CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5(a), 5(c) and 5(d) **CRD23**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-First Session

Comments of Brazil (Revised)

Brazil would like to submit some comments on the following documents:

AGENDA ITEM 5a - CX/FA 19/51/7 - General Standard for Food Additives (GSFA): Report of the EWG on the GSFA

Appendix 2: Provision for trisodium citrate in FC 01.1.1

Brazil strongly supports the following proposal, based on the comments forwarded to the eWG:

Adopt with Note 438 “Only for use as emulsifier or stabilizer” and Note 227 “for use in sterilized and UHT treated milks only”

Remove Note 439 “For use in sterilized and UHT treated milks from non-bovine species only”

Brazil justifications for the use of trisodium citrate (INS 331iii) in bovine UHT milk.

- **Safety:** according to the 17th JECFA, this additive has “no limited IDA”, indicating no health concern (GMP additive). It is approved even in GSFA for use in infant formulae.
- **Technological need**: the thermal stability of milk is influenced by several factors, and can be reduced due to high calcium activity, low phosphate and citrate activity, as well as successive heat treatments (SILVA, 2003).

  Several factors may influence the milk composition and, therefore, its stability. According to Fox (1991), feed has relatively little effect on the level of most elements in milk because the skeleton acts as a reservoir of such. Milk fever is the resulto f the cow deleting its skleton Ca to mantain the level of Ca in its milk. The level of citrate in milk decreases on diets very deficient in roughage and results in the “Utrecht phenomenon” – milk of very low stability. Relatively small changes in the concentrations of milk salts, especially of Ca, Pi and citrate, can have very significant effects on the processing characteristics of milk and hence these can be altered by the level and type of feed**,** but definite studies on this are lacking.

  Fox (1991) also states that the composition of milk salts is influenced by some factors, including breed, individuallity of the cow, state of lactation, feed, infection of the udder and season of the year.

  In Brazil, the study performed by Silva (2003), showed that the levels of calcium, phosphorus and citrate vary significantly among states and seasons, as observed in the figures below. This confirms Fox's (1991) statement that feed and season may affect the chemical composition of bovine milk.

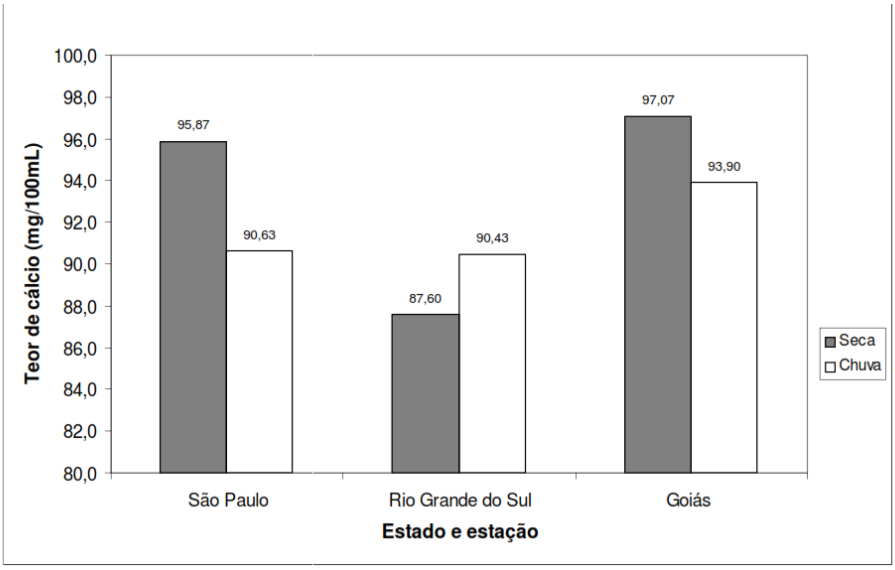

Figure 1. Average calcium content in raw milk by Brazilian State and season.

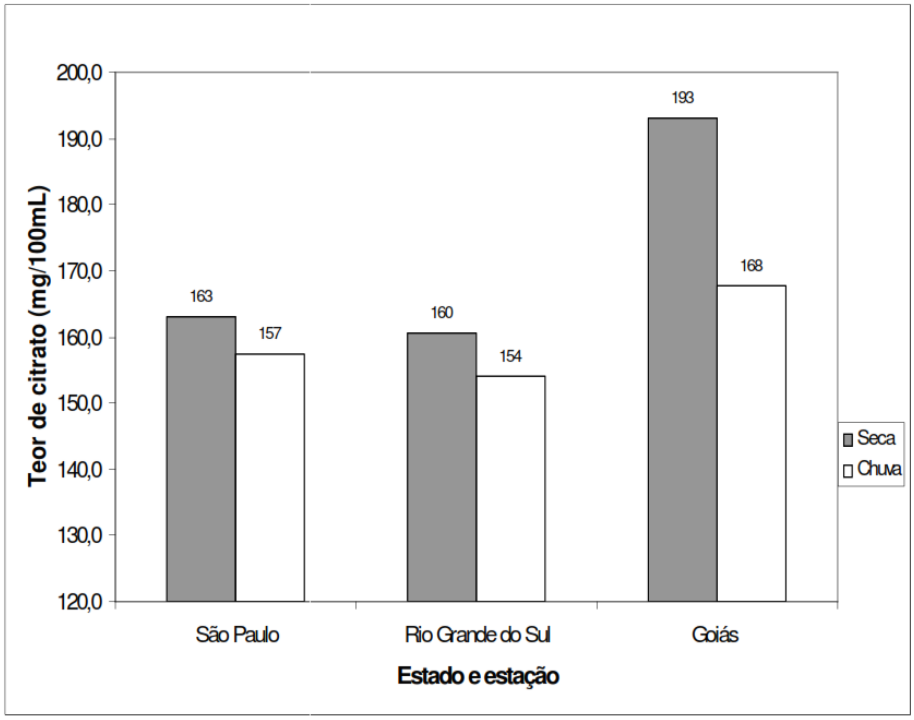

Figure 2. Average citrate content in raw milk by Brazilian State and season.

As reported in the eWG, Brazilian bovine cattle milk has a lower content of natural citrate, most probably by the influence of the extensive and semi-extensive breeding system, with the whole herd to the pasture. Feeding of Brazilian cattle based on low nutrient forage results in the production of a milk with saline imbalance (lower sodium citrate content). Here again we present the table that shows the difference in citrate levels of Brazilian cattle, when compared to the other countries:

Reference	**Country**	**Citrate average (as citric acid)**
FOX, P.F, 1991 (Fox,P.F Food chemistry. Part III. Cork: Cork University College, 1991. 201 p)	Ireland	176 mg/100 mL
JENNES AND PATTON, 1999	Maryland, EUA	175 mg/100 mL
WALSTRA P. AND JENNES, 1978 (Walstra P, Jenness R. Dairy chemistry and physics. Wiley Intersciences, New York, 1984)	New York, EUA	175 mg/100 mL
WHITE & DAVIES, 1958 (Davies, D.T. and White, J.C.D. (1958). The relation between the chemical composition of milk and the stability of the casein complex. II. Coagulation by ethanol. J. Dairy Res., 25, 256-266)	EUA	179 mg/100 mL
SILVA, P.H.F, 2004	**Brazil**	**158,5 mg/100 mL**

The composition of the milk also varies according to the breed of the animal and climatic conditions. For example, in the arid and semi-arid regions of Brazil, where water is scarce, cattle, which are more rustic, tend to present milk with higher calcium contents. Moreover, in Brazil there are not always pastures in conditions of excellence. Brazil is a country of continental dimensions with climatic conditions that can be unfavorable to cattle, which turns the herd more rustic, mestizo and with low individual milk production. For this reason, in Brazil it is common to use a system of community tanks where the milk of several properties is agglomerated, in order to obtain enough milk volume to be sent to dairy industries.

Fox (1991) informs that the solubility of calcium phosphate is markedly temperature-dependent. Unlike most compounds, the solubility of calcium phosphate decreases with the increasing temperature – therefore, heating causes a precipitation of calcium phosphate, while cooling increases the concentrations of soluble calcium. So, UHT milk presentes stablity problems.

Fox (1991) also states that the addition of sodium phosphates and/or citrates to milk generally increases the stability both by sequestring Ca+2 and, especially in the case of citrates, by reducing citrate colloids through conversion to soluble unionized calcium citrates; high levels of citrate cause micellar disintegration. Phosphates and/or citrates are commonly added to concentrated milks to improve stability during heat sterilization.

It should also be noted that phosphates are already permitted as stabilizers for food category 01.1.1 with note 227: "For use in sterilized and UHT treated milks only", ie for phosphates there is no restriction on the animal species. Therefore, it is assumed that the stabilizer function is recognized for bovine milks as well. Considering that the function of stabilizer is recognized to citrate by CAC-GL 36/1989, it would be inconsistent/unreasonable not to approve it as a stabilizer for UHT bovine milks.

Finally, it should be clarified that the food category under discussion is UHT fluid milks, which are not used for cheeses manufacture. Therefore, the discussion raised by some members that the addition of citrates would negatively impact the process of coagulation for cheeses manufacture has no technological basement.

In UHT process, the desnaturation of whey proteins is followed by the aggregatiom of molecules wich may be caused by intermolecular dissulphide bridges. This complex cause interation of kapa- casein and beta- lactoglobulin. The observed release of sialic acid wich is contained in the glycomacropeptide of K— casein on unfolding of the molecules due the UHT heating is reduced, so the UHT treatment is not recommended for cheese milks (FIL New monograf on UHT milk, 1981)

- **Milk Fraud:** in Brazil, several authors have reported the occurrence of casein instability in milk with normal acidity and low somatic cell count, which means that good quality bovine milks also have stabilization problems. In the State of Rio Grande do Sul, Brazil, a high frequency of cases of milk from healthy animals that react positively to the alcohol test was observed, without high titratable acidity (SILVA, 2003).

  If the concern is the use of stabilizers to mask poor quality bovine milk with a high content of somatic cells, preventing its precipitation, it is worth clarifying that the same concern should be raised regarding the phosphates, ie the discussion should be around the stabilizing function rather than the citrate itself. Another important point to note is that citrate is a natural constituent of bovine milk, and its use is self-limiting, which means that the excessive use of citrate causes the decrease in the availabe calcium content, which can also promote coagulation by heat treatment.

  If the concern is in fact fraud in bovine milks, the same concern should also be raised regarding non-bovine species milks, which are also susceptible to fraud**.** Therefore, the concern of frauds only for bovine milks, without considering non-bovine species, would be an incoherent and unreasonable discussion.

- **Conclusions:** in view of the above, Brazil strongly supports the use of trisodium citrate (INS 331 iii) for UHT bovine milk, since it is safe, technologically necessary and is not used for the purpose of masking GMP failures. So it meets all principles set out in the GSFA.

  Brazil understands that the purpose of the Codex Alimentarius is to establish food standards that are globally representative, what means that they should cover the conditions of all signatory countries, as far as possible, provided they ensure food safety and are always based on scientific references, as demonstrated by Brazil.

REFERENCES

FOX, P. F. Food Chemistry: Part. 111 – The milk proteins system, including milk salts and the proteins of egg white. Dept. of Food Chemistry, University College, Cork, Ireland, 1991.

SILVA, P. H. F. UHT MILKS: determinants for sedimentation and gelation (thesis). Federal University of Lavras, 2003.

Appendix 3: Proposed draft provisions related to FC 01.1.2 (Other fluid milks (plain)) with the technological function of emulsifier and stabilizer

Brazil understands that reconstituted milk (FC 01.1.2) must have the same characteristics as the original milk (FC 01.1.1). Therefore, provisions for thickeners, which are not permitted in Food Category 01.1.1, are not justified in Food Category 01.1.2. Brazil requests that countries which support the use of these additives submit studies and analytical data (with the respective methodologies) that prove that these additives when used at the proposed limits, do not cause thickening of the products.

Appendix 4: Draft and proposed draft provisions in Table 1 and 2 of the GSFA in food categories 01.0 through 16.0, with the exception of those additives with technological functions of colour (excluding

those provisions discussed in point (i)) or sweetener, adipates, nitrites and nitrates, the provisions in food category 14.2.3 and its subcategories, and provisions awaiting a reply from CCSCH, CCPFV or CCFO

- Food Category No. 01.1.2 (Other fluid milks (plain) - SODIUM HYDROXIDE (INS 524)

As commented in the 1st circular, Brazil strongly opposes to the use of sodium hydroxide in fluid milk, since in Brazil this additive has been frequently associated with fraud, being used to mask poor quality (acid) milk. This additive has also been targeted by police operations involving milk fraud in Brazil. Although some acidity regulators have already been approved for this food category in the GSFA, it should be emphasized that, unlike the other approved acidity regulators, except for potassium hydroxide, sodium hydroxide is alkalinizing, ie it increases the pH of the product, masking acid milk of poor quality. We emphasize that Brazil is opposed to the inclusion of sodium hydroxide in fluid milk not because of the health risk of the additive itself but because it contradicts one of the principles established in the GSFA preamble that the additive cannot be used to disguise the use of poor raw materials or undesirable (including hygienic) practices. In addition, in comparison to potassium hydroxide, sodium hydroxide is economically more viable, justifying its extensive use in milk fraud. It should also be remembered that, as sodium hydroxide is degraded into calcium caseinate and sodium, it is not detected in the laboratory analyzes, which hampers sanitary inspection of these products and hampers the responsibility of fraudsters. Moreover, there are alternative acidity regulators already approved for these products, and that do not present the concerns pointed out. Finally, Brazil highlights that the issue “food fraud” is so important that a guideline to help authorities to address the dramatic increase in food fraud is being discussed in the CCFICS (Codex Committee on Food Import and Export Inspection and Certification Systems).

- Food Categories No. 14.1.4.1 Carbonated water-based flavoured drinks, No. 14.1.4.2 Non-carbonated water-based flavoured drinks and No. 14.1.4.3 Concentrates (liquid or solid) for water-based flavoured drinks - *PROPYLENE GLYCOL (INS 1520)*

As informed in previous circulars, Brazil supports the discontinuation of the provision. The propylene glycol is carried to the final beverage by means of flavourings (ingredient) and plays no technological function in the final beverage. So, it is already covered by the carry-over principle mentioned in the GSFA preamble. Moreover, according to item 3.5 of CAC-GL 66/2008 (Guidelines for the use of flavourings), “Flavourings may contain non-flavouring food ingredients, including food additives and foodstuffs, necessary for their production, storage, handling, and use. Such ingredients shoul be: c) used in accordance with the provisions of the Codex General Standard for Food Additives (GSFA; CODEX STAN 192) whenever they are intended to provide a technological function in the finished food”. Therefore, since propylene glycol has no function in final beverages, its mention in GSFA should not be made. Finally, Brazil fears that the approval of this provision may open precedent for the inclusion in the GSFA of additives carried by the ingredients, and the carry-over principle is already clearly expressed in the GSFA preamble.

AGENDA ITEM 5c - CX/FA 19/51/9 - Discussion paper on the use of nitrates (INS 251, 252) and nitrites (INS 249,250)

Recommendation 1: “In light of the available information, the Committee is invited to consider and possibly decide on the most appropriate risk management approach on addressing the uses and use levels for nitrates and nitrites in the GSFA. The Committee can take into account the suggestions made by the EWG members as outlined in paragraph 16 of this paper.

Note: In the absence of consensus on a preferred approach, the Committee might consider establishing both ingoing and residual levels as a compromise solution”.

Brazil understands that minimum and maximum residual limits for nitrites and nitrates should be established in order to ensure both their effectiveness in relation to C. botulinum and the protection of human health against toxicological risk.

Brazil also believes that the adoption of the "ingoing" approach is advantageous in terms of microbiological safety, as stated in the EFSA document "Statement o nitrites in meat products" (2010). This is because products vary in process, pH, water activity, moisture, meat type, form and time of storage, packaging, etc., which hinders (but does not prevent) the establishment of residual limits. However, it should be noted that the initial addition of sodium nitrite may not inhibit *C. botulinum* spores, so a minimal residual is required in the final product to ensure protection against this bacterium.

This "ingoing" approach makes it difficult to control and supervise the products available in the national and international market, since there will be no parameters for fiscal analysis. Operationally, it would only be possible to control the nitrite and nitrate contents added by on-site inspection in the industry. If the limits are defined as residuals, the control can be done through sample collection and analysis at any point in the food chain. It is also important to look at the shelf life issue of the products. Brazil is a country of continental dimensions, with great climatic variety and territorial extension, which is a challenge for the establishment of risk management measures. In the eWG discussion, Brazil did not clearly identify the auditable methodology used by the countries who defend the ingoing approach to verify the compliance with the parameters for nitrite and nitrate, both for the national and international market. For example, is the factory inspected in the exporting country? What is the operational and economic viability of these inspections?

In addition, for the purpose of refined risk exposure assessment, it is more appropriate to use the residual approach, since it considers the nitrite and nitrate content that will in fact be ingested by the consumer.

Therefore, at the moment, with the available information, Brazil is in favor of adopting minimum and maximum limits of nitrites and nitrates as residuals, and also agrees with adopting an approach of concomitant use with other additives (eg ascorbic acid) in order to reduce the formation of nitrosamines.

Recommendation 2: In light of the information available and taking into account the views of JECFA secretariat the Committee should consider whether the provided information addresses the concerns raised or whether further scientific advice is feasible and needed.

Note: If the Committee agrees on the approach (Recommendation 1) and decides that there is no need for further scientific advice (Recommendation 2) it might consider start working on the provisions. If the Committee decides that there is a need for further scientific advice a request for the scientific advice will have to be formulated.

Brazil suggests that the exposure assessment to nitrites and nitrates should be performed considering the total diet, including food additives and other sources as the natural occurrence in food and water, according to the data provided by eWG to GEMS Food.

AGENDA ITEM 5d - CX/FA 18/50/10 - Discussion paper on the development of wording for an alternative to Note 161 relating to the use of sweeteners

Brazil supports the proposals.