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To: FSANZ

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ANSWER FROM THE FRENCH DAIRY SECTOR TO THE CALL FOR SUBMISSIONS - FSANZ - PROPOSAL 1022

Primary production & processing requirements for raw milk products

I. Context

The French Dairy Sector has taken note that FSANZ would like to modify the regulation regarding raw milk cheese production. We have carefully read the documents written by FSANZ and make some comments in connection with the French experience in the production of cheeses. The preparation of this comment follows a meeting between the French Dairy Board, and a FSANZ delegation in October 2013, during which we presented the French approach for the production of raw milk cheese and exchanged about the potential changes in Australian regulation.

This response is linked to the three supporting documents of the Proposal P1022, with a particular focus on Supporting Document 1, which offers a modified version of Standard 4.2.4 of the Code.

We approve the approach adopted by FSANZ, breaking out with the approach by categories of cheese Proposal of 1007, and giving place to a risk analysis approach for the assessment of appropriate requirements for the production of raw milk cheeses.

Requirements proposed provide a quite secure frame for the production of raw milk cheeses and will provide an acceptable level of public health. We have also noticed the publication of the proposal in 1017 by FSANZ, proposing an amendment to Standard 1.6.1 for the microbiological criterion *Listeria monocytogenes* in RTE foods.

Specific comments are provided below, based on French experience in this type of production.

II. Specific comments on the supporting document 1: Guide to the requirements for raw milk products in standard 4.2.4 – Primary production and processing standard for Dairy products – Proposal 1022

Comment 1

Section "Primary production of milk for raw milk products"

2. Animal Health

Raw milk products requirements

- **General animal health and carrier status (*page 6 of the document*)**

Raw milk quality control starts on the farm. It depends mainly on herd management and milking conditions. Producers are required to comply with European standards for herd health, milking hygiene practices, milk storage temperature and the cleanliness of the farm, equipment and staff. The milk must come from herds that are healthy and free of tuberculosis and brucellosis. Sick animal are isolated from the herd and their milk is not collected.

Concerning herd monitoring for EHEC/STEC, as ruminants are healthy carriers of STEC, we believe that, at this stage, only strict hygiene practices at farm level need to be implemented in order to prevent contamination. Many studies are underway to determine the best combination of the available hurdles, appropriate herd management practices, elimination of high-shedders, vaccination, diet and/or probiotics in feed (Farrokh et al, 2012).

Recommended monitoring criteria (page 7 of the document)

Milk quality was a priority in France as early as 1969. That year, the French milk industry introduced a system of payment by quality. Apart from its fat and protein content, the cow milk at farm level must meet strict hygiene standards, with fewer than 100 000 germs and 400 000 cells per ml. There must be no antibiotics and cryoscopy is tested. In 2011, more than 90% of cow milk had total plate count below 50000 cfu/ml and more than 85% had cell count below 400 000 cells/ml. Achieving results like these requires daily preventive actions to ensure the herd management, the hygiene of animals, buildings, milking and milk storage. Milk used for products made from raw milk comes from producers with a satisfactory history of supplying milk, free of all pathogenic bacteria (*Salmonella*, *Listeria monocytogenes*). A premium is paid to farmers who commit to such high standards. This system of milk payment, based on a reference price plus a bonus and malus system, encourages farmers to produce milk of the highest quality.

- Regarding total plate count, experience shows that levels below 50000 cfu/ml seem to affect the organoleptic quality of raw milk products and addition of starter is needed to adjust milk microflora composition. Additionally, the barrier effect of the positive flora of raw milk can be mitigated.

- In the proposal 1022, the acceptable limit for *E. coli* is 10 cfu/ml. This limit seems to be very restrictive. However, we agree that this criterion could be used as an indicator of milk hygiene on the farm and that specifying corrective actions is essential.

- In the proposal 1022, the acceptable limit for *S. aureus* is 100 cfu/ml. As for *E. coli*, this criterion is not regulated in France/Europe for raw milk at farm level and companies are free to determine the limit regarding the performance objective. The risk is linked to enterotoxins production by *S. aureus,* when concentration are above 10^5 cfu/g (Tatini et al, 1971, 1975; Bryan et al, 1997).

Finally, in the proposal 1022, the frequency of analysis of raw milk proposed once a week may induce a huge analytical cost. In France, a milk sample is taken every day at the time of milk collection but the analysis is made randomly 2 or 3 times a month.

Comment 2
Section "Primary production of milk for raw milk products"
8. Milk cooling and storage
Raw milk products requirements *(page 16 of the document)*

In the proposal 1022, it is specified that "milk for raw milk products must be cooled to a temperature of 6°C or below within 2 hours of it being milked, unless processing is to commence within 2 hours of it being milked. Moreover, milk for raw milk products must be stored at a temperature of 5°C or below, unless processing is to commence within 2 hours of it being milked".

These requirements are close to, but more restrictive than the ones of the EC regulation 853/2004, which requires cooling of milk at the temperature of 8°C or below within the 2 hours following milking (however when milking is not performed every day, the milk must then be cooled at 6°C or below).

Comment 3
Section "Processing of raw milk products"
2. Food handling controls
Requirements for raw milk products
- **Raw milk processing *(page 25 of the document)***

In the proposal 1022, one of the main changes proposed for the Standard 4.2.4 is the following: "The processing of milk for raw milk products must: (a) result in no net increase in the level of pathogenic microorganisms that may be present in the milk at the commencement of processing; and (b) ensure that the raw milk product does not support the growth of pathogenic microorganisms".

The new requirement for raw milk product appears to us an important change in the vision of cheese safety assessment. Indeed, despite the growth of microorganisms at the beginning of cheese making, there can be an inactivation of microorganisms during the ripening phase of cheese.

Regarding the first Food safety Outcome ("no net increase"), it will be observed for pathogenic micro-organisms such as *L. monocytogenes* in some cheeses with long ripening. However, in the case of *S. aureus*, the growth peak is reached after the cheese-making phase and decreases rapidly during ripening whereas enterotoxins could be produced.

The tools recommended in the supporting document 2 "Guide to the validation of raw milk products" is of major importance for the manufacturers. Specific comments on this guide are provided later in the document (paragraph III).

Comment 4
Section "Processing of raw milk products"
4. Process verification
Microbiological sampling and testing *(page 28 of the document)*

We have two comments regarding process hygiene criteria that are applicable to raw milk products:

- Coagulase positive *staphylococci*:

Food outbreaks due to ingestion of food contaminated with *S. aureus* is possible when the strain has multiplied in food and produced one or more enterotoxins. A minority of SCP strains has the ability to produce enterotoxin. Enterotoxins are produced by *S. aureus* when concentration is above 10^5 cfu/g (Tatini et al, 1971, 1965; Bryan et al 1997).
In Europe, the regulation requires to search for enterotoxins in raw milk cheeses when *S. aureus* concentration is above 10^5 cfu/g. Thus, a concentration of 10^3 cfu/g in food couldn't be justified in terms of food safety and the detection of enterotoxin impractical due to the low level of bacteria concentration.

- *E. coli* :

Most *E. coli* are commensal bacteria, naturally present in the intestinal microflora of man and ruminant with no danger to the host. In this respect, the *E. coli* in foods are sought as indicators of fecal contamination. It is considered as a process hygiene criterion and is not the cause of food poisoning. However, a minority of them can cause intestinal or extra-intestinal diseases, as is the case of Shiga toxin producing *E. coli* (STEC or VTEC). Because of the very low prevalence of these bacteria in the cheese, there is no microbiological criterion set in Europe. The best prevention is through good hygiene practices on the farm and during milking (Farrokh et al, 2012).

References of interest:

- Bryon, F.L, Guzewich, J.J, Todd, E.C.D, 1997. Surveillance of foodborne disease.2. Summary and presentation of descriptive data and epidemiologic patterns ; Their value and limitations. Journal of Food protection 60(5) :567-578
- Tatini, S.R., Jezeski, J.J., Olson, J.C., Casman, E.P., (1971). Factors influencing the production of staphylococcal enterotoxin A in milk. J. Dairy Sci., 54, 312-20.
- Tatini, S.R., Soo, H.M., Cords, B.R., Bennett, R.W ., (1975). Heat-stable nuclease for assessment of staphylococcal growth and likely presence of enterotoxins in foods. J. Food Sci., 40, 352-56.

- Farrokh, C., et al., Review of Shiga-toxin-producing Escherichia coli (STEC) and their significance in dairy production, International Journal of Food Microbiology (2012)

III. Comments on the supporting document 2: Guide to the validation of raw milk product – Proposal 1022

This guide is based on the information documented in the supporting document 3 (Scientific information for the assessment of raw milk products – cheeses – P1022) and provides some recommendation to demonstrate two Food safety Outcomes proposed in Standard 4.2.4.

Specific comment on SD2:

In the guide, the link between the results of a challenge-test and the equation $\sum reduction + \sum croissance \leq 0$ to demonstrate the Food Safety Outcome "no net increase" is not enough documented. Indeed, growth can occur in the milk, the curd and the cheese (liquid or solid) and the log increase observed during a challenge test or by predictive modeling won't have the same unit. The application of the equation should be clearly described and illustrated with an example.

General comment on SD2:

General comments for this document will concern mainly the French experience in Quantitative microbiological risk assessment for the management of safety in the French Dairy Sector.

In Europe, and thus in France, the manufacturer has to guaranty the safety of its products for the consumer. In accordance with EU Hygiene Package regulations, the application of Good Hygiene Practices, the HACCP plan and traceability are necessary tools to prevent microbiological hazards. However, microbiological analyses performed regularly on the milk at different levels (farm and tank) and on cheeses(during process), combined with technological parameters, allow to create significant databases that, if statistically analyzed, can provide useful information for the management of the dairy product safety, **including the demonstration of the two Food safety Outcomes proposed by FSANZ in Proposal 1022.**

In this context, the French dairy sector has been developing since 2003 operational tools based on the quantitative microbiological risk assessment (QMRA) approach, that allow dairy manufacturers to better manage the safety quality of dairy products. The tools follow an integrated approach of the whole dairy chain, from the milk collection to the consumption of the dairy product and consider the potential sources of contamination at each step of the process, including raw milk contamination. The French dairy sector also participated to the development of the software Sym'previus, that provides a web-based interface to test predictive microbiological models.

Two main toolkits are available:

- The first tool is a statistical toolkit for microbiological dairy data analysis using non-conformity results regarding a given microbiological criterion. Results obtained will help assessing temporal trends and identifying seasonality for the raw milk contamination prevalence, quantifying the efficiency of intervention sampling strategies, optimizing milk sorting, etc.

- The second tool is a set of stochastic Quantitative Microbiological Risk Assessment models adapted to several cheese technologies and pathogenic bacteria. Inputs are the results of the microbiological dairy data analysis with the first toolkit, the steps of the manufacturing process, the physical and chemical parameters of the products during the process, challenge-tests results and information on the bacteria of interest. Monte-Carlo simulations allow taking into account variability and uncertainty. The outputs of the QMRA model are the prevalence of contamination and the concentration of the product at each step of the process, and the associated risk of illness.

These tools can help the food safety manager to optimize safety management options during cheese production process, identify parameters and steps having the most impact on the food safety objectives and the risk level.
The approach was recently presented at:

- the Food Safety conference of the 2013 World Dairy Summit, in November 2013 in Japan
- the International Conference on Predictive Modelling in Foods in September 2013 in Paris

References of interest:

- Quantitative microbiological risk assessment for the management of safety in the French Dairy Sector, F. Tenenhaus-Aziza. Oral communication presented in November 2013 at the World Dairy Summit in Japan
- Quantitative Microbiological Risk Assessment Approach In The French Dairy Sector. H. Souaifi, V. Michel, F. Perrin, F. Tenenhaus-Aziza. Poster presented at the International Conference on Predictive Modelling in Foods in September 2013 in Paris
- Quantitative exposure assessment to *Listeria monocytogenes* in uncooked pressed cheeses with a long ripening based on challenge-test data. Chatelard Chauvin C., Souaifi H., Michel V., Hulin S., Tenenhaus-Aziza F., Montel M.C. Poster presented at the International Conference on Predictive Modelling in Foods in September 2013 in Paris
- Link to Sym'previus website : http://www.symprevius.net/index.php?vrs=sym_previus_predictive_microbiology