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# NF VALIDATION
# Validation of alternative analytical methods
*Application in food microbiology*

## Summary report

Validation study according to the EN ISO 16140-2:2016

## ESIA™ One Day method

(Certificate number: BIO 12/37 - 11/14)

**for the detection of *Cronobacter* spp. in:**

- **Milk powders, infant formula and infant cereals without probiotics including ingredients (25 g sample size)**
- **Infant formula and infant cereals with probiotics (25 g sample size)**
- **Milk powder, infant formula and infant cereals with or without probiotics including ingredients (excluding whey protein concentrates) (375 g sample size)**
- **Production environmental samples**

### Qualitative method

| | |
|---|---|
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This report consists of 73 pages, including 6 appendices.
Only copies including the totality of this report are authorised.
Competencies of the laboratory are certified by COFRAC accreditation for the analyses marked with the symbol◆.

Version 0
03 November 2022.

Quality Assurance documents related to this study can be consulted upon request from **bioMérieux**.

The technical protocol and the result interpretation were carried out according to the EN ISO 16140-2:2016 and the AFNOR technical rules (PR Revision 7).

| | |
|---|---|
| **Validation protocols** | ▪ ISO 16140-1 (2016): Microbiology of the food chain - Method validation — *Part 1: Vocabulary*<br>▪ ISO 16140-2 (2016): Microbiology of the food chain - Method validation — *Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*<br>▪ AFNOR technical rules (PR Revision 7). |
| **Reference method**♦ | ISO 22964 (April 2017) - Microbiology of the food chain - Horizontal method for the detection of *Cronobacter* spp. |
| **Alternative method** | **ESIA™ One Day for *Cronobacter* spp.** |
| **Scope** | ☒ **Milk powders, infant formula and infant cereals without probiotics including ingredients** *(25 g sample size)*<br>☒ **Infant formula and infant cereals with probiotics** *(25 g sample size)*<br>☒ **Milk powder, infant formula and infant cereals with or without probiotics including ingredients (excluding whey protein concentrates)** *(375 g sample size)*<br>☒ **Production environmental samples** |
| **Certification organism** | AFNOR Certification (http://nf-validation.afnor.org/) |

♦ Analyses performed according to the COFRAC accreditation

# 1 INTRODUCTION

The ESIA™ One Day method was validated in November 2014 (Certificate number BIO 12/37 - 11/14), according to EN ISO 16140:2003 against the ISO/TS 22964:2006 reference method.

The revision of the reference method was published in April 2017. As the modifications between the ISO/TS 22964:2006 and the ISO 22964:2017 are considered as major, the following parts of the validation were run again:

- Method comparison study:
    * Sensitivity study,
    * Relative level of detection.

- Inter-laboratory study.

The following categories were tested:

- Milk powders, infant formula and infant cereals without probiotics including ingredients *(25 g sample size)*,
- Infant formula and infant cereals with probiotics (*25 g sample size)*,
- Milk powder, infant formula and infant cereals with or without probiotics including ingredients (excluding whey protein concentrates) *(375 g sample size)*,
- Production environmental samples.

The certification was renewed in October 2022.

# 2 METHOD PROTOCOLS

## 2.1 Alternative method

The flow diagram of the alternative method is provided in **Appendix 1**.

### 2.1.1 Principle

The ESIA One Day method is based on an enrichment step and streaking on a chromogenic selective Agar plate, ESIA (*Enterobacter sakazakii* isolation Agar). *Cronobacter* spp. appears as blue colonies on the plates.

### 2.1.2 Protocol

Different enrichment protocols are available depending on the tested categories and sample sizes; they are described in **Table 1**.

## Table 1 Enrichment protocols

| Protocol steps | Protocol ① Milk powder, infant formula and infant cereals without probiotics including ingredients | Protocol ② Infant formula and infant cereals with probiotics | Protocol ③ Milk powder, infant formula and infant cereals with or without probiotics | Protocol ④ Ingredients *(excluding whey protein concentrates)* | Protocol ① Production environmental samples |
|---|---|---|---|---|---|
| **Test portion** | 25 g | 25 g | 375 g | 375 g | 25 g or ml or sample device |
| **Enrichment broth** | BPW* | BPW* + Novobiocin (10 mg/l) | Pre-warmed BPW* + Novobiocin (10 mg/l) | Pre-warmed BPW | BPW |
| **Volume of enrichment broth** | 225 ml | 225 ml | 1 875 ml (d 1/6) | 3 375 ml (d 1/10) | 225 ml or 10 ml (swab) or 100 ml (sponge) or 225ml (wipe) |
| **Incubation** | 18 - 24 h at 37°C ± 1°C | 18 - 24 h at 37°C ± 1°C | 20 - 26h at 37°C ± 1°C | 20 - 26 h at 37°C ± 1°C | 18 - 24 h at 37°C ± 1°C |
| **Streaking** | 10 µl onto ESIA plate<br>Incubation at 44°C ± 1°C for 24 h ± 3 h | | | | |
| **Confirmation** | Typical colonies are confirmed by:<br>- The tests described in the reference method after purification step (Oxidase + API ID32E)<br>- API ID 32E on isolated colony without purification step;<br>- Fast Crono confirmation test<br>- VITEK MS / VITEK MS PRIME TEST | | | | |

*Addition of α-amylase for infant cereals (0.1 g/l)

It is possible to store the enrichment broths for 72 h at 5°C ± 3°C before testing and confirmation.

### 2.1.3 Restrictions

There is no restriction for use.

## 2.2 Reference method◆

The reference method is the ISO 22964 (April 2017) - Microbiology of the food chain - Horizontal method for the detection of *Cronobacter* spp. (See **Appendix 2**).

Note that, based on previous data, big sample sizes cannot be used in the reference method procedure due to the impact on the detection levels and the sensitivity performances.

## 2.3 Study design

As different sample sizes were tested for the reference (10 g) and the alternative methods, it was an unpaired study design for all tested categories except for the type c (surfaces) in the production environmental category

# 3 INITIAL VALIDATION, EXTENSION/RENEWAL STUDIES: RESULTS

## 3.1 Method Comparison Study

***The method comparison study is a study performed by the expert laboratory to compare the alternative method with the reference method.***

*The study was carried out on a diversity of samples and strains representative of agri-food products. This does not constitute an exhaustive list of the different matrices included in the scope.*
*For any comment on the alternative method, please contact AFNOR Certification at http://nf-validation.afnor.org/contact-2/.*

◆ Analysis performed according to the COFRAC accreditation

### 3.1.1 Sensitivity study

*The sensitivity (SE) is the ability of the method to detect the analyte by either the reference or alternative method.*

#### 3.1.1.1 Number and nature of samples

**344 samples were analyzed, providing 178 positive and 166 negative results**. The distribution per tested category and type is given in Table 2.

**Table 2 – Distribution per tested category and type**

| Category | | Type | | Positive samples | Negative samples | Total |
|---|---|---|---|---|---|---|
| 1 | Milk powders and ingredients, infant formula and infant cereals without probiotics | a | *Infant formula* | 11 | 11 | 22 |
| | | b | *Infant cereals* | 11 | 11 | 22 |
| | | c | *Ingredients: lactoserum, maltodextrin …* | 16 | 15 | 31 |
| | | | **Total** | 38 | 37 | 75 |
| 2 | Infant formula and infant cereals with probiotics | a | *Infant formula* | 16 | 16 | 32 |
| | | b | *Infant cereals* | 15 | 17 | 32 |
| | | | **Total** | 31 | 33 | 64 |
| 3 | Milk powders, ingredients, infant formula and infant cereals with or without probiotics 375g | a | *Milk powders, Infant formula and infant cereals without probiotics* | 22 | 15 | 37 |
| | | b | *Infant formula and infant cereals with probiotics* | 19 | 15 | 34 |
| | | c | *Ingredients: maltodextrin, whey, lactose, starch, caseinate,…* | 33 | 31 | 64 |
| | | | **Total** | 74 | 61 | 135 |
| 4 | Production environmental samples | a | *Process water* | 11 | 11 | 22 |
| | | b | *Residues and dusts* | 12 | 10 | 22 |
| | | c | *Surfaces* | 12 | 14 | 26 |
| | | | **Total** | 35 | 35 | 70 |
| **All categories** | | | | **178** | **166** | **344** |

#### 3.1.1.2 Artificial contamination of samples

Artificial contaminations were done by seeding (lyophilized strains or suspensions) or spiking (heat injured strain) protocol. The artificial contaminations are presented in **Appendix 3**.

197 samples were artificially contaminated, using 56 different strains. 168 gave a positive result.
The repartition of the positive samples per inoculation protocol and inoculation level is given in Table 3.

**Table 3 - Repartition of the positive samples per inoculation protocol and inoculation level**

| | Artificially contaminated | | | | Naturally contaminated | Total |
|---|---|---|---|---|---|---|
| | Seeding | | Spiking | | | |
| | ≤ 3 CFU | 3<x≤10 | ≤ 5 CFU | 5<x≤10 | | |
| Number of positive samples | 127 | 34 | 7 | 0 | 10 | 178 |
| % | 71,3% | 19,1% | 3,9% | 0,0% | 5,6% | 100,0% |

**5.6 % of the samples were naturally contaminated.**

### *3.1.1.3 Protocols applied during the validation study*

> **Incubation time**

The following incubation times were applied (See Table 4).

**Table 4 - Incubation time**

| | Protocols ① and ② | Protocols ③ and④ |
|---|---|---|
| Enrichment | 18 h | 20 h |
| ESIA | 21 h | |

> **Confirmation protocols**

The different confirmation protocols which were applied during the validation study are listed in Table 4.

**Table 5 - Confirmation protocols**

| Media | | After enrichment broth incubation | After enrichment broth storage |
|---|---|---|---|
| ESIA with purification step onto TSA | Oxidase test | X | / |
| | API ID 32E | X | / |
| ESIA without purification step | API ID 32E | X | X |
| | Fast Crono | X | X |

As the use of VITEK MS was validated in a specific extension study using 152 *Cronobacter* strains and 100 non-target strains, this option was not tested for the study. The extension for the VITEK MS PRIME was presented and accepted in June 2022.

In addition, all the broths with a negative result were transferred to CSB and then streaked on CCI Agar plates.

> **Enrichment broth storage**

The positive samples were tested again after storage of the enrichment broth for 72 h at 5°C ± 3°C.

#### *3.1.1.4 Test results*

Raw data per category are given in **Appendix 4**. The results are given in Table 6.

**Table 6 – Interpretation of sample results between the reference and alternative method (based on the confirmed alternative)**

| Category | | PA | NA* | PD | ND** | TOTAL |
|---|---|---|---|---|---|---|
| 1 | Milk powders and ingredients, infant formula and infant cereals without probiotics | 21 | 37 | 9 | 8 | 75 |
| 2 | Infant formula and infant cereals with probiotics | 16 | 33 | 9 | 6 | 64 |
| 3 | Milk powders, ingredients, infant formula and infant cereals with or without probiotics 375g | 55 | 61 | 10 | 9 | 135 |
| 4 | Production environmental samples | 33 | 35 | 2 | 0 | 70 |
| **All the categories** | | **125** | **166** | **30** | **23** | **344** |

* PPNA not included ** PPND not included

#### *3.1.1.5 Calculation of relative trueness (RT), sensitivity (SE) and false positive ratio (FPR)*

The calculations are presented in Table 7.

**Table 7 – Calculation of the relative trueness (RT), the sensitivity (SE) and the false positive ratio (FPR)**

| Category | | Type | | PA | NA* | PD | ND** | PPND | PPNA | SE $_{alt}$ % | SE $_{ref}$ % | RT % | FPR % |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | Milk powders and ingredients, infant formula and infant cereals without probiotics | a | *Infant formula* | 6 | 11 | 2 | 3 | 0 | 0 | 72,7 | 81,8 | 77,3 | 0 |
| | | b | *Infant cereals* | 6 | 11 | 3 | 2 | 0 | 0 | 81,8 | 72,7 | 77,3 | 0 |
| | | c | *Ingredients: lactoserum, maltodextrin, milk powders.* | 9 | 15 | 4 | 3 | 0 | 0 | 81,3 | 75,0 | 77,4 | 0,0 |
| | | | **Total** | 21 | 37 | 9 | 8 | 0 | 0 | 78,9 | 76,3 | 77,3 | 0,0 |
| 2 | Infant formula and infant cereals with probiotics | a | *Infant formula* | 7 | 16 | 6 | 3 | 0 | 0 | 81,3 | 62,5 | 71,9 | 0,0 |
| | | b | *Infant cereals* | 9 | 17 | 3 | 3 | 0 | 0 | 80,0 | 80,0 | 81,3 | 0,0 |
| | | | **Total** | 16 | 33 | 9 | 6 | 0 | 0 | 80,6 | 71,0 | 76,6 | 0,0 |
| 3 | Milk powders, ingredients, infant formula and infant cereals with or without probiotics 375g | a | *Milk powders, Infant formula and infant cereals without probiotics* | 14 | 15 | 3 | 5 | 0 | 0 | 77,3 | 86,4 | 78,4 | 0,0 |
| | | b | *Infant formula and infant cereals with probiotics* | 16 | 15 | 2 | 1 | 0 | 0 | 94,7 | 89,5 | 91,2 | 0,0 |
| | | c | *Ingredients: maltodextrin, whey, lactose, starch, caseinate…* | 25 | 30 | 5 | 3 | 0 | 1 | 90,9 | 84,8 | 87,5 | 3,2 |
| | | | **Total** | 55 | 60 | 10 | 9 | 0 | 1 | 87,8 | 86,5 | 85,9 | 1,6 |
| 4 | Production environmental samples | a | *Process water* | 10 | 11 | 1 | 0 | 0 | 0 | 100,0 | 90,9 | 95,5 | 0 |
| | | b | *Residues and dusts* | 11 | 9 | 1 | 0 | 0 | 1 | 100,0 | 91,7 | 95,5 | 10 |
| | | c | *Surfaces* | 12 | 14 | 0 | 0 | 0 | 0 | 100 | 100,0 | 100,0 | 0,0 |
| | | | **Total** | 33 | 34 | 2 | 0 | 0 | 1 | 100,0 | 94,3 | 97,1 | 2,9 |
| **All the categories** | | | | **125** | **164** | **30** | **23** | **0** | **2** | **87,1** | **83,1** | **84,6** | **1,2** |

* PPNA not included ** PPND not included

A summary of the results is given in Table 8.

**Table 8 - Summary of results**

| | | |
|---|---|---|
| **Sensitivity for the alternative method** | $SE_{alt} = \frac{(PA+PD)}{(PA+ND+PD)} \times 100\%$ | 87.1 % |
| **Sensitivity for the reference method** | $SE_{ref} = \frac{(PA+ND)}{(PA+ND+PD)} \; x \; 100\,\%$ | 83.1 % |
| **Relative trueness** | $RT = \frac{(PA+NA)}{N} \times 100\%$ | 84.6 % |
| **False positive ratio for the alternative method* FP = PPNA + PPND** | $FPR = \frac{(FP)}{NA} \times 100\%$ | 1,2 % |

*With* *ND = ND + PPND*
*NA = NA + PPNA*

### *3.1.1.6 Analysis of discordant results*

The negative deviations are given in Table 9 and the positive deviations in Table 10.

23 negative deviations were observed, all on artificially contaminated samples.

For all the samples, a subculture is CSB broth was carried out before streaking onto CCI Agar in order to have the same incubation time and steps as the reference method. Two additional positive results were observed when using this protocol: samples 2620 (infant formula with probiotics) and 3126 (starch). This is probably due to the seeding protocol used (lyophilizate) and the inoculation level.

30 positive deviations were observed: 26 on artificially contaminated samples and 4 on naturally contaminated samples (375 g sample size).

## Table 9 - Negative deviations

| Sample N° | Product | Artificial contamination (spiking protocol) | | Protocol | ISO 22964♦ Result | Alternative method: ESIA One Day | | | | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Strain | Inoculation level (CFU/sample) | | | Typical colonies | Confirmation | Final result | Agreement | | |
| **7621** | **Infant formula without probiotics** | *C. sakazakii* Ad1446 | <0,2 | 1 | + | st | / | - | **ND** | 1 | a |
| **7801** | **Infant formula without probiotics** | *C. sakazakii* Ad2396 | 0,3 | 1 | + | st | / | - | **ND** | 1 | a |
| **7802** | **Infant formula without probiotics** | *C. sakazakii* Ad1420 | 0,1 | 1 | + | st | / | - | **ND** | 1 | a |
| **7628** | **Infant cereals without probiotics** | *C. sakazakii* Ad2394 | 1,0 | 1 | + | st | / | - | **ND** | 1 | b |
| **7630** | **Infant cereals without probiotics** | *C. sakazakii* Ad2400 | 2,0 | 1 | + | - | / | - | **ND** | 1 | b |
| **7633** | **Milk proteins** | *C. sakazakii* Ad1420 | 0,7 | 1 | + | st | / | - | **ND** | 1 | c |
| **2610** | **Whole milk powder** | *C. muytjensis* E769 | 1,0 | 1 | + | - | / | - | **ND** | 1 | c |
| **2613** | **Skim milk powder** | *C. muytjensis* E888 | <0,25 | 1 | + | st | / | - | **ND** | 1 | c |
| **8027** | **Infant formula with probiotics (3,6.10$^{2}$ CFU/g)** | *C. sakazakii* Ad2370 | 0,6 | 2 | + | st | / | - | **ND** | 2 | a |
| **8031** | **Infant formula with probiotics (1,8.10$^{5}$ CFU/g)** | *C. sakazakii* Ad2350 | 0,3 | 2 | + | st | / | - | **ND** | 2 | a |
| **8033** | **Infant formula with probiotics (4,8.10$^{5}$ CFU/g)** | *C. sakazakii* Ad2348 | 2,1 | 2 | + | st | / | - | **ND** | 2 | a |
| **8035** | **Infant cereals with probiotics (7,1.10$^{4}$ CFU/g)** | *C. sakazakii* Ad2370 | 0,6 | 2 | + | st | / | - | **ND** | 2 | b |
| **8037** | **Infant cereals with probiotics (2,5.10$^{5}$ CFU/g)** | *C. sakazakii* Ad2350 | 0,3 | 2 | + | st | / | - | **ND** | 2 | b |
| **8038** | **Infant cereals with probiotics (5,1.10$^{5}$ CFU/g)** | *C. sakazakii* Ad2350 | 0,3 | 2 | + | st | / | - | **ND** | 2 | b |
| **2591** | **Skim milk powder** | *C. muytjensis* E769 | 1,0 | 3 | + | st | / | - | **ND** | 3 | a |
| **2593** | **Skim milk powder** | *C. muytjensis* E888 | <0,25 | 3 | + | - | / | - | **ND** | 3 | a |
| **2596** | **Infant cereals without probiotics** | *C. turincensis* Ad1445 | 1,0 | 3 | + | st | / | - | **ND** | 3 | a |
| **2603** | **Infant formula without probiotics** | *C. sakazakii* Ad2367 | 10,0 | 3 | + | st | / | - | **ND** | 3 | a |
| **2606** | **Infant formula without probiotics** | *C. sakazakii* Ad2380 | 1,0 | 3 | + | st | / | - | **ND** | 3 | a |
| **2620** | **Infant formula with probiotics (7,2.10$^{4}$ CFU/g)** | *C. sakazakii* Ad2353 | 4,0 | 3 | + | st | / | - | **ND** | 3 | b |
| **3109** | **Starch** | *C. sakazakii* Ad946 | 2,4 | 4 | + | - | / | - | **ND** | 3 | c |
| **3111** | **Corn starch** | *C. sakazakii* Ad2286 | 0,8 | 4 | + | - | / | - | **ND** | 3 | c |
| **3126** | **Wheat starch** | *C. sakazakii* Ad2288 | 2,3 | 4 | + | st | / | - | **ND** | 3 | c |

♦ Analyses performed according to the COFRAC accreditation

## Table 10 - Positive deviations

| Sample N° | Product | Artificial contamination (spiking protocol) | | Protocol | ISO 22964♦ Result | Alternative method : ESIA One Day | | | | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Strain | Inoculation level (CFU/sample) | | | Typical colonies | Confirmation | Final result | Agreement | | |
| **7622** | **Infant formula without probiotics** | *C. sakazakii* Ad1420 | 0,7 | 1 | - | +p | + | + | **PD** | 1 | a |
| **7623** | **Infant formula without probiotics** | *C. sakazakii* Ad2394 | 1,0 | 1 | - | +p | + | + | **PD** | 1 | a |
| **7631** | **Infant cereals without probiotics** | *C. sakazakii* Ad1446 | <0,2 | 1 | - | +p | + | + | **PD** | 1 | b |
| **7798** | **Infant cereals without probiotics** | *C. sakazakii* Ad893 | 4,7 | 1 | - | +p | | + | **PD** | 1 | b |
| **9130** | **Infant cereals without probiotics** | *C. sakazakii* Ad2413 | 0,7 | 1 | - | +p | + | + | **PD** | 1 | b |
| **7635** | **Caseinate** | *C. sakazakii* Ad2395 | 1,7 | 1 | - | +p | + | + | **PD** | 1 | c |
| **7805** | **Corn flour** | *C. sakazakii* Ad2383 | 0,6 | 1 | - | +p | + | + | **PD** | 1 | c |
| **8459** | **Whey protein concentrate** | *C. sakazakii* Ad2349 | 3,0 | 1 | - | +p | + | + | **PD** | 1 | c |
| **2612** | **Skim milk powder** | *C. muytjensis* E888 | <0,25 | 1 | - | +pd | + | + | **PD** | 1 | c |
| **8028** | **Infant formula with probiotics (<10 CFU/g)** | *C. sakazakii* Ad2370 | 0,6 | 2 | - | +p | + | + | **PD** | 2 | a |
| **8029** | **Infant formula with probiotics (1,3.$10^5$ CFU/g)** | *C. sakazakii* Ad2370 | 0,6 | 2 | - | +p | + | + | **PD** | 2 | a |
| **8032** | **Infant formula with probiotics (3,0.$10^4$ CFU/g)** | *C. sakazakii* Ad2348 | 2,1 | 2 | - | +M | + | + | **PD** | 2 | a |
| **8135** | **Infant formula with probiotics (4,2.$10^5$ CFU/g)** | *C. sakazakii* Ad2352 | 0,7 | 2 | - | +p (3) | + | + | **PD** | 2 | a |
| **8448** | **Infant formula with probiotics (4,2.$10^5$ CFU/g)** | *C. turincensis* Ad1445 | 6,0 | 2 | - | +p | + | + | **PD** | 2 | a |
| **9610** | **Infant formula with probiotics (4,2.$10^5$ CFU/g)** | *C. sakazakii* Ad940 | 1,6 | 2 | - | +p | + | + | **PD** | 2 | a |
| **8140** | **Infant cereals with probiotics (7,1.$10^4$ CFU/g)** | *C. sakazakii* Ad2361 | 0,7 | 2 | - | +p | + | + | **PD** | 2 | b |
| **9126** | **Infant cereals with probiotics (7,1.$10^4$ CFU/g)** | *C. sakazakii* Ad2413 | 0,7 | 2 | - | +p | + | + | **PD** | 2 | b |
| **9127** | **Infant cereals with probiotics (5,6.$10^5$ CFU/g)** | *C. sakazakii* Ad2413 | 0,7 | 2 | - | +p | + | + | **PD** | 2 | b |
| 2640 | Skim milk powder | | | 3 | - | +p | + | + | **PD** | 3 | a |
| 2649 | Infant cereals without probiotics | | | 3 | - | +m/+ | + | + | **PD** | 3 | a |
| **3472** | **Infant formula without probiotics** | *C. sakazakii* Ad2411 | 3,4 | 3 | - | +p | + | + | **PD** | 3 | a |
| **2636** | **Infant cereals with probiotics (3,2.$10^6$ CFU/g)** | *C. sakazakii* SU12-74 | 0,9 | 3 | - | +p | + | + | **PD** | 3 | b |
| 2869 | Infant formula with probiotics (9,6.$10^6$ CFU/g) | | | 3 | - | +M | + | + | **PD** | 3 | b |
| **3104** | **Wheat starch** | *C. sakazakii* Ad916 | 1,5 | 4 | - | +p | + | + | **PD** | 3 | c |
| **3112** | **Wheat starch** | *C. sakazakii* Ad2286 | 0,8 | 4 | - | +p | + | + | **PD** | 3 | c |
| 3631 | Starch | | | 4 | - | +p | + | + | **PD** | 3 | c |
| 3642 | Starch | | | 4 | - | +p | + | + | **PD** | 3 | c |
| 3643 | Starch | | | 4 | - | +p | + | + | **PD** | 3 | c |
| **2467** | **Process water (rinse)** | *C. sakazakii* Ad1226 | 7,6 | 1 | - | +p | + | + | **PD** | 4 | a |
| **3146** | **Dust from vacuum** | *C. sakazakii* SU 12-7 | 1,5 | 1 | - | +p | + | + | **PD** | 4 | b |

♦ Analyses performed according to the COFRAC accreditation

The analyses of discordant results according to the EN ISO 16140-2:2016 is the following (See Table 11).

## Table 11 - Analyses of discordant results

| Category | | Type | | Study design | N+ | ND | PPND | PD | Paired study | | | | Unpaired study | | Combined | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | (ND+ PPND)-PD | AL | (ND+ PPND)+PD | AL | (ND+ PPND)-PD | AL | (ND+ PPND)-PD | AL |
| 1 | **Milk powders and ingredients, infant formula and infant cereals without probiotics** | a | *Infant formula* | Unpaired | 11 | 3 | 0 | 2 | | | | | 1 | | 1 | |
| | | b | *Infant cereals* | Unpaired | 11 | 2 | 0 | 3 | | | | | -1 | | -1 | |
| | | c | *Ingredients: lactoserum, maltodextrin, milk powders.* | Unpaired | 16 | 3 | 0 | 4 | | | | | -1 | | -1 | |
| | | | | **Total** | **38** | 8 | 0 | 9 | | | | | **-1** | **3** | **-1** | **3** |
| 2 | **Infant formula and infant cereals with probiotics** | a | *Infant formula* | Unpaired | 16 | 3 | 0 | 6 | | | | | -3 | | -3 | |
| | | b | *Infant cereals* | Unpaired | 15 | 3 | 0 | 3 | | | | | 0 | | 0 | |
| | | | | **Total** | **31** | 6 | 0 | 9 | | | | | **-3** | **3** | **-3** | **3** |
| 3 | **Milk powders, ingredients, infant formula and infant cereals with or without probiotics 375g** | a | *Milk powders, Infant formula and infant cereals without probiotics* | Unpaired | 22 | 5 | 0 | 3 | | | | | 2 | | 2 | |
| | | b | *Infant formula and infant cereals with probiotics* | Unpaired | 19 | 1 | 0 | 2 | | | | | -1 | | -1 | |
| | | c | *Ingredients: maltodextrin, whey, lactose, starch, caseinate…* | Unpaired | 33 | 3 | 0 | 5 | | | | | -2 | | -2 | |
| | | | | **Total** | **74** | 9 | 0 | 10 | | | | | **-1** | **3** | **-1** | **3** |
| 4 | **Production environmental samples** | a | *Process water* | Unpaired | 11 | 0 | 0 | 1 | | | | | -1 | | -1 | |
| | | b | *Residues and dusts* | Unpaired | 12 | 0 | 0 | 1 | | | | | -1 | | -1 | |
| | | c | *Surfaces* | Paired | 12 | 0 | 0 | 0 | 0 | | 0 | | | | 0 | |
| | | | | **Total** | **35** | 0 | 0 | 2 | **0** | **3** | **0** | **6** | **-2** | **3** | **-2** | **3** |
| **All the categories** | | | | | **178** | **23** | **0** | **30** | **0** | **3** | **0** | **3** | **-7** | **5** | **-7** | **5** |

**The observed values for (ND + PPND) - PD) and (ND + PPND + PD) meet the acceptability limit for each individual category and for all the combined categories (observed values<AL).**

#### *3.1.1.7 Enrichment broth storage at 5 ± 3 °C for 72 h*

The following changes were observed (See Table 12).

**Table 12 - Changes observed after storage**

| Sample N° | Product | Agreement before storage | Agreement after storage | Category | Type |
|---|---|---|---|---|---|
| 2611 | Skim milk powder | PA | ND | 1 | c |
| 8454 | Infant cereals with probiotics ($7,1.10^4$ CFU/g) | PA | ND | 2 | b |
| 2602 | Infant formula without probiotics | PA | ND | 3 | a |
| 3125 | Maltodextrine | PA | ND | 3 | c |
| 3146 | Dust from vacuum | PD | NA | 4 | b |

The analyses of discordant results become (See Table 13).

## Table 13 - Analysis of discordant after storage 72 h at 5 ± 3°C

| | | | | | | | | | Paired study | | | | Unpaired study | | Combined | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Category | | | Type | Study design | N+ | ND | PPND | PD | (ND+ PPND)-PD | AL | (ND+ PPND)+PD | AL | (ND+ PPND)-PD | AL | (ND+ PPND)-PD | AL |
| 1 | **Milk powders and ingredients, infant formula and infant cereals without probiotics** | a | *Infant formula* | Unpaired | 11 | 3 | 0 | 2 | | | | | 1 | | 1 | |
| | | b | *Infant cereals* | Unpaired | 11 | 2 | 0 | 3 | | | | | -1 | | -1 | |
| | | c | *Ingredients: lactoserum, maltodextrin, milk powders.* | Unpaired | 16 | 4 | 0 | 4 | | | | | 0 | | 0 | |
| | | | | **Total** | **38** | 9 | 0 | 9 | | | | | **0** | **3** | **0** | **3** |
| 2 | **Infant formula and infant cereals with probiotics** | a | *Infant formula* | Unpaired | 16 | 3 | 0 | 6 | | | | | -3 | | -3 | |
| | | b | *Infant cereals* | Unpaired | 15 | 4 | 0 | 3 | | | | | 1 | | 1 | |
| | | | | **Total** | **31** | 7 | 0 | 9 | | | | | **-2** | **3** | **-2** | **3** |
| 3 | **Milk powders, ingredients, infant formula and infant cereals with or without probiotics** | a | *Milk powders, Infant formula and infant cereals without probiotics* | Unpaired | 22 | 6 | 0 | 3 | | | | | 3 | | 3 | |
| | | b | *Infant formula and infant cereals with probiotics* | Unpaired | 19 | 1 | 0 | 2 | | | | | -1 | | -1 | |
| | | c | *Ingredients: maltodextrin, whey, lactose, starch, caseinate…* | Unpaired | 33 | 4 | 0 | 5 | | | | | -1 | | -1 | |
| | | | | **Total** | **74** | 11 | 0 | 10 | | | | | **1** | **3** | **1** | **3** |
| 4 | **Production environmental samples** | a | *Process water* | Unpaired | 11 | 0 | 0 | 1 | | | | | -1 | | -1 | |
| | | b | *Residues and dusts* | Unpaired | 11 | 0 | 0 | 0 | | | | | 0 | | 0 | |
| | | c | *Surfaces* | Paired | 12 | 0 | 0 | 0 | 0 | | 0 | | | | 0 | |
| | | | | **Total** | **34** | 0 | 0 | 1 | **0** | **3** | **0** | **6** | **-1** | **3** | **-1** | **3** |
| **All the categories** | | | | | **177** | **27** | **0** | **29** | **0** | **3** | **0** | **3** | **-2** | **5** | **-2** | **5** |

**The observed values for (ND + PPND) - PD) and (ND + PPND + PD) meet the acceptability limit for each individual category and for all the combined categories (observed values<AL)**

#### 3.1.1.8 Confirmation

All the typical colonies isolated on ESIA plates were confirmed with both confirmation procedure (API ID 32E and Fast Crono) except for two samples (1792 and 3634). In these cases, doubtful and typical colonies were respectively observed on ESIA plates and were confirmed as *Escherichia vulneris* (sample 1792) and *Leclercia adecarboxylata* (sample 3634)

### 3.1.2 Relative level of detection

*The relative level of detection is the level of detection at P = 0.50 ($LOD_{50}$) of the alternative (proprietary) method divided by the level of detection at P = 0.50 ($LOD_{50}$) of the reference method.*

The RLOD is defined as the ratio of the alternative and reference methods:

$$RLOD = \frac{LOD_{Alt.}}{LOD_{Ref.}}$$

#### 3.1.2.1 Experimental design

One matrix should be tested per category and per protocol. At least, three inoculation levels were used:

- A negative control: 5 samples,
- A low contamination level providing fractional recovery data, with 20 replicates,
- A high contamination level, with 5 replicates.

A total plate count determination on each matrix was performed to estimate the total microbial load on the day of analysis.

Four matrix/strain pairs were analyzed by the reference method and by the alternative method (See Table 14).

**Table 14 - Defined (matrix/strain) pairs for the RLOD determination**

| | Category | Matrix | Strain | Origin | Storage conditions after inoculation and before analysis | Sample size | Protocol | Study design |
|---|---|---|---|---|---|---|---|---|
| 1 | **Milk powders, infant formula and infant cereals without probiotics including ingredients** | Infant cereals | *Cronobacter dublinensis* E798 | Unknown | Seeding protocol<br>Lyophilized strain<br>2 weeks at room temperature | 25 g | ① | *Unpaired* |
| 2 | **Infant formula and infant cereals with probiotics** | Infant formula with probiotics | *Cronobacter sakazakii* Ad2413 | Dairy product | Seeding protocol<br>Lyophilized strain<br>2 weeks at room temperature | 25 g | ② | *Unpaired* |
| 3 | **Milk powders infant formula and infant cereals with or without probiotics, including ingredients** | Maltodextrin | *Cronobacter turicensis* Ad1445 | Milk powder | Seeding protocol<br>Lyophilized strain<br>2 weeks at room temperature | 375 g | ④ | *Unpaired* |
| | | Infant formula with probiotics | *Cronobacter sakazakii* Ad2412 | Infant formula | Seeding protocol<br>Lyophilized strain<br>2 weeks at room temperature | 375 g | ③ | *Unpaired* |
| 4 | **Production environmental samples** | Process water | *Cronobacter muytjensii* E888 | Milk powder | Seeding protocol<br>48 h at 5°C ± 3°C | 25 ml | ① | *Unpaired* |

### *3.1.2.2 Calculation and interpretation of the RLOD*

The raw data are given in **Appendix 5**.

The RLOD calculations were performed using the Excel spreadsheet available at http://standards.iso.org/iso/16140 - RLOD (clause 5-1-4-2 Calculation and interpretation of RLOD) version 06.07.2015. The RLOD are given Table 15.

**Table 15 – Presentation of RLOD before and after confirmation of the alternative method results**

| Name | AL | RLOD | RLODL | RLODU | b=ln(RLOD) | sd(b) | z-Test statistic | p-value |
|---|---|---|---|---|---|---|---|---|
| Infant cereals / *Cronobacter dublinensis* E798 | 2,5 | 2,063 | 0,855 | 4,980 | 0,724 | 0,441 | 1,644 | 0,100 |
| Infant formula with probiotics / *Cronobacter sakazakii* Ad2413 | 2,5 | 1,227 | 0,707 | 2,129 | 0,205 | 0,276 | 0,743 | 0,457 |
| Maltodextrin (375g) / *Cronobacter turicensis* Ad1445 | 2,5 | 1,986 | 0,951 | 4,147 | 0,686 | 0,368 | 1,863 | 0,062 |
| Infant formula with probiotics (375g) / *Cronobacter sakazakii* Ad2412 | 2,5 | 0,699 | 0,312 | 1,564 | -0,358 | 0,403 | 0,890 | 1,626 |
| Process water (rinse) / *Cronobacter muytjensii* E888 | 2,5 | 1,406 | 0,530 | 3,729 | 0,341 | 0,488 | 0,699 | 0,485 |
| **Combined** | **2.5** | 1,337 | 0,983 | 1,820 | 0,290 | 0,154 | 1,886 | 0,059 |

**The Relative Levels of Detection (RLOD) meet the Acceptability Limit (AL) for all the tested matrix/strain pairs.**

The $LOD_{50\,\%}$ calculations according to Wilrich & Wilrich POD-LOD calculation program - version 11, 2022-10-12 test are given in Table 16.

**Table 16 - $LOD_{50}$ results**

| Category | (Strain / matrix) pair | Level of detection at 50% (CFU / test portion) according to Wilrich & Wilrich[1] | |
|---|---|---|---|
| | | Reference method | Alternative method |
| 1 | Infant cereals / *Cronobacter dublinensis* E798 | 0,8 [0,5;1,4] | 1,5 [0,8;2,8] |
| 2 | Infant formula with probiotics / *Cronobacter sakazakii* Ad2413 | 0,4 [0,2;0,7] | 0,7 [0,4;1,2] |
| 3 | Maltodextrin (375g) / *Cronobacter turicensis* Ad1445 | 0,3 [0,2;0,6] | 0,7 [0,4;1,2] |
| 4 | Infant formula with probiotics (375g) / *Cronobacter sakazakii* Ad2412 | 0,6 [0,4;1,0] | 0,4 [0,3;0,8] |
| 5 | Process water (rinse) / *Cronobacter muytjensii* E888 | 0,5 [0,3;1,0] | 0,7 [0,4;1,5] |
| | **Combined results** | **0,5 [0,4;0,7]** | **0,8 [0,6;1,0]** |

**The $LOD_{50}$ varies from 0.3 to 0.8 CFU/ test portion for the reference method and from 0.4 to 1,5 CFU/ test portion for the alternative method.**

### 3.1.3 Inclusivity / exclusivity

*The inclusivity is the ability of the alternative method to detect the target analyte from a wide range of strains. The exclusivity is the lack of interference from a relevant range of non-target strains of the alternative method.*

#### 3.1.3.1 Test protocols

- **Inclusivity**

The study was run again on 50 target strains. The strains were grown in BHI and then diluted in order to inoculate between 10 to 100 cells /225 ml BPW + Novobiocin (10mg /L). The broths were then streaked onto ESIA plates before proceeding to the confirmatory tests.

- **Exclusivity**

33 non-target strains were tested for the initial validation study (study run by ISHA). 31 non-target strains were tested for the previous renewal validation study.

[1] Wilrich, C., and P.-Th. Wilrich: Estimation of the POD function and the LOD of a qualitative microbiological measurement method. AOAC International **92** (2009) 1763 - 1772.

#### 3.1.3.2 Results

Raw data are given in **Appendix 6**.

> **Inclusivity**

The 50 tested target strains gave typical colonies on ESIA plates and were confirmed using the API ID 32E or the Fast Crono test.

Note that for 15 strains, addition of milk in the BPW + Novobiocin was necessary to recover the *Cronobacter* spp. strain.

> **Exclusivity**

No cross reaction was observed with 33 and 31 non-target strains tested for initial validation and renewal validation studies respectively.

### 3.1.4 Practicability

The alternative method practicability was evaluated according to the AFNOR criteria relative to method comparison study.

| | | | |
|---|---|---|---|
| ***Storage conditions, shelf-life and modalities of utilization after first use*** | Store the plates at 2 - 8°C in their boxes until the expiry date. | | |
| ***Time to result*** | Steps | **Reference method** | **Alternative method** |
| | **Negative samples** | | |
| | Sampling, enrichment | Day 0 | Day 0 |
| | Subculture in CSB | Day 1 | / |
| | Streaking on plates | Day 2 | Day 1 |
| | Final negative result | Day 3 | Day 2 |
| | **Positive results** | | |
| | Streaking onto TSA | Day 3 | Day2 |
| | Confirmation result | Day 4 | Days 2 (tests without purification step) or 3 (tests after purification step |
| ***Common step with the reference method*** | None | | |

The negative and positive results are available in 2 days with the ESIA method, while 4 days are required for positive results with the reference method.

## 3.2 Inter-laboratory study

***The inter-laboratory study is a study performed by multiple laboratories testing identical samples at the same time, the results of which are used to estimate alternative-method performance parameters.***

### 3.2.1 Study organisation

> *Collaborators number*

15 laboratories (16 collaborators) participated to the study.
2 collaborators for Lab G were involved in the study.

> *Matrix and strain used*

Infant formula with probiotics (*Lactobacillus reuteri* DSM 17938) was inoculated with *Cronobacter sakazakii* Ad 940 strain.
In order to facilitate the study, infant formula was first homogenized in sterile water.

> *Samples*

Samples were prepared and inoculated on Monday 29th of January 2018.

> *Inoculation*

The targeted inoculation levels were the following:

- Level 0: 0 CFU/g,
- Level 1: level providing as much as possible fractional positive result (2 CFU/sample),
- Level 2:10 CFU/sample.

> *Analyses*

Collaborative study laboratories and the expert laboratory carried out the analyses on Tuesday 30th or Wednesday 31st January 2018 with the alternative (protocol ② dedicated to infant formula with probiotics and infant cereals) and reference methods. The typical colonies were confirmed by the Fast Crono except for collaborator N which used Biochemical galleries.

### 3.2.2 Experimental parameters controls

#### 3.2.2.1 Strain stability and background microflora stability

Strain stability was checked by inoculating the matrix at 2 CFU/sample and 100 CFU/g. Enumerations were performed for the high contamination level and

detection analyses were performed for the low contamination level after 24 h and 48 h storage at 5 ± 3°C. *Triplicates* were analysed. The aerobic mesophilic flora was also enumerated; the results are given in Table 17.

**Table 17 - Sample stability**

| Day | Reference method (detection) - 10 g | | | Alternative method (detection) - 25 g | | | CFU/g | | | Lactic acid flora (CFU/g) |
|---|---|---|---|---|---|---|---|---|---|---|
| | Sample 1 | Sample 2 | Sample 3 | Sample 1 | Sample 2 | Sample 3 | Sample 1 | Sample 2 | Sample 3 | |
| Day 0 | - | + | + | + | + | + | 281 | 273 | 455 | $3.8\ 10^5$ |
| Day 1 | + | + | + | - | + | + | 110 | 60 | 90 | $6.2\ 10^5$ |
| Day 2 | + | + | + | + | + | + | 50 | 20 | 0 | $5.5\ 10^5$ |

A decrease in the count level was observed during storage at 5°C ± 3°C.

### *3.2.2.2 Contamination levels*

The contamination levels and the sample codification were the following (see Table 18).

**Table 18 - Contamination levels**

| Level | Samples | Theoretical target level (b/sample) | True level (b/ sample)* | Low limit / sample | High limit / sample |
|---|---|---|---|---|---|
| Level 0 | 1 - 4 - 6 - 11 - 14 - 18 - 20 - 24<br>26 - 28 - 31 - 34 - 37 - 40 - 43 - 44 | / | / | / | / |
| Level 1 | 3 - 5 - 10 - 15 - 16 - 19 - 22 - 23<br>27 - 30 - 35 - 38 - 41 - 42 - 46 - 48 | 2 | 2.6 | 2.2 | 3.1 |
| Level 2 | 2 - 7 - 8 - 9 - 12 - 13 - 17 - 21<br>25 - 29 - 32 - 33 - 36 - 39 - 45 - 47 | 10 | 9.8 | 8.0 | 12.0 |

* **Due to the decrease in the count level observed in the stability study, the true levels at the time of the study were probably lower.**

### *3.2.2.3 Logistic conditions*

Temperature conditions are given in Table 19.

**Table 19 - Sample temperatures at receipt**

| Collaborators | Temperature measured by the probe (°C) | Temperature measured at receipt (°C) | Receipt date and time | Analysis date |
|---|---|---|---|---|
| A | 3.6 | 2.0 | 31/01/2018 15h00 | 31/01/2018 |
| B | 1.8 | 5.1 | 30/01/2018 09h00 | 30/01/2018 |
| C | 6.1 | 3.5 | 30/01/2018 10h300 | 30/01/2018 |
| D | 1.8 | 4.2 | 30/01/2018 09h35 | 30/01/2018 |
| E | -16.5 | 5.0 | 30/01/2018 18h00 | 30/01/2018 |
| F | 6.7 | 9.7 | 30/01/2018 12h00 | 30/01/2018 |
| G1 | 1.2 | 1.4 | 31/01/2018 10h00 | 31/01/2018 |
| G2 | 1.4 | 1.5 | 31/01/2018 10h00 | 31/01/2018 |
| H | 1.7 | 1.8 | 30/01/2018 11h40 | 30/01/2018 |
| I | 5.9 | 4.1 | 30/01/2018 10h00 | 30/01/2018 |
| J | 1.5 | 2.6 | 30/01/2018 09h45 | 30/01/2018 |
| K | 2.1 | 4.9 | 31/01/2018 09h00 | 31/01/2018 |
| L | 1.4 | 1.4 | 30/01/2018 11h00 | 30/01/2018 |
| M | 1.3 | 3.9 | 30/01/2018 09h30 | 30/01/2018 |
| N | 1.5 | 6.0 | 30/01/2018 10h20 | 30/01/2018 |
| O | 2.9 | 6.0 | 30/01/2018 11h00 | 30/01/2018 |

No problem was encountered during the transport or at receipt except for 2 collaborators:

- For Lab E, the probe measured a temperature of -16.5°C; the probe probably failed as the Lab measured a temperature at receipt of 5.0°C.
- For Lab F, the temperature measured at receipt by the Lab was 9.7°C but the probe measured a temperature of 6.7°C.

For the other collaborators, all the samples were delivered on time and in appropriate conditions. Temperatures during shipment and at receipt were all correct.

### 3.2.3 Results analysis

#### 3.2.3.1 Expert laboratory results

The results obtained by the expert laboratory are given in Table 20.

**Table 20 – Results obtained by the expert Lab.**

| Level | Reference method | Alternative method |
|---|---|---|
| L0 | 0/8 | 0/8 |
| L1 | 8/8 | 7/8 |
| L2 | 8/8 | 8/8 |

### 3.2.3.2 Results observed by the collaborative laboratories

#### Aerobic mesophilic flora enumeration

Depending on the Lab results, the enumeration levels varied from 4.0 $10^4$ to 8.1 $10^5$ CFU/g.

#### *Cronobacter* spp. detection

16 collaborators participated to the study. The results obtained are provided in Table 21 (reference method) and Table 22 (alternative method).

**Table 21 - Positive results by the reference method (ALL the collaborators)**

| Collaborators | Contamination level | | |
|---|---|---|---|
| | L0 | L1 | L2 |
| A | 0 | 7 | 8 |
| B | 0 | 7 | 8 |
| C | 0 | 6 | 8 |
| D | 0 | 7 | 8 |
| E | 0 | 7 | 8 |
| F | 0 | 7 | 8 |
| G1 | 0 | 7 | 8 |
| G2 | 0 | 5 | 8 |
| H | 0 | 6 | 8 |
| I | 0 | 7 | 8 |
| J | 0 | 8 | 8 |
| K | 0 | 7 | 8 |
| L | 0 | 6 | 8 |
| M | 0 | 6 | 8 |
| N | 0 | 7 | 8 |
| O | 0 | 8 | 8 |
| Total | $P_0 = 0$ | $P_1 = 108$ | $P_2 = 128$ |

**Table 22 - Positive results (before and after confirmation) by the alternative method (ALL the collaborators)**

| Collaborators | Contamination level | | | | | |
|---|---|---|---|---|---|---|
| | L0 | | L1 | | L2 | |
| | *ESIA* | *Final result* | *ESIA* | *Final result* | *ESIA* | *Final result* |
| A | 0 | 0 | 5 | 5 | 8 | 8 |
| B | 0 | 0 | 3 | 3 | 8 | 8 |
| C | 0 | 0 | 5 | 5 | 8 | 8 |
| D | 0 | 0 | 6 | 6 | 8 | 8 |
| E | 0 | 0 | 5 | 5 | 8 | 8 |
| F | 0 | 0 | 6 | 6 | 8 | 8 |
| G1 | 0 | 0 | 6 | 6 | 8 | 8 |
| G2 | 0 | 0 | 6 | 6 | 8 | 8 |
| H | 0 | 0 | 7 | 7 | 8 | 8 |
| I | 0 | 0 | 7 | 7 | 8 | 8 |
| J | 0 | 0 | 8 | 8 | 8 | 8 |
| K | 0 | 0 | 7 | 7 | 8 | 8 |
| L | 0 | 0 | 6 | 6 | 8 | 8 |
| M | 0 | 0 | 7 | 7 | 8 | 8 |
| N | 3 | 3 | 8 | 8 | 8 | 8 |
| O | 0 | 0 | 7 | 7 | 8 | 8 |
| **Total** | **$P_0$ = 3** | **$CP_0$ = 3** | **P1=99** | **$CP_1$ = 99** | **$P_2$=128** | **$CP_2$ = 128** |

Lab N obtained typical colonies on ESIA plates for unspiked samples (N4, N6, N20 and N24). The colonies were confirmed as *Cronobacter* spp. This Lab mentioned that some flasks leaked. This could explain these contaminations.

According to the AFNOR technical rules, it is possible to include the results from a collaborator with maximum one cross contamination at Level 0. For this study, this rule was applied and the results from Lab N were excluded for interpretation.

#### *3.2.3.3 Results of the collaborators retained for interpretation*

The results obtained with the 15 collaborators kept for interpretation are presented in Table 23 (reference method) and Table 24 (alternative method).

**Table 23 - Positive results by the reference method (Without Lab N)**

| Collaborators | Contamination level | | |
|---|---|---|---|
| | L0 | L1 | L2 |
| A | 0 | 7 | 8 |
| B | 0 | 7 | 8 |
| C | 0 | 6 | 8 |
| D | 0 | 7 | 8 |
| E | 0 | 7 | 8 |
| F | 0 | 7 | 8 |
| G1 | 0 | 7 | 8 |
| G2 | 0 | 5 | 8 |
| H | 0 | 6 | 8 |
| I | 0 | 7 | 8 |
| J | 0 | 8 | 8 |
| K | 0 | 7 | 8 |
| L | 0 | 6 | 8 |
| M | 0 | 6 | 8 |
| O | 0 | 8 | 8 |
| Total | $P_0 = 0$ | $P_1 = 101$ | $P_2 = 120$ |

**Table 24 - Positive results (before and after confirmation) by the alternative method (Without Lab N)**

| Collaborators | Contamination level | | | | | |
|---|---|---|---|---|---|---|
| | L0 | | L1 | | L2 | |
| | *ESIA* | *Final result* | *ESIA* | *Final result* | *ESIA* | *Final result* |
| A | 0 | 0 | 5 | 5 | 8 | 8 |
| B | 0 | 0 | 3 | 3 | 8 | 8 |
| C | 0 | 0 | 5 | 5 | 8 | 8 |
| D | 0 | 0 | 6 | 6 | 8 | 8 |
| E | 0 | 0 | 5 | 5 | 8 | 8 |
| F | 0 | 0 | 6 | 6 | 8 | 8 |
| G1 | 0 | 0 | 6 | 6 | 8 | 8 |
| G2 | 0 | 0 | 6 | 6 | 8 | 8 |
| H | 0 | 0 | 7 | 7 | 8 | 8 |
| I | 0 | 0 | 7 | 7 | 8 | 8 |
| J | 0 | 0 | 8 | 8 | 8 | 8 |
| K | 0 | 0 | 7 | 7 | 8 | 8 |
| L | 0 | 0 | 6 | 6 | 8 | 8 |
| M | 0 | 0 | 7 | 7 | 8 | 8 |
| O | 0 | 0 | 7 | 7 | 8 | 8 |
| Total | $P_0 = 0$ | $CP_0 = 0$ | P1=91 | $CP_1 = 91$ | $P_2$=120 | $CP_2 = 120$ |

### 3.2.4 Calculation and interpretation

#### 3.2.4.1 Calculation of the specificity percentage (SP)

The percentage specificity (SP) of the reference method and of the alternative method, using the data after confirmation, based on the results of level L0 is the following (See Table 25).

**Table 25 - Percentage specificity**

| | | |
|---|---|---|
| **Specificity for the reference method** | $SP_{ref} = \left(1 - \left(\frac{P_0}{N\_}\right)\right) x\ 100\ \% =$ | 100 % |
| **Specificity for the alternative method** | $SP_{alt} = \left(1 - \left(\frac{CP_0}{N\_}\right)\right) x\ 100\ \% =$ | 100 % |

N: number of all L0 tests
$P_0$ = total number of false-positive results obtained with the blank samples before confirmation
$CP_0$ = total number of false-positive results obtained with the blank samples

#### 3.2.4.2 Calculation of the sensitivity ($SE_{alt}$), the sensitivity for the reference method ($SE_{ref}$), the relative trueness (RT) and the false positive ratio for the alternative method (FPR)

Fractional positive results were obtained for the low inoculation level (L1). This inoculation level was retained for calculation.

A summary of the results of the collaborators retained for interpretation, and obtained with the reference and the alternative methods for Level 1 is provided in Table 26.

**Table 26 - Summary of the obtained results with the reference method and the alternative method for Level 1**

| Response | Reference method positive (R+) | Reference method negative (R-) |
|---|---|---|
| **Alternative method positive (A+)** | Positive agreement (A+/R+)<br>**PA = 81** | Positive deviation (R-/A+)<br>**PD = 10** |
| **Alternative method negative (A-)** | Negative deviation (A-/R+)<br>**ND = 20 (PPND = 0)** | Negative agreement (A-/R-)<br>**NA = 9 (PPNA = 0)** |

Based on the data summarized in Table 26, the values of sensitivity of the alternative and reference methods, as well as the relative trueness and false positive ratio for the alternative method taking account the confirmations, are the following (See Table 27).

**Table 27 - Sensitivity, relative trueness and false positive ratio percentages**

| | | |
|---|---|---|
| **Sensitivity for the alternative method:** | $SE_{alt} = \frac{(PA+PD)}{(PA+PD+ND)} x\ 100\% =$ | 82.0 % |
| **Sensitivity for the reference method:** | $SE_{ref} = \frac{(PA+ND)}{(PA+PD+ND)} x\ 100\% =$ | 91.0 % |
| **Relative trueness** | $RT = \frac{(PA+NA)}{N} x\ 100\% =$ | 75.0 % |
| **False positive ratio for the alternative method** | $FPR = \frac{FP}{NA} x\ 100\% =$ | 0.0 % |

### 3.2.5 Interpretation of data

The negative deviations are listed in Table 28 for Level 1.
The positive deviations are listed in Table 29 for Level 1.

20 negative deviations were observed. These results could be related to:

- The different sample size tested in the reference method (10g) and the alternative method (25 g);
- The use of a selective enrichment broth for the alternative method;
- The unpaired study design.

**Table 28 - Negative deviations for Level 1**

| Collaborator | Sample N° | Confirmation result |
|---|---|---|
| A | **A3** | - |
| | **A16** | - |
| B | **B15** | - |
| | **B16** | - |
| | **B22** | - |
| | **B23** | - |
| C | **C19** | - |
| D | **D10** | - |
| E | **E5** | - |
| | **E19** | - |
| F | **F10** | - |
| | **F15** | - |
| G1 | **G16** | - |
| | **G23** | - |
| G2 | **G46** | - |
| H | **H10** | - |
| K | **K15** | - |
| L | **L19** | - |
| M | **M15** | - |
| O | **O16** | - |

**Table 29 - Positive deviations for Level 1**

| Collaborator | Sample N° |
|---|---|
| F | **F19** |
| G1 | **G15** |
| G2 | **G30** |
| | **G35** |
| H | **H3** |
| | **H5** |
| K | **K22** |
| L | **L16** |
| M | **M3** |
| | **M16** |

For an **unpaired study design**, the difference between (ND – PD) is calculated for the level(s) where fractional recovery is obtained (so $L_1$ in this study). The observed value found for (ND – PD) shall not be higher than the AL. The AL is defined as [(ND – PD)$_{max}$] and calculated per level where fractional recovery is obtained as described below using the following three parameters:

$$(p+)_{\text{ref}} = \frac{P_x}{N_x}$$

where

$P_x$ = number of samples with a positive result obtained with the reference method at level $L_1$ for all the collaborators

$N_x$ = number of samples tested at level $L_1$ with the reference method by all the collaborators

$$(p+)_{\text{alt}} = \frac{CP_x}{N_x}$$

where

$CP_x$ = number of samples with a confirmed positive result obtained with the alternative method at level $L_1$ for all the collaborators;

$N_x$ = number of samples tested at level $L_1$ with the alternative method by all the collaborators.

$$(\text{ND-PD})_{\max} = \sqrt{3N_x \times \left((p+)_{\text{ref}} + (p+)_{\text{alt}} - 2\left((p+)_{\text{ref}} \times (p+)_{\text{alt}}\right)\right)}$$

where

$N_x$ = number of samples tested for level $L_1$ with the reference method by all the collaborators.

The calculations are the following, according to the EN ISO 16140-2:2016 (See Table 30).

**Table 30 - Calculations**

| | |
|---|---|
| $N_X$ | 120 |
| $(p+)_{ref}$ | 0.8 |
| $(p+)_{alt}$ | 0.8 |
| AL = (ND - PD) max | 10.79 |
| ND - PD | 10 |
| Conclusion | ND - PD ≤ AL |

**The ISO 16140-2 (2016) requirements are fulfilled as (ND - PD) meet the AL.**

### 3.2.6 *Evaluation of the RLOD between laboratories*

The RLOD was calculated using the EN ISO 16140-2:2016 Excel spreadsheet available at https://standards.iso.org/iso/16140/-5/ed-1/en/RLOD_inter-lab-study_16140-2_AnnexF_ver1_28-06-2017.xls. The results are used only for information (see Table 31).

**Table 31 - LOD $_{50\%}$, LOD $_{95\%}$ and RLOD**

| Method | LOD 50% | LOD 95% | RLOD |
|---|---|---|---|
| Reference | 0,8 [0,6; 0,9] | 3,3 [2,6; 4,1] | 1,3 [1,0; 1,7] |
| Alternative | 1,0 [0,8;1.2] | 4,2 [3.5; 5,2] | |

## 3.3 Conclusion

The **method comparison study conclusions** are:

☒ In the sensitivity study, 4 categories were tested. The protocol of the alternative method showed 30 positive deviations (PD) and 23 negative deviations (ND). The observed values for (ND + PPND) - PD) and (ND + PPND + PD) meet the acceptability limit (observed values ≤ AL) for each individual category and for all the combined categories.

☒ The Relative Levels of Detection (RLOD) meet the Acceptability Limit (AL) for all the tested matrix/strain pairs.

☒ The inclusivity and exclusivity testing did give the expected results for 50 target strains and the 64 non-target strains.

☒ It is possible to store the enrichment broth for 72 h at 5 ± 3°C.

☒ The negative and positive results are available in 2 days, while 4 days are required for positive results with the reference method.

☒ The alternative method fulfils all the EN ISO 16140-2:2016 and AFNOR technical rules (PR Revision 7).

The **inter-laboratory study conclusions** are:

☒ The data and interpretations comply with the EN ISO 16140-2:2016 requirements. **The ESIA™ One Day *Cronobacter* method is considered equivalent to the ISO standard.**

Quimper, 03 November 2022

Maryse RANNOU
Project Manager
Validation of Alternative methods

I hereby attest to the validation of the verification of the conformity of the report (opinion and interpretation).

## Appendix 1 – Flow diagram of the alternative method: ESIA™ One Day

**Enrichment**

| Protocol ① | Protocol ② | Protocol ③ | Protocol ④ | Protocol ① |
|---|---|---|---|---|
| **Milk powders, infant formula and infant cereals without probiotics including ingredients** | **Infant formula and infant cereals with probiotics** | **Milk powders, infant formula and infant cereals with or without probiotics** | **Ingredients** *(excluding whey protein concentrates)* | **Production environmental samples** |
| 25 g + 225 ml BPW* d 1/10 | 25 g + 225 ml BPW* + Novobiocin (10 mg/l) d 1/10 | 375 g + 1 875 ml pre-warmed BPW* + Novobiocin 10 mg/l) d 1/6 | 375 g + 3 375 ml pre-warmed BPW d 1/10 | 25 g or 25 ml or 225 ml BPW d 1/10 or 1 swab + 10 ml BPW[2] 1 sponge + 100 ml BPW[1] 1 wipe + 225 ml BPW[1] |

*Possibility to store for 72 h at 5°C ± 3°C*

18 - 24 h at 37°C ± 1°C for 25 g test portion
20-26h at 37°C± 1°C for 375g test portion

↓

Streaking 10 µl onto ESIA plates

↓

Incubation for 24 h ± 3 h at 44°C ± 1°C

↓

**Confirmation**

↓

Typical colonies

↓

TSA

↓

Tests described in the reference method (API ID32E and oxidase test)
or Fast Crono confirmation test
or VITEK MS / VITEK MS PRIME test

Biochemical identification
API ID32E on isolated colony
or Fast Crono confirmation test
or VITEK MS / VITEK MS PRIME test

**Addition of α-amylase for infant cereals (0.1 g/l)*

[2] Pre-moisten dehydrated sponge (1 ml) or swab with BPW (10 ml) and add 9 ml or 90 ml BPW for analysis. If neutralization is needed, substitute the BPW with Letheen broth for pre-moisten.

## Appendix 2 – Flow diagram of the reference method: ISO 22964 (April 2017) - Microbiology of the food chain - Horizontal method for the detection of *Cronobacter* spp.

10 g + 90 ml BPW*

1 swab + 10 ml BPW [3]

1 sponge + 100 ml BPW [2]

1 wipe + 225 ml BPW [2]

↓

Incubation 18 h ± 2 h

at 34 – 38°C

↓

0.1 ml + 10 ml CSB

↓

Incubation 24 h ± 2 h

at 41.5°C ± 1°C

↓

Streaking onto CCI Agar plate

↓

Incubation 24 h ± 2 h

at 41.5°C ± 1°C

↓

Confirmatory test on one typical colony, and four other colonies

*(if the first one is negative (typical colony: blue to blue-green))*

↓

Streaking onto TSA

↓

Incubation 18 h – 24 h

at 37°C ± 1°C

↓

Biochemical confirmation (oxidase, mini-galleries)

[3] Pre-moisten dehydrated sponge (1 ml) or swab with BPW (10 ml) and add 9 ml or 90 ml BPW for analysis. If neutralization is needed, substitute the BPW with Letheen broth for pre-moisten.

# Appendix 3 – Artificial contamination of samples

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2017 | **7618** | **Infant formula without probiotics** | *C. sakazakii* Ad2394 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,0 | 1 | + | 1 | a |
| 2017 | **7619** | **Infant formula without probiotics** | *C. sakazakii* Ad2395 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,7 | 1 | + | 1 | a |
| 2017 | **7620** | **Infant formula without probiotics** | *C. sakazakii* Ad2400 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,0 | 1 | + | 1 | a |
| 2017 | **7621** | **Infant formula without probiotics** | *C. sakazakii* Ad1446 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,2 | 1 | + | 1 | a |
| 2017 | **7622** | **Infant formula without probiotics** | *C. sakazakii* Ad1420 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 1 | + | 1 | a |
| 2017 | **7623** | **Infant formula without probiotics** | *C. sakazakii* Ad2394 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,0 | 1 | + | 1 | a |
| 2017 | **7795** | **Infant formula without probiotics** | *C. sakazakii* Ad893 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 4,7 | 1 | + | 1 | a |
| 2017 | **7796** | **Infant formula without probiotics** | *C. sakazakii* Ad2378 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,2 | 1 | + | 1 | a |
| 2017 | **7799** | **Infant formula without probiotics** | *C. sakazakii* Ad893 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 4,7 | 1 | - | 1 | a |
| 2017 | **7801** | **Infant formula without probiotics** | *C. sakazakii* Ad2396 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,3 | 1 | + | 1 | a |
| 2017 | **7802** | **Infant formula without probiotics** | *C. sakazakii* Ad1420 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,1 | 1 | + | 1 | a |
| 2017 | **9128** | **Infant formula without probiotics** | *C. sakazakii* Ad2413 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 0,7 | 1 | + | 1 | a |
| 2017 | **9129** | **Infant formula without probiotics** | *C. sakazakii* Ad2413 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 0,7 | 1 | - | 1 | a |
| 2017 | **7624** | **Infant cereals without probiotics** | *C. sakazakii* Ad2395 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,7 | 1 | + | 1 | b |
| 2017 | **7625** | **Infant cereals without probiotics** | *C. sakazakii* Ad2400 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,0 | 1 | + | 1 | b |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2017 | **7626** | **Infant cereals without probiotics** | *C. sakazakii* Ad1446 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,2 | 1 | - | 1 | b |
| 2017 | **7627** | **Infant cereals without probiotics** | *C. sakazakii* Ad1420 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 1 | - | 1 | b |
| 2017 | **7628** | **Infant cereals without probiotics** | *C. sakazakii* Ad2394 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,0 | 1 | + | 1 | b |
| 2017 | **7629** | **Infant cereals without probiotics** | *C. sakazakii* Ad2395 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,7 | 1 | + | 1 | b |
| 2017 | **7630** | **Infant cereals without probiotics** | *C. sakazakii* Ad2400 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,0 | 1 | + | 1 | b |
| 2017 | **7631** | **Infant cereals without probiotics** | *C. sakazakii* Ad1446 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,2 | 1 | + | 1 | b |
| 2017 | **7797** | **Infant cereals without probiotics** | *C. muytjensis* E888 | Milk powder | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 1 | + | 1 | b |
| 2017 | **7798** | **Infant cereals without probiotics** | *C. sakazakii* Ad893 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 4,7 | 1 | + | 1 | b |
| 2017 | **7800** | **Infant cereals without probiotics** | *C. sakazakii* Ad1420 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,1 | 1 | + | 1 | b |
| 2017 | **8455** | **Infant cereals without probiotics** | *C. muytjensis* E769 | Milk powder | Seeding lyophilized strain 2 weeks at room temperature | / | / | 3,0 | 1 | - | 1 | b |
| 2017 | **8456** | **Infant cereals without probiotics** | *C. sakazakii* Ad2341 | Wheat starch | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,0 | 1 | - | 1 | b |
| 2017 | **9130** | **Infant cereals without probiotics** | *C. sakazakii* Ad2413 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 0,7 | 1 | + | 1 | b |
| 2017 | **9131** | **Infant cereals without probiotics** | *C. sakazakii* Ad2413 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 0,7 | 1 | + | 1 | b |
| 2017 | **7632** | **Lactoserum** | *C. sakazakii* Ad1420 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 1 | + | 1 | c |
| 2017 | **7633** | **Milk proteins** | *C. sakazakii* Ad1420 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 1 | + | 1 | c |
| 2017 | **7634** | **Lactose** | *C. sakazakii* Ad2394 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,0 | 1 | + | 1 | c |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2017 | **7635** | **Caseinate** | *C. sakazakii* Ad2395 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,7 | 1 | + | 1 | c |
| 2017 | **7636** | **Lactoserum proteins concentrate** | *C. sakazakii* Ad2400 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,0 | 1 | + | 1 | c |
| 2017 | **7637** | **Maltodextrine** | *C. sakazakii* Ad1446 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,2 | 1 | + | 1 | c |
| 2017 | **7638** | **Lactoserum proteins concentrate** | *C. sakazakii* Ad1420 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 1 | - | 1 | c |
| 2017 | **7803** | **Lactoserum** | *C. malonaticus* E752 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,1 | 1 | - | 1 | c |
| 2017 | **7804** | **Lactoserum** | *C. sakazakii* Ad2381 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,7 | 1 | - | 1 | c |
| 2017 | **7805** | **Corn flour** | *C. sakazakii* Ad2383 | Environmental sample | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,6 | 1 | + | 1 | c |
| 2017 | **7806** | **Milk powder (ingredient)** | *C. sakazakii* Ad2359 | Environmental sample | Seeding lyophilized strain 2 weeks at room temperature | / | / | 3,7 | 1 | + | 1 | c |
| 2017 | **8458** | **Lactose** | *C. turicensis* Ad1445 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 6,0 | 1 | + | 1 | c |
| 2017 | **8459** | **Whey protein concentrate** | *C. sakazakii* Ad2349 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 3,0 | 1 | + | 1 | c |
| 2017 | **2609** | **Skim milk powder** | *C. muytjensis* E769 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 1 | + | 1 | c |
| 2017 | **2610** | **Whole milk powder** | *C. muytjensis* E769 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 1 | + | 1 | c |
| 2017 | **2611** | **Skim milk powder** | *C. muytjensis* E769 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 1 | + | 1 | c |
| 2017 | **2612** | **Skim milk powder** | *C. muytjensis* E888 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | <0,3 | 1 | + | 1 | c |
| 2017 | **2613** | **Skim milk powder** | *C. muytjensis* E888 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | <0,3 | 1 | + | 1 | c |
| 2017 | **2614** | **Skim milk powder** | *C. muytjensis* E888 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | <0,3 | 1 | + | 1 | c |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2017 | **8027** | **Infant formula with probiotics (3,6.10$^{2}$ CFU/g)** | *C. sakazakii* Ad2370 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,6 | 2 | + | 2 | a |
| 2017 | **8028** | **Infant formula with probiotics (<10 CFU/g)** | *C. sakazakii* Ad2370 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,6 | 2 | + | 2 | a |
| 2017 | **8029** | **Infant formula with probiotics (1,3.10$^{5}$ CFU/g)** | *C. sakazakii* Ad2370 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,6 | 2 | + | 2 | a |
| 2017 | **8030** | **Infant formula with probiotics (<10 CFU/g)** | *C. sakazakii* Ad2350 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,3 | 2 | + | 2 | a |
| 2017 | **8031** | **Infant formula with probiotics (1,8.10$^{5}$ CFU/g)** | *C. sakazakii* Ad2350 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,3 | 2 | + | 2 | a |
| 2017 | **8032** | **Infant formula with probiotics (3,0.10$^{4}$ CFU/g)** | *C. sakazakii* Ad2348 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,1 | 2 | + | 2 | a |
| 2017 | **8033** | **Infant formula with probiotics (4,8.10$^{5}$ CFU/g)** | *C. sakazakii* Ad2348 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,1 | 2 | + | 2 | a |
| 2017 | **8131** | **Infant formula with probiotics (5,6.10$^{5}$ CFU/g)** | *C. dublinensis* DSM18705 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,4 | 2 | - | 2 | a |
| 2017 | **8132** | **Infant formula with probiotics (1,2.10$^{7}$ CFU/g)** | *C. dublinensis* DSM18705 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,4 | 2 | - | 2 | a |
| 2017 | **8133** | **Infant formula with probiotics (4,3.10$^{5}$ CFU/g)** | *C. sakazakii* Ad2351 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 3,4 | 2 | + | 2 | a |
| 2017 | **8134** | **Infant formula with probiotics (6,8.10$^{5}$ CFU/g)** | *C. sakazakii* Ad2351 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 3,4 | 2 | + | 2 | a |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2017 | **8135** | **Infant formula with probiotics (4,2.10$^5$ CFU/g)** | *C. sakazakii* Ad2352 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 2 | + | 2 | a |
| 2017 | **8136** | **Infant formula with probiotics (6,8.10$^5$ CFU/g)** | *C. sakazakii* Ad2352 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 2 | + | 2 | a |
| 2017 | **8137** | **Infant formula with probiotics (7,5.10$^5$ CFU/g)** | *C. sakazakii* Ad2356 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,7 | 2 | + | 2 | a |
| 2017 | **8138** | **Infant formula with probiotics (8,6.10$^5$ CFU/g)** | *C. sakazakii* Ad2361 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 2 | + | 2 | a |
| 2017 | **8448** | **Infant formula with probiotics (4,2.10$^5$ CFU/g)** | *C. turicensis* Ad1445 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 6,0 | 2 | + | 2 | a |
| 2017 | **8449** | **Infant formula with probiotics (<10 CFU/g)** | *C. sakazakii* Ad2349 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 3,0 | 2 | - | 2 | a |
| 2017 | **8450** | **Infant formula with probiotics (7,0.10$^5$ CFU/g)** | *C. muytjensis* E769 | Milk powder | Seeding lyophilized strain 2 weeks at room temperature | / | / | 3,0 | 2 | - | 2 | a |
| 2017 | **9610** | **Infant formula with probiotics (4,2.10$^5$ CFU/g)** | *C. sakazakii* Ad940 | Dairy product | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,6 | 2 | + | 2 | a |
| 2017 | **9611** | **Infant formula with probiotics (5,9.10$^5$ CFU/g)** | *C. sakazakii* Ad940 | Dairy product | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,6 | 2 | + | 2 | a |
| 2017 | **8034** | **Infant cereals with probiotics (5,6.10$^5$ CFU/g)** | *C. sakazakii* Ad2370 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,6 | 2 | - | 2 | b |
| 2017 | **8035** | **Infant cereals with probiotics (7,1.10$^4$ CFU/g)** | *C. sakazakii* Ad2370 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,6 | 2 | + | 2 | b |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2017 | **8036** | **Infant cereals with probiotics (1,7.10$^4$ CFU/g)** | *C. sakazakii* Ad2350 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,3 | 2 | - | 2 | b |
| 2017 | **8037** | **Infant cereals with probiotics (2,5.10$^5$ CFU/g)** | *C. sakazakii* Ad2350 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,3 | 2 | + | 2 | b |
| 2017 | **8038** | **Infant cereals with probiotics (5,1.10$^5$ CFU/g)** | *C. sakazakii* Ad2350 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,3 | 2 | + | 2 | b |
| 2017 | **8039** | **Infant cereals with probiotics (6,7.10$^5$ CFU/g)** | *C. sakazakii* Ad2348 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,1 | 2 | + | 2 | b |
| 2017 | **8040** | **Infant cereals with probiotics (2,7.10$^3$ CFU/g)** | *C. sakazakii* Ad2348 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,1 | 2 | + | 2 | b |
| 2017 | **8041** | **Infant cereals with probiotics (1,7.10$^5$ CFU/g)** | *C. sakazakii* Ad2348 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,1 | 2 | + | 2 | b |
| 2017 | **8139** | **Infant cereals with probiotics (6,7.10$^6$ CFU/g)** | *C. sakazakii* Ad2361 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 2 | + | 2 | b |
| 2017 | **8140** | **Infant cereals with probiotics (7,1.10$^4$ CFU/g)** | *C. sakazakii* Ad2361 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 2 | + | 2 | b |
| 2017 | **8141** | **Infant cereals with probiotics (2,7.10$^3$ CFU/g)** | *C. sakazakii* Ad2356 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,7 | 2 | + | 2 | b |
| 2017 | **8142** | **Infant cereals with probiotics (2,3.10$^5$ CFU/g)** | *C. sakazakii* Ad2356 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,7 | 2 | + | 2 | b |
| 2017 | **8143** | **Infant cereals with probiotics (5,6.10$^5$ CFU/g)** | *C. sakazakii* Ad2352 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 2 | + | 2 | b |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2017 | **8144** | **Infant cereals with probiotics (1,7.10$^5$ CFU/g)** | *C. sakazakii* Ad2351 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 3,4 | 2 | + | 2 | b |
| 2017 | **8145** | **Infant cereals with probiotics (5,1.10$^5$ CFU/g)** | *C. dublinensis* DSM18705 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | <0,4 | 2 | - | 2 | b |
| 2018 | **8451** | **Infant cereals with probiotics (2,3.10$^5$ CFU/g)** | *C. sakazakii* Ad2341 | Wheat starch | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,0 | 2 | - | 2 | b |
| 2018 | **8452** | **Infant cereals with probiotics (5,6.10$^5$ CFU/g)** | *C. sakazakii* Ad704 | Milk powder | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,7 | 2 | - | 2 | b |
| 2018 | **8453** | **Infant cereals with probiotics (1,7.10$^5$ CFU/g)** | *C. turicensis* Ad1445 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 6,0 | 2 | - | 2 | b |
| 2018 | **8454** | **Infant cereals with probiotics (7,1.10$^4$ CFU/g)** | *C. sakazakii* Ad2349 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 3,0 | 2 | + | 2 | b |
| 2018 | **9126** | **Infant cereals with probiotics (7,1.10$^4$ CFU/g)** | *C. sakazakii* Ad2413 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 0,7 | 2 | + | 2 | b |
| 2018 | **9127** | **Infant cereals with probiotics (5,6.10$^5$ CFU/g)** | *C. sakazakii* Ad2413 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 0,7 | 2 | + | 2 | b |
| 2018 | **2589** | **Skim milk powder** | *C. muytjensis* E769 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 3 | + | 3 | a |
| 2018 | **2590** | **Whole milk powder** | *C. muytjensis* E769 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 3 | + | 3 | a |
| 2018 | **2591** | **Skim milk powder** | *C. muytjensis* E769 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 3 | + | 3 | a |
| 2018 | **2592** | **Skim milk powder** | *C. muytjensis* E888 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | <0,3 | 3 | - | 3 | a |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2018 | **2593** | **Skim milk powder** | *C. muytjensis* E888 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | <0,3 | 3 | + | 3 | a |
| 2018 | **2594** | **Skim milk powder** | *C. muytjensis* E888 | Milk powder | Seeding lyophilized strain 1 weeks at room temperature | / | / | <0,3 | 3 | - | 3 | a |
| 2018 | **2595** | **Infant cereals without probiotics** | *C. turicensis* Ad1445 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 3 | + | 3 | a |
| 2018 | **2596** | **Infant cereals without probiotics** | *C. turicensis* Ad1445 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 3 | + | 3 | a |
| 2018 | **2597** | **Infant cereals without probiotics** | *C. turicensis* Ad1445 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 3 | + | 3 | a |
| 2018 | **2598** | **Infant cereals without probiotics** | *C. turicensis* Ad1445 | Infant formula | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 3 | + | 3 | a |
| 2018 | **2599** | **Infant cereals without probiotics** | *C. sakazakii* Ad1418 | Environmental sample from dairy industry | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,3 | 3 | + | 3 | a |
| 2018 | **2600** | **Infant cereals without probiotics** | *C. sakazakii* Ad1418 | Environmental sample from dairy industry | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,3 | 3 | + | 3 | a |
| 2018 | **2601** | **Infant cereals without probiotics** | *C. sakazakii* Ad1418 | Environmental sample from dairy industry | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,3 | 3 | + | 3 | a |
| 2018 | **2602** | **Infant formula without probiotics** | *C. sakazakii* Ad2367 | Environmental sample from dairy industry | Seeding lyophilized strain 1 weeks at room temperature | / | / | 10,0 | 3 | + | 3 | a |
| 2018 | **2603** | **Infant formula without probiotics** | *C. sakazakii* Ad2367 | Environmental sample from dairy industry | Seeding lyophilized strain 1 weeks at room temperature | / | / | 10,0 | 3 | + | 3 | a |
| 2018 | **2604** | **Infant formula without probiotics** | *C. sakazakii* Ad2367 | Environmental sample from dairy industry | Seeding lyophilized strain 1 weeks at room temperature | / | / | 10,0 | 3 | + | 3 | a |
| 2018 | **2606** | **Infant formula without probiotics** | *C. sakazakii* Ad2380 | Environmental sample from dairy industry | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 3 | + | 3 | a |
| 2018 | **2607** | **Infant formula without probiotics** | *C. sakazakii* Ad2380 | Environmental sample from dairy industry | Seeding lyophilized strain 1 weeks at room temperature | / | / | 1,0 | 3 | - | 3 | a |
| 2018 | **3469** | **Skim milk powder** | *C. sakazakii* Ad831 | Milk powder | Spiking HT 8min 56°C | 1,68 | 6-4-3-4-6 | 4,6 | 3 | + | 3 | a |
| 2018 | **3470** | **Skim milk powder** | *C. sakazakii* Ad935 | Dairy product | Spiking HT 8min 56°C | 1,00 | 5-1-3-1-4 | 2,8 | 3 | + | 3 | a |
| 2018 | **3471** | **Infant formula without probiotics** | *C. sakazakii* Ad2411 | Infant formula | Spiking HT 8min 56°C | 1,48 | 3-4-4-2-4 | 3,4 | 3 | + | 3 | a |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2018 | **3472** | **Infant formula without probiotics** | *C. sakazakii* Ad2411 | Infant formula | Spiking HT 8min 56°C | 1,48 | 3-4-4-2-4 | 3,4 | 3 | + | 3 | a |
| 2018 | **3473** | **Infant formula without probiotics** | *C. sakazakii* Ad941 | Dairy product | Spiking HT 8min 56°C | 1,70 | 3-5-5-3-9 | 5,0 | 3 | + | 3 | a |
| 2018 | **2620** | **Infant formula with probiotics (7,2.10$^4$ CFU/g)** | *C. sakazakii* Ad2353 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 4,0 | 3 | + | 3 | b |
| 2018 | **2621** | **Infant formula with probiotics (6,0.10$^4$ CFU/g)** | *C. sakazakii* Ad2353 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 4,0 | 3 | + | 3 | b |
| 2018 | **2623** | **Infant formula with probiotics (6,1.10$^6$ CFU/g)** | *C. sakazakii* Ad2353 | Infant formula | Seeding lyophilized strain 2 weeks at room temperature | / | / | 4,0 | 3 | + | 3 | b |
| 2018 | **2625** | **Infant formula with probiotics (5,1.10$^5$ CFU/g)** | *C. sakazakii* SU12-116 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 3 | + | 3 | b |
| 2018 | **2626** | **Infant formula with probiotics (4,7.10$^5$ CFU/g)** | *C. sakazakii* SU12-116 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 3 | + | 3 | b |
| 2018 | **2627** | **Infant formula with probiotics (1,1.10$^6$ CFU/g)** | *C. sakazakii* SU12-116 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 3 | + | 3 | b |
| 2018 | **2628** | **Infant formula with probiotics (1,4.10$^4$ CFU/g)** | *C. sakazakii* SU12-116 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 3 | + | 3 | b |
| 2018 | **2629** | **Infant formula with probiotics (3,0.10$^4$ CFU/g)** | *C. sakazakii* SU12-116 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 3 | + | 3 | b |
| 2018 | **2630** | **Infant cereals with probiotics (1,4.10$^5$ CFU/g)** | *C. sakazakii* Ad2393 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,9 | 3 | + | 3 | b |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2018 | **2631** | **Infant cereals with probiotics (2,1.10$^5$ CFU/g)** | *C. sakazakii* Ad2393 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,9 | 3 | + | 3 | b |
| 2018 | **2632** | **Infant cereals with probiotics (7,8.10$^5$ CFU/g)** | *C. sakazakii* Ad2393 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,9 | 3 | + | 3 | b |
| 2018 | **2633** | **Infant cereals with probiotics (2,5.10$^5$ CFU/g)** | *C. sakazakii* Ad2393 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,9 | 3 | + | 3 | b |
| 2018 | **2634** | **Infant cereals with probiotics (4,5.10$^4$ CFU/g)** | *C. sakazakii* Ad2393 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,9 | 3 | + | 3 | b |
| 2018 | **2635** | **Infant cereals with probiotics (9,1.10$^3$ CFU/g)** | *C. sakazakii* SU12-74 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,9 | 3 | + | 3 | b |
| 2018 | **2636** | **Infant cereals with probiotics (3,2.10$^6$ CFU/g)** | *C. sakazakii* SU12-74 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,9 | 3 | + | 3 | b |
| 2018 | **2637** | **Infant cereals with probiotics (1,3.10$^5$ CFU/g)** | *C. sakazakii* SU12-74 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,9 | 3 | + | 3 | b |
| 2018 | **2638** | **Infant cereals with probiotics (1,4.10$^6$ CFU/g)** | *C. sakazakii* SU12-74 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,9 | 3 | + | 3 | b |
| 2018 | **2639** | **Infant cereals with probiotics (2,2.10$^5$ CFU/g)** | *C. sakazakii* SU12-74 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,9 | 3 | + | 3 | b |
| 2018 | **3101** | **Starch** | *C. sakazakii* Ad916 | Milk powder | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 4 | + | 3 | c |
| 2018 | **3102** | **Caseinates** | *C. sakazakii* Ad916 | Milk powder | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 4 | + | 3 | c |
| 2018 | **3103** | **Corn starch** | *C. sakazakii* Ad916 | Milk powder | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 4 | + | 3 | c |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2018 | **3104** | **Wheat starch** | *C. sakazakii* Ad916 | Milk powder | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 4 | + | 3 | c |
| 2018 | **3106** | **Lactose** | *C. sakazakii* Ad946 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,4 | 4 | + | 3 | c |
| 2018 | **3107** | **Maltodextrine** | *C. sakazakii* Ad946 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,4 | 4 | + | 3 | c |
| 2018 | **3108** | **Whey** | *C. sakazakii* Ad946 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,4 | 4 | + | 3 | c |
| 2018 | **3109** | **Starch** | *C. sakazakii* Ad946 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,4 | 4 | + | 3 | c |
| 2018 | **3110** | **Caseinates** | *C. sakazakii* Ad946 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,4 | 4 | + | 3 | c |
| 2018 | **3111** | **Corn starch** | *C. sakazakii* Ad2286 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,8 | 4 | + | 3 | c |
| 2018 | **3112** | **Wheat starch** | *C. sakazakii* Ad2286 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,8 | 4 | + | 3 | c |
| 2018 | **3113** | **Corn starch** | *C. sakazakii* Ad2286 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,8 | 4 | + | 3 | c |
| 2018 | **3114** | **Lactose** | *C. sakazakii* Ad2286 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,8 | 4 | + | 3 | c |
| 2018 | **3122** | **Starch** | *C. sakazakii* Ad2286 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 0,8 | 4 | + | 3 | c |
| 2018 | **3123** | **Whey** | *C. sakazakii* Ad2288 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,3 | 4 | + | 3 | c |
| 2018 | **3124** | **Maltodextrine** | *C. sakazakii* Ad2288 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,3 | 4 | + | 3 | c |
| 2018 | **3125** | **Maltodextrine** | *C. sakazakii* Ad916 | Milk powder | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 4 | + | 3 | c |
| 2018 | **3126** | **Wheat starch** | *C. sakazakii* Ad2288 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,3 | 4 | + | 3 | c |
| 2018 | **3127** | **Caseinates** | *C. sakazakii* Ad2288 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,3 | 4 | + | 3 | c |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2018 | **3128** | **Corn starch** | *C. sakazakii* Ad2288 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,3 | 4 | + | 3 | c |
| 2018 | **3129** | **Lactose** | *C. sakazakii* Ad2288 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,3 | 4 | + | 3 | c |
| 2018 | **3130** | **Corn starch** | *C. sakazakii* SU 12-7 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 4 | + | 3 | c |
| 2018 | **3131** | **Starch** | *C. sakazakii* Ad946 | Dairy product | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,4 | 4 | + | 3 | c |
| 2018 | **3132** | **Maltodextrine** | *C. sakazakii* SU 12-7 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 4 | + | 3 | c |
| 2018 | **3133** | **Whey** | *C. sakazakii* Ad2357 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 6,0 | 4 | + | 3 | c |
| 2018 | **3134** | **Starch** | *C. sakazakii* Ad2357 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 6,0 | 4 | + | 3 | c |
| 2018 | **3135** | **Lactose** | *C. sakazakii* Ad2344 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 4 | + | 3 | c |
| 2018 | **3136** | **Caseinates** | *C. sakazakii* Ad2344 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 4 | + | 3 | c |
| 2018 | **3474** | **Maltodextrine** | *C. sakazakii* Ad831 | Milk powder | Spiking HT 8min 56°C | 1,68 | 6-4-3-4-6 | 4,6 | 4 | + | 3 | c |
| 2018 | **3475** | **Whey** | *C. sakazakii* Ad935 | Dairy product | Spiking HT 8min 56°C | 1,00 | 5-1-3-1-4 | 2,8 | 4 | + | 3 | c |
| 2018 | **386** | **Water after cleaning** | *C. sakazakii* Ad2289 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-7-5-2 | 4,4 | 1 | + | 4 | a |
| 2018 | **387** | **Water after cleaning** | *C. sakazakii* Ad2342 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 2-1-5-4-1 | 2,6 | 1 | + | 4 | a |
| 2018 | **388** | **Water after cleaning** | *C. sakazakii* Ad2360 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 3-6-5-4-5 | 4,6 | 1 | + | 4 | a |
| 2018 | **389** | **Water before cleaning** | *C. sakazakii* Ad2379 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-4-1-1 | 2,8 | 1 | - | 4 | a |
| 2018 | **390** | **Water before cleaning** | *C. sakazakii* Ad2289 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-7-5-2 | 4,4 | 1 | - | 4 | a |
| 2018 | **391** | **Water before cleaning** | *C. sakazakii* Ad2342 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 2-1-5-4-1 | 2,6 | 1 | - | 4 | a |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2018 | **392** | **Water before cleaning** | *C. sakazakii* Ad2360 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 3-6-5-4-5 | 4,6 | 1 | + | 4 | a |
| 2018 | **2465** | **Process water (rinse)** | *C. sakazakii* Ad12-26 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 8-6-8-10-6 | 7,6 | 1 | + | 4 | a |
| 2018 | **2466** | **Process water (rinse)** | *C. sakazakii* Ad12-26 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 8-6-8-10-6 | 7,6 | 1 | + | 4 | a |
| 2018 | **2467** | **Process water (rinse)** | *C. sakazakii* Ad1226 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 8-6-8-10-6 | 7,6 | 1 | + | 4 | a |
| 2018 | **2468** | **Process water (rinse)** | *C. sakazakii* Ad2355 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 11-7-5-9-8 | 8,0 | 1 | + | 4 | a |
| 2018 | **2469** | **Process water (rinse)** | *C. sakazakii* Ad2355 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 11-7-5-9-8 | 8,0 | 1 | + | 4 | a |
| 2018 | **2470** | **Process water (rinse)** | *C. sakazakii* Ad2355 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 11-7-5-9-8 | 8,0 | 1 | + | 4 | a |
| 2018 | **3137** | **Dust from vacuum** | *C. sakazakii* Ad2357 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 6,0 | 1 | + | 4 | b |
| 2018 | **3138** | **Dust from vacuum** | *C. sakazakii* SU 12-7 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 1 | + | 4 | b |
| 2018 | **3139** | **Dust from vacuum** | *C. sakazakii* SU 12-7 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 1 | + | 4 | b |
| 2018 | **3140** | **Dust from vacuum** | *C. sakazakii* SU 12-7 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 1 | + | 4 | b |
| 2018 | **3141** | **Dust from vacuum** | *C. sakazakii* Ad2357 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 6,0 | 1 | + | 4 | b |
| 2018 | **3142** | **Dust from vacuum** | *C. sakazakii* Ad2344 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 1 | + | 4 | b |
| 2018 | **3143** | **Dust from vacuum** | *C. sakazakii* Ad2344 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 1 | + | 4 | b |
| 2018 | **3144** | **Dust from vacuum** | *C. sakazakii* Ad2344 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 2,5 | 1 | + | 4 | b |
| 2018 | **3145** | **Dust from vacuum** | *C. sakazakii* Ad2357 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 6,0 | 1 | + | 4 | b |

| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Artificial contaminations (spiking or seeding protocol) | | | | | | Protocol | Global result | Category | Type |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Strain | Origin | Protocol | Injury measure-ment | Inoculation level/sample | | | | | |
| | | | | | | | Enume-ration | Mean | | | | |
| 2018 | **3146** | **Dust from vacuum** | *C. sakazakii* SU 12-7 | Environmental sample from dairy industry | Seeding lyophilized strain 2 weeks at room temperature | / | / | 1,5 | 1 | + | 4 | b |
| 2018 | **393** | **Wipe after cleaning** | *C. sakazakii* Ad2289 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-7-5-2 | 4,4 | 1 | - | 4 | c |
| 2018 | **394** | **Wipe after cleaning** | *C. sakazakii* Ad2342 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 2-1-5-4-1 | 2,6 | 1 | - | 4 | c |
| 2018 | **395** | **Wipe before cleaning** | *C. sakazakii* Ad2360 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 3-6-5-4-5 | 4,6 | 1 | + | 4 | c |
| 2018 | **396** | **Wipe before cleaning** | *C. sakazakii* Ad2360 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 3-6-5-4-5 | 4,6 | 1 | + | 4 | c |
| 2018 | **397** | **Wipe before cleaning** | *C. sakazakii* Ad2379 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-4-1-1 | 2,8 | 1 | - | 4 | c |
| 2018 | **398** | **Wipe before cleaning** | *C. sakazakii* Ad2379 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-4-1-1 | 2,8 | 1 | - | 4 | c |
| 2018 | **399** | **Wipe before cleaning** | *C. sakazakii* Ad2289 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-7-5-2 | 4,4 | 1 | + | 4 | c |
| 2018 | **400** | **Wipe before cleaning** | *C. sakazakii* Ad2342 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 2-1-5-4-1 | 2,6 | 1 | + | 4 | c |
| 2018 | **2159** | **Wipe after cleaning** | *C. sakazakii* Ad2406 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-6-6-5 | 5,0 | 1 | + | 4 | c |
| 2018 | **2160** | **Wipe after cleaning** | *C. sakazakii* Ad2406 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-6-6-5 | 5,0 | 1 | + | 4 | c |
| 2018 | **2161** | **Wipe after cleaning** | *C. sakazakii* Ad2406 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 5-3-6-6-5 | 5,0 | 1 | + | 4 | c |
| 2018 | **2162** | **Wipe after cleaning** | *C. sakazakii* Ad2408 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 6-1-2-4-2 | 3,0 | 1 | + | 4 | c |
| 2018 | **2163** | **Wipe after cleaning** | *C. sakazakii* Ad2408 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 6-1-2-4-2 | 3,0 | 1 | + | 4 | c |
| 2018 | **2164** | **Wipe before cleaning** | *C. sakazakii* Ad2409 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 2-2-1-4-2 | 2,2 | 1 | + | 4 | c |
| 2018 | **2165** | **Wipe before cleaning** | *C. sakazakii* Ad2409 | Environmental sample from dairy industry | Seeding 48h 2-8°C | / | 2-2-1-4-2 | 2,2 | 1 | + | 4 | c |

# Appendix 4 – Sensitivity study: raw data

**Bold typing : artificially inoculated samples**

***Cronobacter* detection results:**

| | |
|---|---|
| m: | minority level of target analyte |
| M : | majority level of target analyte |
| P: | pure culture level of target analyte |
| 1/2 : | 50% level of target analyte |
| d: | doubtful colony |
| (x): | number of colonies in the plate |
| (ia): | inoculation area |
| -: | no typical colonies but presence of background microflora |
| st: | plate without any colony |
| PA: | positive agreement |
| NA: | negative agreement |
| ND: | negative deviation |
| PD: | positive deviation |
| PPNA: | positive presumptive negative agreement |
| PPND : | positive presumptive negative deviation |
| NC: | non-characteristic colony |

| MILK POWDERS AND INGREDIENTS, INFANT FORMULA AND INFANT CEREALS WITHOUT PROBIOTICS (25 g sample size – protocol 1) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2017 | **7618** | **Infant formula without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | a |
| 2017 | **7619** | **Infant formula without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | a |
| 2017 | **7620** | **Infant formula without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | a |
| 2017 | **7621** | **Infant formula without probiotics** | 1 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 1 | a |
| 2017 | **7622** | **Infant formula without probiotics** | 1 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 1 | a |
| 2017 | **7623** | **Infant formula without probiotics** | 1 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 1 | a |
| 2017 | **7795** | **Infant formula without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | a |
| 2017 | **7796** | **Infant formula without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | a |
| 2017 | **7799** | **Infant formula without probiotics** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | **7801** | **Infant formula without probiotics** | 1 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 1 | a |
| 2017 | **7802** | **Infant formula without probiotics** | 1 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 1 | a |
| 2017 | 8433 | Infant formula without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | 8434 | Infant formula without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | 8435 | Infant formula without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | 8436 | Infant formula without probiotics | 1 | st | / | - | - | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | 8437 | Infant formula without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | 8438 | Infant formula without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | 8439 | Infant formula without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | 8440 | Infant formula without probiotics | 1 | - | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | 8441 | Infant formula without probiotics | 1 | - | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | **9128** | **Infant formula without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | a |
| 2017 | **9129** | **Infant formula without probiotics** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | a |
| 2017 | **7624** | **Infant cereals without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | b |
| 2017 | **7625** | **Infant cereals without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | b |

♦ Analyses performed according to the COFRAC accreditation

| MILK POWDERS AND INGREDIENTS, INFANT FORMULA AND INFANT CEREALS WITHOUT PROBIOTICS (25 g sample size – protocol 1) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | CSB + CCI | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2017 | **7626** | **Infant cereals without probiotics** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | **7627** | **Infant cereals without probiotics** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | **7628** | **Infant cereals without probiotics** | 1 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 1 | b |
| 2017 | **7629** | **Infant cereals without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +M | + | + | + | **PA** | 1 | b |
| 2017 | **7630** | **Infant cereals without probiotics** | 1 | +p | + | + | - | | | - | **ND** | - | - | | | - | **ND** | 1 | b |
| 2017 | **7631** | **Infant cereals without probiotics** | 1 | st | / | - | +p | + | + | + | **PD** | | +M | + | + | + | **PD** | 1 | b |
| 2017 | **7797** | **Infant cereals without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | b |
| 2017 | **7798** | **Infant cereals without probiotics** | 1 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 1 | b |
| 2017 | **7800** | **Infant cereals without probiotics** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | b |
| 2017 | 8426 | Infant cereals without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | 8427 | Infant cereals without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | 8428 | Infant cereals without probiotics | 1 | st | / | - | - | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | 8429 | Infant cereals without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | 8430 | Infant cereals without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | 8431 | Infant cereals without probiotics | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | 8432 | Infant cereals without probiotics | 1 | - | / | - | st | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | **8455** | **Infant cereals without probiotics** | 1 | st | / | - | - | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | **8456** | **Infant cereals without probiotics** | 1 | - | / | - | st | | | - | **NA** | - | | | | | | 1 | b |
| 2017 | **9130** | **Infant cereals without probiotics** | 1 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 1 | b |
| 2017 | **9131** | **Infant cereals without probiotics** | 1 | +p | + | + | +M | + | + | + | **PA** | | +m | + | + | + | **PA** | 1 | b |
| 2017 | **7632** | **Lactoserum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | c |
| 2017 | **7633** | **Milk proteins** | 1 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 1 | c |
| 2017 | **7634** | **Lactose** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | c |
| 2017 | **7635** | **Caseinate** | 1 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 1 | c |
| 2017 | **7636** | **Lactoserum proteins concentrate** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | c |
| 2017 | **7637** | **Maltodextrine** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | c |
| 2017 | **7638** | **Lactoserum proteins concentrate** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2017 | **7803** | **Lactoserum** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |

| MILK POWDERS AND INGREDIENTS, INFANT FORMULA AND INFANT CEREALS WITHOUT PROBIOTICS (25 g sample size – protocol 1) | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2017 | **7804** | **Lactoserum** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2017 | **7805** | **Corn flour** | 1 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 1 | c |
| 2017 | **7806** | **Milk powder (ingredient)** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | c |
| 2017 | 8442 | Caseinate | 1 | st | / | - | st | | | - | **NA** | - | st | | | - | **NA** | 1 | c |
| 2017 | 8443 | Lactose | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2017 | 8444 | Whey protein concentrate | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2017 | 8445 | Milk proteins | 1 | - | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2017 | 8446 | Maltodextrine | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 1 | c |
| 2017 | 8447 | Whey permeate | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2017 | **8458** | **Lactose** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | c |
| 2017 | **8459** | **Whey protein concentrate** | 1 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 1 | c |
| 2017 | 9132 | Milk proteins | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2018 | **2609** | **Skim milk powder** | 1 | +p | + | + | +Md | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | c |
| 2018 | **2610** | **Whole milk powder** | 1 | +p | + | + | - | | | - | **ND** | - | st | | | - | **ND** | 1 | c |
| 2018 | **2611** | **Skim milk powder** | 1 | +p | + | + | +p | + | + | + | **PA** | | st | | | - | **ND** | 1 | c |
| 2018 | **2612** | **Skim milk powder** | 1 | st | / | - | +pd | + | + | + | **PD** | | +p | + | + | + | **PD** | 1 | c |
| 2018 | **2613** | **Skim milk powder** | 1 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 1 | c |
| 2018 | **2614** | **Skim milk powder** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 1 | c |
| 2018 | 2615 | Skim milk powder | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2018 | 2616 | Whole milk powder | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2018 | 2617 | Skim milk powder | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |
| 2018 | 2618 | Skim milk powder | 1 | st | / | - | - | | | - | **NA** | - | | | | | | 1 | c |
| 2018 | 2619 | Skim milk powder | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 1 | c |

| INFANT FORMULA AND INFANT CEREALS WITH PROBIOTICS (25 g sample size – protocol 2) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | CSB + CCI | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2017 | **8027** | **Infant formula with probiotics (3,6.10² CFU/g)** | 2 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 2 | a |
| 2017 | **8028** | **Infant formula with probiotics (<10 CFU/g)** | 2 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 2 | a |
| 2017 | **8029** | **Infant formula with probiotics (1,3.10⁵ CFU/g)** | 2 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 2 | a |
| 2017 | **8030** | **Infant formula with probiotics (<10 CFU/g)** | 2 | +p | + | + | +M | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | a |
| 2017 | **8031** | **Infant formula with probiotics (1,8.10⁵ CFU/g)** | 2 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 2 | a |
| 2017 | **8032** | **Infant formula with probiotics (3,0.10⁴ CFU/g)** | 2 | st | / | - | +M | + | + | + | **PD** | | +p | + | + | + | **PD** | 2 | a |
| 2017 | **8033** | **Infant formula with probiotics (4,8.10⁵ CFU/g)** | 2 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 2 | a |
| 2017 | **8131** | **Infant formula with probiotics (5,6.10⁵ CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | **8132** | **Infant formula with probiotics (1,2.10⁷ CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | **8133** | **Infant formula with probiotics (4,3.10⁵ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | a |
| 2017 | **8134** | **Infant formula with probiotics (6,8.10⁵ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | a |
| 2017 | **8135** | **Infant formula with probiotics (4,2.10⁵ CFU/g)** | 2 | st | / | - | +p (3) | + | + | + | **PD** | | +p (ia) | + | + | + | **PD** | 2 | a |
| 2017 | **8136** | **Infant formula with probiotics (6,8.10⁵ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | a |
| 2017 | **8137** | **Infant formula with probiotics (7,5.10⁵ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | a |
| 2017 | **8138** | **Infant formula with probiotics (8,6.10⁵ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | a |
| 2017 | 8403 | Infant formula with probiotics (4,2.10⁵ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | 8404 | Infant formula with probiotics (5,9.10⁵ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | 8405 | Infant formula with probiotics (4,3.10⁵ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | 8406 | Infant formula with probiotics (6,8.10⁵ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | 8407 | Infant formula with probiotics (8,6.10⁵ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |

♦ Analyses performed according to the COFRAC accreditation

| INFANT FORMULA AND INFANT CEREALS WITH PROBIOTICS (25 g sample size – protocol 2) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2017 | 8408 | Infant formula with probiotics (8,0.10$^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | 8409 | Infant formula with probiotics (<10 CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | 8410 | Infant formula with probiotics (<10 CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | 8411 | Infant formula with probiotics (<10 CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | st | | | - | **NA** | 2 | a |
| 2017 | 8412 | Infant formula with probiotics (1,2.10$^7$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | 8413 | Infant formula with probiotics (4,2.10$^6$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | 8414 | Infant formula with probiotics (7,0.10$^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | **8448** | **Infant formula with probiotics (4,2.10$^5$ CFU/g)** | 2 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 2 | a |
| 2017 | **8449** | **Infant formula with probiotics (<10 CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | **8450** | **Infant formula with probiotics (7,0.10$^5$ CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | a |
| 2017 | **9610** | **Infant formula with probiotics (4,2.10$^5$ CFU/g)** | 2 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 2 | a |
| 2017 | **9611** | **Infant formula with probiotics (5,9.10$^5$ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | a |
| 2017 | **8034** | **Infant cereals with probiotics (5,6.10$^5$ CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | **8035** | **Infant cereals with probiotics (7,1.10$^4$ CFU/g)** | 2 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 2 | b |
| 2017 | **8036** | **Infant cereals with probiotics (1,7.10$^4$ CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | **8037** | **Infant cereals with probiotics (2,5.10$^5$ CFU/g)** | 2 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 2 | b |
| 2017 | **8038** | **Infant cereals with probiotics (5,1.10$^5$ CFU/g)** | 2 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 2 | b |
| 2017 | **8039** | **Infant cereals with probiotics (6,7.10$^5$ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | b |
| 2017 | **8040** | **Infant cereals with probiotics (2,7.10$^3$ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | b |
| 2017 | **8041** | **Infant cereals with probiotics (1,7.10$^5$ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | b |
| 2017 | **8139** | **Infant cereals with probiotics (6,7.10$^6$ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | b |

| INFANT FORMULA AND INFANT CEREALS WITH PROBIOTICS (25 g sample size – protocol 2) | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2017 | **8140** | **Infant cereals with probiotics ($7,1.10^4$ CFU/g)** | 2 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 2 | b |
| 2017 | **8141** | **Infant cereals with probiotics ($2,7.10^3$ CFU/g)** | 2 | +M | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | b |
| 2017 | **8142** | **Infant cereals with probiotics ($2,3.10^5$ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | b |
| 2017 | **8143** | **Infant cereals with probiotics ($5,6.10^5$ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | b |
| 2017 | **8144** | **Infant cereals with probiotics ($1,7.10^5$ CFU/g)** | 2 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 2 | b |
| 2017 | **8145** | **Infant cereals with probiotics ($5,1.10^5$ CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8415 | Infant cereals with probiotics ($7,4.10^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8416 | Infant cereals with probiotics ($2,3.10^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8417 | Infant cereals with probiotics ($8,7.10^6$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8418 | Infant cereals with probiotics ($5,6.10^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8419 | Infant cereals with probiotics ($1,0.10^6$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8420 | Infant cereals with probiotics ($1,7.10^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8421 | Infant cereals with probiotics ($4,0.10^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8422 | Infant cereals with probiotics ($7,1.10^4$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8423 | Infant cereals with probiotics ($4,4.10^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8424 | Infant cereals with probiotics ($5,1.10^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | 8425 | Infant cereals with probiotics ($6,7.10^5$ CFU/g) | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | **8451** | **Infant cereals with probiotics ($2,3.10^5$ CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | **8452** | **Infant cereals with probiotics ($5,6.10^5$ CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | **8453** | **Infant cereals with probiotics ($1,7.10^5$ CFU/g)** | 2 | st | / | - | st | | | - | **NA** | - | | | | | | 2 | b |
| 2017 | **8454** | **Infant cereals with probiotics ($7,1.10^4$ CFU/g)** | 2 | +p | + | + | +p (3) | + | + | + | **PA** | | st | | | - | **ND** | 2 | b |

| INFANT FORMULA AND INFANT CEREALS WITH PROBIOTICS (25 g sample size – protocol 2) | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2017 | **9126** | **Infant cereals with probiotics ($7,1.10^4$ CFU/g)** | 2 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 2 | b |
| 2017 | **9127** | **Infant cereals with probiotics ($5,6.10^5$ CFU/g)** | 2 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 2 | b |

| MILK POWDERS, INGREDIENTS, INFANT FORMULA AND INFANT CEREALS WITH OR WITHOUT PROBIOTICS (375 g sample size – protocols 3 and 4 (ingredients)) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2018 | **2589** | **Skim milk powder** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |
| 2018 | **2590** | **Whole milk powder** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p(4) | + | + | + | **PA** | 3 | a |
| 2018 | **2591** | **Skim milk powder** | 3 | +p | + | + | st | | | - | **ND** | - | - | | | - | **ND** | 3 | a |
| 2018 | **2592** | **Skim milk powder** | 3 | st | / | - | - | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | **2593** | **Skim milk powder** | 3 | +p | + | + | - | | | - | **ND** | - | - | | | - | **ND** | 3 | a |
| 2018 | **2594** | **Skim milk powder** | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | **2595** | **Infant cereals without probiotics** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |
| 2018 | **2596** | **Infant cereals without probiotics** | 3 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 3 | a |
| 2018 | **2597** | **Infant cereals without probiotics** | 3 | +p | + | + | +M | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |
| 2018 | **2598** | **Infant cereals without probiotics** | 3 | +p | + | + | +M | + | + | + | **PA** | | +M | + | + | + | **PA** | 3 | a |
| 2018 | **2599** | **Infant cereals without probiotics** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |
| 2018 | **2600** | **Infant cereals without probiotics** | 3 | +p | + | + | +M | + | + | + | **PA** | | +1/2 | + | + | + | **PA** | 3 | a |
| 2018 | **2601** | **Infant cereals without probiotics** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |
| 2018 | **2602** | **Infant formula without probiotics** | 3 | +p | + | + | - | + | + | + | **PA** | | - | | | - | **ND** | 3 | a |
| 2018 | **2603** | **Infant formula without probiotics** | 3 | +p | + | + | st | | | - | **ND** | - | - | | | - | **ND** | 3 | a |
| 2018 | **2604** | **Infant formula without probiotics** | 3 | +p | + | + | +Md | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |
| 2018 | **2606** | **Infant formula without probiotics** | 3 | +p | + | + | st | | | - | **ND** | - | st | | | - | **ND** | 3 | a |
| 2018 | **2607** | **Infant formula without probiotics** | 3 | st | / | - | - | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 2640 | Skim milk powder | 3 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 3 | a |
| 2018 | 2641 | Skim milk powder | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 2642 | Skim milk powder | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 2643 | Half-skim milk powder | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 2644 | Infant formula without probiotics | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 2645 | Infant formula without probiotics | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 2646 | Infant formula without probiotics | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 2647 | Infant cereals without probiotics | 3 | st | / | - | - | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 2648 | Infant cereals without probiotics | 3 | st | / | - | st | | | - | **NA** | - | st | | | - | **NA** | 3 | a |
| 2018 | 2649 | Infant cereals without probiotics | 3 | st | / | - | +m/+ | + | + | + | **PD** | | +m/+ | + | + | + | **PD** | 3 | a |
| 2018 | **3469** | **Skim milk powder** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |

♦ Analyses performed according to the COFRAC accreditation

| MILK POWDERS, INGREDIENTS, INFANT FORMULA AND INFANT CEREALS WITH OR WITHOUT PROBIOTICS (375 g sample size – protocols 3 and 4 (ingredients)) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2018 | **3470** | **Skim milk powder** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |
| 2018 | **3471** | **Infant formula without probiotics** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |
| 2018 | **3472** | **Infant formula without probiotics** | 3 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 3 | a |
| 2018 | **3473** | **Infant formula without probiotics** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | a |
| 2018 | 3751 | Infant cereals without probiotics | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 3752 | Infant cereals without probiotics | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 3753 | Infant cereals without probiotics | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | 3797 | Infant formula without probiotics | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | a |
| 2018 | **2620** | **Infant formula with probiotics ($7,2.10^4$ CFU/g)** | 3 | +p | + | + | st | | | - | **ND** | + | st | | | - | **ND** | 3 | b |
| 2018 | **2621** | **Infant formula with probiotics ($6,0.10^4$ CFU/g)** | 3 | +p | + | + | +p (2) | + | + | + | **PA** | | +p (1) | + | + | + | **PA** | 3 | b |
| 2018 | **2623** | **Infant formula with probiotics ($6,1.10^6$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2625** | **Infant formula with probiotics ($5,1.10^5$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2626** | **Infant formula with probiotics ($4,7.10^5$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2627** | **Infant formula with probiotics ($1,1.10^6$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2628** | **Infant formula with probiotics ($1,4.10^4$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2629** | **Infant formula with probiotics ($3,0.10^4$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2630** | **Infant cereals with probiotics ($1,4.10^5$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2631** | **Infant cereals with probiotics ($2,1.10^5$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2632** | **Infant cereals with probiotics ($7,8.10^5$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2633** | **Infant cereals with probiotics ($2,5.10^5$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2634** | **Infant cereals with probiotics ($4,5.10^4$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2635** | **Infant cereals with probiotics ($9,1.10^3$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2636** | **Infant cereals with probiotics ($3,2.10^6$ CFU/g)** | 3 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 3 | b |
| 2018 | **2637** | **Infant cereals with probiotics ($1,3.10^5$ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |

| MILK POWDERS, INGREDIENTS, INFANT FORMULA AND INFANT CEREALS WITH OR WITHOUT PROBIOTICS (375 g sample size – protocols 3 and 4 (ingredients)) | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2018 | **2638** | **Infant cereals with probiotics (1,4.10⁶ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | **2639** | **Infant cereals with probiotics (2,2.10⁵ CFU/g)** | 3 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | b |
| 2018 | 2864 | Infant cereals with probiotics (2,9.10⁵ CFU/g) | 3 | st | / | - | - | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 2865 | Infant cereals with probiotics (4,8.10⁴ CFU/g) | 3 | st | / | - | - | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 2866 | Infant cereals with probiotics (1,2.10⁷ CFU/g) | 3 | st | / | - | - | | | - | **NA** | - | st | | | - | **NA** | 3 | b |
| 2018 | 2867 | Infant formula with probiotics (1,6.10⁶ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 2868 | Infant formula with probiotics (1,5.10⁶ CFU/g) | 3 | st | / | - | - | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 2869 | Infant formula with probiotics (9,6.10⁶ CFU/g) | 3 | st | / | - | +M | + | + | + | **PD** | | +p | + | + | + | **PD** | 3 | b |
| 2018 | 3754 | Infant cereals with probiotics (2,5.10⁵ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 3755 | Infant cereals with probiotics (1,4.10⁶ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 3756 | Infant cereals with probiotics (2,2.10⁵ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 3757 | Infant cereals with probiotics (4,8.10⁴ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 3758 | Infant cereals with probiotics (2,9.10⁵ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 3798 | Infant formula with probiotics (1,6.10⁶ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 3799 | Infant formula with probiotics (7,2.10⁴ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 3800 | Infant formula with probiotics (6,0.10⁴ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 3801 | Infant formula with probiotics (1,5.10⁶ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 3802 | Infant formula with probiotics (4,7.10⁵ CFU/g) | 3 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | b |
| 2018 | 2870 | Starch | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 2871 | Whey | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 2872 | Caseinates | 4 | st | / | - | st | | | - | **NA** | - | st | | | - | **NA** | 3 | c |
| 2018 | 2873 | Lactose | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | **3101** | **Starch** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3102** | **Caseinates** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3103** | **Corn starch** | 4 | +p | + | + | +md/+ | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |

| MILK POWDERS, INGREDIENTS, INFANT FORMULA AND INFANT CEREALS WITH OR WITHOUT PROBIOTICS (375 g sample size – protocols 3 and 4 (ingredients)) | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2018 | **3104** | **Wheat starch** | 4 | - | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 3 | c |
| 2018 | **3106** | **Lactose** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3107** | **Maltodextrine** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3108** | **Whey** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3109** | **Starch** | 4 | +p | + | + | - | | | - | **ND** | - | st | | | - | **ND** | 3 | c |
| 2018 | **3110** | **Caseinates** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3111** | **Corn starch** | 4 | +p | + | + | - | | | - | **ND** | - | st | | | - | **ND** | 3 | c |
| 2018 | **3112** | **Wheat starch** | 4 | - | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 3 | c |
| 2018 | **3113** | **Corn starch** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3114** | **Lactose** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3122** | **Starch** | 4 | +p | + | + | +p (4) | + | + | + | **PA** | | +p (1) | + | + | + | **PA** | 3 | c |
| 2018 | **3123** | **Whey** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3124** | **Maltodextrine** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3125** | **Maltodextrine** | 4 | +p | + | + | +p (1) | + | + | + | **PA** | | st | | | - | **ND** | 3 | c |
| 2018 | **3126** | **Wheat starch** | 4 | +p | + | + | st | | | - | **ND** | + | st | | | - | **ND** | 3 | c |
| 2018 | **3127** | **Caseinates** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3128** | **Corn starch** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3129** | **Lactose** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3130** | **Corn starch** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3131** | **Starch** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3132** | **Maltodextrine** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p (2) | + | + | + | **PA** | 3 | c |
| 2018 | **3133** | **Whey** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3134** | **Starch** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3135** | **Lactose** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3136** | **Caseinates** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3474** | **Maltodextrine** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | **3475** | **Whey** | 4 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 3 | c |
| 2018 | 3739 | Caseinate | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3631 | Starch | 4 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 3 | c |
| 2018 | 3632 | Starch | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3633 | Lactose | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3634 | Starch | 4 | +p | - (Buttiauxella agrestis/Leclercia adecaboxylata) | - | +p | - (Leclercia adecarboxylata) | + | - | **PPNA** | - | | | | | | 3 | c |
| 2018 | 3635 | Whey | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3636 | Starch | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3637 | Maltodextrine | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3638 | Maltodextrine | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3639 | Maltodextrine | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3640 | Maltodextrine | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3641 | Starch | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3642 | Starch | 4 | st | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 3 | c |

| MILK POWDERS, INGREDIENTS, INFANT FORMULA AND INFANT CEREALS WITH OR WITHOUT PROBIOTICS (375 g sample size – protocols 3 and 4 (ingredients)) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2018 | 3643 | Starch | 4 | - | / | - | +p | + | + | + | **PD** | | +p | + | + | + | **PD** | 3 | c |
| 2018 | 3644 | Lactose | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3645 | Caseinate | 4 | st | / | - | st | | | - | **NA** | - | st | | | - | **NA** | 3 | c |
| 2018 | 3803 | Whey | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3804 | Whey | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3805 | Whey | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3806 | Whey | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3807 | Lactose | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3808 | Lactose | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3809 | Lactose | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3810 | Lactose | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3811 | Starch | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3812 | Starch | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3813 | Maltodextrin | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3814 | Maltodextrin | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3815 | Maltodextrin | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |
| 2018 | 3816 | Maltodextrin | 4 | st | / | - | st | | | - | **NA** | - | | | | | | 3 | c |

| PRODUCTION ENVIRONMENTAL SAMPLES (25 g (mL) sample size – protocol 1) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2018 | 347 | Water before cleaning | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | 348 | Water before cleaning | 1 | +M | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | 349 | Water before cleaning | 1 | +md/- | / | - | st | | | - | **NA** | - | - | | | - | **NA** | 4 | a |
| 2018 | **386** | **Water after cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | **387** | **Water after cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | **388** | **Water after cleaning** | 1 | +p | + | + | +M | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | **389** | **Water before cleaning** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | **390** | **Water before cleaning** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | **391** | **Water before cleaning** | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | **392** | **Water before cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | 1789 | Rinse water | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | 1790 | Process water | 1 | st | / | - | - | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | 1791 | Rinse water | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | 2166 | Process water | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | 2167 | Process water | 1 | - | / | - | st | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | 2168 | Process water | 1 | - | / | - | st | | | - | **NA** | - | | | | | | 4 | a |
| 2018 | **2465** | **Process water (rinse)** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | **2466** | **Process water (rinse)** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | **2467** | **Process water (rinse)** | 1 | st | / | - | +p | + | + | + | **PD** | | +M | + | + | + | **PD** | 4 | a |
| 2018 | **2468** | **Process water (rinse)** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | **2469** | **Process water (rinse)** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | **2470** | **Process water (rinse)** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | a |
| 2018 | 345 | Waste | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | b |
| 2018 | 346 | Waste | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | b |
| 2018 | 350 | Dusts | 1 | - | / | - | - | | | - | **NA** | - | - | | | - | **NA** | 4 | b |
| 2018 | 351 | Dusts | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | b |
| 2018 | 352 | Dust from vacuum | 1 | +M | + | + | +M | + | + | + | **PA** | | +M | + | + | + | **PA** | 4 | b |
| 2018 | 1792 | Waste | 1 | - | / | - | +md(1)/+d | - (E.vulneris) | - | - | **PPNA** | - | - | | | - | **NA** | 4 | b |
| 2018 | 1793 | Dust | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | b |
| 2018 | 1794 | Dust from vacuum | 1 | +1/2 | + | + | +M | + | + | + | **PA** | | +m | + | + | + | **PA** | 4 | b |
| 2018 | 2169 | Waste | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | b |
| 2018 | 2170 | Waste | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | b |
| 2018 | 2171 | Dust from vacuum | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | b |
| 2018 | 2172 | Dust from vacuum | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | b |
| 2018 | **3137** | **Dust from vacuum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +M | + | + | + | **PA** | 4 | b |
| 2018 | **3138** | **Dust from vacuum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | b |
| 2018 | **3139** | **Dust from vacuum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | b |
| 2018 | **3140** | **Dust from vacuum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | b |
| 2018 | **3141** | **Dust from vacuum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | b |
| 2018 | **3142** | **Dust from vacuum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | b |

♦ Analyses performed according to the COFRAC accreditation

| PRODUCTION ENVIRONMENTAL SAMPLES (25 g (mL) sample size – protocol 1) | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Year of analysis | Sample N° | Product (lactic bacteria enumeration done by the expert laboratory) | Protocol | Reference method: ISO 22964♦ | | | Alternative method: ESIA One Day | | | | | | | | | | | Category | Type |
| | | | | CSB | Confirmation | ISO 22964 Result | Enrichment | | | | | CSB + CCI | Enrichment after 72h at 5°C ± 3°C | | | | | | |
| | | | | | | | ESIA | | | | | | ESIA | | | | | | |
| | | | | CCI | | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | Typical colonies | API ID32E | Fast Crono | Final result | Agreement | | |
| 2018 | **3143** | **Dust from vacuum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | b |
| 2018 | **3144** | **Dust from vacuum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | b |
| 2018 | **3145** | **Dust from vacuum** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | b |
| 2018 | **3146** | **Dust from vacuum** | 1 | st | / | - | +p | + | + | + | **PD** | | - | | | - | **NA** | 4 | b |
| 2018 | 338 | Sponge before cleaning | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | 339 | Sponge before cleaning | 1 | - | / | - | - | | | - | **NA** | - | - | | | - | **NA** | 4 | c |
| 2018 | 340 | Sponge before cleaning | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | 341 | Sponge before cleaning | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | 342 | Sponge before cleaning | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | 343 | Wipe before cleaning | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | 344 | Wipe before cleaning | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | **393** | **Wipe after cleaning** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | **394** | **Wipe after cleaning** | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | **395** | **Wipe before cleaning** | 1 | +M | + | + | +m | + | + | + | **PA** | | +m | + | + | + | **PA** | 4 | c |
| 2018 | **396** | **Wipe before cleaning** | 1 | +M | + | + | +m | + | + | + | **PA** | | +M | + | + | + | **PA** | 4 | c |
| 2018 | **397** | **Wipe before cleaning** | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | **398** | **Wipe before cleaning** | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | **399** | **Wipe before cleaning** | 1 | +p | + | + | +M | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | c |
| 2018 | **400** | **Wipe before cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | c |
| 2018 | 1795 | Wipe before cleaning | 1 | st | / | - | st | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | 1796 | Wipe before cleaning | 1 | +md/- | / | - | - | | | - | **NA** | - | - | | | - | | 4 | c |
| 2018 | 1797 | Wipe before cleaning | 1 | +M | + | + | +M | + | + | + | **PA** | | +1/2 | + | + | + | **PA** | 4 | c |
| 2018 | 1798 | Wipe before cleaning | 1 | - | / | - | - | | | - | **NA** | - | | | | | | 4 | c |
| 2018 | **2159** | **Wipe after cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | c |
| 2018 | **2160** | **Wipe after cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | c |
| 2018 | **2161** | **Wipe after cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | c |
| 2018 | **2162** | **Wipe after cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | c |
| 2018 | **2163** | **Wipe after cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | c |
| 2018 | **2164** | **Wipe before cleaning** | 1 | +p | + | + | +p | + | + | + | **PA** | | +p | + | + | + | **PA** | 4 | c |
| 2018 | **2165** | **Wipe before cleaning** | 1 | +M | + | + | +M | + | + | + | **PA** | | +M | + | + | + | **PA** | 4 | c |

# Appendix 5 – Relative level of detection study: raw data

**Matrix : Infant cereals without probiotics**
**Strain : *Cronobacter sakazakii* E798**
Aerobic mesophilic flora :<10 CFU/g

**Protocol 1**
Sample size: 25 g

| N° sample | Level | Contamination level- (cfu/sample) | **Reference method: ISO 22964 ♦** | | | Number positive samples/ Total | **Alternative method: ESIA One Day** | | | CSB + CCI | Number positive samples/ Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CSB CCI | Confirmation | Final result | | ESIA | Confirmation | Final result | | |
| 8857 | 0 | / | st | / | - | 0/5 | st | / | - | - | 0/5 |
| 8858 | | | st | / | - | | st | / | - | - | |
| 8859 | | | st | / | - | | - | / | - | - | |
| 8860 | | | st | / | - | | st | / | - | - | |
| 8861 | | | st | / | - | | st | / | - | - | |
| 8862 | Low | 1,0 | +p | + | + | 11/20 | st | / | - | - | 7/20 |
| 8863 | | | +p | + | + | | st | / | - | - | |
| 8864 | | | +p | + | + | | +p | + | + | / | |
| 8865 | | | +M | + | + | | st | / | - | - | |
| 8866 | | | st | / | - | | st | / | - | - | |
| 8867 | | | st | / | - | | st | / | - | - | |
| 8868 | | | st | / | - | | +p | + | + | / | |
| 8869 | | | +p | + | + | | +p | + | + | / | |
| 8870 | | | st | / | - | | st | / | - | - | |
| 8871 | | | st | / | - | | st | / | - | - | |
| 8872 | | | +p | + | + | | st | / | - | - | |
| 8873 | | | st | / | - | | +p | + | + | / | |
| 8874 | | | +p | + | + | | +p | + | + | / | |
| 8875 | | | st | / | - | | +p | + | + | / | |
| 8876 | | | st | / | - | | st | / | - | - | |
| 8877 | | | +p | + | + | | st | / | - | - | |
| 8878 | | | +p | + | + | | st | / | - | - | |
| 8879 | | | st | / | - | | +p | + | + | / | |
| 8880 | | | +p | + | + | | st | / | - | - | |
| 8881 | | | +p | + | + | | st | / | - | - | |
| 8882 | High | 3,1 | +p | + | + | 5/5 | +p | + | + | / | 4/5 |
| 8883 | | | +p | + | + | | - | / | - | + | |
| 8884 | | | +p | + | + | | +p | + | + | / | |
| 8885 | | | +p | + | + | | +p | + | + | / | |
| 8886 | | | +p | + | + | | +p | + | + | / | |

♦ Analyses performed according to the COFRAC accreditation

**Matrix : Infant formula with probiotics**
**Strain : *Cronobacter sakazakii* Ad2413**
Aerobic mesophilic flora : 9,8.10$^5$ CFU/g

**Protocol 2**
Sample size :25 g

| N° sample | Level | Contamination level- (cfu/sample) | **Reference method: ISO 22964 ♦** | | | Number positive samples/ Total | **Alternative method: ESIA One Day** | | | CSB + CCI | Number positive samples/ Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CSB CCI | Confirmation | Final result | | ESIA | Confirmation | Final result | | |
| 9102 | 0 | / | st | - | - | 0/5 | st | / | - | - | 0/5 |
| 9103 | | | st | - | - | | st | / | - | - | |
| 9104 | | | st | - | - | | st | / | - | - | |
| 9105 | | | - | - | - | | st | / | - | - | |
| 9106 | | | st | - | - | | st | / | - | - | |
| 9430 | Low | 1,0 | +p | + | + | 16/20 | +p | + | + | / | 16/20 |
| 9431 | | | +p | + | + | | +p | + | + | / | |
| 9432 | | | +p | + | + | | +p | + | + | / | |
| 9433 | | | +p | + | + | | +p | + | + | / | |
| 9434 | | | +p | + | + | | st | / | - | - | |
| 9435 | | | +p | + | + | | +p | + | + | / | |
| 9436 | | | +p | + | + | | +p | + | + | / | |
| 9437 | | | +p | + | + | | +p | + | + | / | |
| 9438 | | | +p | + | + | | +p | + | + | / | |
| 9439 | | | +p | + | + | | +p | + | + | / | |
| 9440 | | | +p | + | + | | +p | + | + | / | |
| 9441 | | | +p | + | + | | +p | + | + | / | |
| 9442 | | | st | - | - | | +p | + | + | / | |
| 9443 | | | +p | + | + | | st | / | - | - | |
| 9444 | | | st | - | - | | st | / | - | - | |
| 9445 | | | +p | + | + | | st | / | - | - | |
| 9446 | | | +p | + | + | | +p | + | + | / | |
| 9447 | | | st | - | - | | +p | + | + | / | |
| 9448 | | | st | - | - | | +p | + | + | / | |
| 9449 | | | +p | + | + | | +p | + | + | / | |
| 9097 | High | 5,4 | +p | + | + | 5/5 | +p | + | + | / | 4/5 |
| 9098 | | | +p | + | + | | st | / | - | - | |
| 9099 | | | +p | + | + | | +p | + | + | / | |
| 9100 | | | +p | + | + | | +p | + | + | / | |
| 9101 | | | +p | + | + | | +p | + | + | / | |

♦ Analyses performed according to the COFRAC accreditation

**Matrix : Maltodextrin**
**Strain : *Cronobacter turicensis* Ad1445**
Aerobic mesophilic flora : <200 CFU/g

**Protocol 4**
Sample size: 375 g

| N° sample | Level | Contamination level- (cfu/sample) | Reference method: ISO 22964 ♦ | | | Number positive samples/ Total | Alternative method: ESIA One Day | | | CSB + CCI | Number positive samples/ Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CSB CCI | Confirmation | Final result | | ESIA | Confirmation | Final result | | |
| 3349 | 0 | / | st | / | - | 0/5 | st | / | - | - | 0/5 |
| 3350 | | | st | / | - | | st | / | - | - | |
| 3351 | | | st | / | - | | st | / | - | - | |
| 3352 | | | st | / | - | | st | / | - | - | |
| 3353 | | | st | / | - | | st | / | - | - | |
| 3354 | Low | 1,1 | st | / | - | 18/20 | st | / | - | - | 15/20 |
| 3355 | | | +p | + | + | | +p | + | + | / | |
| 3356 | | | +p | + | + | | +p | + | + | / | |
| 3357 | | | st | / | - | | +p | + | + | / | |
| 3358 | | | +p | + | + | | st | + | + | / | |
| 3359 | | | +p | + | + | | +p | + | + | / | |
| 3360 | | | +p | + | + | | st | / | - | - | |
| 3361 | | | +p | + | + | | +p | + | + | / | |
| 3362 | | | +p | + | + | | +p | + | + | / | |
| 3363 | | | +p | + | + | | +p | + | + | / | |
| 3364 | | | +p | + | + | | +p | + | + | / | |
| 3365 | | | +p | + | + | | st | / | - | - | |
| 3366 | | | +p | + | + | | +p | + | + | / | |
| 3367 | | | +p | + | + | | +p | + | + | / | |
| 3368 | | | +p | + | + | | +p | + | + | / | |
| 3369 | | | +p | + | + | | +p | + | + | / | |
| 3370 | | | +p | + | + | | +p | + | + | / | |
| 3371 | | | +p | + | + | | st | / | - | - | |
| 3372 | | | +p | + | + | | st | / | - | - | |
| 3373 | | | +p | + | + | | +p | + | + | / | |
| 3374 | High | 2,1 | +p | + | + | 5/5 | +p | + | + | / | 3/5 |
| 3375 | | | +p | + | + | | +p | + | + | / | |
| 3376 | | | +p | + | + | | st | / | - | - | |
| 3377 | | | +p | + | + | | +p | + | + | / | |
| 3378 | | | +p | + | + | | st | / | - | + | |

♦ Analyses performed according to the COFRAC accreditation

**Matrix : Infant formula with probiotics**
**Strain : *Cronobacter sakazakii* Ad2412**
Aerobic mesophilic flora: 1,9.10$^6$ CFU/g

**Protocol 3**
Sample size: 375 g

| N° sample | Level | Contamination level- (cfu/sample) | Reference method: ISO 22964 ♦ | | | Number positive samples/ Total | Alternative method: ESIA One Day | | | CSB + CCI | Number positive samples/ Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CSB CCI | Confirmation | Final result | | ESIA | Confirmation | Final result | | |
| 3439 | 0 | / | st | / | - | 0/5 | st | / | - | - | 0/5 |
| 3440 | | | st | / | - | | st | / | - | - | |
| 3441 | | | st | / | - | | st | / | - | - | |
| 3442 | | | st | / | - | | st | / | - | - | |
| 3443 | | | st | / | - | | st | / | - | - | |
| 3444 | Low | 1,5 | +p | + | + | 16/20 | +p | + | + | / | 18/20 |
| 3445 | | | +p | + | + | | +p | + | + | / | |
| 3446 | | | +p | + | + | | +p | + | + | / | |
| 3447 | | | +p | + | + | | +p | + | + | / | |
| 3448 | | | +p | + | + | | +p | + | + | / | |
| 3449 | | | +p | + | + | | +p | + | + | / | |
| 3450 | | | +p | + | + | | st | / | - | - | |
| 3451 | | | +p | + | + | | st | / | - | - | |
| 3452 | | | st | / | - | | +p | + | + | / | |
| 3453 | | | +p | + | + | | +p | + | + | / | |
| 3454 | | | +p | + | + | | +p | + | + | / | |
| 3455 | | | +p | + | + | | +p | + | + | / | |
| 3456 | | | st | / | - | | +p | + | + | / | |
| 3457 | | | st | / | - | | +p | + | + | / | |
| 3458 | | | +p | + | + | | +p | + | + | / | |
| 3459 | | | st | / | - | | +p | + | + | / | |
| 3460 | | | +p | + | + | | +p | + | + | / | |
| 3461 | | | +p | + | + | | +p | + | + | / | |
| 3462 | | | +p | + | + | | +p | + | + | / | |
| 3463 | | | +p | + | + | | +p | + | + | / | |
| 3464 | High | 3,0 | +p | + | + | 5/5 | +p | + | + | / | 5/5 |
| 3465 | | | +p | + | + | | +p | + | + | / | |
| 3466 | | | +p | + | + | | +p | + | + | / | |
| 3467 | | | +p | + | + | | +p | + | + | / | |
| 3468 | | | +p | + | + | | +p | + | + | / | |

♦ Analyses performed according to the COFRAC accreditation

**Matrix : Process water (rinse)**
**Strain : *Cronobacter muytjensii* E888**
Aerobic mesophilic flora : 1,3.10$^2$ CFU/g

**Protocol 1**
Sample size: 25 mL

| N° sample | Level | Contamination level- (cfu/sample) | Reference method: ISO 22964 ♦ | | | Number positive samples/ Total | Alternative method: ESIA One Day | | | CSB + CCI | Number positive samples/ Total |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | CSB CCI | Confirmation | Final result | | ESIA | Confirmation | Final result | | |
| 3298 | 0 | / | st | / | - | 0/5 | st | / | - | - | 0/5 |
| 3299 | | | st | / | - | | st | / | - | - | |
| 3300 | | | st | / | - | | st | / | - | - | |
| 3301 | | | st | / | - | | st | / | - | - | |
| 3302 | | | st | / | - | | st | / | - | - | |
| 3303 | Low | 0,3 | st | / | - | 6/20 | st | / | - | - | 5/20 |
| 3304 | | | st | / | - | | st | / | - | - | |
| 3305 | | | st | / | - | | st | / | - | - | |
| 3306 | | | st | / | - | | st | / | - | - | |
| 3307 | | | +p | + | + | | st | / | - | - | |
| 3308 | | | st | / | - | | st | / | - | - | |
| 3309 | | | st | / | - | | st | / | - | - | |
| 3310 | | | st | / | - | | st | / | - | - | |
| 3311 | | | st | / | - | | st | / | - | - | |
| 3312 | | | st | / | - | | +p | + | + | / | |
| 3313 | | | st | / | - | | +p | + | + | / | |
| 3314 | | | +p | + | + | | +p | + | + | / | |
| 3315 | | | +p | + | + | | +p | + | + | / | |
| 3316 | | | +p | + | + | | st | / | - | - | |
| 3317 | | | st | / | - | | st | / | - | - | |
| 3318 | | | +p | + | + | | +p | + | + | / | |
| 3319 | | | st | / | - | | st | / | - | - | |
| 3320 | | | st | / | - | | st | / | - | - | |
| 3321 | | | +p | + | + | | st | / | - | - | |
| 3322 | | | st | / | - | | st | / | - | - | |
| 3323 | High | 1,0 | st | / | - | 4/5 | st | / | - | - | 3/5 |
| 3324 | | | +p | + | + | | st | / | - | - | |
| 3325 | | | +p | + | + | | +p | + | + | / | |
| 3326 | | | +p | + | + | | +p | + | + | / | |
| 3327 | | | +p | + | + | | +p | + | + | / | |

♦ Analyses performed according to the COFRAC accreditation

# Appendix 6 – Inclusivity and exclusivity study: raw data

| INCLUSIVITY (protocol 2) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| n° | Genus | Species | Reference | Origin | Inoculation Level CFU/225ml | Confirmation | | |
| | | | | | | Direct streaking | Confirmation | |
| | | | | | | | API ID 32E | Fast Crono |
| 1 | *Cronobacter* | *dublinensis* | DSM18705 | Dairy Product | 12 | + | + | + |
| 2 | *Cronobacter* | *malonaticus* | DSM18702 | Dairy Product | 11 | + | + | + |
| 3 | *Cronobacter* | *malonaticus* | Ad1708 | Dairy Product | 59 | + | + | + |
| 4 | *Cronobacter* | *muytjensii* | CIP103581 | / | 18 | st | / | / |
| | | | | | 8 + milk | + (4) | + | + |
| 5 | *Cronobacter* | *turicensis* | Ad1445 | Infant formula | 23 | st | / | / |
| | | | | | 16 + milk | + | + | + |
| 6 | *Cronobacter* | *turicensis* | E681 | Ready to reheat food | 44 | + | + | + |
| 7 | *Cronobacter* | *sakazakii* | Ad941 | Infant formula | 39 | + | + | + |
| 8 | *Cronobacter* | *sakazakii* | Ad942 | Infant formula | 51 | + | + | + |
| 9 | *Cronobacter* | *sakazakii* | Ad943 | Infant formula | 30 | st | / | / |
| | | | | | 30 + milk | + (10) | + | + |
| 10 | *Cronobacter* | *sakazakii* | Ad944 | Infant formula | 40 | st | / | / |
| | | | | | 19 + milk | + | + | + |
| 11 | *Cronobacter* | *sakazakii* | Ad945 | Infant formula | 37 | + | + | + |
| 12 | *Cronobacter* | *sakazakii* | Ad946 | Infant formula | 54 | + | + | + |
| 13 | *Cronobacter* | *sakazakii* | Ad947 | Infant formula | 30 | + | + | + |
| 14 | *Cronobacter* | *sakazakii* | Ad948 | Infant formula | 24 | + | + | + |
| 15 | *Cronobacter* | *sakazakii* | Ad949 | Infant formula | 41 | + | + | + |
| 16 | *Cronobacter* | *sakazakii* | Ad950 | Infant formula | 27 | + | + | + |
| 17 | *Cronobacter* | *sakazakii* | Ad951 | Infant formula | 20 | + | + | + |
| 18 | *Cronobacter* | *sakazakii* | Ad952 | Infant formula | 30 | + | + | + |
| 19 | *Cronobacter* | *sakazakii* | Ad953 | Infant formula | 43 | + | + | + |
| 20 | *Cronobacter* | *sakazakii* | Ad963 | Infant formula | 23 | + | + | + |
| 21 | *Cronobacter* | *sakazakii* | Ad704 | Infant formula | 21 | + | + | + |
| 22 | *Cronobacter* | *sakazakii* | Ad831 | Infant formula | 41 | st | / | / |
| | | | | | 18 + milk | + | + | + |
| 23 | *Cronobacter* | *sakazakii* | Ad829 | Infant formula | 37 | + | + | + |
| 24 | *Cronobacter* | *sakazakii* | Ad916 | Infant formula | 40 | + | + | + |
| 25 | *Cronobacter* | *sakazakii* | Ad893 | Infant formula | 22 | + | + | + |
| 26 | *Cronobacter* | *sakazakii* | Ad894 | Infant formula | 12 | + | + | + |
| 27 | *Cronobacter* | *sakazakii* | Ad895 | Infant formula | 14 | + | + | + |
| 28 | *Cronobacter* | *sakazakii* | Ad896 | Infant formula | 9 | st | / | / |
| | | | | | 25 + milk | + | + | + |
| 29 | *Cronobacter* | *sakazakii* | Ad897 | Infant formula | 10 | + | + | + |
| 30 | *Cronobacter* | *sakazakii* | Ad898 | Infant formula | 9 | + | + | + |
| 31 | *Cronobacter* | *dublinensis lactaridi* | DSMZ18707 T | Dairy Product | 18 | + | + | + |
| 32 | *Cronobacter* | *dublinensis lausannensis* | DSMZ 18706 T | Dairy Product | 32 | + | + | + |
| 33 | *Cronobacter* | *sakazakii* | Ad1418 | Infant formula | 14 | + | + | + |
| 34 | *Cronobacter* | *sakazakii* | Ad1419 | Infant formula | 13 | + | + | + |

| INCLUSIVITY (protocol 2) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| n° | Genus | Species | Reference | Origin | Inoculation Level CFU/225ml | Confirmation | | |
| | | | | | | Direct streaking | Confirmation | |
| | | | | | | | API ID 32E | Fast Crono |
| 35 | *Cronobacter* | *sakazakii* | Ad1420 | Infant formula | 18 | + | + | + |
| 36 | *Cronobacter* | *sakazakii* | Ad1421 | Infant formula | 13 | + | + | + |
| 37 | *Cronobacter* | *sakazakii* | Ad1424 | Infant formula | 11 | st | / | / |
| | | | | | 16 + milk | + | + | + |
| 38 | *Cronobacter* | *sakazakii* | Ad1425 | Infant formula | 28 | + | + | + |
| 39 | *Cronobacter* | *sakazakii* | Ad1433 | Infant formula | 9 | + | + | + |
| 40 | *Cronobacter* | *sakazakii* | Ad1434 | Infant formula | 25 | + | + | + |
| 41 | *Cronobacter* | *sakazakii* | Ad1435 | Infant formula | 5 | + | + | + |
| 42 | *Cronobacter* | *sakazakii* | Ad939 | Infant formula | 10 | st | / | / |
| | | | | | 18 + milk | + (5) | + | + |
| 43 | *Cronobacter* | *malonaticus* | E684 | Food | 26 | st | / | / |
| | | | | | 26 + milk | st | / | / |
| | | | | | 134 | + | + | + |
| 44 | *Cronobacter* | *malonaticus* | E752 | Baby food | 7 | + | + | + |
| 45 | *Cronobacter* | *muytjensii* | E888 | Milk powder | 7 | st | / | / |
| | | | | | 27 + milk | + (7) | + | + |
| 46 | *Cronobacter* | *muytjensii* | E769 | Milk powder | 5 | st | / | / |
| | | | | | 4 + milk | + (2) | + | + |
| | | | | | 38 | st | / | / |
| | | | | | 38 + milk | + (8) | + | + |
| 47 | *Cronobacter* | *dublinensis* subsp *dublinensis* | LMG 23823T | Environment | 7 | + | + | + |
| 48 | *Cronobacter* | *dublinensis* subsp *lausanensis* | E798 | / | 5 | + | + | + |
| 49 | *Cronobacter* | *universalis* | NCTC 9529T | water | 12 | st | / | / |
| | | | | | 26 + milk | + | + | + |
| | | | | | 71 | st | / | / |
| | | | | | 71 + milk | + | + | + |
| 50 | *Cronobacter* | *condimenti* | LMG 26250T | Spiced meat | 32 | st | / | / |
| | | | | | 32 + milk | st | / | / |
| | | | | | 124 | + | + | + |

| EXCLUSIVITY (Initial validation study realized by ISHA) | | | | | | |
|---|---|---|---|---|---|---|
| N° | Code | Strain | Origin | Alternative method: ESIA One Day | | |
| | | | | ESIA | Confirmation | Final result |
| 1. | ENTB.1.1 | *Enterobacter aerogenes* | Dairy industry | - ∅ | + M 4 | A |
| 2. | ENTB.1.2 | *Enterobacter aerogenes* | CIP 60.86T | - L 0 | / | A |
| 3. | ENTB.2.1 | *Enterobacter cloacae* | Waste water | - L 0 | / | A |
| 4. | ENTC.2.1 | *Enterococcus faecium* | Dairy industry | - ∅ | / | A |
| 5. | ESC.1.3 | *Escherichia coli* | Dairy industry | - ∅ | / | A |
| 6. | ESC.1.5 | *Escherichia coli* | Cheese | - ∅ | / | A |
| 7. | HAF.1.1 | *Hafnia alvei* | Tabouleh | - ∅ | / | A |
| 8. | HAN.1.1 | *Hansenula anomala* | Dairy industry | - ∅ | / | A |
| 9. | LACB.1.1 | *Lactobacillus casei* | Dairy product | - L 0 | / | A |
| 10. | STA.2.1 | *Staphylococcus epidermis* | Dairy product | - ∅ | / | A |
| 11. | PSE.1.2 | *Pseudomonas aeruginosa* | Omelette with cheese | - ∅ | / | A |
| 12. | PSE.2.2 | *Pseudomonas fluorescens* | CIP 102127 | - ∅ | / | A |
| 13. | SAL.1.98 | *Salmonella enterica* Newport | Raw milk cheese | - ∅ | / | A |
| 14. | SAL.1.163 | *Salmonella enterica* Infantis | Milk (food) | - ∅ | / | A |
| 15. | SER.1.1 | *Serratia ficaria* | CIP 79.23 | - ∅ | / | A |
| 16. | SER.2.1 | *Serratia fonticola* | CIP 103580 | - L 0 | / | A |
| 17. | SHI.1.1 | *Shigella flexneri* | CIP 82.48T | - ∅ | / | A |
| 18. | ESC.2.1 | *Escherichia hermanii* | CIP 103176 | - ∅ | / | A |
| 19. | CIT.1.1 | *Citrobacter freundii* | CIP 53.62 | - ∅ | / | A |
| 20. | KLE.2.1 | *Klebsiella pneumonia* | Pastry | - ∅ | / | A |
| 21. | KLE.1.1 | *Klebsiella oxytoca* | Deli salad | - ∅ | / | A |
| 22. | CIT.2.1 | *Citrobacter koseri* | CIP 72.11 | - ∅ | / | A |
| 23. | ENTB.4.1 | *Enterobacter hormaechei* | CIP 104956 | - ∅ | / | A |
| 24. | ENTB.5.1 | *Enterobacter amnigenus* | CIP 104982 | - ∅ | / | A |

| EXCLUSIVITY (Initial validation study realized by ISHA) | | | | | | |
|---|---|---|---|---|---|---|
| N° | Code | Strain | Origin | Alternative method: ESIA One Day | | |
| | | | | ESIA | Confirmation | Final result |
| 25. | ENTB.9.1 | *Enterobacter asburiae* | CIP 66.35 | - ∅ | / | A |
| 26. | ENTB.7.1 | *Enterobacter nimpressuralis* | CIP 105047 | - ∅ | / | A |
| 27. | EBTB.8.1 | *Enterobacter pyrinus* | CIP 104019 | - L 0 | / | A |
| 28. | SAL1.121 | *Salmonella enterica* Salamae | Raw milk | - ∅ | / | A |
| 29. | SHI.2.1 | *Shigella sonnei* | ATCC 9290 | - ∅ | / | A |
| 30. | SAL.1.6 | *Salmonella enterica arizonae* | Dry sausage | - ∅ | / | A |
| 31. | CIT.3.1 | *Citrobacter braakii* | CIP 110053 | - ∅ | / | A |
| 32. | PAN.1.2 | *Pantoea agglomerans* | CIP 57.51T | - ∅ | / | A |
| 33. | SAL.143 | *Salmonella* Dublin | Milk | - ∅ | / | A |

| EXCLUSIVITY (Renewal validation study realized by Adria) | | | | | | |
|---|---|---|---|---|---|---|
| **N°** | **Genus** | **Species** | **Reference** | **Origin** | **Inoculation Level CFU/mL** | **ESIA** |
| 1 | *Citrobacter* | *braakii* | Ad833 | Beef | $4,3.10^5$ | st |
| 2 | *Citrobacter* | *diversus* | Ad100 | Pork liver | $1,5.10^6$ | st |
| 3 | *Citrobacter* | *fameri* | Ad116 | Environmental sample | $3,5.10^5$ | st |
| 4 | *Citrobacter* | *freundi* | 39 | Environmental sample | $3,7.10^5$ | st |
| 5 | *Citrobacter* | *koseri* | CIP105177 | / | $5,0.10^5$ | st |
| 6 | *Enterobacter* | *aerogenes* | Ad889 | Meat flour | $7,5.10^5$ | st |
| 7 | *Enterobacter* | *agglomerans* | A00L065 | Dairy product | $5,1.10^5$ | st |
| 8 | *Enterobacter* | *agglomerans* | 136 | Dairy product | $1,8.10^4$ | st |
| 9 | *Enterobacter* | *amnigenus* | 52 | Vegetables | $2,3.10^5$ | st |
| 10 | *Enterobacter* | *amnigenus* | 129 | Raw milk | $1,7.10^5$ | st |
| 11 | *Enterobacter* | *amnigenus* | A00C068 | Poultry | $4,9.10^5$ | st |
| 12 | *Enterobacter* | *cloacae* | 51 | Vegetables | $8,9.10^5$ | st |
| 13 | *Enterobacter* | *cloacae* | 10 | Dairy product | $3,0.10^5$ | st |
| 14 | *Enterobacter* | *fergusonii* | 2876 | Environmental sample | $1,5.10^6$ | st |
| 15 | *Enterobacter* | *gergoviae* | CIP76.1 | / | $5,9.10^5$ | st |
| 16 | *Enterobacter* | *helveticus* | DSM 18396 T | fruit powder | $2,0.10^5$ | st |
| 17 | *Enterobacter* | *hormaechei* | Ad990 | Butter | $5,6.10^5$ | st |
| 18 | *Enterobacter* | *intermedius* | 60 | Vegetables | $1,6.10^5$ | st |
| 19 | *Enterobacter* | *kobei* | Ad706 | Milk powder | $3,0.10^5$ | st |
| 20 | *Escherichia* | *coli* | 16 | Dairy product | $2,4.10^5$ | st |
| 21 | *Escherichia* | *hermanii* | Ad462 | Dairy product | $2,4.10^5$ | st |
| 22 | *Hafnia* | *alvei* | Ad2274 | Dairy product | $6,5.10^5$ | st |
| 23 | *Klebsiella* | *pneumoniae* | 122 | Dairy product | $2,9.10^5$ | st |
| 24 | *Leclercia* | *adecarboxylata* | Ad707 | Milk powder | $6,8.10^5$ | st |
| 25 | *Salmonella* | *arizonae* (51:z4,z23) | CIP 5523 | / | $2,9.10^5$ | st |
| 26 | *Salmonella* | *diarizonae* SIIIb 65 :c :z | Ad 1298 | Dairy environmental sample | $3,3.10^5$ | st |
| 27 | *Salmonella* | *Typhimurium* | Ad1333 | Dairy product | $4,9.10^5$ | st |
| 28 | *Serratia* | *ficaria* | 113 | Vegetables | $7,9.10^5$ | st |
| 29 | *Serratia* | *fonticola* | Ad1696 | Raw milk | $1,2.10^4$ | st |
| 30 | *Yersinia* | *intermedia* | Ad133 | Dairy product | $8,1.10^5$ | st |
| 31 | *Escherichia* | *vulneris* | Ad 2853 | Dairy industry environment | $2,0.10^5$ | st |