



## Report of the Scientific Committee of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) on the criteria necessary to apply the indication “Suitable for the preparation of infant food” to natural mineral waters

### Section of Food Safety and Nutrition

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## Abstract

Article 9.3 of Directive 2009/54/EC of the European Parliament and the Council, of 18 June 2009, on the exploitation and marketing of natural mineral waters establishes that Member States may adopt provisions that regulate the use –both on packaging or labels and in advertising– of indications referring to the suitability of a natural mineral water for infant food.

However, Royal Decree 1798/2010 of 30 December, which regulates the exploitation and marketing of natural mineral waters and spring waters bottled for human consumption, and transposes the Directive, has not developed the criteria under which the indication “Suitable for the preparation of infant food” set out in Annex III can be used for natural mineral waters from the national territory.

The Executive Director of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) has requested that the Scientific Committee establish the criteria necessary to apply the indication “Suitable for the preparation of infant food” to natural mineral waters.

In the proposal of the criteria to use the special indication “Suitable for the preparation of infant food” for natural mineral waters, note was taken mostly of the following:

- Toxicological criteria, deriving a reference value (RV) according to the tolerable daily intake (TDI) for the parameter in question, assuming for infants a mean weight of 5 kg and a daily water consumption of 750 ml. The contribution from water to daily intake of the substance used for the calculation was 50 %.
- Normative criteria. As a basic rule, the latest report of the World Health Organisation on “Guidelines for drinking-water quality” (4<sup>th</sup> edition) was taken into account along with the “Codex standard for natural mineral waters”. In the national sphere the provisions of Royal Decree 140/2003 of 7 February, establishing the sanitary standards for the quality of water for human consumption were considered, as well as Royal Decree 1798/2010 of 30 December, which

regulates the exploitation and marketing of bottled natural mineral waters and spring waters for human consumption. French legislation, the most thorough in Europe on these matters, was also taken into consideration.

In drawing up this report, parameters with established levels in natural mineral waters above those in water for human consumption were considered, along with others that are not fixed in natural mineral waters and should be taken into account when evaluating the health of infants. Parameters with established levels in natural mineral waters considered sufficient to protect the health of infants and those whose maximum concentration or lack thereof is a required condition in current legislation on natural mineral waters were not included.

In accordance with the considerations set out in the report for each of the parameters considered, the Committee believes that in order to adequately preserve the health of infants:

1. Natural mineral waters using the special indication "Suitable for the preparation of infant food" must meet the specifications on the chemical parameters laid out in Annex IV, Paragraph 1, Part B of Royal Decree 1798/2010 and Regulation (EU) No 115/2010.
2. They must also meet the organoleptic and purity conditions specified in Annex I of Royal Decree 1798/2010.
3. In addition to that established in Points 1 and 2, natural mineral waters using the special indication "Suitable for the preparation of infant food" should take into account the reference value specifications indicated for the following chemical parameters: boron (0.5 mg/l), calcium (150 mg/l), cyanides (10 µg/l), chloride (100 mg/l), CO<sub>2</sub> (250 mg/l), copper (0.2 mg/l), chromium (5 µg/l), fluoride (0.5 mg/l), magnesium (50 mg/l), manganese (50 µg/l), nitrate (10 mg/l), nickel (20 µg/l), dry residue (1,000 mg/l), sodium (100 mg/l), sulphates (200 mg/l), uranium (2 µg/l) and zinc (0.1 mg/l).

## Keywords

Natural mineral waters, reference values, chemical parameters, infant food.

## 1. Introduction

Article 9.3 of Directive 2009/54/EC of the European Parliament and the Council, of 18 June 2009, on the exploitation and marketing of natural mineral waters establishes that Member States may adopt provisions that regulate the use –both on packaging or labels and in advertising– of indications referring to the suitability of a natural mineral water for infant food (EU, 2009). Such provisions may also concern the properties of the water which determine the use of those indications.

However, Royal Decree 1798/2010 of 30 December, which regulates the exploitation and marketing of natural mineral waters and spring waters bottled for human consumption, and transposes the Directive, has not developed the criteria under which the indication "Suitable for the preparation of infant food" set out in Annex III can be used for natural mineral waters from the national territory (BOE, 2010).

In this context, the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) considers it necessary to regulate these criteria in order to protect the infant population given their particular vulnerability. The Executive Director of the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN) has requested that the Scientific Committee establish the criteria necessary to apply the indication "Suitable for the preparation of infant food" to natural mineral waters.

## 2. Terms of reference

The Scientific Committee has been asked to establish the reference values for the chemical parameters of the water in order to guarantee the quality and safety of mineral waters with the special indication "Suitable for the preparation of infant food", considering that this may be the principal source of water used in the preparation of such food.

## 3. Definition and characteristics of natural mineral waters in accordance with Royal Decree 1798/2010

Royal Decree 1798/2010, of 30 December, which regulates the exploitation and marketing of natural mineral waters and spring waters bottled for human consumption, in its article 2, defines natural mineral waters as "microbiologically wholesome water, originating in an underground water table or deposit and emerging from a spring tapped at one or more natural or bore exits, or the combination of any of these" (BOE, 2010).

This water can be clearly distinguished from ordinary drinking water:

- by its nature, which is characterised by its mineral content, trace elements or other constituents and, where appropriate, by certain effects,
- by its chemical constancy and
- by its original purity,

which characteristics have been preserved intact because of the underground origin of such water which has protected it from all risk of pollution.

To use this designation, the waters shall comply with the characteristics established in part A of

Annex I and the claim and authorisation requirements established in article 3 for this type of water, and the conditions for exploitation and marketing established in chapter II of this provision.

This annex I (part A) indicates that natural mineral waters shall comply with the specifications indicated forthwith:

### 1. Generals characteristics

- a) In addition to the characteristics listed in section a) of article 2 of this provision, the composition, temperature and other essential characteristics of natural mineral water shall remain stable within the limits of natural fluctuation.
- b) For the purposes of this provision, stable composition is understood as the permanence of the mineralisation type, a characteristic determined by the principal constituents and, where applicable, by those other parameters characterising the water.
- c) In addition, the effects derived from the normal evolution of the water are accepted. These include the variation in temperature, radioactivity, dissolved gases and precipitated salts.

### 2. Specifications of a diverse nature

- a) Organoleptic: They shall not contain any defect from the organoleptic point of view considering, smell, flavour, colour, turbidity or sediments, other than the characteristics of the water itself.
- b) Microbiological and parasitological:
  - i. At source, the total revivable colony count of a natural mineral water shall conform to its normal viable colony count and give satisfactory evidence of the protection of the source against all contamination. The total revivable colony count shall not normally exceed, respectively, 20 colonies per millilitre after incubation at 20-22 °C for 72 hours and 5 colonies per millilitre after incubation at 37 °C for 24 hours, on the understanding that they shall be considered as guide figures and not as maximum permitted concentrations. The colony count shall be measured within the 12 hours following bottling; during this time, the water shall be maintained at a temperature of between 4 °C to 1 °C.
  - ii. After bottling, the total colony count at source may not exceed 100 per millilitre after incubation at 20-22 °C for 72 hours on agar-agar and 20 colonies per millilitre after incubation at 37 °C for 24 hours on agar-agar. The colony count shall be measured within the 12 hours following bottling; during this time, the water shall be maintained at a temperature of between 4 °C to 1 °C.
  - iii. At source and during its marketing, a natural mineral water shall be free from:
    - Parasites and pathogenic microorganisms,
    - *Escherichia coli* and other coliforms, and faecal streptococci in any 250 millilitre sample examined,
    - Sporulated sulphite-reducing anaerobes in any 50 ml sample examined and
    - *Pseudomonas aeruginosa*, in any 250 ml sample examined.
  - iv. Without prejudice to that established in the above paragraphs and in article 4, during the marketing stage, the revivable total colony count of a natural mineral water may only be that resulting from the normal increase in the bacterial count which it had at source.

c) **Chemical:**

i. They shall comply, at minimum, with the specifications relating to the chemical parameters established in part B of section 1 of annex IV.

In this annex IV, section 1, part B of Royal Decree 1798/2010 the parameters and parametric values are established for the natural mineral waters with respect to chemical parameters (Table 1).

Parameter	Parametric value	Unit	Notes
Antimony	5.0	µg/l	
Total arsenic	10	µg/l	
Barium	1.0	mg/l	
Benzene	1.0	µg/l	
Benzo(a)pyrene	0.010	µg/l	
Cadmium	3.0	µg/l	
Chromium	50	µg/l	
Copper	1.0	mg/l	
Cyanide	70	µg/l	
Fluoride	5.0	mg/l	
Lead	10	µg/l	
Manganese	0.5	mg/l	
Mercury	1.0	µg/l	
Nickel	20	µg/l	
Nitrate	50	mg/l	
Nitrite	0.1	mg/l	
Selenium	10	µg/l	
Pesticides	0.10	µg/l	Notes 1 and 2
Total pesticides	0.50	µg/l	Notes 1 and 3
Polycyclic aromatic hydrocarbons	0.10	µg/l	Sum of concentrations of compounds specified (note 4)

Note 1: «Pesticides» are understood as: organic insecticides, organic herbicides, organic fungicides, organic nematocides, organic acaricides, organic algaecides, organic rodenticides, organic molluscicides, related products (including growth regulators) and their relevant metabolites and reaction and degradation products. It is only necessary to control those pesticides that are likely to be present in a given supply. Note 2: The parametric value applies to each of the pesticides. In the case of aldrin, dieldrin, heptachlor and heptachlor epoxide, the parametric value is 0,030 µg/l. Note 3: «Total pesticides» is understood as the sum of all the pesticides detected and measured in the control procedure. Note 4: the specified compounds are: Benzo(b)fluorantene, benzo(k)fluorantene, benzo(ghi)perylene and indene (1,2,3-cd)pyrene. **Source:** (BOE, 2010).

- ii. When the relevant health authority considers that any of the special characteristics of a certain water may be contraindicated for a sector of the population, it may refuse authorisation for bottling or require the inclusion in the labelling of the warning as established in annex III. Annex III establishes the specific requirements for the labelling of natural mineral waters, complementary to the general rules laid down in article 2 of Royal Decree 1798/2010. Moreover, the use of indications is authorised, provided these meet the relevant criteria laid down and on the condition of their establishment on the basis of physico-chemical analyses and, where necessary, pharmacological, physiological and clinical examinations carried out according to recognised scientific methods, in accordance with annex II, section 1 (Table 2).

<b>Table 2. Criteria for the use of content-based indications</b>	
<b>Indications</b>	<b>Criteria for the use of content-based indications</b>
Very low mineral content	Up to 50 mg/l of dry residue
Oligometallic or low mineral content	Up to 500 mg/l of dry residue
Medium mineral content	From 500 mg/l to 1 500 mg/l of dry residue
High mineral content	More than 1 500 mg/l of dry residue
Contains bicarbonate	Bicarbonate content greater than 600 mg/l
Contains sulfate	Sulfate content greater than 200 mg/l
Contains chloride	Chloride content greater than 200 mg/l
Contains calcium	Calcium content greater than 150 mg/l
Contains magnesium	Magnesium content greater than 50 mg/l
Contains fluoride	Fluoride content greater than 1 mg/l
Contains iron	Bivalent iron content greater than 1 mg/l
Acidic	Free carbon dioxide content greater than 250 mg/l
Contains sodium	Sodium content greater than 200 mg/l
Suitable for the preparation of infant food	-
Suitable for a low-sodium diet	Sodium content less than 20 mg/l
May be laxative	-
May be diuretic	-

**Source:** (BOE, 2010).

d) **Purity.** The following substances shall not exceed the detection limits: Residual chlorine, phenolic compounds, tensioactive agents, chlorinated biphenyls, oils, fats and any other product not considered in part B of section 1 of annex IV of this provision, regarding possible exogenous pollution indicators not from an underground source.

Annex V of Royal Decree 1798/2010 indicates the specifications for the analysis of the parameters and, specifically, lays down the detection limits.

Lastly, annex VI of Royal Decree 1798/2010 lays down the "Maximum limits for the sub-products of

techniques authorised for natural mineral waters and spring waters", with specific reference to the technique of ozone-enriched air, with the following parametric values (Table 3):

<b>Table 3.</b> Maximum limits for the sub-products of the authorised techniques	
<b>Sub-products of the technique</b>	<b>Maximum limits (µg/l)</b>
Dissolved ozone	50
Bromates	3
Bromoforms	1

**Source:** (BOE, 2010).

With regard to authorised treatments, Regulation (EU) No 115/2010 (EU, 2010) authorises the treatment of natural mineral waters and spring waters with activated alumina for the removal of fluoride. In its annex, it specifies the total amount of aluminium ions in the treated water as it results after the release of aluminium, the main component of activated alumina, shall not exceed 200 µg/l, as established in Directive 98/83/EC (EU, 1998).

#### **4. Legislation with respect to the maximum limits for natural mineral waters "Suitable for the preparation of infant food"**

Although annex III of Royal Decree 1798/2010, establishes the possibility of the indication "Suitable for the preparation of infant food", in Spain there is no specific legislation for natural mineral waters with that indication. The most complete legislation for this type of water is, without a doubt, the French legislation (Arrêté, 2010), which lays down quality limits for a total of 44 parameters (including radioactive parameters). Germany establishes levels for only 8 parameters (Germany, 1984).

Table 4 compares the 8 parameters established in Germany for natural mineral waters "Suitable for the preparation of infant food" with the proposal from France and with the values admitted in Spain for natural mineral waters in general.

**Table 4.** Comparison of levels of chemical parameters in natural mineral waters (NMW)

Parameters	Bottled NMW Spain (BOE, 2010)	NMW and Spring Waters Infants, France (Arrêté, 2010)	Mineral waters and table waters Infants, Germany (Germany, 1984)
Arsenic	10 µg/l	10 µg/l	5 µg/l
Fluoride	5 mg/l	0.5 mg/l (0.3 mg/l)*	0.7 mg/l
Manganese	500 µg/l	50 µg/l	50 µg/l
Nitrate	50 mg/l	10 mg/l	10 mg/l
Nitrite	0.1 mg/l	0.05 mg/l	0.02 mg/l
Sodium	-	200 mg/l	20 mg/l
Sulfate	-	140 mg/l	240 mg/l
Uranium	-	-	2 µg/l

\*With medical supplementation.

Another point to consider is the different indications for natural mineral waters listed in annex III of Royal Decree 1798/2010. These types of waters contain minerals (or some of them) in quantities far higher than those required for natural mineral waters "in general" (Table 5).

**Table 5.** Mineral content in natural mineral waters (NMW), NMW with "special indication" and chemical parameter levels in waters "suitable for the preparation of infant food"

Parameters	Bottled NMW Spain (BOE, 2010)	NMW and Spring Waters Infants, France (Arrêté, 2010)	Bottled NMW with indication Spain (BOE, 2010)
Bicarbonate	-	-	>600 mg/l (bicarbonated)
Sulfates	-	140 mg/l	>200 mg/l (sulfated)
Chlorides	-	250 mg/l	>200 mg/l (chloride-containing)
Calcium	-	100 mg/l	150 mg/l (calcium-containing)
Magnesium	-	50 mg/l	>50 mg/l (magnesium-containing)
Fluorides	5 mg/l	0.5 mg/l (0.3 mg/l)*	>1 mg/l (fluoridated-containing)
Iron	-	-	>1 mg/l (ferruginous)
CO <sub>2</sub>	-	250 mg/l	>250 mg/l (acidified)
Sodium	-	200 mg/l	>200 mg/l (sodium)

\*With medical supplementation.



## 5. Proposal for criteria to be able to use the indication "Suitable for the preparation of infant food" with natural mineral waters

### 5.1 Preliminary considerations

In the proposal for the criteria in order to use the special indication "suitable for the preparation of infant food" in natural mineral waters, the following have been considered:

a) **Toxicological criteria.** Deriving a reference value in accordance with the tolerable daily intake (TDI) for the parameter in question and considering for the infant a mean weight of 5 kg and a water intake of 750 ml/day (WHO, 2011a). For the calculation, a water contribution to the daily intake of the substance considered of 50 % has been taken (as used by the World Health Organisation in the derivation of the guideline value (GV) for children in the case of lead).

i. Calculation of the guideline values from the tolerable daily intake (TDI)

The WHO (World Health Organisation) has published guidelines for drinking-water quality and has recommended quality limits (GV) applicable to the chemical substances that may be present in water (WHO, 2011a).

- For non-carcinogenic substances (with a threshold dose) the GV is calculated from the TDI in accordance with:

$$GV = TDI \times \text{body weight} \times P / C$$

Where C is the daily water intake (litres) and P the fraction of TDI allocated to water, that is, the contribution of water to the total daily intake of the substance considered.

In the case of an adult, the default values considered by the WHO are 2 litres/day for water intake and 60 kg body weight. For children, a body weight of 10 kg and an intake of 1 litre/day is assumed and for infants, a body weight of 5 kg and an intake of 0.75 litres/day.

With respect to the allocation of water to the daily intake of the substance (P), the WHO considers for an adult a standard value of 20 % (WHO, 2011a). Nevertheless, in certain particular cases it uses a lower allocation (for example: 10 %) or much higher (for example: 80 %). The WHO document indicates the value of P used in each case. For children it only specified the value of P in the case of lead (P=50 %), which is used by AFSSA (2003a) and which we will use in our calculations for infants.

According to the above, the calculation of the GV for infants (for P=50 % and P=80 %) are defined by:

$$\begin{aligned} VG_{\text{infants}/50\%} &= TDI \times 5 \times 0.50 / 0.75 = 3.3 \text{ TDI} \\ VG_{\text{infants}/80\%} &= TDI \times 5 \times 0.80 / 0.75 = 5.33 \text{ TDI} \end{aligned}$$

And for adults, according to the value of P considered

$$\begin{aligned} VG_{\text{adults}/10\%} &= TDI \times 60 \times 0.10 / 2 = 3 \text{ TDI} \\ VG_{\text{adults}/20\%} &= TDI \times 60 \times 0.20 / 2 = 6 \text{ TDI} \end{aligned}$$

$$VG_{\text{adults/40 \%}} = TDI \times 60 \times 0.40 / 2 = 12 \text{ TDI}$$

$$VG_{\text{adults/80 \%}} = TDI \times 60 \times 0.80 / 2 = 24 \text{ TDI}$$

Hence it is deduced that the GV calculated by the WHO for adults are not always going to be suitable for infants.

- For carcinogenic substances, the GV are presented as concentrations in drinking water associated with a risk assessment of cancer of  $1 \times 10^{-5}$  (an additional case of cancer for every 100 000 individuals who drink water containing the substance at a concentration equal to the GV for 70 years) (WHO, 2011a). This is not the number of cases of cancer caused by exposure to the substance at the GV concentration, but only the maximum potential risk considering major uncertainties. It is highly likely that the true risk is much lower, and may even be close to zero. Obviously the acceptable risk for deriving the GV can be established at other levels ( $1 \times 10^{-4}$  or  $1 \times 10^{-6}$ ), considering that a risk of  $1 \times 10^{-6}$  is considered insignificant. The GV derived with this methodology must be interpreted in a different way to those derived from the TDI (in the case of non-carcinogenics) due to the lack of accuracy of the models on which they are based.

b) **Normative criteria.** The basic standards used include the latest report from the WHO "Guidelines for Drinking Water Quality" 4th edition (WHO, 2011a), and the "Codex Standard for Natural Mineral Waters" (Codex, 2011). At national level, that established in Royal Decree 140/2003, of 7 February, was considered, laying down the health criteria for the quality of water intended for human consumption (BOE, 2003) and Royal Decree 1798/2010, of 30 December, regulating the exploitation and marketing of natural mineral waters and spring waters bottled for drinking (BOE, 2010). The French standard (Arrêté, 2010) has also been considered and is the most complete currently existing in Europe in this respect.

c) **Criteria used by the French Food Safety Agency (AFSSA)** in different reports (AFSSA, 2003a,b, 2008a,b) relating to natural mineral waters "Suitable for the preparation of infant food".

d) **Composition of breast milk** (Maldonado et al., 2010) (Bueno et al., 2012) (EFSA, 2013a).

e) **Intake of water by infants and children.** Water may be drunk directly or used to prepare infant food with powdered milk (infant formulae). One interesting fact to be considered is that in France (AFSSA, 2003a) surveys show that 28.6 % of children under the age of 1 year only drink tap water. The European Food Safety Authority (EFSA) considers a consumption of 700-1 000 ml/day suitable for the majority of children aged between 0 and 6 months and 800-1 000 ml/day for children from 6 to 12 months old (EFSA, 2013a). These values are similar to those considered by the WHO for infants of 750 ml/day (WHO, 2011a). Although the intake may reach a maximum of 1 200 ml/day, in our calculations we have used the value of 750 ml/day recommended by the WHO.

To develop our discussion and recommendation for reference values for natural mineral waters with the special indication "Suitable for the preparation of infant food", the French legislation (Arrêté,

2010) has been taken as reference as it is the most complete legislation, establishing requirements for the use of the special indication.

Under the premise that drinking water is considered suitable for the preparation of infant food (in fact in France it is used in almost 30 % of cases) the requirements for the use of "natural mineral" water should be no more than those for drinking water, except in cases in which the legislation establishes a specific value for natural mineral water or it is considered that it may be harmful for infants. However, in any case, the minimum requirements will be the same as for drinking water.

Various types of parameters can be distinguished (AFSSA, 2003a) (EU, 2003) (WHO, 2011a) which have established the methodology for proposing a reference value:

- Parameters which may be naturally present in natural mineral waters. Some of these parameters do not have limits established for either natural mineral waters or for drinking water.

In this group of parameters, the basic criteria for establishing a reference value in natural mineral waters "Suitable for the preparation of infant food" has been toxicological. The concentration of the substance normally found in natural mineral waters has also been considered together with analytical aspects such as the limit of detection (LOD) or the limit of quantification (LOQ) of the available methods and organoleptic aspects. In some special cases, given that its presence may be due to a problem of pollution (purity of natural mineral water), the criteria of not exceeding the LOD of the parametric value has been applied (Royal Decree 1798/2010, annex IV, section 1, part B).

In addition, the daily requirements in infants and the concentration in breast milk and artificial milks have also been considered.

- Parameters indicating pollution. These parameters, in principle, should not be present in the water. The criteria applied in these cases is the absence of the substance (<LOD), in accordance with Royal Decree 1798/2010, annex IV, section 1, part B or the value established for drinking water in Spanish and/or European legislation, when considered sufficient by analytic limits. The *Codex Alimentarius* establishes that, for natural mineral waters, purity can be considered good when the concentration of a certain element is less than the quantification limit (<LOQ) in the method proposed by the WHO (*Codex*, 2011). For those substances from this group included in annex IV, section 1, part B, the toxicological criteria and analytical aspects (LOD of the technique) have also been considered.
- Parameters indicating the treatment of the water. Disinfection treatments are not authorised in natural mineral waters, with the exception of ozone treatment (in this case the levels of sub-products are specified in natural mineral water regulations). Similarly, the use of activated alumina for the removal of fluoride is authorised. Consequently, the criteria applied, in the other cases, is the absence (<LOD or LOQ).

## 5.2 Chemical parameters to be considered in the present report

In accordance with that indicated in the above section in this report, we will consider those parameters with established parametric values in natural mineral water different to those of drinking water and others that are not established in natural mineral waters and which should be considered when

assessing the health of infants. Those parameters with established parametric values in natural mineral waters considered sufficient for protecting the health of infants and those others with a maximum concentration or the absence of which is a condition required under current regulations for natural mineral waters are not considered.

Tables 6 and 7 list the quality limits established under the French legislation (Arrêté, 2010) for natural mineral waters and spring waters "Suitable for the preparation of infant food" in comparison with the composition of natural mineral waters bottled in Spain in accordance with Royal Decree 1798/2010 and the Codex Standard (2011). The recommended levels for drinking (WHO, 2011a) (BOE, 2003) are also listed. The last column lists our proposal in order that natural mineral waters may use the indication "Suitable for the preparation of infant food".

### 5.2.1 Parameters for which the levels established in natural mineral waters are lowered

For all the parameters listed in table 6, levels are established for both natural mineral waters and for drinking waters. We can consider various subgroups:

1. **Chromium and nitrate**, in which the parametric value for drinking water and natural mineral waters is the same, but the French recommendation for natural mineral waters "Suitable for the preparation of infant food" reduces this value five- or ten-fold.
2. **Cyanide, fluoride, manganese and nickel**, in which the parametric value in natural mineral waters is greater than in drinking water. In these cases, the French proposal for natural mineral waters "Suitable for the preparation of infant food" lowers the values of the natural mineral waters.
3. **Copper**, in which the parametric value in natural mineral waters (1 mg/l) is less than that in drinking water (2 mg/l) and France recommends lowering the value for the natural mineral waters suitable for the preparation of infant food.

For the parameters in this group, with the exception of nickel, our recommendation (see annex I) coincides with that of France. With the reference values proposed for all the parameters included in this section, which in no event shall exceed those established for drinking water (BOE, 2003), in principle, a risk does not exist for infants (0-12 months) considering that drinking water is suitable for the preparation of infant food. In the majority of cases, the absence of the risk is confirmed in accordance with toxicological criteria.

Nevertheless, that the water is "suitable" is not sufficient reason to be able to use the indication "Suitable for the preparation of infant food". The use of this special indication, as the name suggests, supposes an added value for the natural mineral water and therefore it would seem reasonable to be more demanding in the chemical criteria that must be met. This is the approach followed in the proposals for the reference values for the parameters of this group.

**Table 6.** Chemical parameters for which the levels established in natural mineral waters (NMW) are lowered<sup>b</sup>

Parameters	NMW bottled Spain (BOE, 2010)	NMW and Spring Waters Infants France (Arrêté, 2010)	NMW Codex Standard (Codex, 2011)	WHO Guidelines for drinking water quality (WHO, 2011a)	Drinking water Spain (BOE, 2003)	AECOSAN SC Proposal NMW "Suitable for the preparation of infant food" <sup>a</sup>
Chromium	50 µg/l	5 µg/l	50 µg/l	50 µg/l	50 µg/l	5 µg/l
Copper	1 mg/l	0.2 mg/l	1 mg/l	2 mg/l	2 mg/l	0.2 mg/l
Cyanide	70 µg/l	10 µg/l	70 µg/l	Not established GV <sup>c</sup>	50 µg/l	10 µg/l
Fluoride	5 mg/l Fluoridated water >1 mg/l	0.5 mg/l (0.3 mg/l) <sup>b</sup>	<1.5 mg/l	1.5 mg/l	1.5 mg/l	0.5 mg/l
Manganese	500 µg/l	50 µg/l	400 µg/l	Not established GV <sup>d</sup>	50 µg/l	50 µg/l
Nickel	50 µg/l	2 µg/l	20 µg/l	70 µg/l	20 µg/l	20 µg/l
Nitrate	50 mg/l	10 mg/l	50 mg/l	50 mg/l	50 mg/l	10 mg/l

<sup>a</sup>A detailed analysis of each of the parameters and the "reference value" proposal can be found in annex I. <sup>b</sup>With medical supplementation. <sup>c</sup>Not of concern to health at levels that cause problems of acceptability in drinking water.

<sup>d</sup>The concentrations present in drinking water are usually far below the concentrations of concern to health.

### 5.2.2 Chemical parameters for which levels have not been established in natural mineral waters

Unlike the parameters analysed above, in this group we include those for which levels have not been established in natural mineral waters (AMN) (BOE, 2010), although many of these do have parametric values in drinking water (Table 7).

There are four parameter groups:

1. **Chloride and sodium**, for which the French legislation establishes the same quality limits as for "drinking water". Our proposal for chloride and sodium is much lower (approximately half of the French proposal, which maintains the same value as for drinking water).
2. **Boron and sulfates**, for which the quality limits established by France are lower than those of "drinking water". In this case our reference value proposal is slightly higher, although it remains below the values in drinking water.
3. **Calcium, CO<sub>2</sub>, magnesium and zinc**, for which France establishes quality limits that are not established in "drinking water". Except in the case of calcium, for which our proposal is higher

than that of France, in the other parameters from this group, we propose the same reference values.

- 4. Others: Dry residue and uranium.** Our proposal for the dry residue is the same as that of France. In the case of uranium, France does not propose a quality limit; however, in view of the toxicity and its broad distribution, we propose a reference value that coincides with the German proposal.

For all the parameters in this group, which do not have established levels in the natural mineral waters, priority consideration is given to the safety of the infant and in addition, the usual concentration in the Spanish natural mineral waters, when this information is available, without, in any case, exceeding the parametric values in drinking water (in those cases in which these values exist).

**Table 7.** Chemical parameters for which "new" reference values are established<sup>a</sup>

Parameters	NMW bottled Spain (BOE, 2010)	NMW and Spring Waters Infants France (Arrêté, 2010)	NMW Codex Standard (Codex, 2011)	WHO Guidelines for drinking water quality (WHO, 2011a)	Drinking water Spain (BOE, 2003)	AECOSAN SC Proposal NMW "Suitable for the preparation of infant food" <sup>a</sup>
Boron	-	0.3 mg/l	5 mg/l	2.4 mg/l	1 mg/l	<b>0.5 mg/l</b>
Calcium	Calcium-containing waters >150 mg/l	100 mg/l	-	Not considered	-	<b>150 mg/l</b>
Chloride	Chloride-containing waters >200 mg/l	250 mg/l	-	Not established GV <sup>b</sup>	250 mg/l	<b>100 mg/l</b>
CO <sub>2</sub>	Acidified waters >250 mg/l	250 mg/l	-	Not considered	-	<b>250 mg/l</b>
Dry residue	Very low mineral content <50 mg/l Low 50-500 mg/l Medium 500-1 500 mg/l High >1 500 mg/l	1 000 mg/l	-	-	-	<b>1 000 mg/l</b>
Magnesium	Magnesium-containing waters >50 mg/l	50 mg/l	-	Not considered	-	<b>50 mg/l</b>
Sodium	Sodium-containing waters >200 mg/l	200 mg/l	-	Not established GV <sup>(b)</sup>	200 mg/l	<b>100 mg/l</b>
Sulfates	Sulfated water >200 mg/l	140 mg/l	-	Not established GV <sup>(b)</sup>	250 mg/l	<b>200 mg/l</b>
Uranium	-	-	-	30 µg/l	-	<b>2 µg/l</b>
Zinc	-	0.1 mg/l	-	Not established GV <sup>(b)</sup>	-	<b>0.1 mg/l</b>

<sup>a</sup>A detailed analysis of each of the parameters and the "reference value" proposal can be found in annex I. <sup>b</sup>The concentrations present in drinking water are usually much lower than the concentration of concern to health.

## Conclusions of the Scientific Committee

In accordance with the considerations laid out in annex I for each of the parameters considered, the Scientific Committee considers that to correctly safeguard the health of infants:

1. Natural drinking waters that use the special indication "Suitable for the preparation of infant food" must comply with the specifications relating to the chemical parameters established in annex IV, section 1, part B of Royal Decree 1798/2010 and Regulation (EU) No 115/2010.
2. The organoleptic and purity conditions specified in annex I of Royal Decree 1798/2010 must also be met.
3. In addition to the specifications listed in points 1 and 2, natural mineral waters (NMW) that use the special indication "Suitable for the preparation of infant food" should take into account those listed in the following table:



<b>Reference values for chemical parameters for natural mineral waters which use the special indication "Suitable for the preparation of infant food"</b>			
<b>Parameters</b>	<b>NMW bottled Spain (BOE, 2010)</b>	<b>Drinking water Spain (BOE, 2003)</b>	<b>AECOSAN SC Proposal NMW "Suitable for the preparation of infant food"</b>
Boron	-	1 mg/l	<b>0.5 mg/l</b>
Calcium	Calcium-containing waters >150 mg/l	-	<b>150 mg/l</b>
Chloride	Chloride-containing waters >200 mg/l	250 mg/l	<b>100 mg/l</b>
Chromium	50 µg/l	50 µg/l	<b>5 µg/l</b>
CO <sub>2</sub>	Acidified waters >250 mg/l	-	<b>250 mg/l</b>
Copper	1 mg/l	2 mg/l	<b>0.2 mg/l</b>
Cyanide	70 µg/l	50 µg/l	<b>10 µg/l</b>
Fluoride	5 mg/l Fluoridated water >1 mg/l	1.5 mg/l	<b>0.5 mg/l</b>
Magnesium	Magnesium-containing waters >50 mg/l	-	<b>50 mg/l</b>
Manganese	500 µg/l	50 µg/l	<b>50 µg/l</b>
Nickel	50 µg/l	20 µg/l	<b>20 µg/l</b>
Nitrate	50 mg/l	50 mg/l	<b>10 mg/l</b>
Dry residue	Very low mineral content <50 mg/l Low 50-500 mg/l Medium 500-1 500 mg/l High >1 500 mg/l	-	<b>1 000 mg/l</b>
Sodium	Sodium-containing waters >200 mg/l	200 mg/l	<b>100 mg/l</b>
Sulfates	Sulfated water >200 mg/l	250 mg/l	<b>200 mg/l</b>
Uranium	-	-	<b>2 µg/l</b>
Zinc	-	-	<b>0.1 mg/l</b>

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## Annex I. Detailed analysis of the parameters included in the proposal

### 1. Boron

Its presence in water is the result of the dissolution of rocks and soils containing borates and borosilicates and, normally its content is <0.5 mg/l (WHO, 2009b). The WHO has established a GV of 2.4 mg/l in drinking water (based on a TDI of 0.17 mg/kg/day and a water contribution of 40 %) (WHO, 2011a). Recently the EFSA (2013b) has established the TDI for boron at 0.16 mg/kg/day. For infants (section 5.1.a) the GV would be 0.5 mg/l.

In drinking water the parametric value is 1 mg/l (BOE, 2003) and it is not established for natural mineral waters. France proposes a limit value in natural mineral waters and spring waters "Suitable for the preparation of infant food" of 0.3 mg/l using the same criteria as the WHO, but considering the lowest value proposed for the TDI (0.1 mg/kg/day) (AFSSA, 2003a).

From a toxicological point of view, the GV estimated for infants (0.5 mg/l) would be sufficient to safeguard the health of the children, and therefore this is our proposal for natural mineral waters that use the indication "Suitable for the preparation of infant food".

### 2. Calcium

The calcium content in natural mineral waters varies greatly depending on the origin and composition of the rocks (WHO, 2009a) (EFSA, 2013a). For mineral waters, the mean concentration is 100±125 mg, with a range of 3-310 mg/l and a median concentration of 8 mg/l (WHO, 2009a). In Spain, the mean concentration of calcium in natural mineral waters is 55.9 mg/l and the median is 54.1 mg/l (Vitoria y Arias, 2000). In addition, natural mineral waters are considered "calcium-rich" when the calcium concentration is >150 mg/l (BOE, 2010).

The adequate intake of calcium for children aged 0-6 months is 210 mg/day and for 7-12 months it is 270 mg/day (WHO, 2009a). The dietary intake in the United States and Canada is 372-842 mg/day. Regarding the maximum daily intake (UL: Upper Level), above which there may be adverse effects, the data available for children is limited and is normally obtained by extrapolating the data for adults. For adults the UL is 2 500 mg/day (EFSA, 2013a) and in children aged 0-12 months 1 000- 1 500 mg/day (Institute of Medicine, 2006).

The calcium concentration in breast milk is in the range of 200 to 300 mg/l, and therefore the daily intake of calcium in infants (250 mg/l x 0.8 l) is considered suitable for the majority of infants aged 0-6 months (EFSA, 2013a). In addition, formula milk for children under 6 months old contains approximately 500 mg/l, equivalent to a daily intake of calcium of 375 mg, equally sufficient for the infant's requirements. Therefore, the water used to prepare infant feeding bottles is not required to provide more calcium.

Given these figures, we can assume a reference value of 150 mg/l, for the natural mineral waters with the indication "Suitable for the preparation of infant food". The additional intake thorough the water with respect to the content of formula milks would be approximately 112 mg/day, resulting in a total dietary intake for infants of some 490 mg/day, which would be within the range of 372-842 mg/day (United States and Canada).

On the basis of the figures presented, our proposal for the natural mineral waters with the indication

"Suitable for the preparation of infant food" would be 150 mg/l, which defines the limit of the waters with the special indication of "calcium-rich". The reference value of 150 mg/l, would exclude calcium-rich waters and, in principle, would not represent a risk of adverse effects for the infant.

### 3. Cyanide

It is considered to be a constituent naturally present in natural mineral waters (EU, 2003) but essentially comes from the industrial contamination or from the treatments carried out in the water. The normal concentrations in water are very low, although high concentrations have been observed in groundwaters (WHO, 2011a).

The WHO considers that it is not necessary to establish a GV for drinking water because it is not a concern for health in concentrations that cause problems of acceptability of the water (WHO, 2011a). For natural mineral waters the limit established (BOE, 2010) (Codex, 2011) is 70 µg/l and in drinking water the parametric value is 50 µg/l (BOE, 2003).

The limit of 70 µg/l is based on a TDI of 12 µg/kg/day and a water contribution of 20 % (WHO, 2003a) which is considered sufficient to provide protection from acute and chronic effects.

For infants (section 5.1.a) the guideline value would be:

$$GV_{\text{infants}} = 3.33 \times \text{TDI} = 3.33 \times 12 = 39.96 \mu\text{g/l} \sim 40 \mu\text{g/l}$$

From the toxicological point of view, this value would be sufficient to protect infants from the acute and chronic effects of cyanide.

In addition, if we consider cyanide as a contaminant of industrial origin, in accordance with the purity criteria for natural mineral water, its concentration should not exceed the limit of quantification. The LOD for determining cyanide in water using titration and photometric techniques is 2 µg/l (WHO, 2003a) and, consequently, the LOQ would be 3 x LOD = 6 µg/l. If we consider the LOD of 10 % of the parametric value established for drinking water (BOE, 2003) and mineral waters (BOE, 2010) it would be 5-7 µg/l.

The limit of 10 µg/l proposed by France (Arrêté, 2010) seems reasonable and therefore, our "reference value" proposal for cyanide in natural mineral waters that use the indication "Suitable for the preparation of infant food" is 10 µg/l. This value represents a compromise between the toxicity of the cyanide ( $GV_{\text{infants}} = 40 \mu\text{g/l}$ ) and its contaminating nature (concentration <LOQ or <LOD, depending on the criteria applied).

### 4. Chloride

Chloride may be of natural origin or may be the result of pollution. The WHO has not established a GV as it considers that it is present in drinking water in concentrations well below those of concern to health (WHO, 2011a). The content of chlorides in uncontaminated waters is usually <10 mg/l and even <1 mg/l (WHO, 2003b). In Spain, the mean concentration of chlorides in natural mineral waters is 36.6 mg/l and the median is 11.75 mg/l (Vitoria y Arias, 2000). In drinking waters the limit is 250 mg/l (BOE, 2003), the same as that proposed by France (Arrêté, 2010) for natural mineral waters "Suitable for the preparation

of infant food". Royal Decree 1798/2010 considers the special indication of "chloride-containing" natural mineral waters when the chloride content is >200 mg/l (BOE, 2010).

The daily intake considered adequate for children aged 0-6 months old is 300 mg/day and for those aged 6-12 months is 270-570 mg/day and the mean content of breast milk is 400 mg/l (EFSA, 2013a). Formula milks contain 400-500 mg/l of chlorides, and therefore the waters used for the preparation of infant food are not required to provide chlorides.

If we consider chloride as a natural constituent (WHO, 2011a) and its low toxicity (WHO, 2003b) we can assume for natural mineral waters "Suitable for the preparation of infant food" a reference value of 200 mg/l, which would exclude "chloride-containing" waters. If we consider it as a contaminant, as it is not included in annex IV, section 1, part B of Royal Decree 1798/2010 the limit would be the LOD of the technique for determining chloride (25 mg/l), as in accordance with that laid down in Royal Decree 140/2003 for chloride in drinking waters, the LOD must be 10 % of the parametric value (250 mg/l).

According to the available information, 27.8 % of natural mineral waters in Spain exceed the value of 25 mg/l (Vitoria y Arias, 2000).

In light of the above, we can assume a reference value of 100 mg/l, for the natural mineral waters with the indication "Suitable for the preparation of infant food".

In accordance with the figures presented and considering the possible double source of chlorides, our "reference value" proposal for natural mineral water with the indication "Suitable for the preparation of infant food" would be 100 mg/l. This value would exclude chloride-containing waters and, in principle, would not pose a risk of adverse effects for the infant.

## 5. Copper

Although it is a constituent naturally present in natural mineral waters (EU, 2003), it comes primarily from the drinking water distribution network. The WHO has established a GV of 2 mg/l for drinking water (WHO, 2011a), which is maintained in drinking water (BOE, 2003) and is lowered to 1 mg/l in natural mineral waters (BOE, 2010) (Codex, 2011).

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) estimated a TDI of 0.05-0.5 mg/kg/day (given the uncertainties with regard to the toxicity of this metal) (FAO/WHO, 1982a) and in accordance with this TDI, the GV for adults, considering a water contribution to the daily intake of 20 % (WHO, 2003d) would be (section 5.1.a):

$$GV_{\text{adults}} = 6 \times TDI = 0.3-3 \text{ mg/l}$$

which would be in line with the WHO proposal of 2 mg/l. And in the case of infants:

$$GV_{\text{infants}} = 3.33 \times TDI = 0.16-1.7 \text{ mg/l}$$

According to these calculations, a GV of 1.7 mg/l would not pose a problem for infant health. In addition, copper is an essential nutrient although if consumed in excess it may cause toxic effects. Therefore, for example, a maximum limit of 1 mg/day is established for children aged from 1 to 3 years (EFSA, 2013a).

The mean intake of copper through breast milk, in infants aged 0-6 months is 0.3 mg/day (350 µg/l x 0.8 l) (EFSA, 2013a) and is considered sufficient for these children. For infants aged 6-12 months, the recommended intake is also 0.3 mg/day.

If we consider the copper content in formula milk (500-580 µg/l) it is clear that the water used for the preparation of infant feeding bottles is not required to provide any additional copper in order to meet the requirements of infants aged 0-12 months. Although, in principle, the maximum  $GV_{\text{infants}}$  calculated does not imply toxic effects for the infant if we consider the contribution of formula milk, the maximum recommended limit of 1 mg/day may be exceeded (EFSA, 2013a).

Even the limit in natural mineral waters of 1 mg/l (BOE, 2010) (Codex, 2011) could lead to levels of excess copper intake for infants.

If we consider the lowest value of the GV estimated for infants (0.16 mg/l) and the contribution of formula milk, then we would be within the recommended daily intake margins for infants. Furthermore, the concentration of 0.2 mg/l is never reached in bottled waters (AFSSA, 2003a).

In short, the limit of 0.2 mg/l proposed by France for natural mineral waters and spring waters "Suitable for the preparation of infant food", given the purity criteria (the same as those for chromium and nickel), is, in our opinion, adequate to guarantee the health of infants. Our "reference value" proposal for copper in natural mineral waters that use the indication "Suitable for the preparation of infant food" is 0.2 mg/l.

## 6. Chromium

Chromium is widely distributed in the earth's crust (WHO, 2011a) although in bottled waters it is generally provided by the installations (AFSSA, 2003a). According to the WHO, total chromium concentrations in drinking water are usually less than 2 µg/l, although higher concentrations may be found (WHO, 2011a). Considering that analytical techniques determine the total chrome (given the difficulty in analysing for the hexavalent form only, which is the carcinogenic form) the WHO considers it sufficient to establish a GV of 50 µg/l for total chromium. This same value is established for drinking water (BOE, 2003) and for natural mineral waters (BOE, 2010) (Codex, 2011).

However France, even admitting that this concentration does not pose a risk for health, applies the precautionary principle in the sense that "the water used for the preparation of infant food must not contain traces of contamination of a human, agricultural or industrial origin", which results in the lowering of the limits of the corresponding parameters (AFSSA, 2003a). As chromium is a contaminant usually provided by the installations, France proposes a total chromium limit of 5 µg/l for natural mineral waters "Suitable for the preparation of infant food" (10 times lower than in drinking water and natural mineral waters). The LOD for total chromium by AAS (Atomic Absorption Spectrometry) is 0.05-0.2 µg/l, and therefore technically there is no problem in the analysis of these concentrations.

Observing the same precautionary principle, our "reference value" proposal for total chromium in natural mineral waters that use the indication "Suitable for the preparation of infant food" is 5 µg/l.



## 7. Carbon dioxide (CO<sub>2</sub>)

The AFSSA (2003a) considers that carbonated water must not be used in the preparation of infant feeding bottles, given the risk of gas pains in infants. In addition, Royal Decree 1798/2010 considers natural mineral waters to be "acidified" if they contain >250 mg/l of CO<sub>2</sub> (BOE, 2010). It is clear that water used in the preparation of infant food must not be effervescent and therefore the CO<sub>2</sub> content should be less than 250 mg/l. Our "reference value" proposal for natural mineral waters with the indication "Suitable for the preparation of infant food" is 250 mg/l, and therefore acidified waters would be excluded. This proposal coincides with the limit proposed by France for natural mineral waters suitable for the preparation of infant food.

## 8. Fluoride

Fluoride is a natural constituent of natural mineral waters and its concentration in groundwaters may be highly variable depending on the nature of the rocks and the presence of minerals containing fluorine (WHO, 2011a). Water is the main source of exposure to fluoride. In Spain, the mean concentration of fluoride in natural mineral waters is 0.36 mg/l and the median is 0.2 mg/l (Vitoria y Arias, 2000).

For fluoride, the WHO establishes a guideline value of 1.5 mg/l in drinking water (WHO, 2011a) which is the same as that established for drinking water in Spain (BOE, 2003). This GV is calculated for adults considering a TDI of 0.122 mg/kg/day (WHO, 2003e) and a contribution of 40 %. For infants (section 5.1.a) the GV would be:

$$GV_{\text{infants}} = 3.33 \times TDI = 3.3 \times 0.122 = 0.4 \text{ mg/l}$$

However, legislation for natural mineral waters establishes a parametric value of 5 mg/l (BOE, 2010), specifying that if the fluoride content is >1 mg/l these must bear the label "fluoridated water". According to the Codex (2011) if the concentration of fluoride in natural mineral waters is >1.5 mg/l this must be indicated on the label as "not suitable for babies and children <7 years old".

The GV proposed by the WHO (WHO, 2011a) and Royal Decree 140/2003 for drinking water (BOE, 2003) do not consider the possible risk for infants. The AFSSA (2003c) issued a scientific opinion distinguishing the case of adults and infants and for the latter the possibility that the water is supplemented, therefore France has lowered this limit in "natural mineral waters and spring waters "Suitable for the preparation of infant food" to 0.5 mg/l (if there is no medical supplementation) and 0.3 mg/l (if there is medical supplementation).

Another point to consider is the fluoride content in breast milk and the contribution in formula milk. The fluoride content in breast milk is variable (0-100 µg/l). Taking the maximum value, the mean intake of 80 µg/day (100 µg/l x 0.8 l/day) is considered adequate for the majority of infants aged 0-6 months (EFSA, 2013a), although according to other sources the adequate intake for infants and children is 50 µg/kg/day (EFSA, 2013c). For infants aged 6-12 months, the adequate intake is 0.4 mg/day. In a study conducted in Iowa the daily intake of fluorine in infants aged 0-6 months was 300-350 µg (EFSA, 2013c). Regarding the maximum daily intake (UL: Upper Level), above which adverse effects may appear, this is 700 µg/day for infants aged 0-6 months (NAP, 1997). In formula milks, the fluoride

content is 25-28 µg/l (EFSA, 2013a), therefore in this case the fluoride contribution in infants would essentially e through water used in the preparation of feeding bottles.

In light of the above, our "reference value" proposal for fluoride in natural mineral waters that use the indication "Suitable for the preparation of infant food" would be 0.5 mg/l. This value would exclude fluorinated natural mineral waters and represents a compromise between safety for the infant and the usual values found in natural mineral waters in Spain.

## 9. Magnesium

Exposure to magnesium has been linked to bowel disturbances in infants (AFSSA, 2003a). The mean magnesium content in mineral waters is 24±42 mg/l (range of 1-130 mg/l) and the median concentration is 7 mg/l (WHO, 2009a). In Spain, the mean concentration of magnesium in natural mineral waters is 16.1 mg/l and the median is 10.3 mg/l (Vitoria y Arias, 2000). When the magnesium content is >50 mg/l, the natural mineral waters are considered "magnesium-rich" (BOE, 2010).

The adequate intake for children aged 0-6 months is 25-30 mg/day and 75-80 mg/day for 6-12 month-olds (WHO, 2009a) (EFSA, 2013a). The dietary intake in the United States and Canada is 33-140 mg/day. Regarding the maximum daily intake (UL: Upper Level), above which adverse effects may appear, this is 250 mg/day for all age groups (SCF, 2003).

Breast milk contains a median concentration of 31 mg/l, therefore the magnesium contribution through breast milk is considered sufficient for the requirements of the infant. Formula milks contain 60-80 mg/l, therefore in this case the magnesium contribution is sufficient. As for calcium, the water used for the preparation of infant feeding bottles does not need to provide more magnesium.

Given these figures, we can assume a reference value of 50 mg/l, for the natural mineral waters with the indication "Suitable for the preparation of infant food". The additional intake through the water with respect to the content of formula milks would be approximately 37 mg/day, resulting in a total dietary intake for infants of some 97-117 mg/day, which would be within the range of 33-140 mg/day (United States and Canada) (WHO, 2009a).

On the basis of the figures presented, our proposal for the natural mineral waters with the indication "Suitable for the preparation of infant food" would be 50 mg/l, which defines the limit of the waters with the special indication "magnesium-containing". This reference value, which is the same as that proposed by France (Arrêté, 2010), would exclude "magnesium-containing" waters and, in principle, would not represent a risk of adverse effects for the infant.

## 10. Manganese

Manganese is one of the most abundant metals in the Earth's crust, and is a naturally occurring constituent in natural mineral waters (UE, 2003).

Although the WHO does not establish a GV it considers that a limit of 0.4 mg/l could be derived without adverse effects for health (WHO, 2011a), considering a TDI of 0.06 mg/kg/day and a contribution of 20 % (WHO, 2011c). The GV for infants (section 5.1.a) would be:

$$GV_{\text{infants}} = 3.33 \times TDI = 3.3 \times 0.06 = 0.198 \approx 0.2 \text{ mg/l}$$

The parametric value of manganese in natural mineral waters is 500 µg/l (BOE, 2010) although the Codex Standard establishes a limit of 400 µg/l for the same waters (Codex, 2011). Manganese is naturally present in groundwaters and may reach high concentrations, which would justify the limit in natural mineral waters, 10 times higher than that of drinking water. In drinking water, the parametric value is 50 µg/l which is the limit proposed by France (Arrêté, 2010) for natural mineral waters and spring waters "Suitable for the preparation of infant food".

Although from the toxicological point of view the GV for infants would be 200 µg/l, it should be noted that concentrations of more than 50 µg/l may cause precipitates of manganese dioxide in bottles with the resultant black deposits. In this case, it would not be a health problem but a problem of an organoleptic nature.

Consequently, our "reference value" proposal for manganese in natural mineral waters that use the indication "Suitable for the preparation of infant food" is 50 µg/l, as for drinking water.

## 11. Nickel

It is a natural constituent in water and may also be the result of pollution from taps and fittings. The concentration of nickel in drinking water is usually <0.02 mg/l. In any case, the contribution from water to the intake of nickel is minimum (WHO, 2005).

The WHO has established a GV for nickel in drinking waters of 70 µg/l (WHO, 2011a), based on the TDI of 12 µg/kg/day and considering a contribution of 20 %. in accordance with that established in Section 5.1:

$$GV_{\text{adults}} = 6 \times TDI = 6 \times 12 = 72 \mu\text{g/l}$$

and for infants:

$$GV_{\text{infants}} = 3.33 \times TDI = 39.36 \mu\text{g/l} \sim 39 \mu\text{g/l}$$

That is, a concentration of nickel in water of 39 µg/l would not have negative consequences for the infant.

In drinking water, the parametric value is 20 µg/l (BOE, 2003), which would be sufficient to protect the health of infants and in natural mineral waters the Codex Standard establishes the same limit as for drinking waters (20 µg/l) (Codex, 2011), although Spanish legislation for natural mineral waters considers a value of 50 µg/l (BOE, 2010).

France, for natural mineral waters "Suitable for the preparation of infant food" proposes a quality limit of 2 µg/l (Arrêté, 2010). From the toxicological point of view, the limit for drinking waters (20 µg/l) would be acceptable for natural mineral waters "Suitable for the preparation of infant food", however, although admitting that this concentration does not pose a risk for health, France applies the precautionary principle in the sense that "the water used for infant food must not contain traces of contamination of human, agricultural or industrial origin", leading it to reduce the limits of the corresponding parameters (AFSSA, 2003a). As nickel is a contaminant usually released from the fittings, France proposes a limit 10 times lower than in drinking water.

Given its possible double source and based on safety criteria, our "reference value" proposal for nickel in natural mineral water that uses the indication "Suitable for the preparation of infant food" is 20 µg/l.

## 12. Nitrate

Nitrates are natural constituents of drinking water although they may also be the result of contamination. The most important source of exposure to nitrates is in the diet (through vegetables and meat). However, in the case of infants, water can be the major source of exposure (WHO, 2011d). In Spain, the mean concentration of nitrates in natural mineral waters is 5.7 mg/l and the median is 2.9 mg/l (Vitoria y Arias, 2000).

The WHO establishes a GV for the nitrate ion of 50 mg/l (WHO, 2011a), a value which is maintained for drinking water (BOE, 2003) and for natural mineral waters (BOE, 2010) (Codex, 2011). According to the WHO, this GV would offer protection against methaemoglobinaemia in infants (short-term exposure) (WHO, 2011d).

The Joint FAO/WHO Experts Committee on Food Additives (JECFA) established an ADI of 0-3.7 mg/kg/day although it specified that this value was not applicable to infants under the age of 3 months (FAO/WHO, 1995). If we consider the maximum value of the TDI (3.7 mg/l) the GV for children (section 5.1.a) would be:

$$GV_{\text{infants}} = 3.33 \times TDI = 12.3 \text{ mg/l}$$

and for infants under 3 months, should be reduced, given their increased level of sensitivity. Nevertheless, the epidemiological data (WHO, 2011d) indicate that in the cases described of methaemoglobinaemia in infants under the age of 3 months, the quantities of nitrates consumed were 37.1-108.6 mg/kg, with a mean value of 56.7 mg of nitrate/kg per weight. According to these figures the GV of 50 mg/l proposed by the WHO is sufficient.

The natural concentration of nitrate in groundwaters in aerobic conditions is a few mg/l and largely depends on the soil type and geology of the ground. Thus, for example, in the United States, the natural levels are not usually more than 4-9 mg/l (WHO, 2011d).

If we consider nitrate as a contaminant, based on the definition of "natural mineral water" (BOE, 2010) that lists its "original purity" as a defining characteristic, the presence of nitrates would be indicative of contamination incompatible with the definition of natural mineral water. Under this criteria France recommends a nitrate limit of 10 mg/l (Arrêté, 2010).

Considering the criteria of "purity" of the natural mineral waters, the GV estimated for infants and natural concentrations of nitrate in natural mineral waters, our "reference value" proposal for nitrate in natural mineral waters with the indication "Suitable for the preparation of infant food" would be 10 mg/l. Germany also recommends a limit of nitrates of 10 mg/l for these waters (Germany, 1984).

### 13. Dry residue

Natural mineral water contains a minimum of dissolved solids of 250 mg/l (WHO, 2009a, 2011b). Based on the general principle in which reconstituted milk must be as similar as possible to breast milk and that certain mineral elements must be limited, the AFSSA (2003a) proposes that the dry residue content of the waters should be less than 1 000 mg/l.

Royal Decree 1798/2010, in its annex III, defines waters with a very low mineral content as those with up to 50 mg/l of dry residue, with a low mineral content when the dry residue content is up to 500 mg/l, with an average mineral content when the dry residue content is from 500 to 1 500 mg/l and with a high mineral content when the dry residue content is more than 1 500 mg/l.

Consequently, our proposal for natural mineral waters with the indication "Suitable for the preparation of infant food" would be a maximum dry residue content of 1 000 mg/l. Natural mineral waters with a high mineral content would be excluded.

### 14. Sodium

This is found naturally in drinking water and although the concentrations are typically less than 20 mg/l (WHO, 2003f), in some areas they may be much higher. In addition, some treatments may increase the sodium content, in particular the use of water softeners. The WHO does not establish a GV for sodium because it considers that the usual concentrations are not of concern to health (WHO, 2011a). In Spain, the mean concentration of sodium in natural mineral waters is 49.43 mg/l and the median is 13.1 mg/l (Vitoria y Arias, 2000).

In drinking waters, the parametric value is 200 mg/l (BOE, 2003) which is the same as the value recommended by France for natural mineral waters "Suitable for the preparation of infant food". Royal Decree 1798/2010 considers the special indication "sodium-containing waters" when the sodium content is >200 mg/l and concentrations >150 mg/l may affect the organoleptic properties (BOE, 2010).

The adequate daily intake for children aged 0-6 months is 120 mg/day and 170-370 mg/day for 6-12 month-olds (EFSA, 2013a). The mean content of breast milk is 140-160 mg/l. In addition, formula milk contains 170 mg/l of sodium (0-6 months) and 370 mg/l (>6 months), and therefore the water used for the preparation of infant feeding bottles does not need provide more sodium.

If we consider sodium as a natural component (WHO, 2011a) and from the safety point of view for infants, we can assume for natural mineral waters "Suitable for the preparation of infant food" a limit of 200 mg/l, which would exclude "sodium-containing" waters. In any case, the sodium content is linked to the chloride content and should be as low as possible (AFSSA, 2003a).

According to the available information, 42 % of natural mineral waters in Spain exceed the value of 20 mg/l (Vitoria y Arias, 2000).

In light of the above, our "reference value" proposal for sodium in natural mineral water with the indication "Suitable for the preparation of infant food" would be 100 mg/l. This value would exclude sodium-containing waters and, in principle, would not pose a risk of adverse effects for the infant. Major inconsistencies in the existing legislation are found with this parameter. While France proposes a limit of 200 mg/l (the same as the limit for drinking water) (Arrêté, 2010), Germany proposes a

maximum limit of 20 mg/l (Germany, 1984). With this limit, only those waters "Suitable for low-sodium diets" might be considered "Suitable for the preparation of infant food" as established in Royal Decree 1798/2010. Considering the parametric value in drinking water (considered suitable for the preparation of infant food) we consider this limit to be too restrictive.

Our proposal considers safety for infants and is in line with the mean content of natural mineral waters in Spain.

## 15. Sulfates

These occur naturally in drinking water although some treatments may increase the sulfate content. The highest levels are usually found in groundwaters and are from natural sources. The WHO does not establish a GV for sulfates because it considers that the usual concentrations are not of concern to health (WHO, 2011a).

In drinking water the parametric value is 250 mg/l (BOE, 2003) and levels >250 mg/l may affect the organoleptic properties (WHO, 2004). A parametric value has not been established for natural mineral waters and the special indication "sulfated water" must be used when the content is >200 mg/l (BOE, 2010). In Spain, the mean concentration of sulfates in natural mineral waters is 52.7 mg/l and the median is 19.8 mg/l (Vitoria y Arias, 2000).

If we consider sulfates as a natural component (WHO, 2011a), we can assume for natural mineral waters "Suitable for the preparation of infant food" a limit of 200 mg/l, which would exclude "sulfated" waters.

An excess of sulfates in the water may cause diarrhoea in children and reduce the absorption of calcium (AFSSA, 2003a). Therefore France proposes for natural mineral waters "Suitable for the preparation of infant food" that the content does not exceed the sulfate content in breast milk (140 mg/l) (Bueno et al., 2012). Nevertheless, without dismissing the possibility of the existence of a link between the cases of diarrhoea to exposure to sulfates in drinking water, the studies carried out are not conclusive and in any case, would involve very high doses (EPA, 1999).

In light of the above, our "reference value" proposal for sulfates in natural mineral water with the indication "Suitable for the preparation of infant food" would be 200 mg/l. This value would exclude "sulfated" natural mineral waters and, in principle, would not pose a risk of adverse effects for the infant.

## 16. Uranium

In accordance with the terms of reference, uranium is considered in this report from a chemical point of view without considering its radioactive properties. Uranium is not considered in the Spanish legislation for drinking water (BOE, 2003) nor for natural mineral waters (BOE, 2010). Nor does the Codex Standard refer to this parameter in natural mineral waters (Codex, 2011). France does not include this parameter in its proposal (Arrêté, 2010) for quality limits for natural mineral waters and spring waters "Suitable for the preparation of infant food".

Nevertheless, the WHO establishes a provisional GV of 30 µg/l (WHO, 2011a). The EFSA (2009) issued a scientific opinion on uranium in food products and mineral water in particular, considering only the chemical toxicity of uranium.

Considering the TDI of 0.6 µg/kg/day (EFSA, 2009) and a water contribution of 50 %, the GV for adults would be 9 µg/l and for infants 2 µg/l (section 5.1.a). If we assume a contribution from water of 80 %, the GV for adults and infants would be 15 µg/l and 3.2 µg/l, respectively. Considering the mean content of uranium in bottled water (EFSA, 2009) of 1.83 µg/l and an intake of 0.75 l/day, the daily intake of uranium by infants would be 1.37 µg/day (0.27 µg/kg/day) equivalent to 45 % of the TDI.

Given that Uranium is widespread in nature, our "reference value" proposal for natural mineral waters with the indication "Suitable for the preparation of infant food" would be 2 µg/l, which corresponds to the mean concentration usually found in natural mineral waters in Europe. Similarly, Germany proposes a limit of 2 µg/l for natural mineral waters "suitable for the preparation of infant food" (Germany, 1984).

## 17. Zinc

Zinc may have two sources: occurring naturally in groundwaters and the result of the degradation of pipes. In natural mineral waters its presence, therefore, is of a natural origin.

The WHO considers that, at the levels found in drinking water, it is not of concern to health and therefore does not establish a GV for zinc (WHO, 2011a). The concentration in ground waters is 10-40 µg/l (WHO, 2003h). There is no parametric value for zinc in drinking water, and nor has a value been established for natural mineral waters.

In breast milk, the mean concentration of zinc is 2.5 mg/l and in formula milk the concentration is 6-7 mg/l (EFSA, 2013a). It is clear that breast milk or formula milk provide sufficient zinc as the recommended daily intake is 2-4 mg/day for children aged 0-6 months and 6-12 months, respectively (EFSA, 2013a). Therefore, the contribution of zinc through water for the preparation of infant feeding bottles is unnecessary. In addition, the maximum daily intake (UL: Upper Level) is 4 and 5 mg/day for infants aged 0-6 months and 6-12 months, respectively (NAP, 2001).

From a toxicological point of view, considering the PMTDI (Provisional Maximum Tolerable Daily Intake) of 1 mg/kg/day (WHO/FAO, 1982b) and in accordance with that established in section 5.1.a, the GV for infants would be 3 mg/l. This concentration would not have negative consequences for the infant, although it may affect the organoleptic characteristics of the water (WHO, 2003h), making it unacceptable for consumption.

Considering the normal content of zinc, the daily requirements of the infant and toxicological aspects, our proposal for natural mineral waters with the indication "Suitable for the preparation of infant food" would be 0.1 mg/l, similar to the French proposal (AFSSA, 2003a) based on the fact that the concentration of zinc in bottled waters is clearly lower than this concentration.