CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 9 **CX/FA 23/53/16**

January 2023

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-third Session

DISCUSSION PAPER ON THE FOOD ADDITIVE PROVISION FOR THE USE OF TRISODIUM CITRATE IN FC 01.1.1 "FLUID MILK (PLAIN)"

Prepared by Brazil

BACKGROUND

1. The 51st session[1] of the Codex Committee on Food Additives (CCFA51) endorsed the recommendation of the Physical Working Group (PWG) on the GSFA to forward the following draft provision for trisodium citrate (INS 331(iii)) in Food Category (FC) No. 01.1.1 "Fluid milk (plain)" and the corresponding notes 438, 439 and B25 to the Commission for adoption at Step 8. Note B25 was revised to read "For use in UHT milk from bovine species to compensate for citrate or calcium content to prevent sedimentation as a result of climatic conditions".

Food Category No. 01.1.1 Fluid Milk (plain)

Additive	INS	Step	Year	Max Level	Notes
TRISODIUM CITRATE	331(iii)	8	2019	GMP	438, 439, B25

Notes to the General Standard for Food Additives

Note 438	For use as emulsifier or stabilizer only.
Note 439	For UHT milk from non-bovine species only.
Note B25	For use in UHT milk from bovine species to compensate for citrate or calcium content to prevent sedimentation as a result of climatic conditions only.

2. During CAC42 (2019)[2], different views were expressed by delegations and the provision was returned to CCFA to further consider possible solutions, e.g., setting numeric use levels and/or clarifying the notes further.

3. During CCFA52[3] (2021), different views were expressed on the provision. Some Members who were against the adoption of the draft provision expressed the view that the technological justification for the use of trisodium citrate (INS 331(iii)) was lacking. These Members were of the opinion that this substance could mask poor quality of the product and mislead consumers. On the other hand, other Members supported the adoption and manifested that the technical justification was addressed, and that adding citrate to fluid milk would not change the nature of the product given that citrate naturally occurs in milk.

4. CCFA52 agreed to: hold the draft provision at the current Step (Step 7); and request the Codex Secretariat to issue a Circular Letter (CL) collecting information on technological justification for the use of trisodium citrate in FC 01.1.1 "Fluid milk (plain)" as well as the use level; and request Brazil to prepare a discussion paper based on the response to the CL.

[1] REP19/FA, paragraph 79 and Appendix VI, A3

[2] REP19/CAC, paragraph 29

[3] REP21/FA, paragraph 19

5. In December 2021, CL 2021/92/OCS-FA was distributed to collect comments on the use of trisodium citrate (INS 331(iii)) in FC 01.1.1 “Fluid milk (plain)”. Codex Members and Observers were invited to submit comments on whether trisodium citrate should be allowed for use in FC 01.1.1 “Fluid milk (plain)”. If the answer was yes, Members and Observers were asked to provide technological justification as well as the use level; or if the answer was no, they were asked to provide evidence to prove that the use of this additive could alter the nature of the product, mask poor quality, mislead consumers and cause potential misuse.

SUMMARY OF THE COMMENTS RECEIVED IN RESPONSE TO CL 2021/92/OCS-FA

Responses were received from 16 Members and one Observer, and these were classified as follows:

a. Those not in favour of the use of INS 331(iii) in UHT treated milk from bovine species:

Egypt, European Union, Kenya, India, Panama and Uganda

b. Those in favour of the use of INS 331(iii) in UHT treated milk from bovine species:

Argentina, Brazil, Colombia, Ecuador, El Salvador, Honduras, Indonesia, Paraguay, Peru and Uruguay

c. Other comments

International Dairy Federation

6. Comments not in favour of the use of trisodium citrate in UHT treated milks from bovine species focused on whether the use has an advantage or would mislead the consumer. Several Members noted that only phosphates were allowed for use as stabilizers in bovine milks in their countries, and that no other stabilizers are necessary. These comments mentioned that milk from bovine species is less sensitive to protein coagulation than other milks and this is as a reason why trisodium citrate is not necessary in bovine milk. One comment stated that the use of citrates can mislead the consumer by buffering a low pH (which is an indicator of spoilage) while another comment noted that the use of stabilizers could be used to mask bad handling practices. Another comment expressed concern that the use of trisodium citrate may change the organoleptic properties of milk and affect milk fermentation, although UHT milk is not fermented. However, information received was not able to demonstrate that its use can mask bad handling practices.

7. On the other hand, comments from Members in favour of the use of trisodium citrate in UHT milk from bovine species addressed the advantage of the use, the technological justification and rebutted the arguments that the use would mislead the consumer. These Members noted that trisodium citrate is allowed in bovine milks in their countries. They also noted that UHT bovine milks utilize stabilizers, and that trisodium citrate has advantages that other stabilizer (i.e., phosphates) do not. One Member provided information that trisodium citrate is required for pastured cattle as feeding cattle forage results in production of milk with a lower natural sodium citrate content, which results in greater tendency for gelation of these milks under UHT processes. Sodium citrate is a natural component of milk. The use of trisodium citrate corrects the natural citrate deficiency in milk from pastured cattle, which the use of phosphates cannot do. The use would not mislead the consumer as stabilizers are already allowed for use in bovine milks. One Member noted that restricting the use of trisodium citrate to non-bovine species is contrary to the principles of Codex as the restriction would not benefit public health but would have an adverse trade impact on countries that use this producing system.

8. It was clarified that trisodium citrate is not to be added to raw milk, but instead it is added only to milk stored in tanks destined to technological processing (UHT and sterilization) after passing all required physicochemical analysis and the results have been approved, removing the possibility of fraud or bad practices. It was emphasized in some comments that the use of this stabilizer in UHT and sterilized milk is intended only to prevent coagulation due to the low concentration of intrinsic citrate in raw milk, stabilizing it.

RECOMMENDATIONS AND CONCLUSION

9. Given that:

a) trisodium citrate levels vary by producing system, region and season, and the mean values may be low in some regions according to scientific studies;

b) the use of trisodium citrate as additive in UHT milk has been allowed since 1996 by the Southern Common Market (Mercosur) (Mercosur, 1996);

c) there is no evidence that the use of trisodium citrate is used to mask bad handling practices;

d) according to the 17th JECFA, this additive has “no limited ADI”, indicating no health concern (GMP additive) and its use is approved in infant formulas;

e) the use of trisodium citrate in bovine milk is technologically justified, safe to human health and is not used to mask bad handling practices;

f) level of 1000 mg/kg as citric acid was reported to be sufficient to stabilize bovine UHT milk; and

g) a Codex standard is intended to reflect global conditions.

The following provision is proposed for adoption by CCFA53, as GMP, maintaining note 438 “Only for use as emulsifier or stabilizer”, replacing note 439 by note 227 “For use in sterilized and UHT treated milks only” and adding a new note YY “Excluding milk from bovine species where Trisodium citrate (INS 331(iii)) may be used as stabilizer at 1000 mg/kg as citric acid, to compensate low raw milk intrinsic citrate content”.

Trisodium citrate INS 331(iii)	Functional Class:	Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer		
Food Cat No.	**Food Category**	**ML (mg/kg)**	**Notes**	**Step**
01.1.1	Fluid milk (plain)	GMP	438, 227, YY	8

438: For use as emulsifier or stabilizer only.

227: For use in sterilized and UHT treated milks only

YY: Excluding milk from bovine species, where Trisodium citrate (INS 331(iii)) may be used only as stabilizer at 1000 mg/kg expressed as acid citric, to compensate low raw milk intrinsic citrate content.

Appendix I

SUMMARY REPORT

(For information)

REVIEW OF THE COMMENTS NOT IN FAVOUR OF USING TRISODIUM CITRATE (INS 331(III)) IN UHT BOVINE MILK

1. Egypt, European Union and Uganda are not in favour of the use of Trisodium citrate (INS 331(iii)) in milk from bovine species, while India, Kenya and Panama do not support the use of trisodium citrate (INS 331(iii)) in Food Category 01.1.1 “Fluid milk (plain)”.

2. European Union, Egypt and Uganda understand that the technological need for trisodium citrate is recognized only for UHT goat milk since goat milk produces heavy sediment on UHT treatment. Therefore, technological controls are needed to avoid protein coagulation.

3. They were of the view that the use of the additive in bovine milk could ensure the stability of low-quality milk and maintain its organoleptic properties. This would be deceptive to consumers thus would contradict section 3.2 c) in the preamble to the GSFA. Whereas high heat treatment on bovine milk causes less problems on protein coagulation and therefore the use of citrates is not indicated, in their view. However, they believe that the use of citrates in bovine milk can be misleading by buffering a low pH which is an indicator of spoilage.

4. Milk of bovine species is generally less sensitive to protein coagulation and therefore only phosphates are considered as technologically needed and appropriate in the EU. According to the EU, there is experimental evidence that trisodium citrate is able to act as an efficient stabilizer reducing ionic calcium (citrates react with calcium limiting the pH decrease and increasing the buffering capacity) which prevents formation of the sediment. Hence the amount of citrate is also an important parameter that governs the ionic calcium level. To the EU’s knowledge the maximum level up to 4000 ppm is appropriate to adjust milk pH to an optimum range as regards the heat stability without having any possible adverse effect as for the nature and quality of goat milk. Nevertheless, the EU mentioned that is looking forward to receiving explanations and justifications from those advocating the need for trisodium citrate for milks from bovine species.

5. Egypt mentioned that trisodium citrate is needed only in UHT goat milk for the purpose of stabilization, acidity regulator and anticaking agent, according to the EFSA assessments.

6. India, Kenya and Panama do not support the use of trisodium citrate (INS 331(iii)) in Food Category 01.1.1 “Fluid milk (plain)”. In compliance with section 3.2 of the preamble to the GSFA the use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d), and only where these objectives cannot be achieved by other means that are economically and technologically practicable.

7. One country mentioned many publications:

A) COITINHO ET AL., 2017 that describes a methodology to identify adulteration in raw milk by corn starch, sodium bicarbonate, sodium citrate, formaldehyde, saccharose, water or whey;

B) HOORFAR (2012) book entitled “Case Studies in Food Safety and Authenticity” that join many articles with real experience in this area. Regarding milk adulteration, the article cited is from Brazil experience that assesses addition of water, whey, stabilizing agents, preservatives such as hydrogen peroxide and acidity regulator such as sodium hydroxide, nitric acid and urea. It is important to highlight that these analyses should be made before milk go into industrialization and that sodium citrate is allowed in UHT milk in Brazil since 1996 ; and

C) PASTORINO, et al., 2003, that evaluated the effect of sodium citrate on the relationship between structure and function on cheddar cheese. This evaluation does not address any bad handling practices considering this food additive is allowed for this product in the GSFA.

8. National Food Regulation of India requires that total sodium content in the milk shall not be more than 650mg/100 g SNF. This parameter supports in determination of adulteration with sodium salts in milk. Therefore, if Trisodium citrate is allowed in milk it will promote adulteration with other sodium salts to mask acidity. Further, India understands that it will be very difficult to differentiate between whether the total sodium content is increased in milk due to permitted salts or because of adulteration. Therefore, allowance of trisodium citrate in plain milk will encourage bad practices and adulteration of milk and also increase the number of additives allowed for use in this category.

9. Kenya is of the view that the technological justification has to be a major factor of consideration considering that CXS 192 (GSFA) (section 3.1 states that food additives should be used in 'lowest level necessary to achieve the intended technical effect' and its use among other conditions, 'are justified only when such use has an advantage' (section 3.2 of CXS 192). In their view, countries interested or with justification to use the additive had the option for a regional standard to address their specific need.

10. Kenya informed that their priority is to reduce the use of food additives to the extent possible and only have them used in cases where no alternative exists and in total compliance of the preamble of GSFA, which has been adopted as Kenya Standard to guide the safe use of food additives. In the case of UHT milk, the Country have not recorded sufficient complaints from consumers on sedimentations neither has the industry reported any processing challenge that Kenya has had for the longest period of time. They therefore see no advantage that the use of trisodium citrate will introduce to UHT milk. Sedimentation has been observed in reconstituted milks thus in their opinion, use of trisodium citrate may lead to passing reconstituted milk as fluid milk thus misleading the consumers in making informed choices of products based on the true nature of the products as provided for by CXS 1-1985, section 4.1.1. It is considering this background that they object the inclusion of the additive in UHT milk.

11. Panama mentioned that there is not enough monitoring of reference data on the behaviour of trisodium citrate on the FC 01.1.1, but is of the view that in practice it could mask changes that occur in the product on a regular basis, causing damage to its sanitary quality. Thus, believes that could be a poor quality liquid milk masker. They understand that this has a misleading effect on the consumer, indicating that the product is healthily acceptable when this additive is not used. For their country, the additive is allowed for some dairy derivatives detailed in the Central American Technical Regulation (RTCA 67.04.54:18), but not for liquid or fluid milk.

12. Another country mentioned the following publications:

A) Yang (2018) that evaluated the combined use of trisodium citrate and transglutaminase in relation to the gel properties of acidified yak milk (domesticated cattle in China). The purpose of this study is not to identify bad practices related to the use of citrate, consequently, it does not justify limiting the use of citrate in UHT bovine milk;

B) Ozcan-Yilsay et al (2006) investigated the use of trisodium citrate in the physical and rheological properties and in the microstructure of yogurt, and therefore is not related to the use of citrate in milk for processing UHT milk;

C) Chen et al. (2012) compared the thermal stability of goat milk subjected to UHT treatment and sterilization, observing that adding low quantities of citrate (6.4 mM) reduced the sediment formation in UHT treated milk, but high levels (12.8) produced an increase in sediment formation;

D) Udabage et al (2000) evaluated the effect of adding different minerals and calcium chelating agents on reconstituted milk and therefore does not relate to addition of trisodium citrate in UHT milk;

E) Gaur (2017) thesis mentioned the use of phosphates and citrates as calcium chelators to reduce ionic calcium in goat milk, bovine micellar casein solutions and bovine milk. The articles analysed by Gaur verified that the use of stabilizers above a certain concentration caused the fragmentation of the micelles and that fragmented micelles were more prone to aggregate and form sediment than the native micelles. It was also reported that orthophosphates, added as stabilizers to the milk, form calcium phosphate complexes that precipitate on the micelles; while the citrates form calcium citrate salts that remain in the serum phase.

13. Considering the information provided, trisodium citrate can act as a stabilizer reducing ionic calcium (citrates react with calcium limiting the pH decrease and increasing the buffering capacity) which prevents formation of the sediment in both goat milk and bovine milk. However, information received was not able to demonstrate that its use can mask bad handling practices.

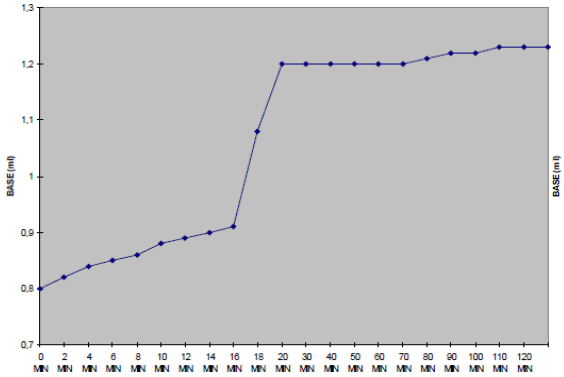
REVIEW OF THE COMMENTS SUPPORTING THE USE OF TRISODIUM CITRATE (INS 331(III)) IN UHT BOVINE MILK

14. Argentina, Brazil, Colombia, Ecuador, El Salvador, Honduras, Indonesia, Paraguay, Peru and Uruguay comments are in favour of the use of Trisodium citrate (INS 331(iii)) in milk from bovine species. In general, they agree that its use is necessary to stabilize the proteins in milk treated at high temperature. Some mentioned its use to maintain pH as a buffering system. Additionally, it was mentioned that trisodium citrate has the advantage of being an organic acid and having low level of toxicity.

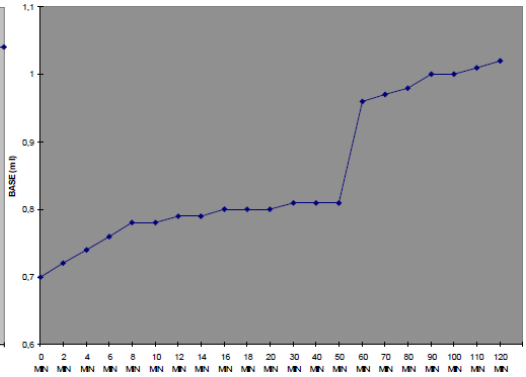
15. In Mercosur, it is allowed to add trisodium citrate as stabilizer in UHT milk as GMP since 1996 (Res. GMC N° 135/96). The corresponding regulation is being revised and this food additive will remain permitted as stabilizer. Argentina proposed adoption of trisodium citrate at a maximum level of 1000 mg/kg for UHT milk and other high heat treated milks, considering this concentration is sufficient to achieve the desired effect.

16. Brazil mentioned that the use of trisodium citrate in bovine milk is technologically justified, safe to human health and is not used to mask bad handling practices. Therefore, its use in bovine milk complies with the Codex Alimentarius principles for food additives.

17. Brazil explained that in some regions of the country 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). Thus, the addition of sodium citrate as a stabilizing additive promotes the reduction of the calcium content available for the formation of salt bridges between the protein complexes, preventing milk sedimentation and favouring the stability of the product, as can be observed in the charts (Graphs 1 and 2):



Graph 1. Induction time of amorphous calcium phosphate formation without citrate.



Graph 2. Induction time of amorphous calcium phosphate formation with citrate.

18. Based on the study of SILVA et al. (2003), Brazil described the variation of citrate content in milk produced in different regions of the country. Comparing citrate concentration in milk from three different Brazilian states that have significant milk production and considering dry and rainy seasons, it was observed that Goiás had a higher concentration of citrate than São Paulo and Rio Grande do Sul. The observed concentrations in São Paulo, Rio Grande do Sul and Goiás, were, respectively, 163, 160 and 193mg/100mL in dry season and 157, 154 and 168mg/100mL in the rainy season.

19. It was concluded that the natural citrate contents vary widely between regions of Brazil and seasons of the year, which affects the final citrate content in UHT milk. The milk evaluated, except for the dry season in Goiás, has showed lower citrate content when compared to the results of other studies mentioned in Table 1, with levels around 175 mg/100 mL in milk from other countries.

Table 1. Average citrate levels in bovine milk from different countries

Reference	Country	Average citrate level (as citric acid)
FOX, P. F, 1991	Ireland	176 mg/100 mL
JENNESS AND PATTON, 1999	USA	175 mg/100 mL
WALSTRA P. AND JENNESS, 1978	USA	175 mg/100 mL

WHITE & DAVIES, 1958	USA	179 mg/100 mL

20. Brazil highlighted that the quality of milk in the country has significantly improved and that the Good Agricultural Practices and the Qualification Plan for Milk Suppliers (PQFL - acronym in Portuguese) provided for in the Self-Control Programs of the dairy industries and described in the Brazilian legislation have driven this continuous improvement in quality (BRAZIL, 2017; BRAZIL, 2018a; BRAZIL, 2018b) as shown in Figure 1. Considering Brazil's five largest milk-producing states, it can be noted that milk quality has been improved year after year (Figs. 2 to 6). These five states accounted for 70% of Brazilian milk production in 2020 (IBGE, 2021). Therefore, the permission to use citrate approved by Mercosur since 1996 is not being used to mask deficiencies in Good Agricultural Practices in Brazil.

21. Considering the concern that the use of citrate could mask bad practices, official data on milk quality in Brazil demonstrate that the microbiological quality of milk has improved over time (BRAZIL, 2021). In this publication, 23,945,670 raw milk samples were analysed for SPC (standard plate count) for 2013 to 2020. Microbiological quality data of raw milk of Brazil in the period from 2013 to 2020 are shown below. Although the legal limit of SPC established in 2018 by Brazilian legislation (BRAZIL, 2018a) is 300,000 CFU/mL, the geometric means observed in the country are lower according to Fig. 1. Also, the Somatic Cell Count (SCC) is below the legal standard (500,000 cells/mL), from 2013 to 2020.

Figure 1: National geometrical means for refrigerated raw milk samples, Standard Plate Count – SPC x 1,000 CFU/mL and Somatic Cell

Figure 2: Geometrical means for refrigerated raw milk

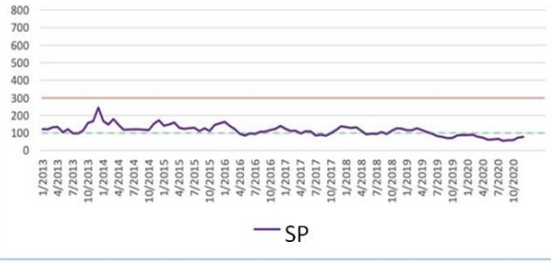


Figure 3: Geometrical means for refrigerated raw milk samples, Standard Plate Count – SPC x 1,000 CFU/mL for the State of Paraná, 2013 to 2020.

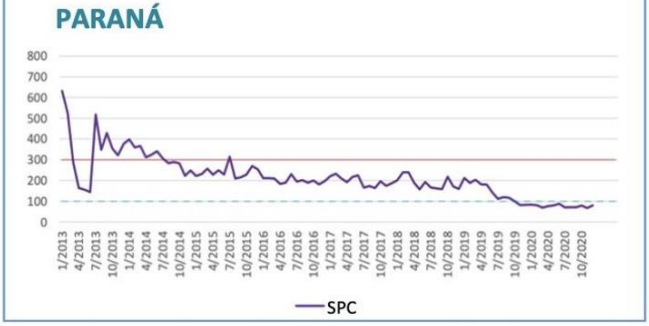
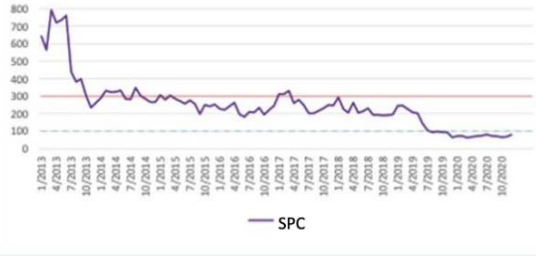


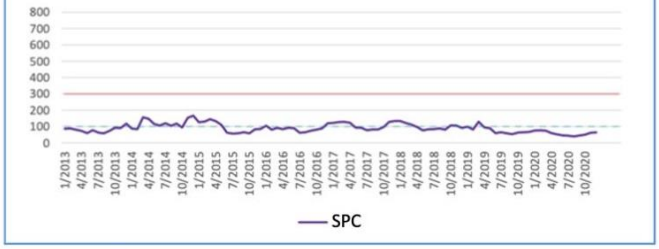
Figure 4: Geometrical means for refrigerated raw milk samples, Standard Plate Count – SPC x 1,000 CFU/mL for the State of Rio Grande do Sul, 2013 to 2020.



Source: Brasil (2021)

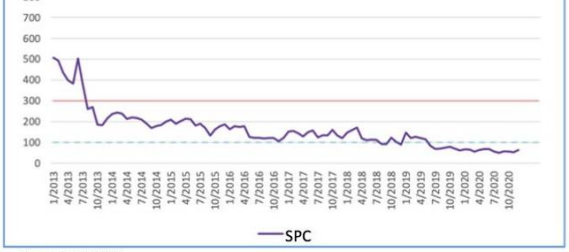
Source: Brasil (2021)

Figure 5: Geometrical means for refrigerated raw milk samples, Standard Plate Count – SPC x 1,000 CFU/mL for the State of Goiás, 2013 to 2020.



Source: Brasil (2021)

Figure 6: Geometrical means for refrigerated raw milk samples, Standard Plate Count – SPC x 1,000 CFU/mL for the State of Santa Catarina, 2013 to 2020.



Source: Brasil (2021)

22. Peru highlighted that study conducted with UHT milk showed that pH below 6.65 or high ionic calcium levels increase sedimentation (GAUR, 2018). Reduction of sedimentation is achieved by elevating pH with alkali or reducing ionic calcium with chelates, and trisodium citrate is effective considering it may increase pH and reduce ionic calcium (CHOI, 2020).

23. Colombia stated that other food additives should be included as stabilizers in UHT milk, but this request is out of the scope of this document and should be addressed in response to the CL 2021/55-FA "Request for proposals for new and/or revision of food additive provisions of the GSFA".

24. Although El Salvador is not in favour of using trisodium citrate in the conditions previously presented by CCFA, they could agree with the use if specific conditions are met. El Salvador recognizes citrates can stabilize casein micellar structure, stabilizing the colloid (calcium phosphate bonds), retarding jellification and inhibiting formation of the protein net. Thus, they are of the opinion that in case of high bacterial load milk, the use of trisodium citrate could mask bad quality and enable consumer misleading practices.

25. El Salvador considers that problems in milk jellification faced by other countries due to climatic conditions can be minimized selecting high quality milk and keeping the cold chain during all production process, which is consistent with CXC 57-2004 (Code of Hygienic Practice for Milk and Milk Products) item 3.3: "the needs for time/temperature control at farm level should be clearly communicated by the manufacturer of the milk products." and item 3.3.4.3: "Transport temperature and time should be such that milk is transported to the dairy or to the collection/chilling centre in a manner that minimizes any detrimental effect on the safety and suitability of milk".

26. El Salvador recognizes the importance of Codex texts and standards and observes that dispositions should be clear, preventing that its application rest subject to each country criteria. Thus, they could agree with the use of trisodium citrate only if the following conditions are met:

- Establishment of the minimum natural citrate content for which compensation with trisodium citrate is necessary
- Establishment of specific climatic conditions that could justify the use of the food additive.

27. Honduras considers that trisodium citrate is a food additive used so that the milk does not spoil, a kind of stabilizer. In their opinion, it can act as a preservative to extend the useful life of the product. Additionally, highlighted that considering raw milk may have a high content of bacteria and failures in the cold chain, the use of trisodium citrate in raw milk may hide its poor quality.

28. Nevertheless, Honduras agreed that the Notes 438 "Only for use as emulsifier or stabilizer" and 227: "For use in sterilized and UHT treated milks only" should be added, with elimination of note 439 "For UHT milk from non-bovine species only.". They pondered that trisodium citrate should not be used in raw milk as emulsifier or stabilizer, but in the milk after it has been submitted to physical-chemical analysis and being considered as apt for human consumption and that is fulfilled note 227. In their view, this clarifies that the technological use is justified and is aligned with General Principles in 3.2 and is not against the General Standard for Milk Products.

OTHER COMMENTS RECEIVED

29. IDF informed that their members had conflicting positions, with some members informing that trisodium citrate was not allowed under their legislation and others noting that no concerns have been raised with the use of trisodium citrates, and no usage level has been reported either. IDF members reported that EU legislation as well as legislation in New Zealand and Switzerland, allowed for the use of INS 331(ii) in the product falling under the GSFA category 1.1.1 for UHT goat milk (either with a ML of 4000 mg/l or at GMP). The justification is that goat

milk is much less heat stable than cow milk and it is therefore more challenging to produce UHT goat milk compared to UHT cow milk.

GENERAL CONSIDERATIONS ABOUT THE USE OF TRISODIUM CITRATE (INS 331(III)) IN BOVINE MILK

30. Milk is a colloidal suspension consisting mainly of water, fat, carbohydrates, proteins, mineral substances and organic acids. Milk fat is to a greater extent made up of triacyl glycerides, however phospholipids, cholesterol, free fatty acids and diglycerides can also be found. The major carbohydrate found in milk is lactose. Milk consists of different kinds of proteins of which caseins make up about 80% of the total protein content. The serum proteins, also called whey proteins, make up the remaining part of the total protein content and consist of β-lactoglobulin (β-LG), α-lactalbumin, serum albumin, immunoglobulins and peptides. The most found minerals in milk are K, Na, Ca, Mg, Cl and P and the most common organic acid is citric (WALSTRA et al., 1999). It means that citrate naturally occurs in milk.

31. The stability of cow's milk is influenced by many factors, the more important ones are temperature, pH, concentration, milk salts, urea, stage of lactation, cattle breed, udder's infection and feed (pasture or confinement). Addition of sodium phosphates and/or citrates to milk generally increases stability both by sequestering Ca^{+2} and especially in the case of citrates, by reducing the Calcium Colloidal Phosphate (CCP) through conversion to soluble unionized calcium citrates. The possible levels of addition of these salts are limited because high levels may cause micellar disintegration. (ALVES, 2006; SILVA, 2003; FOX, 1991)

32. Citrate is present in milk distributed in two phases: soluble and colloidal. 94% of the milk citrate is present in the soluble phase: bound to calcium and magnesium (85%), as trivalent citrate (14%) and divalent citrate (1%). The casein-bound colloidal citrate represents 6% of the total citrate (FOX, 1991). According to FOX (1991), the additions of citrate and phosphate to milk promote an increase in the thermal stability of the milk, by the sequestering effect on ionic calcium and, especially in the case of citrate, by the conversion to soluble citrate. Phosphates and citrates are recognized for increasing the thermal stability of milk (FOX, 1991).

33. The use of trisodium citrate as stabilizer in bovine milk has benefits when compared to other stabilizers (i.e., phosphates). Sodium citrate is a natural component of milk. The use of trisodium citrate corrects the natural citrate deficiency in milk from pastured cattle, which the use of phosphates cannot do. The use of citrate would not mislead the consumer considering that stabilizers are already allowed for use in bovine milks.

34. Phosphate is an authorized additive in FC 01.1.1, but phosphorus has MTDI (Maximum Tolerable Daily Intake) while citrate has no specific ADI and its use is permitted in infant formulas and foods (13.1.1 GMP, 13.1.2 GMP) and in formulas for special medical purposes for infants (13.1.3 - GMP). Therefore, considering the approval of citrate in infant formulas and foods and also for special formulations with medicinal purposes, its use in UHT milk does not represent a health risk. The use of INS 331(iii) will not affect the processes of milk fermentation and other processes of milk processing bovine and non-bovine species. Codex 192 permits the use of INS 331(iii) in fermented milk.

35. Additionally, trisodium citrate is already approved as food additive for FC 13.1.1 infant formulae and sodium citrate is a nutrient permitted as a source of sodium for infant formula (CXG 10-1979 Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children).

36. It was clarified that trisodium citrate should not be added to raw milk. It is only intended to be added to milk stored in tanks destined to technological processing (UHT and sterilization) after passing all required physicochemical analysis and the results have been approved, removing the possibility of fraud or bad practices. It was emphasized in some comments that the use of this stabilizer in UHT and sterilized milk is intended only to prevent its clotting due to the low concentration of intrinsic citrate in raw milk, stabilizing it.

37. Extensive information on UHT treated milk from bovine species demonstrates that the use of trisodium citrate complies with all criteria in section 3.2 of the preamble to the GSFA: it is technologically justified, has an advantage, is safe, does not mask bad handling practices, and stabilizers are allowed in all bovine milks; therefore, their use does not mislead the consumer. It is important to remember that milk has natural citrate levels. Nevertheless, its addition is self-limited because high levels may cause micellar disintegration.

38. Considering different geographical conditions and producing systems around the world result in different levels of citrate in milk, the use of trisodium citrate is justified in accordance with Codex Principles, as Codex is intended to reflect global conditions.

REFERENCES

ALVES, C. *Efeito de variações sazonais na qualidade do leite cru refrigerado de duas propriedades de Minas Gerais*. Masters Dissertation. Universidade Federal de Minas Gerais, Brazil. 2006.

BRAZIL. Decreto nº 9.013, de 29 de março de 2017. Regulamenta a Lei nº 1.283, de 18 de dezembro de 1950, e a Lei nº 7.889, de 23 de novembro de 1989, que dispõem sobre a inspeção industrial e sanitária de produtos de origem animal. Diário Oficial da União, Brasília, DF, 30 de março 2017. Seção 1, p. 3-27. 2017.

BRAZIL. Ministério da Agricultura, Pecuária e Abastecimento. Instrução Normativa n° 76, de 26 de novembro de 2018. Aprova os Regulamentos Técnicos que fixam a identidade e as características de qualidade que devem apresentar o leite cru refrigerado, o leite pasteurizado e o leite pasteurizado tipo A. Diário Oficial da União: Seção 1, Brasília, DF, Ano 2018, Edição: 230, pp. 09-10, 30 de novembro de 2018a.

BRAZIL. Ministério da Agricultura, Pecuária e Abastecimento. Instrução Normativa n° 77, de 26 de novembro de 2018. Estabelece os critérios e procedimentos para a produção, acondicionamento, conservação, transporte, seleção e recepção do leite cru em estabelecimentos registrados no serviço de inspeção oficial. DIÁRIO OFICIAL DA UNIÃO: Seção 1, Brasília, DF, Ano 2018, Edição 230, pp. 10-13, 30 de novembro de 2018b.

BRAZIL. Ministério da Agricultura, Pecuária e Abastecimento. Evolução da qualidade do leite no Brasil: amostras de leite cru avaliadas pela RBQL entre 2013 e 2020/Secretaria de Defesa Agropecuária – Brasília: AECS, 2021.

CHEN, B. Y., GRANDISON, A. S., LEWIS, M. J. Comparison of heat stability of goat milk subjected to ultra-high temperature and in-container sterilization. *Journal of Dairy Sciences*. 2012. Mar; 95(3):1057-63.

CHOI I; ZHONG.Q. Physicochemical properties of skim milk powder dispersions prepared with calcium-chelating sodium tripolyphosphate, trisodium citrate, and sodium hexametaphosphate. *Journal of Dairy Science*; 103(11) p. 9868-9880, 2020.

COITINHO, T. B.; CASSOLI, L. D.; CERQUEIRA, P. H. R.; DA SILVA, H. K.; COITINHO, J. B.; MACHADO, P. F. Adulteration identification in raw milk using Fourier transform infrared spectroscopy. *Journal of Food Science and Technology*, 54(8), 2394-2402, 2017.

FOX, P. F. *Food Chemistry*. Part III. Cork University College, 1991. 201 p.

GAUR, V. *Sedimentation Reduction in UHT milk.* PhD Thesis, University of Canterbury, Christchurch, New Zeland. 2017.

GAUR V., SCHALK J. & ANEMA S. G. Sedimentation Reduction in UHT milk. *International Dairy Journal*, 92-102p. 2018.

HOORFAR, J. (Ed.). *Case studies in food safety and authenticity: Lessons from real-life situations*. Elsevier. 2012.

IBGE. Ranking dos estados com maior produção de leite em 2020. In: *CNA - Comunicado Técnico*. Edição 30/2021| 01 de outubro de 2021.

JENNESS, R. and PATTON, S. *Principles of Dairy Chemistry*. New York, Robert E.1999.

MERCOSUL - GMC no 135/1996 - Inclusion of trissodium citrate in the standard of UHT milk (GMC no 78/94). 1996.

OZCAN, T.; HORNE, D.; LUCEY, J.A. Effect of increasing the colloidal calcium phosphate of milk on the texture and microstructure of yogurt. J Dairy Sci. 2011 Nov;94(11):5278-88. doi: 10.3168/jds.2010-3932. PMID: 22032350.

PASTORINO, J.; HANSEN, C. L.; MCMAHON, D. J. Effect of sodium citrate on structure-function relationships of Cheddar cheese. *Journal of Dairy Science*, 86(10), 3113-3121, 2003.

RTCA - REGLAMENTO TÉCNICO CENTRO AMERICANO. Alimentos Y Bebidas Processadas. Aditivos Alimentares. RTCA 67.04.54:18 CENTROAMERICANO ICS 67.050 1ra Revisión. Available on: http://web-sieca.s3.amazonaws.com/direccion-juridica/COMIECO/RESOLUCIONES/419-2019/ANEXO%20RES%20419-2019%20RTCA%20ADITIVOS%20VERSION%20FINAL%20-Firma%20COMIECO.pdf.

SILVA, P. H. F. *Leite UHT: fatores determinantes para sedimentação e gelificação*. PhD Thesis, Universidade Federal de Lavras, Brazil. 2003.

WALSTRA, P.; JENNESS, R. *Dairy Chemistry and Physics*. Wiley Intersciences, New York. Wiley Interscience Publ. John Wiley & Sons, Inc. New York. 1984.

WHITE, J. C. D.; DAVIES, D. T. The relation between the chemical composition of milk and the stability of the caseinate complex. I. General introduction, description of samples, methods and chemical composition of samples. *Journal of Dairy Research*, Cambridge, v. 25, n. 2, p. 236-255, Oct. 1958.

YANG, Lin. (2018). Combined Use of Trisodium Citrate and Transglutaminase to Enhance the Stiffness and Water-Holding Capacity of Acidified Yak Milk Gels. Journal of Food Quality. 2018. 1-6. 10.1155/2018/1875892.

Appendix II
(Original languages only)

COMMENTS RECEIVED IN RESPONSE TO CL 2021/92/OCS-FA

Comments of Argentina, Brazil, Colombia, Ecuador, Egypt, El Salvador, European Union, Honduras, India, Indonesia, Kenya, Panama, Paraguay, Peru, Uganda, Uruguay and IDF/FIL

COMMENT	MEMBER / OBSERVER
Se acuerda con el uso de citrato trisódico (SIN 331(iii)) en la categoría de alimentos 01.1.1 “Leche líquida (natural/simple)”. Justificación:El uso de citrato de sodio como estabilizante es necesario para lograr la estabilidad de las proteínas para las leches que son sometidas a tratamientos térmicos elevados. En el ámbito del Mercado Común del Sur (MERCOSUR), se permite el agregado de citrato de sodio con función de estabilizante en las leches UAT (UHT), en una concentración quantum satis, es decir, la cantidad necesaria para obtener el efecto tecnológico deseado (Res. GMC N° 135/96 Reglamento Técnico MERCOSUR, Inclusión del citrato de sodio en el Reglamento Técnico MERCOSUR sobre Identidad y Calidad de la leche U.A.T. (UHT), modificatoria de la GMC N° 78/94). En el actual proceso de revisión de la norma, el uso de citrato de sodio con función estabilizante se mantendrá dentro de los aditivos permitidos en este tipo de productos. Al respecto, Argentina propone adoptar una concentración máxima de 0,1 g /100 g, para la leche UAT y otras leches de alto tratamiento térmico, ya que esta concentración es suficiente para permitir el efecto estabilizante que se desea obtener.	**Argentina**
CITRATE IN MILK - COMMENTS ON THE TECHNOLOGICAL NEED FOR THE USE OF THIS FOOD ADDITIVE IN THE MILK OF BOVINE SPECIES 1. INTRODUCTION In February 2019, the JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES, Fifty-First Session, developed The General Standard for Food Additives (GSFA) prepared by the United States of America with the assistance of Australia, Brazil, Canada, Chile, China, Columbia, Costa Rica, Dominican Republic, European Union, Guatemala, India, Indonesia, Ireland, Japan, Korea, Malaysia, Mexico, New Zealand, Norway, Paraguay, Peru, Philippines, Russian Federation, Saudi Arabia, South Africa, Spain, Switzerland, Thailand, Uganda, Zimbabwe, American Beverage Association Calorie Control Council (CCC), Comité Européen des Fabricants de Sucre (CEFS), European Food Emulsifier Manufacturers Association (EFEMA), EU Specialty Food Ingredients, Food Drink Europe, Food Industry Asia (FIA), International Association for the Development of Natural Gums, International Association of Color Manufacturers (IACM), International Alliance of Dietary/Food Supplement Associations (IADSA), International Council of Beverages Associations (ICBA), International Chewing Gum Association (ICGA), International Confectionery Association (ICA/IOCCC), International Council of Grocery Manufacturer Associations (ICGMA), International Dairy Federation (IDF), International Food Additives Council (IFAC), Institute of Food Technologists (IFT), International Fruit and Vegetable Juice Association (IFU), International Glutamate Technical Committee (IGTC), International Organization of the Flavor Industry (IOFI), International Special Dietary Foods Industries (ISDI), Natural Food Colours Association (NATCOL), US Dairy Export Council, and the World Processing Tomato Council (WPTC). The Document CX/FA 18/51/7 Appendix 2/2019 established in its Appendix 2 the provision for sodium citrate in FC 01.1.1. Brazil subsequently presented some comments on the documents Point 5a - CX/FA 9/5 /7 - GENERAL STANDARD FOR FOOD ADDITIVES (GSFA): Report of the EWG - Electronic Working Group) about the GSFA. In the present Technical Note we intend to present some documents of Codex Alimentarius, and technically and scientifically discuss and justify the use of citrate in UHT milk in Brazil.	**Brazil**

COMMENT	MEMBER / OBSERVER
First, we present Appendix 2: Provision for trisodium citrate in FC 01.1.1 (JOINT FAO/WHO FOOD STANDARDS PROGRAMMECODEX COMMITTEE ON FOOD ADDITIVES, Fifty-First Session, which worked on The General Standard for Food Additives (GSFA), 2019); secondly, we show the comments prepared by Brazil and the technical and scientific justifications for the use of citrate, and, finally, we present some data on the quality of raw milk from Brazil from 2013 to 2020 and final remarks. 2. "Appendix 2: Provision for trisodium citrate in FC 01.1.1 Among several topics, CCFA50 requested the EWG on the GSFA to CCFA51 to discuss: Provision for trisodium citrate in FC 01.1.1 (comments on technological need for the use of the food additive in milk from bovine species) Background 1. The EWG on the GSFA to CCFA49 compiled comments on the appropriateness of the food additive provisions both adopted and in the step process in the revised food category 01.1 (Fluid milk and milk products) and its subcategories 01.1.1 (Fluid milk (plain)), 01.1.3 (Fluid buttermilk (plain)) and 01.1.4 (Flavoured fluid milk drinks). 2 The physical working group (PWG) on the GSFA to CCFA49 discussed the proposals and information compiled by the EWG. 3. CCFA49 discussed the general use of trisodium citrate (INS 331(iii)) in UHT and sterilized products conforming to food category 01.1.1. The discussion focused on whether the provision for trisodium citrate should have a numeric use level or a maximum use level of GMP. CCFA49 agreed to direct the EWG on the GSFA to CCFA50 to request comment on the technological need for a numeric or GMP use level for trisodium citrate in food category 01.1.1.4. 4. The PWG on the GSFA to CCFA50 discussed the report of the EWG to CCFA50, including the technological need for a numeric or GMP level for the provision for trisodium citrate in food category 01.1.1.5 The PWG subsequently recommended that the provision be adopted with a GMP use level in food category 01.1.1 with Note A17 that reads "For UHT milk from non-bovine species only." 5. CCFA50 endorsed the PWG recommendation to adopt the provision at GMP after replacing Note A17 with a new note which reads "For use in sterilized and UHT treated milks from non-bovine species only." However, after the Committee endorsed the recommendation for adoption, a member country requested that the provision for trisodium citrate in FC 01.1.1 be held at Step 7 and recirculated for comment to confirm whether there was any technological justification to support the use of the additive in milk from bovine species. The Committee agreed to hold the provision and to task the EWG on the GSFA to recirculate the provision for comments. Working Document 6. The EWG issued three circulars for comment. The first and second circular contained EWG comments on the technological justification for the use of trisodium citrate (INS 331(iii)) in fluid milk (plain) from bovine species. The third circular contained EWG comments on the proposal for the use of trisodium citrate (INS 331(iii)) in food category 0.1.1.1 (fluid milk (plain)) at GMP and with Note 438 "Only for use as emulsifier or stabilizer", Note 227 "for use in sterilized and UHT treated milks only" and remove Note 439 "For use in sterilized and UHT treated milks from non-bovine species only". The document presents a compilation of comments provided by EWG members to the first, second and third circulars. Conventions 7. The current document presents a recommendation for the provision for trisodium citrate in FC 01.1.1 This document presents a proposal (adopt, adopt with revision) for the draft provision under discussion based upon a consensus approach taking into account comments	

COMMENT	MEMBER / OBSERVER
on the first, second and third circulars by members of the EWG. These recommendations are based on the "weight of evidence"; that is, comments containing justifications were given more weight than comments with no supporting justification. Current provision under discussion: Trisodium citrate - Food Cat No. 01.1.1 Functional Class No. Food Category - Fluid milk (plain) 438: Only for use as emulsifier or stabilizer 439: For use in sterilized and UHT treated milks from non-bovine species only I. General Summary of comments provided in response to the First Circular The first circular requested comment on the provision for INS 331(iii) in food category 01.1.1. Specifically, The first circular asked those not favour of the use of INS 331(iii) in milk from bovine species to provide discussion as to why INS 331(iii) would not be technologically justified in milk from bovine species including discussion on what physical properties differ between bovine milk and milk from non-bovine species that would cause INS 331(iii) to be technologically justified in non-bovine sterilized and UHT treated milk but not justified in sterilized and UHT treated milk from bovine species. The first circular also asked those in favour of the use of INS 331(iii) in milk from bovine species to provide justification and supporting information based on the criteria in Section 3.2 of the Preamble of the GSFA and to discuss if there are physical property similarities between milk from bovine species and milk from non-bovine species that would support the general use of INS 331(iii) in all sterilized and UHT treated milks. Comments submitted in response to the first circular that were not in favour of the use of trisodium citrate in UHT treated milks from bovine species focused on whether the use has an advantage or would mislead the consumer. Several Members noted that only phosphates were allowed for use as stabilizers in bovine milks in their countries, and that no other stabilizers are necessary. These comments noted that milk from bovine species is less sensitive to protein coagulation than other milks and therefore trisodium citrate is not necessary in bovine milks. One commented that the use of citrates can mislead the consumer by buffering a low Ph (which is an indicator of spoilage) while another noted that the use of stabilizers could be used to mask bad handling practices. Another expressed concern that the use of trisodium citrate may change the organoleptic properties of milk and affect milk fermentation. However, comments from Members in favour of the use of trisodium citrate in UHT milk from bovine species addressed the advantage of the use and whether the use would mislead the consumer. These members noted that trisodium citrate is allowed in bovine milks in their countries. These members noted that all UHT bovine milks utilize stabilizers, and that trisodium citrate has advantages that other stabilizers (i.e., phosphates) do not. One member provided information that trisodium citrate is required for pastured cattle as feeding cattle forage results in production of milk with a lower natural sodium citrate content, which results in greater tendency for gelation of these milks under UHT processes. Sodium citrate is a natural component of milk. The use of trisodium citrate corrects the natural citrate deficiency in milk from pastured cattle, which the use of phosphates cannot do. The use would not mislead the consumer as stabilizers are already allowed for use in bovine milks. One Member noted that restricting the use of trisodium citrates to non-bovine species is contrary to the principles of Codex as the restriction would not benefit public health but would have an adverse trade impact on developing countries. II. General Summary of comments provided in response to the Second Circular Based on comments submitted to the first circular, and in order to determine an approach to consensus, the second circular requested comment from EWG members on the following: a) Those not in favour of the use of INS 331(iii) in UHT treated milk from bovine species were	

COMMENT	MEMBER / OBSERVER
requested to provide discussion on how the information provided in response to the first circular does not demonstrate that the use meets the criteria listed in Section 3.2 of the preamble of the GSFA. Those who assert that that the use of trisodium citrate can mislead the consumer by masking spoiled milk or bad handling practices were requested to discuss why there is a concern for the use of trisodium citrate in bovine milks but not for phosphates, which would have the same effect. Two comments were received in response to this request. One comment noted that the reported need for INS 331(iii) in UHT treated milk from bovine species is limited to certain Codex Members as a result of bovine feeding systems utilized by those Members. This comment observes that this appears to result in the need to compensate for a lower content of natural citrate in milk produced in Countries utilizing such feeding systems, but that this justification is not applicable to all Codex Members. The second comment asserted that INS 331(iii) is only justified in goats milk but not other non-bovine species. This comment also noted that there is no data on how the use of INS 331(iii) will affect the processes of milk fermentation and other processes of milk, but provided no information explaining why INS 331(iii) would be expected to affect milk fermentation or processing. Neither comment discussed the technological information provided in response to the first circular or how the use of trisodium citrate INS 331(iii) would differ from the currently allowed use of phosphates. b) Those in favour of the use of INS 331(iii) in UHT treated milk from bovine species were requested to provide further discussion on how the use will not mislead the consumer (i.e., is not used to lower pH to cover spoilage, is not used to mask bad handling practice, etc.) Comments in favour of the use of INS 331(iii) in UHT treated milk from bovine species noted that extensive information had been provided to demonstrate that the use complies with all criteria in section 3.2 of the preamble to the GSFA: it is technologically justified, has an advantage, is safe, does not mask bad handling practices and that stabilizers are required in all bovine milks therefore the use does not mislead the consumer. These comments provided information on the need for INS 331(iii) in milks with lower citrate content, that INS 331(iii) is a table three additive and is allowed in infant formula so there is no safety issue, and all bovine milk requires stabilizers to limit the deposition of calcium and protein salts so the use cannot mislead the consumer. Other comments One EWG member proposed establishing a numeric use level in bovine milk to address the concerns of some members that the use of INS 331(iii) can be used to mask bad handling practices. However, other comments noted that the use cannot be used to mask bad handling practices as excessive use would likely spoil the milk. Other EWG members observed that Note 438 “Only for use as an emulsifier or stabilizer” is already attached to this provision and should address concern expressed in comments to the first circular that INS 331(iii) can mask bad handling practices by buffering pH levels. One EWG member noted that an allowance for the use of INS 331(iii) in bovine milk should not impact countries where trisodium citrate is not allowed, due to the limited self-life and need for uninterrupted cold- storage chain for milk which limits its international trade to within specific geographical regions. III. General Summary of comments provided in response to the Third Circular The EWG was invited to comment on the adoption of a provision for INS 331(iii) in food category 01.1.1 at a level of GMP with the Note 438 “Only for use as an emulsifier or stabilizer” and Note 227 ““for use in sterilized and UHT treated milks only” and to remove Note 439 “For use in sterilized and UHT treated milks from nonbovine species only “. The comments received from the EWG indicated some EWG members were in favour of the proposal, while some members were not in favour of the proposal. One EWG member not in favour of the proposal restated their position that there is no technological justification to support the use of INS 331(iii) in the production of mare's, camel's and other types of milk obtained from non-bovine species (mare, camel, sheep and other species of milk) and there is no data on how	

COMMENT	MEMBER / OBSERVER
the use of INS 331(iii) will affect the processes of milk fermentation and other processes of milk processing non-bovine species. IV. Final EWG Proposal Trisodium citrate INS 331(iii) Functional Class: Acidity regulator, Emulsifier, Emulsifying salt, Sequestrant, Stabilizer Food Cat - No. 01.1.1 Food Category - Fluid milk (plain) ML (mg/kg) – GMP Notes - 438, 439 Step – 7 EWG Final Proposal - 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” Overall summary of all comments by EWG Members: a. Those in favour of the use of INS 331(iii) in UHT treated milk from bovine species: Brazil, Colombia, Guatemala, Indonesia, Paraguay, USA, Food Drink Europe, IDF b. Those not in favour of the use of INS 331(iii) in UHT treated milk from bovine species: EU, Russian Federation, Spain, Uganda c. Other Comments: Switzerland, USA Overall summary of comments on the technological purpose for the use of INS 331(iii) in UHT treated milk from bovine species: The use of trisodium citrate in bovine milk is technologically justified, safe to human health and is not used to mask bad handling practices. Therefore, its use in bovine milk complies with the Codex Alimentarius principles for food additives. Milk is a colloidal suspension consisting mainly of water, fat, carbohydrates, proteins, mineral substances and organic acids. Milk fat is to a greater extent made up of triacylglycerides, however phospholipids, cholesterol, free fatty acids and diglycerides can also be found. The major carbohydrate found in milk is lactose. Milk consists of different kinds of proteins of which caseins make up about 80% of the total protein content. The serum proteins, also called whey proteins, make up the remaining part of the total protein content and consist of β-lactoglobulin (β-LG), α-lactalbumin, serum albumin, immunoglobulins and peptides. The most commonly found minerals in milk are K, Na, Ca, Mg, Cl and P and the most common organic acid is citrate (Walstra et al., 1999). It means that citrate naturally occurs in milk. 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). Thus, the addition of sodium citrate as a stabilizing additive promotes the reduction of the calcium content available for the formation of salt bridges between the protein complexes, thus preventing milk sedimentation, and favouring the stability of this product, as can be observed in the charts: Graph 1. Induction time of amorphous calcium phosphate formation without citrate. Graph 2. Induction time of amorphous calcium phosphate formation with citrate. Bovine milk produced in Brazil shows average levels of citrate below international limits, as shown below:	

COMMENT	MEMBER / OBSERVER
Reference - FOX, P.F, 1991/ JENNESS AND PATTON, 1999/ WALSTRA P. AND JENNESS, 1978/ WHITE & DAVIES, 1958/ SILVA, P.H.F, 2004 Country – Ireland/ Maryland, USA/ New York, USA/ USA/ Brazil Citrate average (as citric acid) - 176 mg/100 mL / 175 mg/100 mL/ 175 mg/100 mL/ 179 mg/100 mL/ 158,5 mg/100 mL Citrate is present in milk distributed in two phases: soluble and colloidal. In the soluble phase, 94% of the milk citrate is present, being bound to calcium and magnesium (85%), as trivalent citrate (14%) and divalent citrate (1%). The casein-bound colloidal citrate represents 6% of the total citrate (Fox, 1991). According to Fox (1991), the additions of citrate and phosphate to milk promote an increase in the thermal stability of the milk, by the sequestering effect on ionic calcium and, especially in the case of citrate, by the conversion to soluble citrate. Phosphates and citrates are recognized in increasing the thermal stability of milk (Fox, 1991). Despite the favorable effect of citrate addition, excess of citrate may unbalance milk. Addition of sodium phosphates to milk generally increases stability by sequestering Ca2+, but citrate is more effective. If the milk is stabilized with phosphates, the initial Ca/P ratio is around 1: 1, which can contribute to the deposition of calcium and protein salts in the bottom of the UHT milk package if compared to the product which was added with citrate. Finally, Brazil believes that this is the reality of most developing countries that keep their bovine cattle exclusively on pasture. Therefore, the restriction of sodium citrate use only for non-bovine species would generate a commercial barrier, excluding these countries from international trade, especially MERCOSUR countries, where the use of citrate in UHT cow's milk is widely used and regulated. Brazil understands that the restriction of the use of citrates only for milks from non-bovine species violates the principle of CODEX, which is to promote equal market conditions among its member countries, while observing food security. Sodium citrate is a natural component of bovine milk and it is a food additive whose IDA is not limited and therefore, does not pose a risk to public health. REFERENCES DAVIES, D.T. and WHITE, J.C.D. The relation between the chemical composition of milk and the stability of the casein complex. II. Coagulation by ethanol. Journal of Dairy Research, 25, 256-266. 1958. FOX, P.F Food chemistry. Part III. Cork: Cork University College, 1991. 201 p. JENNESS, R. and PATTON, S. Principles of Dairy Chemistry. New York, Robert E.1999. SILVA, P.H. F. Leite UHT: fatores determinantes para sedimentação e gelificação (Tese de Doutorado, Universidade Federal de Lavras- MG). Brasil. 2004. Walstra, P.; Jenness, R. Dairy Chemistry and Physics. Wiley Intersciences, New York. Wiley Interscience Publ. John Wiley & Sons, Inc. New York. 1984. IDF: Supports the use of INS 331(iii) in milk from bovine species UHT treated in order to prevent Coagulation and sedimentation. The heat treatment to which UHT milk is subjected can destabilize milk proteins by altering its original form, altering its electrical charge, so that protein sedimentation and gelation occur throughout its shelf life. The use of sodium citrate in bovine UHT milk is carried out in order to maintain the stability of the casein micelles by binding sodium citrate with free calcium present in the milk. About 10% of the total calcium present in the milk is in the ionic phase. Calcium and phosphorus ions act as adjuvants, making the connection between casein micelles. The equilibrium of the ionic phase of calcium with its colloidal phase (associated with phosphorus in casein micelles) and soluble (calcium salts) is decisive for the stability of the milk. The	

COMMENT	MEMBER / OBSERVER
charges of casein micelles are controlled by the amount of calcium bound and, therefore, by the free calcium content present in the milk. With the increase of total calcium in milk, the amount of bound calcium increases and reduces the negative charges of the micelles, which decreases the energy barrier for coagulation. When the calcium content is reduced, there is an increase in the negative charges of the micelles and, as a result, the repulsion between them increases, which makes the coagulation difficult. It is important to note that sodium citrate is a natural stabilizer, but insufficient to immobilize all free calcium in milk. **COMMENTS PREPARED BY BRAZIL AND THE TECHNICAL AND SCIENTIFIC JUSTIFICATIONS FOR THE USE OF CITRATE** In this section, we present the comments from Brazil on the revised document "JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVE 51st Session Comments from Brazil (Revised)". Brazil would like to submit some comments on the following documents: Point 5a - CX/FA 19/51/7 - General Standard for Food Additives (GSFA): Report on 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's justifications for the use of trisodium citrate (INS 331iii) in UHT bovine 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 formulas. In addition to being a natural component of the milk, present in any type of milk in different species at different levels of concentration depending on the breed, crossbreed, food, environment, climate and the individuality of each animal. • Technological need: the thermal stability of milk is influenced by various 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 result of the cow deleting its skeleton Ca to maintain the level of Ca in its milk. The level of citrate in milk decreases in 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. Due to the country's size and the possibility of raising cattle for milk production fed exclusively on pastures, consuming only forage, the milk of the Brazilian herd has considerably lower levels of this substance, compared to the citrate levels in the milk of the herds in other countries that do not have it. Fox (1991) also states that the composition of milk salts is influenced by some factors, including breed, individuality of the cow, state of lactation, feed, infection of the udder and season of the year. In Brazil, the study carried out by Silva (2003) showed that the levels of calcium, phosphorus and citrate vary significantly among states and seasons. This confirms Fox's (1991) statement that feed and season may affect the chemical composition of bovine milk. 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	

COMMENT	MEMBER / OBSERVER

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 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	176.0 mg/100 mL
JENNESS & PATTON, 1999	Maryland, USA	175.0 mg/100 mL
WALSTRA P. & JENNESS, 1978 (Walstra P, Jenness, R. Dairy Chemistry and Physics. Willey Intersciences, New York, 1984)	New York, USA	175.0 mg/100 mL
WHITE & DAVIES, 1958 (DAVIES, D.T. and WHITE, J.C.D. The relation between the Chemical composition of milk and the stability of the casein complex. II. Coagulation by ethanol. Journal of Dairy Research, 25, 256-266), 1958.	USA	179.0 mg/100 mL
SILVA, P.H.F, 2004	Brazil	158.5 mg/100 mL
Gonzalez, F.H.D. & Campos R., 2003	Brazil	147.0 mg/100ml

The high temperatures used in UHT cause an imbalance in these structures due to the denaturation of proteins or the loss of salt interaction in micelles, causing protein precipitation. In this condition, the addition of 0.025% to 0.1% sodium citrate or sodium phosphate practically eliminates this defect.

White & Davies (1958) reported average values of 176 mg/100 ml ranging from 166 to 192 mg/100 ml, within which only milk produced in the state of Goiás, in Brazil, fits. Milk produced in the states of São Paulo and Rio Grande do Sul showed average levels well below this limit, so it is necessary to add sodium citrate to milk produced in Brazil and subjected to high temperatures, such as UHT milk.

During ethanol testing and heating, the appearance of changes in milk in Brazil can occur. The low levels of citrate found in milk in most parts of the country help clarify the problem, showing that the probable cause is related to the salt imbalance.

Given the lowest citrate value found in European cows - 0.166 g/100ml - and the highest value found - 0.192 g/100ml - we understand that the restriction should not exceed this higher value. Therefore, for low levels in Europe, the appropriate value of citrate added to compensate for the low levels would be 0.026 if necessary.

Taking into account that in Brazil, due to the influence of feeding and the use of mestizo cattle to obtain milk, the citrate level is even lower, around 0.147g/100ml to 0.158 g/100ml. In this case, we understand that the values for use in the compensatory amounts should not exceed 0.045g/100ml.

It is important to emphasize that it is a compensatory use of extrinsic citrate, to obtain normal levels of citrate in a wide range of milks around the world and thus obtain a product of equal quality, above all nutritional quality, since the lack of stability that naturally provides intrinsic citrate in milks subjected to high temperatures will favor the precipitation of proteins and will reduce the nutritional quality of the food. This situation is even more serious when we consider that this type of product is often the main source of protein in low-income populations.

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The composition of milk also varies according to the breed of the animal and the climatic conditions. For example, in the arid and semi-arid regions of Brazil, where water is scarce, cattle, which are more rustic, tend to produce 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 makes the mestizo herd more rustic, with a low individual milk production. For this reason, in Brazil it is common to use a system of community tanks where milk of several properties is agglomerated, in order to obtain enough milk volume to be sent to dairy industries. Fox (1991) also states that the addition of sodium phosphates and/or citrates to milk generally increases the stability both by sequestering 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. High levels of citrate cause micellar disintegration. Phosphates and/or citrates are commonly added to concentrated milk in order to improve stability during heat sterilization. Based on this, Brazil and the other MERCOSUR countries use UHT milk for a maximum limit for the use of stabilizers, either alone or in combination, the limit being stipulated by the MERCOSUR Resolution of 0.1 g/100ml. 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", i.e. 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 in the manufacture of cheeses. Therefore, the discussion raised by some members that the addition of citrates would negatively impact the process of coagulation for the manufacture of cheeses lacks a technological basis. In the UHT process, the denaturation of whey proteins is followed by the aggregation of molecules which may be caused by intermolecular disulfide bridges. This complex causes the interaction of kappa-casein (k-casein) and betalactoglobulin (β-lactoglobulin). The observed release of sialic acid contained in the k-casein glycomacropeptide on unfolding of the molecules due to UHT heating is reduced. Therefore, UHT treatment is not recommended for milks intended for making cheese. (FIL, New monograph on UHT milk, 1981). • Milk Fraud: In Brazil, several authors have reported casein instability in milk with normal acidity and a low somatic cell count, which means that good quality bovine milks also have stabilization problems. In the Brazilian state of Rio Grande do Sul, 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, i.e. the discussion should be around the stabilizing function rather than the citrate itself. Another important point to note is that citrate is a natural component of bovine milk, and its use is self-limiting, which means that the excessive use of citrate causes the decrease in the available 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 for fraud only in relation to bovine milks, without considering non-bovine species, would be incoherent and unreasonable.	

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• 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 deficiencies, but rather to compensate for the low levels of citrate naturally present in milk, favour the supply of a product of better nutritional quality to the consumer, and balance the disparity between the same products from countries where their herds have higher levels citrate, thus combating unfair competition between markets. Therefore, it complies with all the principles established in the GSFA and Codex criteria. Brazil understands that the purpose of the Codex Alimentarius is to establish food standards that are globally representative, which 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. In addition, we emphasize that no scientific references have been presented that contradict the use of citrate in UHT milk of any kind, or that demonstrate damage to the health or characteristics of the food, or even market problems. Therefore, following the basic precept of the Codex Alimentarius that decisions must be made based on scientific evidence, Brazil once again presents scientific data to supplement the data already presented in 2019 with CRD 23 and we firmly express our position in favor of the exclusion of NOTE 439. References FOX, P. F. The milk proteins system, including milk salts and the proteins of egg white. Food Chemistry, 1991. IDF. New monograph on UHT milk. Bulletin of the International Dairy Federation, n. 133/1981. SILVA, P. H. F. Leite UHT: fatores determinantes para sedimentação e gelificação. (Tese de Doutorado, Universidade Federal de Lavras), 2003. 4. Technical and scientific justifications for use of citrate Considering all the information and data presented on the variation of citrate in milk produced in different regions of Brazil, other important points must be evaluated. The first point has to do with the fact that citrate is approved for use in infant formulas in Mercosur GMC. The second is related to the requirements of the Ministry of Agriculture, Livestock and Supply (MAPA - acronym in Portuguese) regarding the implementation of the Good Agricultural Practices Program (BPA - acronym in Portuguese), and Self-Control Programs (PAC - acronym in Portuguese), among others. The third refers to the steady improvement in the quality of milk in Brazil over several years. In relation to variation of citrate in milk produced in different regions of Brazil, González et al. (2003) and Silva (2004) showed mean values of 147.0 mg/100 mL and 158.5 mg/100 mL, respectively, lower values than those of other countries. Scientific studies show that the concentration of citrate in raw milk produced in Brazil varies by region and season of the year. Silva et al. (2004), for example, when evaluating the citrate concentration in three different Brazilian states whose milk production is representative and in the dry and rainy seasons, observed that Goiás had a higher concentration of citrate than São Paulo and Rio Grande do Sul. Citrate levels were higher in Goiás (193 mg/100 mL - dry and 168 mg/100 mL - rainy) followed by São Paulo (163 mg/100 mL - dry and 157 mg/100 mL rainy) and Rio Grande do Sul (160 mg/100 mL - dry and 154 mg/100 mL - rainy). The milk evaluated, with the exception of the dry season in Goiás, has lower citrate content when compared to the results of Walstra & Jenness (1984), who mention the value of 175 mg/100 mL. An analysis of variance of the data revealed differences between citrate contents in raw milk between states ($p < 0.003$) and between seasons ($p < 0.022$). It is concluded that the natural citrate contents vary between regions of Brazil and seasons of the year, which affects the final citrate content in UHT milk. Thus, given the natural variation in citrate levels in milk produced in different regions of Brazil and seasons of the year, it is important to add citrate to maintain milk stability. It is noteworthy that the quality of milk in Brazil has significantly improved and that the Good Agricultural	

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Practices and the Qualification Plan for Milk Suppliers (PQFL - acronym in Portuguese) provided for in the Self-Control Programs of the dairy industries and described in the Brazilian legislation have driven this continuous improvement in quality (Brasil, 2017; Brasil, 2018a; Brasil, 2018b). Therefore, the permission to use citrate approved by Mercosur since 1996 did not mask deficiencies in Good Agricultural Practices in Brazil, since the quality of Brazilian milk has been improving year after year. Additionally, Brazil highlights that trisodium citrate is already approved for infant formulae, according to GSFA online. If this additive is allowed for infant formulae, a product intended for a vulnerable public, why not approve this additive for bovine milk, if this is a very common ingredient of infant formulae? If the phosphate is already authorized for use in bovine milks and the phosphorus has PTWI, why not allow trisodium citrate, whose ADI is unspecified? If the members contrary to the use of citrates in bovine species argue that bovine milk proteins have no sedimentation problem, why, then, authorize the use of phosphates as stabilizers in these products? As the stabilizer function is already justified and recognized for bovine milk by means of phosphates, why not allow citrates that have lower health concerns as well? Additionally, sodium citrate is intended for infant formula by the GSFA and is a nutrient permitted as a source of sodium for infant formula: (Advisory lists of nutrient compounds for use in foods for special dietary uses intended for infants and young children cac/gl 10-1979 adopted in 1979, link: http://www.fao.org/faowhocodexalimentarius/shproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B101979%252FCXG_010e_2015.pdf)/) Extensive information on UHT treated milk from bovine species demonstrates that the use of citrates complies with all criteria in section 3.2 of the preamble to the GSFA: it is technologically justified, has an advantage, is safe, does not mask bad handling practices, and stabilizers are required in all bovine milks; therefore, their use does not mislead the consumer. It is important to remember that milk has natural citrate levels and the use of citrate as an additive that has been approved by Mercosur since 1996 (Mercosur, 1996). Additionally, citrate, according to Brazilian legislation, has been used in UHT milk since 1996 (Mercosur, 1996) without any reports of misleading consumers. Its use follows all the labeling recommendations laid down by Brazilian regulatory bodies in order to provide the consumers with correct information. Therefore, we strongly believe that the use of citrate as an additive does not mislead consumers. Mercosur member countries (Argentina, Brazil, Paraguay and Uruguay) reviewed the Mercosur/GMC/RES no. 7 /94 for UHT milk and agreed to maintain the quantum satis for sodium citrate. Table 1 Geometric means for Standard Plate Count (SPC) and Somatic Cell Count (SCC) in samples of refrigerated raw milk, by year, tested in the Brazilian Milk Quality Network (RBQL). YEAR - 2013 / 2014 / 2015 / 2016 / 2017 / 2018 / 2019 / 2020 No. of samples analyzed for SPC - 2,618,186 / 2,952,098 / 3,148,224 / 3,104,407 / 3,187,785 / Geometric mean for SPC in tested samples x 1,000 CFU/mL - 3.075.771 / 3.026.340 / 2.832.859 216 / 208 / 183 / 149 / 156 / 149 / 111/ 72 No. of samples tested for SCC - 2,635,718 / 2,837,502 / 3,152,388 / 3,097,566 / 3,091,183 / 3.027.206 / 3.062.972 / 2.785.334 Geometric mean for SCC in tested samples x 1,000 cells/mL - 382 / 407 / 435 / 445 / 437 / 449 / 450 / 432 Source: Brasil (2021)	

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Considering the concern that the use of citrate masks good practice, official data on milk quality in Brazil demonstrate that over time, the microbiological quality of milk has improved (Brasil, 2021). In this publication, 23,945,670 raw milk samples (Table 1) were analyzed for SPC (standard plate count). Microbiological quality data of raw milk of Brazil in the period from 2013 to 2020 are shown below. Although the legal limit of SPC established in 2018 by Brazilian legislation (Brasil, 2018a) is 300,000 CFU/mL, the geometric means observed in the country are lower according to Fig. 1. Also, the Somatic Cell Count (SCC) is below the legal standard (500,000 cells/mL), from 2013 to 2020. Figure 1: National geometrical means for refrigerated raw milk samples, Standard Plate Count – SPC x 1,000 CFU/mL and Somatic Cell Count – SCC x 1,000 cell/mL, for Brazil, 2013 to 2020. Taking into consideration Brazil's five largest milk-producing states, it can be seen that milk quality has been improved year after year (Figs. 2 to 6). These five states accounted for 70% of Brazilian milk production in 2020 (IBGE, 2021). Figure 2: Geometrical means for refrigerated raw milk samples, Standard Plate Count –SPC x 1,000 CFU/mL for the State of Minas Gerais, 2013 to 2020. Figure 3: Geometrical means for refrigerated raw milk samples, Standard Plate Count –SPC x 1,000 CFU/mL for the State of Paraná, 2013 to 2020. Figure 4: Geometrical means for refrigerated raw milk samples, Standard Plate Count – SPC x 1,000 CFU/mL for the State of Rio Grande do Sul, 2013 to 2020. Figure 5: Geometrical means for refrigerated raw milk samples, Standard Plate Count – SPC x 1,000 CFU/mL for the State of Goiás, 2013 to 2020. Figure 6: Geometrical means for refrigerated raw milk samples, Standard Plate Count –SPC x 1,000 CFU/mL for the State of Santa Catarina, 2013 to 2020. It is important to highlight that although citrate has been used as an additive in UHT milk in Brazil since 1996 in compliance with the Mercosur Resolution (Mercosur, 1996), the quality of raw milk has improved over time, indicating that the use of citrate has neither interfered with good agricultural practices nor masked the quality of the raw milk as shown in Figures 1 to 6. The importance of approving the use of citrate as an additive in the technological processing of UHT milk is due to the wide variation in the contents of citrate in milk produced in different Brazilian states, according to data from Silva (2003). It is not used to mask the raw milk quality and the Official data of the Ministry of Agriculture, Livestock and Supply (MAPA), published recently (Brasil, 2021) demonstrates that this quality has steadily improved over a number of years. 5. Final Remarks Given that: a) the citrate levels vary by region and season in Brazil, and the mean values are low according to scientific studies in the country; b) the use of citrate as additive in UHT milk has been allowed since 1996 by Mercosur (Mercosur, 1996); c) its use is approved in infant formulas; d) the country has robust legislation that establishes criteria for the production and quality of raw milk, and e) the official quality data of Brazilian raw milk have steadily improved over several years. Brazil requests approval by Codex for the use of citrate in UHT bovine milk.	

COMMENT	MEMBER / OBSERVER
6. REFERENCES BRASIL. Decreto nº 9.013, de 29 de março de 2017. Regulamenta a Lei nº 1.283, de 18 de dezembro de 1950, e a Lei nº 7.889, de 23 de novembro de 1989, que dispõem sobre a inspeção industrial e sanitária de produtos de origem animal. Diário Oficial da União, Brasília, DF, 30 de março 2017. Seção 1, p. 3-27. 2017. BRASIL. Ministério da Agricultura, Pecuária e Abastecimento. Instrução Normativa n° 76, de 26 de novembro de 2018. Aprova os Regulamentos Técnicos que fixam a identidade e as características de qualidade que devem apresentar o leite cru refrigerado, o leite pasteurizado e o leite pasteurizado tipo A. Diário Oficial da União: Seção 1, Brasília, DF, Ano 2018, Edição: 230, pp. 09-10, 30 de novembro de 2018a. BRASIL. Ministério da Agricultura, Pecuária e Abastecimento. Instrução Normativa n° 77, de 26 de novembro de 2018. Estabelece os critérios e procedimentos para a produção, acondicionamento, conservação, transporte, seleção e recepção do leite cru em estabelecimentos registrados no serviço de inspeção oficial. Diário Oficial da União: Seção 1, Brasília, DF, Ano 2018, Edição: 230, pp. 10-13, 30 de novembro de 2018b. BRASIL. Ministério da Agricultura, Pecuária e Abastecimento. Evolução da qualidade do leite no Brasil: amostras de leite cru avaliadas pela RBQL entre 2013 e 2020 / Secretaria de Defesa Agropecuária. – Brasília: AECS, 2021. FOX, P. F. Food Chemistry. Part III. Cork University College, 1991. 201 p. IBGE. Ranking dos estados com maior produção de leite em 2020. In: CNA - Comunicado Técnico. Edição 30/2021 | 01 de outubro de 2021. MERCOSUL - GMC no 135/1996 - Inclusão do Citrato de sódio no RTIQ do leite UHT (GMC no 78/94). 1996. SILVA, P. H. F. Leite UHT: fatores determinantes para sedimentação e gelificação. (Tese de Doutorado, Universidade Federal de Lavras), 2003. SILVA, P. H. F. da; ABREU, L. R. de; BRITO, J. R. F.; FURTADO, M. A. M. Variações regionais e sazonais nacomposição salina do leite. Revista do Instituto de Laticínios Cândido Tostes, v. 59, p.24-31, 2004. WALSTRA, P.; JENNESS, R. Dairy Chemistry and Physics. Wiley Intersciences, New York, 1984. WHITE, J. C. D.; DAVIES, D. T. The relation between the chemical composition of milk and the stability of the caseinate complex. I. General introduction, description of samples, methods and chemical composition of samples. Journal of Dairy Research, Cambridge, v. 25, n. 2, p. 236-255, Oct. 1958.	
Se debería permitir el uso de citrato trisódico en la categoría de alimentos 01.1.1 “Leche líquida (natural/simple)”. En Colombia se permite el uso de estabilizantes en leche ultrapasteurizada así: Sales de sodio y potasio de los ácidos cítricos y ortofosfórico. Polifosfatos de sodio y potasio (bifosfatos, trifosfatos, polifosfatos lineales con un máximo de 8% de compuestos cíclicos) solos o en combinación en cantidades no superiores al 0.05% m/m expresado como P2O5, para trifosfatos y polifosfatos lineales y máximo el 0.1% expresado como sustancia anhidra con respecto al producto terminado. Estos estabilizantes deberán ser incluidos en la lista de ingredientes.	**Colombia**
Ecuador está de acuerdo con el uso de Citrato Trisódico en la leche líquida (natural/simple) en la Categoría de Alimentos 01.1.1. Este es un aditivo que se utilizaría como estabilizante de la proteína en la leche, en procesos industriales para la obtención de leche UHT por	**Ecuador**

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ejemplo. Actualmente se usan otros tipos de aditivos para este fin ya que en nuestra región, la calidad de la leche que es utilizada para los procesos industriales no es óptima y presenta problemas de acidez, lo que conlleva a problemas post percha. La ventaja del citrato trisódico frente a los demás aditivos es que, al ser un ácido orgánico y por sus bajos niveles de toxicidad, no causaría problemas en la salud en el ser humano. Por lo antes mencionado, como país estamos de acuerdo con el uso del citrato trisódico como estabilizador o emulsionante para uso industrial (leches esterilizadas o UHT), pero siempre debe constar en su rotulado.	
Egypt supports adding sodium citrate in Food Category 01.1.1 “Fluid milk (plain)”, but only in goat milk UHT for the purpose of stabilization, acidity regulator and anticaking agent, according to the EFSA assessments.	**Egypt**
El Salvador agradece el documento remitido por la Secretaría del Codex Alimentarius y agradece el seguimiento del CCFA al tema en cuestión. El Comité Técnico Nacional sobre aditivos alimentarios ha analizado la solicitud de observaciones, según CL 2021/92/OCS-FA, respecto al uso de citrato trisódico (SIN 331 iii)) en la categoría de alimentos 01.1.1 “Leche líquida (natural/simple)”, en ese sentido se presentan las siguientes observaciones de carácter general para consideración del CCFA, en su próximo periodo de sesiones. El Salvador no está de acuerdo con la propuesta de disposición de uso del SIN 331 (iii), como emulsionante o estabilizador en la categoría de alimentos 01.1.1 “Leche líquida (natural/simple)”, específicamente para leche UHT de especies no bovinas y de especies bovinas para compensar el contenido de citrato o de calcio para evitar la sedimentación debido a condiciones climáticas solamente, tal y como dicha propuesta ha sido presentada al CCFA. Se detallan las consideraciones nacionales a continuación: • Se conoce que los citratos estabilizan la estructura micelar de la caseína, estabilizando el coloide (enlace fosfato de calcio), es decir, retarda la gelificación inhibiendo la formación de la red de proteínas, por lo tanto, en el caso de leches con carga bacteriológica alta, su uso podría enmascarar la mala calidad de la leche y propiciar prácticas que tengan por objetivo engañar al consumidor. • Se considera que los problemas de gelificación de la leche, que enfrentan otros países, debido a condiciones climáticas, se pueden minimizar seleccionando leche de alta calidad y manteniendo la cadena de frío durante todo el proceso productivo, lo anterior es congruente con lo establecido en el Código de Prácticas de Higiene para la Leche y los Productos Lácteos CXC 57-2004, en el numeral 3.3 manipulación, almacenamiento y transporte de la leche, "las necesidades de control de tiempo y temperatura en la granja deben ser comunicadas claramente por el elaborador de productor lácteos” y en el numeral 3.3.4.3 “el tiempo y la temperatura de transporte deben ser tales que permitan transportar el producto o al centro de recolección/refrigeración es una forma que reduzca al mínimo cualquier efecto nocivo para inocuidad e idoneidad”. Finalmente, El Salvador reconoce la importancia que las Normas y Textos Afines del Codex Alimentarius representan para los países miembros de la Comisión y en ese sentido insta a que las disposiciones en el proceso de trámite se establezcan tan claras como sea posible, lo anterior para salvaguardar que su aplicación no estará sujeta al criterio de cada país. En ese sentido desea señalar que, se estaría de acuerdo de aprobar el uso del SIN 331 (iii) en leche UHT, solamente si se cumplen las dos condiciones siguientes: • El valor natural crítico por debajo o a partir del cual se podría necesitar el uso de citrato trisódico es establecido como parte del texto de la nota.	**El Salvador**

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• Se establecen específicamente las condiciones climáticas que han afectado a la leche y bajo las cuales, se permitiría el uso del aditivo.	
In the EU, the technological need for trisodium citrate (INS 331(iii)) in Food Category 01.1.1 "Fluid milk (plain)" is recognised only for UHT goat milk since goat milk produces heavy sediment on UHT treatment. There is an experimental evidence that trisodium citrate is able to act as an efficient stabilizer reducing ionic calcium (citrates react with calcium limiting the pH decrease and increasing the buffering capacity) which prevents formation of the sediment. Hence the amount of citrate is also an important parameter that governs the ionic calcium level. To the EU's knowledge the maximum level up to 4000 ppm is appropriate to adjust the milk pH to an optimum range as regards the heat stability without having any possible adverse effect as for the nature and quality of goat milk. Milk of bovine species is generally less sensitive to protein coagulation and therefore the use of trisodium citrate is not considered justified within the production conditions of milk of bovine species in the EU.	**European Union**
El sub comité del CODEX sobre Aditivos Alimentarios determinó lo siguiente en respuesta a la carta circular CL 2021/92/OCS-FA, tomando en consideración el análisis técnico y científico de cada uno de los sectores que lo componen respecto al uso del Citrato trisódico en la categoría de alimentos 01.1.1 "Leche líquida (natural/simple). Consideramos que este es un aditivo utilizado para que la leche no se corte, una especie de estabilizador, y que puede actuar como conservante para alargar la vida útil del producto. Sin embargo, la leche cruda siempre puede tener un alto contenido de bacterias, patógenos y coliformes evitándonos descubrir si es apta para consumo humano. En resumen, su uso permite esconder la leche cruda de mala calidad o la mala cadena de frío. No obstante, concordamos también con la justificación que Brasil presentó CX/LAC 19/21/CRD10, en lo referente a que se adopte lo que introduce la Nota 438 "Solo para uso como emulsionante o estabilizador" y la Nota 227 "Solo para uso en leche esterilizada y leche UHT". Eliminar la nota 439 "Solo para uso en leche esterilizada y leche UHT que provienen de especies no bovinas". En conclusión, no estamos de acuerdo con el uso del citrato trisódico (SIN 331 iii)) como emulsionante o estabilizador en la leche cruda, pero si en aquella que después de haber sido sometida a análisis físico-químicos se determine que es apta para consumo humano y que cumpla con la nota y 227, Esto con el fin de aclarar que el uso justificado es tecnológico y de conformidad con el apartado 3.2 de los Principios Generales para el uso de Aditivos Alimentarios, y sin entrar en contradicción con la aplicación de la Norma General para el uso de Términos Lecheros.	**Honduras**
India does not support the use of trisodium citrate (INS 331(iii)) in Food Category 01.1.1 "Fluid milk (plain)". • Sodium citrate is a known acidity regulator, and in milk is reported as an adulterant which can mask the developed acidity of milk (Coitinho et al., 2017). There has been report of milk adulteration by use of Sodium Citrate along with other adulterants like sodium hydroxide, sodium chloride, sucrose, phosphates, etc. to correct milk defects, such as high acidity and microbial growth (Jeffrey Hoorfar, 2012)2. • Addition of citrates results in concentration of ionic calcium and increased solubilization of colloidal calcium phosphate (CCP) possibly due to increased hydration of casein micelles. This further leads to increased dissociation of caseins from casein micelles. This altered structure of casein micelles results in increase in the milk coagulation time (Pastorino, J. et al., 2003)3. • As per National Food Regulation, total sodium content in the milk shall not be more than 650mg/100gm SNF. This parameter supports in determination of adulteration with	**India**

COMMENT	MEMBER / OBSERVER
sodium salts in milk. Therefore, if Trisodium citrate will be permitted in milk it will promote adulteration with other sodium salts to mask acidity. • Further, it will be very difficult to differentiate between whether the total sodium content is increased in milk due to permitted salts or because of adulteration. • Therefore, allowance of trisodium citrate in plain milk will encourage malpractices and adulteration of milk and will also increase the number of additives allowed for use in this category. References: 1 Coitinho, T. B., Cassoli, L. D., Cerqueira, P. H. R., da Silva, H. K., Coitinho, J. B., & Machado, P. F. (2017). Adulteration identification in raw milk using Fourier transform infrared spectroscopy. Journal of food science and technology, 54(8), 2394-2402. 2 Hoorfar, J. (Ed.). (2012). Case studies in food safety and authenticity: Lessons from real-life situations. Elsevier. 3 Pastorino, J., Hansen, C. L., & McMahon, D. J. (2003). Effect of sodium citrate on structure-function relationships of Cheddar cheese. Journal of dairy science, 86(10), 3113-3121.	
Indonesia supports the use of trisodium citrate (INS.331(iii)) in food category 01.1.1 Fluid milk (plain) with maximum level at GMP. Indonesia considers that the use of trisodium citrate is technologically justified as acidity regulator in food category 01.1.1 to maintain pH with buffering system.	**Indonesia**
Kenya objects the use of trisodium citrate (INS 331(iii)) in Food Category 01.1.1 “Fluid milk (plain). Justification: CXS 192 (GSFA) (Clause 3.1 c) guides that the food additives should be used in ‘lowest level necessary to achieve the intended technical effect’ and its use among other conditions, ‘are justified only when such use has an advantage’ (Clause 3.2 of CXS 192). This means the technological justification has to be a major factor of consideration which according to Para 9 of REP21/FA seemed not to be the case with majority of Codex Members. During CCFA51, Kenya had raised concern and requested for information on specific condition (s) under which such additives may be used (REP19/FA, Para 76). . We note that in CCFA52 (REP21/FA, Para 11 (ii)), Countries interested or with justification to use the additive had the option for a regional standard to address their specific need. As a Country, our priority is to reduce the use of food additives to the extent possible and only have them used in cases where no alternative exists and in total compliance of the preamble of CXS 192, which has been adopted as Kenya Standard to guide the safe use of food additives. In the case of UHT milk, within the Country have not recorded sufficient complaints from consumers on sedimentations neither has the industry reported any processing challenge that Kenya has had for the longest period of time. We therefore see no advantage that the use of trisodium citrate will introduce to UHT milk. Sedimentation has been observed in reconstituted milks thus in our opinion, use of trisodium citrate may lead to passing reconstituted milk as fluid milk thus misleading the consumers in making informed choices of products based on the true nature of the products as provided for by CXS 1-1985, clause 4.1.1. It is against this background that we object the inclusion of the additive in UHT milk.	**Kenya**

COMMENT	MEMBER / OBSERVER
PANAMA: Does not agree with the use of trisodium citrate (INS 331 (iii)) in food category 01.1.1 "Liquid milk (plain)". So far, there is not enough monitoring of reference data on its behavior, but it is known that in practice it could mask changes that occur in the product on a regular basis, causing damage to its sanitary quality. We could be dealing with a poor quality liquid milk masker. This has a misleading effect on the consumer, indicating that the product is healthily acceptable when this additive is not used. For our country, the additive is allowed for some dairy derivatives detailed in the Central American Technical Regulation (RTCA 67.04.54:18), but not for liquid or fluid milk. Our National legislation regarding pasteurized or UHT milk does not allow the addition of additives to these products. Reference document: • (RTCA 67.04.54:18). or http://web-sieca.s3.amazonaws.com/direccion-juridica/COMIECO/RESOLUCIONES/419-2019/ANEXO%20RES%20419-2019%20RTCA%20ADITIVOS%20VERSION%20FINAL%20-Firma%20COMIECO.pdf Panamá no está de acuerdo con el uso de citrato trisódico (SIN 331 (iii)) en la categoría de alimentos 01.1.1 "Leche líquida (natural)". Hasta el momento no se tiene suficiente acompañamiento de datos referentes a su comportamiento, pero se sabe que en la práctica podría enmascarar alteraciones ocurridas en el producto de forma regular, ocasionando afectaciones en cuanto su calidad sanitaria. Podríamos estar frente a un enmascarador de mala calidad de la leche líquida. Esto trae consigo un efecto engaño al consumidor, indicando que el producto es sanitariamente aceptable cuando no es así de llegar a utilizar este aditivo. Para nuestro país el aditivo está permitido para algunos derivados lácteos detallados en el Reglamento Técnico Centroamericano (RTCA 67.04.54:18), no así para la leche líquida o fluida. Nuestra legislación Nacional en cuanto a leche pasteurizada o UHT, no permite la adición de aditivos a estos productos. Documento referencia: • (RTCA 67.04.54:18). o http://web-sieca.s3.amazonaws.com/direccion-juridica/COMIECO/RESOLUCIONES/419-2019/ANEXO%20RES%20419-2019%20RTCA%20ADITIVOS%20VERSION%20FINAL%20-Firma%20COMIECO.pdf	**Panama**
Paraguay supports the use of trisodium citrate (INS 331 iii) in Food category 01.1.1, since it is safe, technologically necesary and is not use for the purpose of masking poor quality bovine milk.	**Paraguay**
En Perú la legislación en materia de aditivos está sujeta a lo establecido por el Codex Alimentarius, sin embargo como país se apoya el uso de citrato trisódico en la categoría de alimentos 01.1.1 “Leche líquida (natural/simple) específicamente para aquella tratada térmicamente UHT y esterilizada, y bajo un nivel máximo de uso. SUSTENTO DE USO TECNOLÓGICO: el citrato tricálcico puede utilizarse para formular productos estables al almacenamiento y al calor, bebidas con claridad mejorada que contiene una cantidad significativa de micelas de caseína; en la sedimentación en muestras de leche UHT directa al aumentar el pH con álcali o reduciendo el calcio iónico con quelantes (siendo el citrato trisódico el más efectivo)1. Estudios realizados en leche con proceso UHT mostraron que a niveles de pH inferiores a 6.65 o a niveles altos de calcio iónico eran propensos a la formación de sedimentos; estos sedimentos podían ser reducidos empleando citrato trisódico ya que este aumenta el pH y disminuye el calcio iónico2. Physicochemical properties of skim milk powder dispersions prepared with calcium-chelating sodium tripolyphosphate, trisodium citrate, and sodium hexametaphosphate. 2020 American	**Peru**

COMMENT	MEMBER / OBSERVER
Dairy Science Association®. Published by Elsevier Inc. and Fass Inc. Inseob Choi and Qixin Zhong* Department of Food Science, The University of Tennessee, Knoxville 37996. 2.Sedimentation in UHT milk.International Dairy Journal.Volume 78, March 2018, Pages 92-102. Vikas Gaur, Jos Schalk, Skelte G. Anema: https://www.sciencedirect.com/science/article/abs/pii/S095869461730225X	
Uganda's milk does not have a problem of milk sedimentation. Uganda therefore, does not support the use of trisodium citrate as a food additive in prevention of sedimentation, coagulation and gelation which is a common phenomenon that occurs during prolonged storage of UHT fluid milk. Justification; 1) The issue of sediment formation as a result of aggregation of K casein type of protein caused by structural changes due to high processing temperature is common in reconstituted UHT fluid milk and yet most of our processors are packing fresh UHT milk hence it is not of big concern to our industry as of now. 2) Sedimentation during storage can be reversed upon mixing by resuspending protein layer. 3) Most of the problems of sedimentation and gelation occur due to use of poor quality raw milk whose PH is above 6.65 and processing raw milk with low Heat coagulation temperature. Majority of our processors if not all currently process UHT milk from resazurin 6 which is the highest grade for it to withstand heat stability. 4) Sedimentation occurs during prolonged storage of UHT plain milk beyond six months and violation of storage conditions especially storage of UHT milk above 30 degrees for a long time. Most of Ugandan fluid milk has shelf life ranging between 3months to 6months and with adherence to storage conditions and appropriate UHT processing conditions and recommended packaging material, sedimentation is not a likely problem neither has it been identified during routine testing to necessitate use of trisodium citrate in stabilization of fluid milk during storage. Whereas it's use is technologically acceptable, it's likely misuse by industry players if allowed can cause more food safety issues as opposed to sensory alteration of milk that has undergone sedimentation. Therefore, we should focus more on training and equipping industry players on how to prevent such problems during storage rather than give them a Lee way to use of chemical preservation whose usage we might not have capacity to control and monitor in the event that we allow it's usage. We therefore do not support use of trisodium citrate because coagulation should be controlled by use of high quality raw milk and using appropriate heat treatment methods, followed by recommended packaging and storage conditions. Sedimentation is not a food safety issue of concern because it affects more of sensory properties which can be reversed by physical mixing. In addition to Uganda's comments submitted earlier in the Codex online commenting system, Uganda wishes to submit the following additional evidence to back her position of no addition of trisodium citrate in fluid milk. Examining the potential of Trisodium Citrate (TSC) to alter or mask quality of raw fluid milk and UHT pasteurised milk i. Data from the Ugandan industries shows UHT milk sedimentation is not a problem. Additionally, the raw milk used for UHT has resazurin 6, grade 1 which has not shown any sedimentation even over long term storage.	**Uganda**

COMMENT	MEMBER / OBSERVER
ii. Trisodium citrate increases the ethanol stability of milk. Thus, a much higher concentration of ethanol is needed to get milk curdling in the alcohol test. Thus poor quality milk, to which trisodium citrate is added, can pass the ethanol test therefore, masking the bad quality. iii. Due to its strong buffering capacity, trisodium citrate will facilitate unscrupulous milk dealers to mask poor quality in milk thus passing off low pH/low heat stability milk as good quality milk. iv. Both low and high ionic calcium can cause sedimentation. Thus, use of trisodium citrate is not necessarily a full proof solution to milk sedimentation. v. The issue of UHT milk sedimentation can be addressed by adjusting to an appropriate UHT heating regime without addition of any additive. vi. Trisodium citrate can be used as part of the cattle feeding/nutrition program as a prophylactic to help stem mastitis, which often substantially contributes to UHT milk sedimentation. vii. Trisodium citrate is regarded as GRAS. However, it may be misused by unscrupulous industrial players thus compromising milk quality. Toxicological reports indicate no safety issues is with the food additive but quality issues are of concern. viii. Current harmonised East African Community standards for raw milk and UHT pasteurised milk do not allow addition of any food additives in milk. These are regional standards adopted by all Partner States in East African Community. • Key argument: TSC affects rheology of fluid milk – could interfere with results of routine platform tests conducted for raw fluid milk in Uganda and many other LMICs thus masking possible poor quality of milk. Platform Tests 1. Appearance of milk: Milk should be free from any churned fat globules and/or any clots. 2. Clot-on-boiling test (acidic milk or mastitis milk). Typically, samples that fail this test might contain acid-producing bacteria and must be rejected. 3. Both low and high ionic calcium can cause sedimentation 4. Reduction of sedimentation in UHT milk Summary of evidence • Ling Yang 2018 – TSC added to raw milk (20 – 40 mmol/L) dissociated particles of yak (domesticated cattle in China) milk into smaller particles – affects milk consistence. • Ozcan-Yilsay et al. 2006 – TSC added to milk for use in yoghurt processing reduced casein-bound calcium and increased solubilisation of colloidal calcium phosphate in milk. Note: This is a positive effect but we need to examine it's implication in raw milk testing.-potential to ulter physical attributes of raw milk testing.-potential to ulter physical attributes of raw milk. • Udabage et al. 2020 – Addition of citrate to skimmed milk reduces the storage modulus, 'G' of milk. In rheology, is the elastic response or measure of the amount of energy stored in a fluid material. This affects enables TSC to be used as an emulsifying stabilizer. Hence can affect/prevent coagulation of poor quality milk.- prevents coagulation of poor quality milk , masks quality. • Chen et al, 2012; J. Dairy Sci. 95 :1057–1063 • Gaur, 2017 Conclusion	

COMMENT	MEMBER / OBSERVER
Uganda concludes that 'NO use of trisodium citrate in fluid milk' because its use alters the nature of the product, masking poor quality, misleading consumers and potential misuse. References https://downloads.hindawi.com/journals/jfq/2018/1875892.pdf https://www.sciencedirect.com/science/article/pii/S0022030207716508 https://www.cambridge.org/core/journals/journal-of-dairy-research/article/abs/mineral-and-casein-equilibria-in-milk-effects-of-added-salts-and-calciumchelating-agents/CE3C6FDF497B1CFC4A89D0270D67AD2B http://dx.doi.org/10.3168/jds.2011-4367 https://ir.canterbury.ac.nz/bitstream/handle/10092/14649/Gaur,%20Vikas_Final%20PhD%20Thesis.pdf?sequence=1	
En el ámbito del MERCOSUR, se permite el agregado de citrato de sodio con función de estabilizante en las leches UAT (UHT), en una concentración quantum satis, es decir, la cantidad necesaria para obtener el efecto tecnológico deseado (Res. GMC N° 135/96 Reglamento Técnico MERCOSUR sobre Identidad y Calidad de la leche U.A.T. (U.H.T) (modificatoria de la GMC N° 78/94). En el proceso de revisión actual de la norma, el citrato se mantendrá como aditivo permitido en este tipo de productos. Por lo cual, Uruguay considera que puede contemplarse su uso para las leches UAT y otras leches con tratamientos térmicos similares, dada la necesidad presentada por algunos países en virtud de las características de su producción, considerando que no hay preocupación de salud al no tener IDA limitada.	**Uruguay**
IDF has surveyed its membership and due to mixed responses is not able to support either of the proposed positions. We note that no concerns have been raised with the use of trisodium citrates, and no usage level has been reported either. IDF members reported that EU legislation as well as legislation in New Zealand and Switzerland, allowed for the use of INS 331(ii) in the product falling under the GSFA category 1.1.1 for UHT goat milk (either with a ML of 4000 mg/l or at GMP). The justification is that goat milk is much less heat stable than cow milk and it is therefore more challenging to produce UHT goat milk compared to UHT cow milk. 6 other countries responded that it was not allowed under their legislation.	**IDF/FIL**