COMMENTS BY THE EUROPEAN UNION TO THE REQUEST BY FSANZ FOR WRITTEN SUBMISSIONS ON THE DRAFT VARIATION TO THE FOOD STANDARDS CODE ARISING FROM THE PROPOSALS P1022 AND 1017 NOTIFIED BY AUSTRALIA

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I. Application or proposals to change the Australia New Zealand Food Standards Code (the code)

- P1022 – Primary Production & Processing Requirements For Raw Milk Products

[redacted] Foods

II. Name and contact details

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III. Comments on the issues raised and any possible options

FSANZ - PROPOSAL 1022
Primary production & processing requirements for raw milk products

1. Context

The European Union (EU) has taken note that FSANZ intends to modify the regulation regarding raw milk cheese production. As part of this work, the EU also notes the valuable information exchanged between the EU and Australia during a study visit of Australian experts (held in October 2013) which allowed the demonstration of the robustness of the EU sanitary framework and the safety of dairy products in the EU.

The EU understands that the draft standards will be applied to Australian products (produced in Australia) and that import requirements may be introduced at a later stage. Thus, the EU expects that the future requirements applied to products imported into Australia will be at least similar to those required to Australian products and will not unnecessarily and unjustifiably restrict trade.

The EU has carefully read the FSANZ proposals and would like to submit the following comments 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.

In general terms, the EU welcomes the approach adopted by FSANZ, breaking with the approach of categories of cheese used in P1007, and giving prominence to a risk analysis approach for the assessment of appropriate requirements for the production of raw milk cheeses.

The requirements proposed seem to provide a robust framework for the production of raw milk cheeses and will provide an acceptable level of public health protection. The EU also notes 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.

2. General comments

The EU would like to inform that there are EU import rules and controls applicable to dairy products and dairy raw materials that need to be complied with, regardless of their place of production or origin, i.e. whether manufactured or sourced in Australia or in another country and then exported to the EU.

The EU does not foresee a "mastitis management program".

There are no provisions for introduction of new animals to herds delivering raw milk in the EU (Australia: e.g. Johne´s disease, vaccination status for Clostridia, etc.).

Australia proposes *L. monocytogenes* management measures for feed. No such thing exists in the EU.

No criteria for the assessment and approval of automatic (robotic) milking systems are mentioned.

The usefulness of a separate storage/transport of milk intended for raw milk products and "normal" milk products is questionable and not feasible.

3. 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 in the EU are required to comply with EU 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, we believe that since ruminants are healthy carriers of STEC only strict hygiene practices at farm level need to be implemented in order to prevent contamination at this stage. 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)*

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. In this respect, the EU would like to ask Australia to please clarify if:

- This limit will be used as an indicator of milk hygiene at the farm level, and
- What other specifications will be taken into consideration, e.g. importance of undertaking corrective actions.

In the proposal 1022, the acceptable limit for *S. aureus* is 100 cfu/ml. As for *E. coli*, this criterion is not regulated in the EU 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 in 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)*

The EU has 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 the EU, 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 could not 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 the EU. 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)

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

General comments:

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.

In the second step of the pre-validation, the identification of the outcome required is directly related to the level of inactivation. Based on the description of this validation step in the Codex Guideline CAC/GL 69 – 2008 the EU understands that this approach is too narrow, i.e. identification of the outcome may be related to other strategies as well, for example using milk from holdings free of specific pathogens, e.g. Salmonella or EHEC.

CAC/GL 69 include both outcome and targets in the description of this validation step, as follows:

"Identify the food safety outcome required.

The food safety outcome can be determined in a number of ways. Industry should determine if there are existing food safety outcomes or targets, established by the competent authority, relevant to the intended use of the food. In the absence of food safety outcomes or targets established by the competent authority, targets should be identified by industry, as appropriate. Industry may also set stricter targets than those set by the competent authority."

See also examples 1, 2 and 4 provided in Annex 1 to the Codex Guideline, using Performance Objectives as food safety outcome.

In short, the EU understands that the proposed FSANZ guide deviates from the Codex Guideline and that such deviation is not substantiated. The EU would therefore suggest FSANZ adjust the proposal to meet the Codex Guideline requirements.

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 of "no net increase" is not sufficiently documented as: a) microbiological growth can occur in milk, curd and cheese (liquid or solid); b) the log increase observed during a challenge test or by predictive modeling will not have the same unit. The EU would like to suggest Australia to please describe the application of the above-mentioned equation and illustrate it with an example.

General comment on SD2:

In the EU, 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 the creation of 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 dairy sector in Member States has been developing 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. For example, 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 QMRAt models adapted to several cheese technologies and pathogenic bacteria. Inputs are the results of the microbiological dairy data analysis from 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 the ability to takie 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