



JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEx COMMITTEE ON FOOD ADDITIVES
Fifty-second Session
GENERAL STANDARD FOR FOOD ADDITIVES (GSFA)

GENERAL INFORMATION ON THE AVAILABILITY OF DATA RELATED TO NITRATES AND NITRITES

Replies to CL 2019/49-FA of Brazil, European Union, Indonesia, Iran, Japan and Paraguay

Brazil

Brazil has available data on the following:

- (i) data on natural occurrence of nitrates and nitrites in vegetables and milk from published literature and;
- (ii) monitoring data on levels of nitrates and nitrites in meat products occurring from use as additives.

These data were not provided in the first call of data requested before 15 January 2019 to the GEMS on-line database. However, Brazil could provide these data in case a new call for data is issued.

European Union

The European Union (EU) would like to provide the following comments:

The EU has already provided comprehensive data on nitrates and nitrites as a response to the CCFA51 EWG on nitrates and nitrites (see CX/FA 19/51/9, para. 27). The data provided by the EU included both natural occurrence data on nitrates and nitrites in food, including drinking water, and data for foods to which nitrites and nitrates were added as food additives.

As regards dietary exposure estimates, EU would like to refer to the EFSA's opinions on nitrates¹ and nitrites² from 2017 which capture the overall exposure as well as the exposure due to food additive uses.

Indonesia

General Descriptive Summary

Nitrate and nitrite are a concern because excessive intake may lead to health risks. The presence of nitrate and nitrite in foods can be due to natural origin, application as food additive or as contaminant due to degradation of food components. To obtain data on nitrate and nitrite levels in foods in Indonesia, a sampling of several types of food products on the market and subsequent determination of nitrate and nitrite in those products have been conducted. The level of nitrate and nitrite in various food products are shown in Table 1 and 2, in which the nitrate levels are in the range of 5.72 to 544.49 mg/kg (Table 1), while those of nitrite are 0.01 - 14.53 mg/kg (Table 2). The highest nitrate levels are found in the food category of 14.1.2.2 which are of natural origin, while the lowest level in the food category of 08.3.2 due to addition as food additive. The highest nitrite levels are found in the food category of 01.6.2.1 due to addition as food additive, while the lowest level in food category of 14.1.1.2 which is of natural origin.

Applying data on nitrate and nitrite levels in various food samples and taking into account national consumption data for each food category, exposure calculations have been conducted and the results are presented in Table 3. and Table 4. The results revealed that the general exposure nitrate is around of 1.389 mg/kg BW/day (37.53% ADI) for adult and 3.333 mg/kg BW/day (90.08% ADI) for children, respectively, while those of nitrite is around 0.081 mg/kg BW/day (134.89% ADI) for adult and 0.194 mg/kg BW/day (323.73% ADI) for children, respectively. The high exposure of nitrate were due to contribution of food categories 04.2.1.1 which are natural origin, while in the case of low exposure of nitrate were due food categories of 01.6.5 as the results of food additives addition. The high exposure of nitrite were due to contribution of food categories 08.2.3 as the results

¹ <http://www.efsa.europa.eu/en/efsajournal/pub/4787>

² <http://www.efsa.europa.eu/en/efsajournal/pub/4786>

of food additives addition, while in the case of low exposure of nitrite were due food categories of 14.1.2.2 which are natural origin.

Based on the data above, in the future the government may need to take appropriate measures to reduce the demand on nitrates and nitrites and limit their application as food additive for certain food category products as an effort to reduce the health risk.

The levels of natural origin nitrate and nitrite might be reduced through the implementation of Good Agriculture Practices (GAP), Good Handling Practices (GHP) and Good Manufacture Practices (GMP) which in turn also requires stakeholder cooperation. Furthermore, as an effort to reduce the exposure at global level, we propose that Codex c.q. JECFA needs to reconsider or reassess the application of nitrate nitrite as food additive related to the type of food and their maximum use levels.

Table 1. Average Concentration of Nitrate in Food (mg/kg)

Food Category	Average concentration of nitrate in food (mg/kg)
01.6.2	37.64
01.6.2.1	46.37
01.6.4.2	31.13
01.6.5	18.04
08.3.1.2	19.1
08.3.2	5.72
04.2.1.1	449.47
09.2.5	158.56
14.1.1.2	7.56
14.1.2.2	544.49

Table 2. Average Concentration of Nitrite in Food (mg/kg)

Food Category	Average concentration of nitrite in food (mg/kg)
01.6.2	11.14
01.6.2.1	14.53
01.6.4	5.58
07.1.5	6.72
08.2.1.1	8.86
08.2.1.2	2.43
08.2.2	9.72
08.2.3	8.23
08.3.1.1	8.64
08.3.1.3	9.11
08.3.2	8.35
08.3.3	9.4
04.2.1.1	0.57
09.2.5	11.47
14.1.1.2	0.01
14.1.2.2	0.18

Table 3. Exposure of Nitrate (mg/kg BW/day)

Food Category	Average				Minimum				Maximum				P-95			
	Adult		Child		Adult		Child		Adult		Child		Adult		Child	
	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
01.6.2	0.009	0.009	0.023	0.023	0.006	0.006	0.014	0.014	0.012	0.012	0.030	0.030	0.012	0.012	0.030	0.030
01.6.2.1	0.012	0.012	0.028	0.028	0.011	0.011	0.027	0.027	0.012	0.012	0.029	0.029	0.012	0.012	0.029	0.029
01.6.4.2	0.010	0.010	0.025	0.025	0.007	0.007	0.017	0.017	0.014	0.014	0.033	0.033	0.013	0.013	0.032	0.032
01.6.5	0.003	0.003	0.007	0.007	0.003	0.003	0.007	0.007	0.003	0.003	0.007	0.007	0.003	0.003	0.007	0.007
08.3.1.2	0.017	0.018	0.042	0.042	0.000	0.000	0.000	0.001	0.035	0.035	0.083	0.083	0.033	0.033	0.079	0.079
08.3.2	0.005	0.005	0.013	0.013	0.002	0.002	0.005	0.005	0.010	0.010	0.024	0.024	0.009	0.009	0.022	0.022
04.2.1.1	0.599	0.599	1.438	1.438	0.000	0.000	0.000	0.000	1.158	1.158	2.780	2.780	1.137	1.137	2.730	2.730
09.2.5	0.062	0.062	0.149	0.149	0.044	0.044	0.106	0.106	0.109	0.109	0.262	0.262	0.098	0.098	0.236	0.236
14.1.1.2	0.125	0.126	0.300	0.302	0.000	0.001	0.000	0.003	0.500	0.500	1.200	1.200	0.412	0.412	0.989	0.989
14.1.2.2	0.544	0.544	1.307	1.307	0.000	0.000	0.000	0.000	0.901	0.901	2.163	2.163	0.835	0.835	2.003	2.003
EDI	1.388	1.389	3.331	3.333	0.073	0.075	0.176	0.179	2.754	2.754	6.610	6.610	2.565	2.565	6.156	6.156

Note : LB : Lower Bound
 UB : Upper bound
 EDI : Estimated Daily Intake
 Children Body Weight : 25 kg
 Adult Body Weight : 60 kg

Tabel 4. Exposure of Nitrite (mg/kg BW/day)

Food Category	Average				Minimum				Maximum				P-95			
	Adult		Child		Adult		Child		Adult		Child		Adult		Child	
	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
01.6.2	0.003	0.003	0.007	0.007	0.000	0.000	0.001	0.001	0.005	0.005	0.011	0.011	0.004	0.004	0.011	0.011
01.6.2.1	0.004	0.004	0.009	0.009	0.004	0.004	0.009	0.009	0.004	0.004	0.009	0.009	0.004	0.004	0.009	0.009
01.6.4	0.002	0.002	0.004	0.004	0.001	0.001	0.002	0.002	0.004	0.004	0.009	0.009	0.003	0.003	0.008	0.008
07.1.5	0.006	0.006	0.013	0.013	0.006	0.006	0.013	0.013	0.006	0.006	0.013	0.013	0.006	0.006	0.013	0.013
08.2.1.1	0.008	0.008	0.019	0.019	0.000	0.000	0.000	0.000	0.035	0.035	0.083	0.083	0.023	0.023	0.055	0.055
08.2.1.2	0.002	0.002	0.005	0.005	0.000	0.000	0.001	0.001	0.005	0.005	0.012	0.012	0.005	0.005	0.011	0.011
08.2.2	0.003	0.003	0.008	0.008	0.000	0.000	0.001	0.001	0.009	0.009	0.023	0.023	0.008	0.008	0.019	0.019
08.2.3	0.016	0.016	0.038	0.038	0.000	0.001	0.000	0.001	0.038	0.038	0.090	0.090	0.034	0.034	0.082	0.082
08.3.1.1	0.008	0.008	0.019	0.019	0.000	0.000	0.000	0.000	0.027	0.027	0.065	0.065	0.026	0.026	0.062	0.062
08.3.1.3	0.008	0.008	0.020	0.020	0.004	0.004	0.010	0.010	0.011	0.011	0.027	0.027	0.011	0.011	0.026	0.026
08.3.2	0.008	0.008	0.018	0.018	0.000	0.000	0.000	0.000	0.028	0.028	0.066	0.066	0.022	0.022	0.053	0.053
08.3.3	0.008	0.008	0.019	0.019	0.000	0.000	0.000	0.000	0.025	0.025	0.059	0.059	0.018	0.018	0.044	0.044
04.2.1.1	0.001	0.001	0.002	0.002	0.000	0.000	0.000	0.000	0.008	0.008	0.020	0.020	0.004	0.004	0.010	0.010
09.2.5	0.005	0.005	0.011	0.011	0.001	0.001	0.002	0.002	0.013	0.013	0.032	0.032	0.011	0.011	0.027	0.027
14.1.1.2	0.000	0.000	0.000	0.001	0.000	0.000	0.000	0.000	0.001	0.001	0.001	0.001	0.000	0.000	0.001	0.001
14.1.2.2	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.001	0.001	0.003	0.003	0.001	0.001	0.002	0.002
EDI	0.081	0.081	0.194	0.194	0.016	0.017	0.038	0.040	0.218	0.218	0.522	0.522	0.180	0.180	0.433	0.433

Tabel 5. Risk Characterization of Nitrate (%)

Food Category	Average				Minimum				Maximum				P-95			
	Adult		Child		Adult		Child		Adult		Child		Adult		Child	
	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
01.6.2	0.25%	0.25%	0.61%	0.61%	0.16%	0.16%	0.38%	0.38%	0.34%	0.34%	0.81%	0.81%	0.33%	0.33%	0.80%	0.80%
01.6.2.1	0.31%	0.31%	0.75%	0.75%	0.30%	0.30%	0.72%	0.72%	0.33%	0.33%	0.79%	0.79%	0.33%	0.33%	0.78%	0.78%
01.6.5	0.08%	0.08%	0.20%	0.20%	0.08%	0.08%	0.20%	0.20%	0.08%	0.08%	0.20%	0.20%	0.08%	0.08%	0.20%	0.20%
01.6.4.2	0.28%	0.28%	0.67%	0.67%	0.19%	0.19%	0.46%	0.46%	0.37%	0.37%	0.88%	0.88%	0.36%	0.36%	0.86%	0.86%
08.3.1.2	0.47%	0.47%	1.13%	1.14%	0.00%	0.01%	0.00%	0.02%	0.94%	0.94%	2.25%	2.25%	0.89%	0.89%	2.14%	2.14%
08.3.2	0.14%	0.14%	0.34%	0.34%	0.05%	0.05%	0.13%	0.13%	0.27%	0.27%	0.64%	0.64%	0.24%	0.24%	0.59%	0.59%
04.2.1.1	16.20%	16.20%	38.87%	38.87%	0.00%	0.00%	0.00%	0.01%	31.30%	31.30%	75.13%	75.13%	30.74%	30.74%	73.78%	73.78%
09.2.5	1.67%	1.67%	4.02%	4.02%	1.19%	1.19%	2.86%	2.86%	2.95%	2.95%	7.07%	7.07%	2.65%	2.65%	6.37%	6.37%
14.1.1.2	3.38%	3.40%	8.12%	8.17%	0.00%	0.03%	0.00%	0.08%	13.51%	13.51%	32.43%	32.43%	11.14%	11.14%	26.72%	26.72%
14.1.2.2	14.72%	14.72%	35.32%	35.32%	0.00%	0.00%	0.00%	0.00%	24.35%	24.35%	58.45%	58.45%	22.56%	22.56%	54.13%	54.13%
Total/EDI	37.51%	37.53%	90.02%	90.08%	1.98%	2.02%	4.75%	4.85%	74.44%	74.44%	178.65%	178.65%	69.32%	69.32%	166.37%	166.38%
Average	3.75%	3.75%	9.00%	9.01%	0.20%	0.20%	0.47%	0.49%	7.44%	7.44%	17.87%	17.87%	6.93%	6.93%	16.64%	16.64%

Tabel 6. Risk Characterization of Nitrite (%)

Food Category	Average				Minimum				Maximum				P-95			
	Adult		Child		Adult		Child		Adult		Child		Adult		Child	
	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB	LB	UB
01.6.2	4.64%	4.64%	11.14%	11.14%	0.80%	0.80%	1.91%	1.91%	7.52%	7.52%	18.04%	18.04%	7.33%	7.33%	17.58%	17.58%
01.6.2.1	6.05%	6.05%	14.53%	14.53%	6.05%	6.05%	14.53%	14.53%	6.05%	6.05%	14.53%	14.53%	6.05%	6.05%	14.53%	14.53%
01.6.4	3.10%	3.10%	7.44%	7.44%	1.34%	1.34%	3.21%	3.21%	6.12%	6.12%	14.68%	14.68%	5.62%	5.62%	13.50%	13.50%
07.1.5	9.33%	9.33%	22.40%	22.40%	9.33%	9.33%	22.40%	22.40%	9.33%	9.33%	22.40%	22.40%	9.33%	9.33%	22.40%	22.40%
08.2.1.1	13.52%	13.53%	32.45%	32.48%	0.00%	0.00%	0.00%	0.00%	57.51%	57.51%	138.03%	138.03%	38.00%	38.00%	91.20%	91.20%
08.2.1.2	3.71%	3.71%	8.91%	8.91%	0.38%	0.38%	0.92%	0.92%	8.34%	8.34%	20.02%	20.02%	7.59%	7.59%	18.23%	18.23%
08.2.2	5.40%	5.40%	12.95%	12.95%	0.71%	0.71%	1.69%	1.69%	15.73%	15.73%	37.75%	37.75%	12.95%	12.95%	31.08%	31.08%
08.2.3	26.15%	26.28%	62.75%	63.08%	0.00%	0.96%	0.00%	2.30%	62.83%	62.83%	150.80%	150.80%	57.04%	57.04%	136.90%	136.90%
08.3.1.1	13.19%	13.20%	31.66%	31.68%	0.00%	0.00%	0.00%	0.01%	44.84%	44.84%	107.62%	107.62%	42.79%	42.79%	102.70%	102.70%
08.3.1.3	13.91%	13.91%	33.39%	33.39%	6.83%	6.83%	16.39%	16.39%	18.58%	18.58%	44.59%	44.59%	18.06%	18.06%	43.34%	43.34%
08.3.2	12.73%	12.75%	30.55%	30.60%	0.00%	0.00%	0.00%	0.00%	45.83%	45.83%	110.00%	110.00%	37.13%	37.13%	89.12%	89.12%
08.3.3	13.02%	13.05%	31.24%	31.32%	0.00%	0.00%	0.00%	0.00%	40.90%	40.90%	98.17%	98.17%	30.81%	30.81%	73.94%	73.94%
04.2.1.1	1.25%	1.27%	3.01%	3.05%	0.00%	0.02%	0.00%	0.05%	13.78%	13.78%	33.07%	33.07%	6.89%	6.90%	16.53%	16.56%
09.2.5	7.97%	7.97%	19.12%	19.12%	1.10%	1.10%	2.63%	2.63%	22.09%	22.09%	53.02%	53.02%	18.72%	18.72%	44.94%	44.94%
14.1.1.2	0.15%	0.37%	0.37%	0.89%	0.00%	0.28%	0.00%	0.67%	0.83%	0.83%	2.00%	2.00%	0.72%	0.72%	1.73%	1.73%
14.1.2.2	0.29%	0.31%	0.70%	0.74%	0.00%	0.02%	0.00%	0.04%	2.33%	2.33%	5.60%	5.60%	1.52%	1.52%	3.64%	3.65%
Total/EDI	134.42%	134.89%	322.60%	323.73%	26.53%	27.82%	63.69%	66.77%	362.62%	362.62%	870.30%	870.30%	300.57%	300.59%	721.38%	721.42%
Average	8.40%	8.43%	20.16%	20.23%	1.66%	1.74%	3.98%	4.17%	22.66%	22.66%	54.39%	54.39%	18.79%	18.79%	45.09%	45.09%

Iran

Iran appreciates the opportunity to provide the following comments for consideration at the forthcoming 52th Session of the Codex Committee on Food Additives (CCFA).

There is a lot of confusion about Nitrates and Nitrites in the diet. These are compounds found naturally in some foods (like vegetables) but also added to processed foods (like meat products) as a preservative. Some people believe that they are harmful and can cause cancer, however, the science isn't as clear and some studies suggest that they may even be healthy.

It seems that the **nitrates** themselves are relatively inert, until they are turned into **nitrites** by bacteria in the mouth or enzymes in the body. Nitrites are the key players, they can either turn into nitric oxide (good) or nitrosamines (bad). Nitrites are the reason cured meat is pink or red. Nitrites turn into Nitric Oxide, which reacts with the oxygen-binding proteins in the meat, changing its color. Without additives like nitrites, the meat would turn brown very quickly.

Vegetables are actually the biggest dietary source of nitrates. The amount we get from processed meat is small compared to vegetables. Our bodies also produce nitrates in large amounts and secrete them into saliva.

Nitrates can even be found [in drinking water](#) in some areas. This can be a problem for infants under 6 months of age, which are unable to process a lot of nitrate.

This can lead to a dangerous condition called methemoglobinemia, which is why nitrate amounts in drinking water are regulated.

There have been numerous studies in Iran in this field, for example in fruits, vegetables and their products, meat and meat products and groundwater. The results showed us that the amount of nitrite and nitrate was higher than the standard in meat products and groundwater.

It is important to consider the mechanism of the conversion of these two substances together and for determination of nitrite and nitrate, the examination must be run during the first 4 days after production because the amount of them will decrease.

So, we have a suggestion to have a draft with a specific frame work to achieve the ultimate goal.

Japan

Japan provides information on available data requested by CL 2019/49-FA as follows.

Dietary exposure to nitrates and nitrites:

Intake of nitrates and/or nitrites was estimated by market basket method (in 1999 (nitrates and nitrites) in 2003 (nitrates)). In these studies, exposure to Nitrates and Nitrites are estimated from all food sources.

Occurrence data:

Available data on natural occurrence level of Nitrates and Nitrites in Japan are described in the table below.

	Food	Number of samples	Year
Nitrates	Fresh vegetables	250	2006, 2008
Nitrates	Processed vegetable products (e.g. juice)	59	2007
Nitrates	Bottled water*	150	2017
Nitrites	Bottled water*	150	2017

*Data have been submitted to GEMS/Food database.

Paraguay

Paraguay welcomes the opportunity to submit data related to nitrites and nitrates in response to Circular Letter CL 2019/49-FA.

Based on the results of laboratory analyzes carried out in the regulatory entity, the presence of INS 250 Nitrites has been detected, at an average of 40 mg / kg, residual expressed in NaNO₂. The maximum allowed being 200 mg / kg for the food categories 8.2.1.1 and 8.2.1.2

On the other hands; the use of Nitrites and Nitrates is not allowed in food categories 1.6.2.3; 1.6.4; 1.6.5; 8.1; 8.1.1; 8.1.2.