAL CRITERIA

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THE PAST SITUATION CONCERNING THE MICROBIOLOGICAL CRITERIA

- A lot of microbiological criteria in different European regulations
- Most of the criteria concerned foods of animal origin

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Microbiological criteria

NOW, HARMONISED CRITERIA HAVE BEEN SET UP AT A EUROPEAN LEVEL

(Regulation (EC)N°2073/2005 of the Commission 15 November 2005)

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OBJECTIVES

- Validation and verification of procedures based on HACCP and other measures for controlling hygiene.
- Microbiological criteria have also to define the acceptability of the products and also set up microbiological safety criteria

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- All operators of the Food Chain have to refer to those criteria which include :
  - **Sampling**
  - **Analysis**
  - **Corrective measures.**

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CONSEQUENTELY

- Necessity to set up **application measures** concerning :

  - Sampling plan , including the number of units to be tested
  - Microbiological limits

  – Methods of analysis and, eventually, measurement uncertainty
  - Eventually , microbiological uncertainty

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IT IS ALSO NECESSARY:

- To take measures concerning foods as well as the critical control points to which those criteria have to be applied or measures to be taken when those criteria are not observed .

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AMONG THOSE MEASURES:

- Control of raw materials
- Control of hygiene
- Control of temperature and shelflife of a given food

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REGULATION (EC) N° 882/2004 of the EUROPEAN PARLIAMENT and COUNCIL of 29 April 2004

Concerning officials controls, request

from Member States official controls ,regularly performed , in connection with the risk and with an approved frequency .

- Those controls must be applied at appropriate points of production, further-processing and distribution.

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RECOMMENDATIONS OF THE SCIENTIFIC COMMITTEE

- 23 September 1999 : the Scientific Commitee for veterinary measures in terms of public health has underlined the importance of setting microbiological criteria based on a formal Risk Assesment . They have to take public health under consideration .

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Recommendations (following 1)

- Recommendation for *Listeria monocytogenes* (less than 100/g) approved 22 June 2004 by the Scientific Committee for Human Nutrition
- Opinion on *Vibrio vulnificus* and *Vibrio parahaemolyticus* of 19 and 20 September 2001 : no justification to set up specific criteria

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Recommendations (following 2)

- 30 /31 January 2002, conventional fecal indicators are not suitable to demonstrate the possible contamination by the Norwalk virus
- Recommendation to use *E.coli* instead of fecal coliforms

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Recommendations (following3)

- 27 February 2002 : for gelatin, a microbiological criteria is mandatory for *Salmonella* only .
- 21 and 22 January 2003 : identification of foods in which VTEC represent a risk for Public Health

  26 and 27 March 2003, criteria applicable to coagulase positive *Staphylococcus* in cheese, raw milk ..had to be revised

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Recommendations (following 4)

- 14 and 15 April 2003 : recommendation for *Salmonella* when possible problem of Public Health
- 9 September 2004 (from group BIOLOGICAL HAZARDS of EFSA), most problems for baby foods concern *Salmonella* and *Enterobacter sakazakii*. Routinely , Enterobacteriaceaeare used for monitoring .

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HARMONISATION OF CRITERIA INCLUDES HARMONISATION OF STANDARDS

- European standards in food microbiology are set up by CEN in connection with ISO (cf Vienna Agreement)
- In 2006, a mandate for standardisation has been addressed by EC to CEN in the field of methods of analysis of foodstuffs concerning hygiene ; that is a very important fact in the field of microbiology .

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MANDATE (following)

- It will finance collaborative studies to fully validate the set of 15 CEN/ISO reference methods

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Harmonisation context (following)

- One other important fact concerns Community Reference Laboratories which have to use the standards adopted by CEN (they can also play a role in their development)

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Another decision

- Another decision seems also of most importance :

The draft IDF/ISO, version 3, April 2006- Protocol for the establishment of precision characteristics of quantitative methods by inter- laboratory studies could be taken as a first basis for organising the collaborative studies for the European mandate in microbiology , together with EN ISO 16140 for qualitative methods .

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A NEW WORKING GROUP

- A new working group (WG3) has been created under ISO TC34/SC9 concerning validation of microbiological methods and especially:
  - intra-laboratories validation
  - validation between 2 or 3 laboratories
  - verification of methods (for accreditation, reference methods...)

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CONCLUSIONS

- A lot of work has been done from the presentation of the « White Paper » by David Byrne , 12 January 2000.
- The result may be considered as an important revolution in the field of Food Safety in order to give the highest safety level to the consumers

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CONCLUSIONS (following)

- The approach is complete and should lead to a lot of improvements in different sectors including the laboratories, their ways of thinking and working
- However , a lot of work remains to be done in terms of harmonisation in different fields

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ONE QUESTION

- So many Member States ...
- May Europe be considered as a « laboratory for the world » ?

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AT LEAST

- The changes in the way of thinking from 2000 are spectacular

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THANK YOU FOR YOUR ATTENTION !

QUESTIONS ?

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