Report of the Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) in relation to the assessment of the risk of exposure for the Spanish population to cadmium resulting from the consumption of food

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Reference number: AESAN-2011-009

Report approved by the Scientific Committee on plenary session November 30th, 2011

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Abstract

Cadmium (Cd) is a heavy metal found as an environmental contaminant, both through natural occurrence and from industrial and agricultural sources. Foodstuffs are the main source of cadmium exposure for the non-smoking general population. Cd absorption after dietary exposure in humans is low (3-5%) but Cd is efficiently retained in the kidney and liver in the human body, with a very long biological half-life ranging from 10 to 30 years. Cd is primarily toxic to the kidney, especially to the proximal tubular cells where it accumulates over time and may cause renal dysfunction. Cd can also cause bone demineralization, either through direct bone damage or indirectly as a result of renal dysfunction. After prolonged and/or high exposure the tubular damage may progress to decreased glomerular filtration rate, and eventually to renal failure. Cd levels in urine are widely accepted as a measure of the body burden and the cumulative amount in the kidneys. The IARC (International Agency for Research on Cancer) has classified Cd as a human carcinogen (Group 1) on the basis of occupational studies. Newer data on human exposure to Cd in the general population have been statistically associated with increased risk of cancer such as in the lung, endometrium, bladder, and breast.

A provisional tolerable weekly intake (PTWI) for cadmium of 7 µg/kg body weight (b.w.) per week was established by JECFA (Joint FAO/WHO Expert Committee on Food Additives), this PTWI was maintained pending further research. The EFSA CONTAM Panel (European Food Safety Authority) carried out a meta-analysis on a selected set of studies to evaluate the dose-response relationship between urinary cadmium and urinary ß-2-microglobulin (B2M). B2M, a low molecular weight protein, is recognized as the most useful biomarker in relation to tubular effects. A Hill model was fitted to the dose-response relationship between urinary cadmium and B2M for subjects over 50 years of age and for the whole population. From the model, a BMDL5 (Benchmark dose lower limit) of 4 µg Cd/g creatinine was

Translated from the original published in the journal: Revista del Comité Científico de la AESAN, 15, pp: 57-102

derived. A chemical-specific adjustment factor of 3.9, to account for inter-individual variation of urinary cadmium within the study populations, was applied, leading to a value of 1.0 µg Cd/g creatinine. In order to remain below 1 µg Cd/g creatinine in urine in 95% of the population by age 50, the average daily dietary cadmium intake should not exceed 0.36 µg Cd/kg b.w. corresponding to a weekly dietary intake of 2.52 µg Cd/kg b.w. The CONTAM Panel established a new TWI (Tolerable Weekly Intake) for cadmium of 2.5 µg/kg b.w./week.

The Scientific Committee of the Spanish Agency for Food Safety and Nutrition (AESAN) was asked by the AESAN to assess the risks to human health related to the presence of cadmium in foodstuffs. To provide an updated assessment of Cd exposure from foodstuffs, about 5,493 data covering the period from 2000 to 2010 on cadmium occurrence in various food commodities were analyzed. The food commodities were included into 15 food categories. The food comodities more representative were fish and seafood (54.3%), meat including offall (22.57%), vegetables, nuts and legumes (5.78%) and cereals and cereal products (4.05%). The number of samples with Cd levels <LOD were 2,156 (39.2%). Nine of the 15 food categories presented a number of samples (>60%) with Cd levels <LOD. For this reason, in the present report, Lower Bound (LB) and Upper Bound (UB) values were estimated. Sampling adjustment factors (SAF) calculated from the German Nutrition Survey with EFSA modifications were applied when aggregating food subcategory averages to category averages. When SAF was applied, the adjusted occurrence mean level was calculated.

Statistical description of concentrations of cadmium for food categories was determined. For most foods only a small percentage of the analyzed samples exceeded the maximum level (ML), where specified. Samples which exceeded the ML were kidney (>17%), horse liver (>50%) and crustaceous (>14%). The dietary exposure assessment was based on the occurrence data on cadmium concentrations in food commodities as well as on consumption data reported for adults and for children. The mean exposure for adults (1.15-2.85 µg Cd/kg b.w./week) is close to, or slightly exceeding, the TWI of 2.5 µg Cd/kg b.w. Subgroups such as children (1.87-4.29 µg Cd/kg b.w./week) may exceed the TWI by about 2-fold.

Key words

Cadmium, food, occurrence, exposure, consumption, tolerable weekly intake, risk assessment.

List of Abbreviations

AAS: Atomic Absorption Spectrometry.

AESAN: Spanish Agency for Food Safety and Nutrition.

ANFACO: Spanish National Association of Fish and Seafood Canneries.

B2M: ß-2-Microglobulin.

BMD: Benchmark Dose (dose of a substance that is expected to result in a 10% level of measurable effect/response).

BMDL5: A lower 95% confidence limit on the BMD.

CSN: Nuclear Safety Council.

EC: European Commission.

EFSA: European Food Safety Authority.

ENIDE: Spanish National Survey on Dietary Intake.

EU: European Union.
FAAS: Flame Atomic Absorption Spectrometry.
FAO: Food and Agriculture Organization of the United Nations.
GEMS/Food: Global Environment Monitoring System-Food Contamination Monitoring and Assessment Programme.
GFAAS: Graphite Furnace Atomic Absorption Spectrometry.
IARC: International Agency for Research on Cancer.
ADI: Acceptable Daily Intake.
JECFA: Joint FAO/WHO Expert Committee on Food Additives.
JRC: Joint Research Centre.
LB: Lower Bound
LOD: Limit of detection.
LOQ: Limit of quantification.
ML: Maximum Legal limit.
NOAEL: No Observable Adverse Effect Level.
NOEL: No Observed Effect Level.
WHO: World Health Organization.
b.w.: body weight.
PNIR: Integrated National Residues Plan.
PTMI: Provisional Tolerable Monthly Intake.
PTWI: Provisional Weekly Tolerable Intake.
SAF: Sampling Adjustment Factors.
TWI: Tolerable Weekly Intake.
UB: Upper Bound.

Introduction: general information

Cadmium (Cd), especially inorganic cadmium, is highly toxic for humans. Exposure is mainly by inhalation or ingestion. The content of cadmium in water is very variable, and there are several inorganic chemical forms potentially bioavailable in the aquatic environment such as $CdCO_3$, $Cd(OH)_2$, CdS and other insoluble inorganic compounds linked to cadmium. In highly industrialised regions, rivers may be polluted by cadmium and therefore cadmium may enter irrigation water intended for agricultural use where it builds up in the sediments. The use in agriculture of phosphate fertilisers also contributes to the presence of high concentrations of cadmium in the soil (Pan et al., 2010). Due to the high water-soil-plant transfer, cadmium is a contaminant found in the majority of foods consumed by humans.

Symptoms of cadmium toxicity depend on the dose and length of exposure. Acute toxicity is associated with acute abdominal pain, nausea, vomiting, diarrhoea, headaches and/or vertigo, and may result in death within 24 hours or 1-2 weeks after exposure, once kidney and liver injury takes place. The NOEL of a single oral dose is estimated at 3 mg Cd/person, and lethal doses range between 350 to 8,900 mg (Bernard and Lauwerys, 1986).

Chronic toxicity symptoms include respiratory and cardiovascular disorders, renal dysfunction, disorders of the calcium metabolism, neurotoxicity and bone diseases such as osteoporosis and spontaneous bone fracture. The itai-itai disease induced by cadmium in Japan is an example of bone disease directly attributed to the chronic exposure of the population to cadmium in food and water.

The kidney is the target organ after exposure to cadmium and kidney damage is characterised by an accumulation of cadmium in the proximal tubules. The first sign of toxic effects related to cadmium is renal tubule damage followed by glomerular damage which leads to an increase in the urinary excretion of low molecular weight proteins (WHO, 1992) (Järup and Akesson, 2009) (Saturug et al., 2010), but there is also evidence to confirm that cadmium is a risk factor in the development of osteoporosis (U.S. Department of Health and Human Services, 2004). Low levels of exposure to cadmium are associated to a lower bone mineral density (Alfvén et al., 2000, 2004) (Akesson et al., 2006) (Gallagher et al., 2008, 2010) (Honda et al., 2003) (Schutte et al., 2008), observations made of workers exposed to cadmium (Nawrot et al., 2010).

Cadmium is also considered as an endocrine disruptor (Darbre, 2006) due to its capacity to bind to estrogenic receptors and mimic the action of estrogen. There is evidence that exposure to cadmium may result in the development of prostate and breast cancer (Waalkes, 2003). The International Agency for Research on Cancer (IARC) classified cadmium compounds as human carcinogens (Group 1) (IARC, 1993).

But in Europe, some compounds of cadmium are classified as possibly carcinogenic (category 2; Annex 1 of Directive 67/548/EEC (EU, 1967)). The Joint Research Centre (JRC) considers that there is insufficient scientific evidence to confirm that cadmium acts as a carcinogenic after oral exposure (EC, 2007). However, data collected in genotoxicity and long-term toxicity tests on animals and epidemiological studies lead to the consideration of cadmium oxide as a suspected human inhalation carcinogen. There is recent evidence to suggest that cadmium may play a role in the development of other cancers, such as testicular, bladder, pancreatic and gall bladder cancers (Huff et al., 2007).

The intake of cadmium in the diet has been the subject of numerous studies. The absorption of cadmium through the gastrointestinal tract is around 5%, and it is mainly accumulated in the liver and kidney. The elimination half-life of cadmium in mice, rats, rabbits and monkeys is calculated to be from several months to several years, in general equivalent to 20-50% of the life span (Nordberg et al., 1985). In humans, Nordberg et al. (1985) calculated a range of elimination half-lives for cadmium in the kidney of 6 to 38 years, and of 4 to 19 years in the liver. The plasma elimination half-life of cadmium reaches values of 10 years (Järup et al., 1983).

Urinary excretion of cadmium depends on the concentration of the element in the blood and kidney, and total excretion at steady state is assumed to be the daily intake. With these assumptions, daily faecal and urinary excretions are estimated to represent 0.007-0.009% of the total body burden, respectively (Kjellstrom and Nordberg, 1978) (Nordberg et al., 1985). Urinary cadmium excretion of occupationally exposed workers increases proportionally with the body burden of cadmium, but the amount of cadmium excreted represents only a small fraction of the body burden, unless renal damage is present, in which case, urinary cadmium excretion markedly increases (Roels et al., 1981).

Given the possible toxic effects on consumers due to the presence of cadmium in food and the recent modification of the tolerable intake values, the Executive Director of the Spanish Agency for Food Safety and Nutrition (AESAN) has requested the Scientific Committee of the AESAN to make an assessment of the risk of exposure of the Spanish population to cadmium due to the intake of food.

Risk assessment: background

Exposure to cadmium in the diet is of increasing concern, and has led to successive assessments. The European Commission is reviewing the maximum concentrations of cadmium in foods and has requested an update of the assessment of the risk in food.

Seven food types make up 40-80% of total intake and *Codex* maximum levels (ML) have been proposed in order to assess the risk (WHO, 2006):

- Rice: 0.4 mg/kg.
- Wheat and other cereals: 0.2 mg/kg.
- Root vegetables: 0.1 mg/kg.
- Tubers, potatoes and others: 0.1 mg/kg.
- Leaf vegetables: 0.2 mg/kg.
- Other vegetables: 0.05 mg/kg.
- Oysters: 3 mg/kg.
- Other molluscs: 1 mg/kg.

In order to establish the safety of cadmium intake, the FAO/WHO established a provisional tolerable weekly intake (PTWI) for cadmium of 400-500 µg/person/week equivalent to 7 µg Cd/week/kg b.w. (WHO, 1989). These levels are based on a critical renal concentration of 100-200 µg Cd/g renal cortex, reached after the intake of 140-260 µg Cd/day over >50 years, or 2,000 mg over a life time (WHO, 1989) and which is equivalent to an urinary limit of 5-10 µg Cd/g creatinine. Nevertheless, renal effects have been observed with urine contents >0.5 µg Cd/g creatinine (Satarug and Moore, 2004).

These findings support the fact that the PTWI did not provide adequate protection for health, and must therefore be reduced.

In any case, the estimated total intakes of cadmium for the seven food types calculated from the food intake described in the GEMS/regional diets is between 2.8 and 4.2 μg/kg b.w./week, equivalent to 40-60% of the PTWI (WHO, 2006).

The PTWI of 7 μg Cd/kg b.w./week was maintained at the FAO/WHO 64 Meeting (WHO, 2006). Subsequently, JECFA (2010) decided to express the tolerable intake as a monthly value establishing a provisional tolerable monthly intake (PTMI) of 25 μg Cd/kg b.w.

The Regulation (EC) No 1881/2006 (EU, 2006) amended by Regulation (EU) No 420/2011 (EU, 2011) established the maximum levels (ML) for cadmium in certain food products, in particular in meat, viscera, fish products, cereals, fruit and vegetables (Table 1).

The criteria for using a particular method of analysis for the official control should meet the provisions of Regulation (EC) No 333/2007 (EU, 2007). This requires a limit of detection (LOD) less than 1/10 of the maximum limit (ML) and a limit of quantification (LOQ) less than 1/5 of the ML. The atomic absorption spectrometry (AAS) with flame (FAAS) and electrothermal (graphite tube) (GFAAS) atomizers are the techniques usually used for the determination of cadmium.

Table 1. Cadmium maximum levels (ML) in foodstuffs according to Regulation (EC) No 1881/2006, amended by Regulation (EU) No 420/2011

Section	Foodstuffs	Maximum levels (mg/kg fresh weight)
3.2.1	Meat (excluding offal) of bovine animals, sheep, pig and poultry	0.050
3.2.2	Horsemeat, excluding offal	0.20
3.2.3	Liver of bovine animals, sheep, pig, poultry and horse	0.50
3.2.4	Kidney of bovine animals, sheep, pig, poultry and horse	1.0
3.2.5	Fish meat , excluding the species listed in points 3.2.6, 3.2.7 and 3.2.8	0.050
3.2.6	Muscle meat of the following fish: Bonito *(Sarda sarda)* Common two-banded seabream *(Diplodus vulgaris)* Eel *(Anguilla anguilla)* Grey mullet *(Chelon labrosus)* Horse mackerel or scad *(Trachurus species)* Louvar or luvar *(Luvarus imperialis)* Mackerel *(Scomber species)* Sardine *(Sardina pilchardus)* Sardinops *(Sardinops species)* Tuna *(Thunnus species, Euthynnus species, Katsuwonus pelamis)* Wedge sole (*Dicologoglossa cuneata*)	0.10
3.2.7	Muscle meat of the following fish: Bullet tuna *(Auxis species)*	0.20
3.2.8	Muscle meat of the following fish: Anchovy (*Engraulis species*)[a], Swordfish (*Xiphias gladius*)	0.30
3.2.9	Crustaceans: Meat from limbs and abdomen. In the case of crabs and similar crustaceans (*Brachyura y Anomura*), meat from the limbs	0.50
3.2.10	Bivalve molluscs	1.0
3.2.11	Cephalopods (without viscera)	1.0
3.2.12	Cereals, excluding bran, germ, wheat and rice	0.10
3.2.13	Bran, germ, wheat and rice	0.20
3.2.14	Soybeans	0.20
3.2.15	Vegetables and fruit, excluding leaf vegetables, fresh herbs, leaf vegetables from the genus *Brassica*, fungi, young stem vegetables, root vegetables and tubers, and seaweed	0.050
3.2.16	Stem vegetables, root vegetables and tubers, excluding celeriacs. For potatoes the maximum level applies to peeled potatoes	0.10
3.2.17	Leaf vegetables, fresh herbs, leaf vegetables of the genus *Brassica*, celeriacs and the following fungi: *Agaricus bisporus* (common mushroom), *Pleurotus ostreatus* (Oyster mushroom) and *Lentinula edodes* (Shiitake mushroom)	0.20
3.2.18	Fungi, excluding those listed in point 3.2.17	1.0
3.2.19	Food supplements, excluding food supplements listed in point 3.2.20	1.0
3.2.20	Food supplements consisting exclusively or mainly of dried seaweed or of products derived from seaweed or dried bivalve molluscs	3.0

[a]A correction factor of 4.5 is applied for anchovies in canneries and brine (AESAN, 2008a).

Royal Decree 1798/2010 (Real Decreto, 2010), governing the commercial exploitation of natural mineral water and spring water bottled for human consumption, and Royal Decree 1799/2010 (Real Decreto, 2010), controlling the preparation and marketing of prepared bottled water for human consumption, establish maximum permitted levels of cadmium (Table 2).

Table 2. Maximum permitted levels of cadmium in bottled mineral water	
Natural mineral water	3 µg/l
Spring water	5 µg/l
Bottled drinking water other than natural mineral and spring water	5 µg/l

The Panel on Contaminants in the Food Chain (CONTAM Panel) of the EFSA (2009a) re-assessed dietary exposure to cadmium, and the risk analysis on the basis of a review of 35 epidemiological studies. The EFSA (2009a) presented food intake data from 16 Member States without including the data from Spain. The mean adult intake was estimated for each food category as the mean of the values from the 16 Member States (Table 3). It also highlights that the food groups that most contribute to cadmium exposure are cereals and derived products, vegetables, nuts, pulses, potatoes, meat, milk and water as they are frequently consumed.

Table 3. Exposure to cadmium for different food groups. Data for cadmium content and intake are taken as mean values from the data supplied by the Member States for each food category (EFSA, 2009a)

Category	Observed content mg/kg	Intake (mean value) g/día	Exposure Cd µg/día	Exposure Cd µg/week/kg b.w.
Cereals and derived products	0.0163	257	4.189	0.4887
Sugar including chocolate	0.0264	43	1.135	0.1324
Fats (vegetable and animal)	0.0062	38	0.236	0.0275
Vegetables, nuts, pulses	0.0189	194	3.667	0.4278
Potatoes or tubers	0.0209	129	2.696	0.3145
Fruit, fruit and vegetable juices, and soft drinks	0.0010	439	0.439	0.0512
Coffee, tea, cocoa	0.0018	601	1.082	0.1262
Alcoholic drinks	0.0042	413	1.735	0.2024
Meat products and substitutes	0.0165	151	2.492	0.2907
Meat and meat products	0.0077	132	1.016	0.1185
Offal and derivatives	0.1263	24	3.031	0.3536
Mixed meat-based dishes	0.0076	84	0.638	0.0744
Fish and shellfish	0.0268	62	1.662	0.1939
Eggs	0.0030	25	0.075	0.0085
Milk and dairy products	0.0039	287	1.119	0.1305
Miscellaneous / Food for special diets	0.0244	14	0.342	0.0399
Tap water	0.0004	349	0.140	0.0163

Source: (EFSA, 2009a).

The mean dietary exposure in European countries was estimated at 2.3 μg Cd/kg b.w./week (in a range of 1.9 to 3.0 μg Cd/kg b.w./week, assuming a body weight of 60 kg) and the highest exposure was estimated at 3.0 μg Cd/kg b.w. per week (in a range of 2.5 to 3.9 μg Cd/kg b.w./week). Due to a high intake of cereals, nuts and other seeds and pulses, vegetarians have a higher exposure reaching 5.4 μg Cd/kg b.w./ week. Tobacco smoking may lead to a similar exposure as that from diet.

A summary of the different exposures to cadmium is given in Table 4. Oral exposure from food is predominant in non-smoking individuals with a small contribution from house dust in contaminated areas. Extreme diets may double the exposure.

Table 4. Overview of mean weekly cadmium exposure estimates (EFSA, 2009a)

	Source	Pathway	Range of exposures μg Cd/kg b.w. per week	
			Adults	**Children**
Dietary exposure	Mean intake of diverse foods	Oral	1.89-2.96	2.56-3.46
	High intake of diverse foods	Oral	2.54-3,91	5.49
	Food in industrial areas	Oral	3.3-5,8[a]	4.6[a]
	Extreme diets	Oral	2.27-4.64	
	Vegetarians	Oral	5.47	
Non-dietary exposure	House dust	Oral	0.076	0.607
	Air	Inhalation	0.0024	0.0033[b]
	Tobacco	Inhalation	0.35-0.70[c]	

[a]Estimated using a factor of 1.86 times average exposure. [b]Assuming a daily inhalation volume of 7 m3 and a body weight of 15 kg.[c]Assuming that the exposure can increase by 15-30% when 20-40 cigarettes/day are smoked. **Source:** (EFSA, 2009a).

Cadmium concentration in urine is accepted as a measure of accumulation in kidneys. The CONTAM Panel performed a meta-analysis (EFSA, 2009b) of the tests selected to assess the dose-response relationship between these concentrations of urinary cadmium and the quantity of urinary ß-2-microglobulin (B2M), a low weight molecular protein recognised as the best biomarker related to tubular effects. The model was established for the dose-response relationship between urinary calcium and B2M for individuals over 50 years of age and for the whole population.

This model was used to calculate a benchmark dose (BMD) and the lowest confidence level for a 5% increase of B2M (BMDL5) of 4 μg Cd/g creatinine, which applying an adjustment or safety factor led to the value of 1 μg Cd/g creatinine in urine as a reference point (RP) modified on the basis of the health-based guidance value (HBGV) of the cadmium intake in diet (EFSA, 2009a). It appears reasonable to assume that lower alterations can be observed in renal biomarkers with values of 1 μg Cd/g creatinine. For the purposes of public health protection, it is crucial to determine the reference point (RP),that is the exposure below which the probability of adverse effects is low.

The BMD approach is used more and more for the assessment of the risk of contaminants, it defines the exposure corresponding to a certain change in the response in comparison to a control, that is the level of exposure that corresponds to an increase in the probability of an adverse response in comparison with a zero or background exposure (U.S. EPA, 1995) (Filipsson et al., 2003) (EFSA, 2009c).

The lowest 95%-confidence of the BMD (BMDL) is used more and more to replace the no observed adverse effect level (NOAEL) in risk assessment (U.S. EPA, 1995) (EFSA, 2009a, 2009c).

The main advantage of the BMD method in comparison with the NOAEL is that it uses the information from the entire dose-response curve. Moreover, the NOAEL requires a reference group without exposure which is less valid in populations in which all the subjects are subject to some degree of exposure. The BMD also corresponds to a certain response or level of risk whereas the risk in the NOAEL is not identified and may vary from case to case.

In order to maintain a level below 1 µg Cd/g creatinine in urine in 95% of the population aged 50, the CONTAM Panel established that the mean daily dietary intake of cadmium should not exceed 0.36 µg Cd/kg b.w. which corresponds to a tolerable weekly intake (TWI) of 2.52 µg Cd/kg b.w. per week approximately three times less than the PTWI of 7 µg Cd/-/kg b.w. per week (WHO, 2006). To establish this TWI the model took into consideration the variability in cadmium absorption rates (1-10%), together with the highest absorption rate common in women of reproductive age. The TWI value proposed (EFSA, 2009a) agreed with a recent estimation of the BMDL for cadmium associated with osteoporosis in women (Suwazono et al., 2010).

The CONTAM Panel (EFSA, 2009a) concluded that in order to minimise the risk of adverse effects, mainly in the kidney, exposure to cadmium must be reduced. Therefore, they reduced the PTWI from 7 µg Cd/kg b.w. per week to 2.5 µg Cd/-kg b.w. per week.

Mean exposure to cadmium among adults in the European Union is low and may be slightly more than the TWI of 2.5 µg Cd/ kg b.w. per week (Table 4). However, certain subgroups such as vegetarians, children, smokers and, in general, populations that live in highly contaminated areas may have as much as twice the TWI.

Risk assessment: current situation

The European Commission recently asked the CONTAM Panel whether it considered that the established TWI value of 2.5 µg Cd/ kg b.w. per week (EFSA 2009a) was still appropriate or whether it should be modified in view of the provisional tolerable monthly intake (PTMI) of 25 µg/kg b.w. established by JECFA (2010) which corresponds to a TWI of 5.8 µg/kg b.w. per week.

Both assessments of the EFSA (2009a) and the JECFA (2010) have two primary components, a concentration-effect model that relates the urinary cadmium concentration to the B2M content, and a toxicokinetic model that relates the urinary cadmium concentration to the dietary cadmium intake, but the methodology used is different. These differences include:

- selection of the RP to derive from the HBGV,
- the statistical treatment in the concentration-effect model of the urinary cadmium concentration and B2M biomarkers, and
- the method for converting the urinary cadmium concentration into dietary cadmium intake values.

The CONTAM Panel (EFSA 2011a) stresses the need to apply an uncertainty or safety factor and again confirms the value of 1 µg Cd/g creatinine in urine established by EFSA (2009a) as the modified RP. JECFA (2010) uses a value of 5.24 µg Cd/g creatinine in urine as the RP.

In order to maintain the modified RP of 1 µg Cd/g creatinine in urine, it is calculated that the mean dietary cadmium intake must not exceed 0.36 µg Cd/kg b.w. and this daily intake is used to estimate the TWI of 2.5 µg Cd/kg b.w. per week (EFSA, 2009a).

Based on the present state of information, the CONTAM Panel concludes that the value of the TWI of 2.5 µg Cd/kg b.w. per week established in 2009 is appropriate and must be maintained in order to guarantee a high degree of protection for consumers, including subgroups of the population such as children, vegetarians or people living in highly contaminated areas. The CONTAM Panel reaffirms that with this exposure the adverse effects are unlikely, but that in any case, cadmium exposure in the population must be reduced (EFSA, 2011a).

The CONTAM Panel again reaffirmed the importance of selecting a safety factor for the final establishment of the HBGV. The established value of the BMDL5 of 4 µg Cd/g creatinine with a safety factor on the basis that the model was created using mean geometric measures and standard deviations and given the individual variations of the urinary cadmium and B2M values in the study groups used for the analysis of the BDM, results in a reference point of 1 µg Cd/g creatinine that must be maintained (EFSA, 2011a, 2011b).

Risk assessment: situation in Spain (2000-2007)

The AESAN lists data on the presence of cadmium in food at a national level, which are sent to EFSA. During 2000-2007, a total of 3,552 figures were collected in Spain (AESAN, 2008b).

The cadmium figures collected by the AESAN were crossed with the data for the diet of the Spanish population (AESAN, 2006). To do so, the contents obtained for each of the individual foods were considered and, in those cases in which there was no information about any specific food, figures were considered for similar foods.

The estimations of daily and weekly cadmium exposure are listed in Tables 5 and 6.

Table 5. Estimations of cadmium daily exposure

Estimated cadmium intake	Mean µg Cd/kg b.w./day (%ADI)	97.5 percentile µg Cd/kg p.c./día (%ADI)
Children (sample population of 900 children, 2000-2007)	0.4518 45.2%	0.8017 80.2%
Adults (sample population of 1,060 adults, 2000-2007)	0.2905 (29.1%)	0.5531 (55.3%)

Table 6. Estimations of cadmium weekly exposure

Dietary exposure	Exposure interval µg Cd/kg b.w./week	
	Adults	Children
Mean intake of diverse foods (oral)	2.03	3.15
High intake of diverse foods (oral)	3.85	5.6

Initially considering a value of the PTWI of 7 µg Cd/kg b.w./week, a PTWI that corresponds to the acceptable daily intake (ADI) of 1 µg Cd/kg b.w. or, the equivalent, 60 µg of cadmium per day for a person with a mean body weight of 60 kg, it was concluded that the cadmium intake for the Spanish population is within highly acceptable levels, as the mean value is significantly lower than the provisional tolerable weekly intake (PTWI) established by the JECFA (45% in children and 29% in adults), and the intake of extreme consumers (97.5 percentile) is also below this PTWI (80% in children and 55% in adults) (AESAN 2008b).

As the EFSA (2011a) has re-assessed the PTWI of 7 µg Cd/kg b.w./week, and established a new TWI of 2.5 µg Cd/kg b.w./week, the AESAN has requested the Scientific Committee to re-assess the risk of exposure for the Spanish population to cadmium resulting from the intake of food.

Risk assessment: situation in Spain (Re-assessment 2000-2010)

1. Cadmium concentration in food

To draw up this report, the data used was collected in Spain during the period 2000-2010. Both the origin of the samples and the type of food for which the cadmium content was analysed were varied, and included foods for which there is currently no legal maximum limit at European Union. This data came from control programmes implemented by the Spanish Autonomous Regions, including the National Plan for Residue Research (PNIR) in animal origin products, and therefore there is no homogeneity in the group distribution. The data collection system used was the not same in 2000-2007 as in 2008-2010, therefore all the data has been reviewed, harmonised and grouped together taking as a reference the classification of the European Food Safety Authority (EFSA) established in the Concise European Food Consumption Database (EFSA, 2008a) which considers 15 groups or categories of food (see Table 7). To include the results in each of those groups, the criteria given in the following document have been observed: "Guidance Document for the use of the Concise European Food Consumption Database in Exposure Assessment" (EFSA, 2008b). In grouping the food by categories, the existence of maximum established limits has also been observed in order to determine the degree of compliance with current legislation. The total number of results collected for the period 2000-2010 was 5,493 samples (N) from different food groups (Table 7), from 14 Autonomous Regions and other Government laboratories (Agrofood Laboratory, Foreign Health, National Food Centre, Spanish Institute of Oceanography) and the food industry (ANFACO).

Table 7. Distribution by food group

	Food group	N	%
1	Cereals and derived products	223	4.05
2	Sugar and sweets, including chocolate	189	3.44
3	Fats (vegetable and animal)	53	0.96
4	Vegetables, nuts, pulses	318	5.78
5	Potatoes or tubers	26	0.47
6	Fruit	154	2.80
7	Fruit juices, soft drinks and bottled water	127	2,31
8	Coffee, tea, cocoa	60	1.09
9	Alcoholic drinks	42	0.76
10	Meat and offal	1,240	22.57
11	Fish and shellfish	2,983	54.30
12	Eggs	5	0.09
13	Milk and dairy products	55	1.00
14	Miscellaneous	18	0.32
15	Tap water	–	–
	Total	**5,493**	**100**

The most represented food groups were fish and shellfish (54.3%), meat and offal (22.57%), vegetables, nuts and pulses (5.78%) and cereals and derived products (4.05%). The differences in the number of samples of the different food groups are linked to the fact that these are official control samples and logically these analyses are essentially directed at those food groups with maximum established legal limits.

34.8% of the results were provided by laboratories which are not accredited or which did not provide information on this point. Various analytical methods were used (in general suitable for the analysis of cadmium) and these are specified in each result, although the laboratory performing the test is not always listed, nor is the limit of detection (LOD) and/or the limit of quantification (LOQ) for the technique used mentioned in all cases.

Many food groups show a significant variation in the LOD of the method used. The LOD and recoveries for cadmium depend on the matrix and method used and inter-laboratory differences must also be assumed. The sensitivity of the method is usually established by the laboratory to meet the legal requirements in the official control, which may result in deficiencies when calculating human exposure. In fact, it can be observed that many results are expressed as <LOD (although the technique is able to provide quantitative results). In accordance with the criteria of the EFSA used in their assessments (EFSA, 2009d), when the laboratory refers an unacceptably high LOD, the results are not considered for the calculations. Similarly, the samples with very high results (≥ x10 times than any other result in a food category) have been rejected, and are considered as outliers (extreme values), as these results would significantly effect the estimated mean value.

The total number of samples with results <LOD was 2,156, equivalent to 39.2%. However, in 9 of the 15 food groups considered, the number of samples with results less than the LOD was greater

than 60%. When the quantified results are less than 40% (more than 60% of the samples <LOD), the GEMS/Food (Global Environment Monitoring System-Food Contamination Monitoring and Assessment Programme) (WHO, 2003) recommends the calculation of Lower Bounds (LB) and Upper Bounds (UB). This has therefore been the criterion used in this report. The estimation of the Lower Bound (LB) is obtained by allocating a zero value (minimum possible) to all the samples for which the result is less than the LOD or the LOQ. The estimation of the Upper Bound (UB) is obtained by allocating the value of the LOD to the results <LOD and the LOQ to those <LOQ depending on the information provided by the laboratory.

In those food groups in which different categories have been considered and subsequently the group as a whole has been used in the estimation of the daily intake, the Sampling Adjustment Factors (SAF) have been used, calculated from the German Nutrition Survey (Mensink and Beitz, 2004), with minor modifications used by the EFSA in recent assessments in order to adjust the information to the structure of the Concise European Food Consumption Database (EFSA, 2009a, 2009d). In those cases in which the SAF correction factor has been applied, the "adjusted means" have been calculated and then used in the estimation of daily intake. Tables 8a and 8b show an example of the use of the SAF to derive the adjusted mean of the sub-categories and categories of foods in a certain group (EFSA, 2009d). In spite of the convenience in using the SAF to adjust the contribution to the daily intake of each food group in the calculations, it must be remembered that the use of the SAF implies some degree of uncertainty as the % contribution to the diet of each food group may vary from one country to another. In this case, the SAF used are those the EFSA considered in their most recent assessments (EFSA, 2009a, 2009d, 2010).

Table 8a. Example of the use of sampling adjustment factors (SAF) to calculate the adjusted mean for sub-cate gories of food

	Food	N	SAF	Mean	Calculation	Adjusted mean
07.A1	Fruit juices	962	10%	0.0101	(0.10/0.15) x 0.0101	0.0067+
07.A2	Vegetable juices	123	1%	0.01	(0.01/0.15) x 0.01	0.0007+
07.A3	Other juices	37	4%	0.0207	(0.04/0.15) x 0.0207	0.0055=
07.A	Juices	1,122	15%	0.0104	–	0.0129

Table 8b. Example of the use of sampling adjustment factors (SAF) to calculate the adjusted mean for categories of food

	Food	N	SAF	Mean	Calculation	Adjusted mean
07.A	Juices	1,122	15%	0.0129[a]	0.15 x 0.0129	0.0019+
07.B	Soft drinks	349	15%	0.0132	0.15 x 0.0132	0.0020+
07.C	Bottled water	6,723	70%	0.0041	0.7 x 0.0041	0.0029=
07	Total juices, soft drinks and bottled water	8,194	100%	–	–	0.0068

[a]Adjusted mean derived from the calculation for the sub-category in Table 8a.

Tables 9 to 22 list the results (expressed in nine columns) for the different additional and detailed categories of food. The statistical descriptors include the median, mean and maximum concentration and the 5 (P5) and 95 (P95) percentiles. For each of these descriptors, estimations of the Lower Bound (LB) and Upper Bound (UB) are given. The column with the descriptor N represents the number of results given. The column with the descriptor <LOD is expressed with the percentage of results less than the LOD or the LOQ. The SAF used (indicated in the last column) has been applied when the food categories have been added. The column ML gives the number of samples (and the percentage of the same) that exceeds the maximum limit legally established at European Union (Regulation EC No 1881/2006, Regulation (EC) No 629/2008 (EU, 2008) and Regulation (EU) No 420/2011). For those food categories in which there is no legally established maximum limit, this is indicated with (–).

Cereals and derived products

The category "Cereals and derived products" (223 samples) has two sub-categories, of which one has been divided into five sub-classes (Table 9).

Table 9. Cadmium concentration (mg/kg) for the food category: "01. Cereals and derived products"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
Total 01.A. Mixed cereal based dishes	**12**	**1 (8.3%)**	**LB 0.0005 UB 0.0010**	**LB 0.0040 UB 0.0050**	**LB 0.0046 UB 0.0079**	**LB 0.0102 UB 0.0251**	**LB 0.0130 UB 0.0400**	**–**	**23%**
01.B1. Bran and wheat germ	-	-	-	-	-	-	-	–	-
01.B2. Products derived from wheat (bread, pasta)	13	3 (23%)	LB 0.0000 UB 0.0035	LB 0.0100 UB 0.0100	LB 0.0110 UB 0.0110	LB 0.0198 UB 0.0198	LB 0.0210 UB 0.0210	–	42%
01.B3. Wheat (grain, flour)	41	11 (26.8%)	LB 0.0000 UB 0.0050	LB 0.0350 UB 0.0350	LB 0.0411 UB 0.0469	LB 0.0810 UB 0.0810	LB 0.4000 UB 0.4000	1 (2.4%)	2%
01.B4. Rice	68	46 (67.6%)	LB 0.0000 UB 0.0020	LB 0.0000 UB 0.0195	LB 0.0103 UB 0.0291	LB 0.0409 UB 0.0500	LB 0.3060 UB 0.3060	2 (2.9%)	9%
01.B5. Cereals excluding bran, germ, wheat and rice	89	14 (15.7%)	LB 0.0000 UB 0.0020	LB 0.0110 UB 0.0170	LB 0.0227 UB 0.0252	LB 0.0884 UB 0.0884	LB 0.3000 UB 0.3000	1 (1.1%)	24%
Total 01.B. Cereals and derived products	**211**	**74 (35%)**	**LB 0.0000 UB 0.0020**	**LB 0.0080 UB 0.0210**	**LB 0.0220 UB 0.0300**	**LB 0.0725 UB 0.0725**	**LB 0.4000 UB 0.4000**	**4 (1.9%)**	**77%**
Total cereals (01.A + 01.B)	**223**	**75 (33.6%)**	**LB 0.0000 UB 0.0020**	**LB 0.0070 UB 0.0200**	**LB 0.0207 UB 0.0286**	**LB 0.0710 UB 0.0734**	**LB 0.4000 UB 0.4000**	**4 (1.8%)**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

From category 01.A. Mixed cereal-based dishes, little data has been collected (Table 9). There are no limits established for this category although the mean cadmium concentrations in the samples analysed are low in comparison to the rest of the foods included in the Table. In the category 01.B. foods, although the number of samples is not very high, the main classes of food are represented for those for which there are established legal limits. In this group, the percentage of samples <LOD is low (33.2%) and therefore the differences between the mean and the median are not significant. The greatest cadmium concentrations are observed in wheat (grain, flour). In any case, the degree of

non-compliance to current legislation is very low as only a small percentage of samples exceed the established limits (the maximum values detected are listed in the column "Max").

Sugar and sweets

The category "Sugar and sweets" includes two sub-categories, although the available data only corresponds to one of these and the 189 results are all for samples taken from honey (Table 10). From the original data, five results were rejected, being much higher than the mean of the quantified cadmium results and therefore considered as outliers (extreme values). All of these results were from the same laboratory which used a non-accredited test method and did not give the LOD/LOQ of the technique. No results are available for "Chocolate and derived products", products which usually have higher cadmium concentrations. The mean concentrations found in the category "Sugar and derived products" are similar to those found by the EFSA for this category (EFSA, 2009a); however this group includes many other foods, in addition to honey (EFSA, 2008b) for which there are no available results. Therefore these results should be considered with caution due to the low representativity of the samples analysed. Probably, the concentrations observed are lower than those really corresponding to this category of food.

If we only take the results given in Table 10, we can see how the majority of the samples give results <LOD (91%). In addition, for this category of food, there are no maximum limits established in European legislation.

Table 10. Cadmium concentration (mg/kg) for the food category: "02. Sugar and sweets"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
02.1. Chocolate and derived products	-	-	-	-	-	-	-	–	33%
02.2. Sugar and derived products (honey, etc.)	189	172 (91%)	LB 0.0000 UB 0.0050	LB 0.0000 UB 0.0050	LB 0.0011 UB 0.0058	LB 0.0130 UB 0.0130	LB 0.0190 UB 0.0300	–	67%
Total 02. Sugar and sweets (including chocolate)	**189**	**172 (91%)**	**LB 0.0000 UB 0.0050**	**LB 0.0000 UB 0.0050**	**LB 0.0011 UB 0.0058**	**LB 0.0130 UB 0.0130**	**LB 0.0190 UB 0.0300**	**–**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

Animal and vegetable fats

The category "Animal and vegetable fats" has been considered together (Table 11).

Table 11. Cadmium concentration (mg/kg) for the food category: "03. Animal and vegetable fats"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
Total 03. Fats	**53**	**38 (71.7%)**	**LB 0.0000 UB 0.0100**	**LB 0.0000 UB 0.0100**	**LB 0.0106 UB 0.0177**	**LB 0.0516 UB 0.0516**	**LB 0.1040 UB 0.1040**	**–**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

The results (Table 11) correspond exclusively to samples taken from oils (olive, sunflower and fish) and no results are available for other animal or vegetable fats.

A large part of the results are lower than the LOD (71.7%). European legislation has not established maximum limits for this group of foods.

Vegetables, nuts, pulses

The data available in this category of food has been subdivided into five sub-categories (Table 12), in accordance with the groups for which there are maximum limits established as defined in Regulation (EC) No 1881/2006 and later amendments.

Table 12. Cadmium concentration (mg/kg) for the food category: "04B. Vegetables, nuts, pulses"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
04.B1. Leaf vegetables	46	44 (95.6%)	LB 0.0000 UB 0.0050	LB 0.0000 UB 0.0300	LB 0.0022 UB 0.0360	LB 0.0000 UB 0.0500	LB 0.1000 UB 0.1000	0	21%
04.B2. Other vegetables	114	92 (80.7%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0100	LB 0.0030 UB 0.0220	LB 0.0087 UB 0.0500	LB 0.0100 UB 0.1700	2 (1.7%)	59%
04.B3. Pulses	50	37 (74%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0050	LB 0.0094 UB 0.0150	LB 0.0433 UB 0.0645	LB 0.2500 UB 0.2500	–	13%
04.B4. Nuts and oleaginous seeds	29	8 (27.6%)	LB 0.0000 UB 0.0030	LB 0.0110 UB 0.0110	LB 0.1120 UB 0.1130	LB 0.4760 UB 0.4760	LB 0.5370 UB 0.5370	–	5%
04.B5. Fungi	79	41 (51.9%)	LB 0.0000 UB 0.0019	LB 0.0000 UB 0.0300	LB 0.0900 UB 0.1081	LB 0.4740 UB 0.4740	LB 2.3400 UB 2.3400	2 (2.5%)	2%
Total 04.B. Vegetables, nuts, pulses	**318**	**222** (69.8%)	**LB 0.0000 UB 0.0014**	**LB 0.0000 UB 0.0300**	**LB 0.0371 UB 0.0520**	**LB 0.1708 UB 0.1706**	**LB 2.3400 UB 2.3400**	**4 (1.2%)**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

The number of results lower than the LOD varies considerably among the sub-categories considered, from 27.6% for nuts and oleaginous seeds to 95.6% for leaf vegetables. Globally the percentage of samples with results <LOD is high (69.4%). The highest concentrations of cadmium are found in nuts, although this food category does not have any established limits under European legislation. The remaining categories of food have lower cadmium concentrations and only a small percentage (1.7-2.5%) of these exceeds the maximum legal limits.

Potatoes or tubers

In this category, two sub-categories are considered, although the available data refers exclusively to potatoes. Only 26.9% of the samples gave a result <LOD, although the total number of samples is quite low (Table 13). Current legislation establishes a maximum limit for peeled potatoes. Twenty of the 26 samples analysed correspond to peeled potatoes and in no case is the maximum legal limit exceeded.

Table 13. Cadmium concentration (mg/kg) for the food category: "05. Potatoes or tubers"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
05.1. Potatoes	26	7 (26.9%)	LB 0.0000 UB 0.0030	LB 0.0050 UB 0.0070	LB 0.0053 UB 0.0136	LB 0.0130 UB 0.0450	LB 0.0140 UB 0.0500	0	96%
02.2. Other	-	-	-	-	-	-	-	–	4%
Total 05. Potatoes or tubers	**26**	**7 (26.9%)**	**LB 0.0000 UB 0.0030**	**LB 0.0050 UB 0.0070**	**LB 0.0053 UB 0.0136**	**LB 0.0130 UB 0.0450**	**LB 0.0140 UB 0.0500**	**0**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

Fruit

Fruit is considered in one single category. As can be seen, a very high percentage of samples have a result <LOD and all the samples analysed are below the maximum legal limit (Table 14).

Table 14. Cadmium concentration (mg/kg) for the food category: "06. Fruit"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
Total 06. Fruit	**154**	**132 (85.7%)**	**LB 0.0000 UB 0.0040**	**LB 0.0000 UB 0.0050**	**LB 0.0015 UB 0.0215**	**LB 0.0073 UB 0.0500**	**LB 0.1000 UB 0.0500**	**0**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

Juices, soft drinks and bottled water

This category has been subdivided into three sub-categories (Table 15). Almost all of the samples analysed gave results <LOD (92.9%) (Table 15).

Table 15. Cadmium concentration (mg/kg or mg/l) for the food category: "07.A. Juices, soft drinks and bottled water"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
07.A1. Fruit juices and vegetables	109	100 (91.7%)	LB 0.0000 UB 0.0004	LB 0.0000 UB 0.0030	LB 0.0023 UB 0.0054	LB 0.0198 UB 0.0254	LB 0.0600 UB 0.0600	–	15%
07.B2. Soft drinks	4	4 (100%)	LB 0.0000 UB 0.0030	LB 0.0000 UB 0.0030	LB 0.0000 UB 0.0030	LB 0.0000 UB 0.0030	LB 0.0000 UB 0.0030	–	15%
07.C3. Bottled water	14	14 (100%)	LB 0.0000 UB 0.0010	LB 0.0000 UB 0.0010	LB 0.0000 UB 0.0010	LB 0.0000 UB 0.0010	LB 0.0000 UB 0.010	–	70%
Total 07. Juices, soft drinks and bottled water	**127**	**118 (92.9%)**	**LB 0.0000 UB 0.0004**	**LB 0.0000 UB 0.0030**	**LB 0.0020 UB 0.0048**	**LB 0.0141 UB 0.0206**	**LB 0.0600 UB 0.0600**	**–**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

There are no maximum limits established at European Union for juices and soft drinks. With respect to bottled water Royal Decree 1798/2010 and Royal Decree 1799/2010 (Real Decreto 1798/2010, 1799/2010) establish for this water maximum cadmium concentrations of 3-5 µg Cd/l (0.003-0.005 mg/l) (See Table 2). Although the number of samples is low, the mean values shown in Table 15 do not exceed these limits. From the original data, six results have been rejected for being too high (500 times greater than the maximum limit established for this water in accordance with Royal Decree 1798/2010), most probably due to an error in the transcription of the laboratory results. In another four results, the LOD of the technique was 25 times higher than the mean values for the group, and therefore these results have also been considered unacceptable for use in statistical calculations.

Coffee, tea, cocoa

This category has been divided into three sub-categories, although no data is available for cocoa (Table 16). This may involve a default estimation of the cadmium content of the group as a whole, although this is probably not very significant if we consider the cocoa intake with respect to the other foods in the group.

Table 16. Cadmium concentration for the food category: "08. Coffee, tea, cocoa"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
08.1. Cocoa	-	-	-	-	-	-	-	–	14%
07.2. Coffee	40	40 (100%)	LB 0.0000 UB 0.0050	LB 0.0000 UB 0.0050	LB 0.0000 UB 0.0050	LB 0.0000 UB 0.0050	LB 0.0000 UB 0.0050	–	60%
08.3. Tea and other infusions	20	0 (0%)	LB 0.0000 UB 0.0000	LB 0.0004 UB 0.0004	LB 0.0005 UB 0.0005	LB 0.0011 UB 0.0011	LB 0.0027 UB 0.0027	–	26%
Total 08. Coffee, tea and cocoa	**60**	**40 (66.6%)**	**LB 0.0000 UB 0.0001**	**LB 0.0000 UB 0.0050**	**LB 0.0000 UB 0.0035**	**LB 0.0007 UB 0.0050**	**LB 0.0030 UB 0.0050**	**–**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

In the original data, the samples of tea and other infusions produced very high values. In the samples of coffee, "extract at 10%" was specified, whereas in all the other products nothing was given, which indicates that the product was in powdered form. Therefore, the original values have been corrected, considering the corresponding dilutions normally used to make tea, chamomile, pennyroyal and lime infusions.

There are no maximum legal limits for the cadmium content established for this group. All the coffee samples have results <LOD and as a whole for this category, the percentage of samples <LOD is 66.6% (Table 16).

Alcoholic drinks

Three sub-categories have been considered, although the number of samples in two of these is clearly deficient, resulting in a high level of uncertainty. Almost all of the samples gave results <LOD (97.6%) (Table 17). European legislation has not established maximum limits for alcoholic drinks.

Table 17. Cadmium concentration (mg/l) for the food category: "09. Alcoholic drinks"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
09.A. Beer	4	4 (100%)	LB 0.0000 UB 0.0100	LB 0.0000 UB 0.0100	LB 0.0000 UB 0.0100	LB 0.0000 UB 0.0100	LB 0.0000 UB 0.0100	–	79%
09.B. Wine	37	36 (97.3%)	LB 0.0000 UB 0.0050	LB 0.0000 UB 0.0050	LB 0.0018 UB 0.0051	LB 0.0000 UB 0.0050	LB 0.0070 UB 0.0070	–	20%
09.C. Liqueurs	1	1 (100%)	LB - UB -	LB 0.0000 UB 0.0070	LB 0.0000 UB 0.0070	LB - UB -	LB 0.0000 UB 0.0070	–	1%
Total 09. Alcoholic drinks	**42**	**41 (97.6%)**	**LB 0.0000 UB 0.0050**	**LB 0.0000 UB 0.0050**	**LB 0.0016 UB 0.0056**	**LB 0.0000 UB 0.0100**	**LB 0.0070 UB 0.0100**	**–**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

Meat and offal

The category "Meat and offal" has been divided into two sub-categories, each of which has been subdivided into seven and four sub-classes respectively, with a total of 1,240 results (Table 18).

To establish the sub-classes the existence of the maximum limits established at European Union has been considered together with the criteria normally followed by EFSA in their most recent assessments (EFSA 2009a, 2009d, 2010).

Table 18. Cadmium concentration (mg/kg) for the food category: "10. Meat and offal"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
10.A1. Mixed meat-based dishes	60	54 (90%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0050	LB 0.0026 UB 0.0065	LB 0.0100 UB 0.0100	LB 0.1000 UB 0.1000	0	2%
10.A2. Bovine, sheep and goat meat	10	10 (100%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0500	LB 0.0000 UB 0.0328	LB 0.0000 UB 0.0500	LB 0.0000 UB 0.0500	0	20%
10.A3. Pork	20	20 (100%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0050	LB 0.0000 UB 0.0119	LB 0.0000 UB 0.0500	LB 0.0000 UB 0.0500	0	42%
10.A4. Rabbit and chicken meat	20	20 (100%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0165	LB 0.0000 UB 0.0500	LB 0.0000 UB 0.0500	0	12.3%
10.A5. Horse meat	28	2 (7.1%)	LB 0.0007 UB 0.0023	LB 0.0060 UB 0.0060	LB 0.0489 UB 0.0491	LB 0.1932 UB 0.1932	LB 0.4300 UB 0.4300	1 (3.6%)	0.1%
10.A6. Game	32	29 (90.6%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	LB 0.0009 UB 0.0031	LB 0.0100 UB 0.0100	LB 0.0100 UB 0.0100	0	0.2%
10.A7. Meat products	41	39 (95.1%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0050	LB 0.0021 UB 0.0057	LB 0.0100 UB 0.0100	LB 0.0600 UB 0.0600	0	16%
Total 10.A. Meat and derived products	**211**	**174 (82.4%)**	**LB 0.0000** **UB 0.0014**	**LB 0.0000** **UB 0.0050**	**LB 0.0070** **UB 0.0141**	**LB 0.0270** **UB 0.0500**	**LB 0.0430** **UB 0.4300**	**1 (0.47%)**	**92.6%**
10.B1. Horse liver	58	0	LB 0.0451 UB 0.0451	LB 0.5060 UB 0.5060	LB 0.6584 UB 0.6584	LB 1.5267 UB 1.5267	LB 5.2750 UB 5.2750	29 (50%)	0.1%

Table 18. Cadmium concentration (mg/kg) for the food category: "10. Meat and offal"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
10.B2. Liver			LB	LB	LB	LB	LB		
(other)	801	83	0.0000	0.0270	0.0875	0.1451	15.0000	10	5%
		(10.4%)	UB	UB	UB	UB	UB	(1.2%)	
			0.0050	0.0330	0.0937	0.1451	15.0000		
10.B3. Kidneys			LB	LB	LB	LB	LB		
	149	3	0.1040	0.5100	0.8535	3.2760	8.2800	26	0.2%
		(2%)	UB	UB	UB	UB	UB	(17.4%)	
			0.1040	0.5100	0.8535	3.2760	8.2800		
10.B4. Other			LB	LB	LB	LB	LB		
	21	21	0.0000	0.0000	0.0000	0.0000	0.0000	–	2.1%
		(100%)	UB	UB	UB	UB	UB		
			0.0014	0.0050	0.0097	0.0500	0.0500		
Total 10.B.			**LB**	**LB**	**LB**	**LB**	**LB**		
Offal and	**1,029**	**107**	**0.0000**	**0.0375**	**0.2289**	**0.9182**	**15.0000**	**65**	**7.4%**
derived		**(10.4%)**	**UB**	**UB**	**UB**	**UB**	**UB**	**(6.3%)**	
products			**0.0050**	**0.0500**	**0.2341**	**0.9182**	**15.0000**		
Total 10.			**LB**	**LB**	**LB**	**LB**	**LB**		
Meat	**1,240**	**281**	**0.0000**	**0.0260**	**0.1913**	**0.8220**	**15.0000**	**66**	**100%**
and offal		**(22.6%)**	**UB**	**UB**	**UB**	**UB**	**UB**	**(5.3%)**	
			0.0014	**0.0340**	**0.1966**	**0.8220**	**15.0000**		

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

In this category we observe a wide interval of results <LOD in the different sub-classes considered. In "meat and derived products" the majority of the results (≥90%) are <LOD, with the exception of horse meat in which only 7.1% of the values were <LOD. On the other hand, in "Offal and derived products" the percentage of results <LOD is only 10.4%. Considering the category "meat and offal" as a whole, the samples less than LOD amount to 22.6% (Table 18).

The greatest cadmium concentrations, as is to be expected, are found in offal, in particular in horse liver and kidneys. Maximum limits are established for all the sub-classes considered in this group of food. In "meat and derived products" only 0.47% of the samples analysed (corresponding to a sample of horse meat) exceed the maximum established limits. On the contrary, the degree of non-compliance is greater in "offal and derived products" where 6.3% of the samples exceed the legally established limits. Horse liver is notable with 50% of the samples exceeding the maximum legal limit of 0.5 mg/kg with a mean concentration of 0.6584 mg/kg (>ML) and a maximum value of 5.27 mg/kg. Of the remaining liver samples (cow, sheep, pig and poultry) only 1.2% exceed the legal limit. The kidneys also have a high degree of non-compliance with current legislation, with 17.4% of the samples above the ML.

Fish and shellfish

In this category, two sub-categories have been considered, "shellfish and shellfish-based products" and "fish and fish-based products" and in turn, four and five sub-classes, respectively, have been identified in each of these (Table 19). The criteria for grouping the different foods included are the same as those used in the previous category, the existence of maximum established limits and other criteria used by the EFSA (EFSA, 2009a, 2009d, 2010). In this category, only 32.6% of the 2,983 samples analysed produced results <LOD with similar percentages in the two sub-categories considered. 7.7% of "fish and fishery products" samples exceed ML, although the mean concentration of the different sub-categories were always lower than ML established (Table 19).

Table 19. Cadmium concentration (mg/kg) for the food category: "11. Fish and shellfish"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
11.A1. Molluscs (bivalves and other)	413	63 (15.2%)	LB 0.0000 UB 0.0100	LB 0.1300 UB 0.1300	LB 0.2596 UB 0.2660	LB 1.0280 UB 1.0280	LB 3.5000 UB 3.5000	21 (5.1%)	0.2%
11.A2. Crustaceans	266	95 (35.7%)	LB 0.0000 UB 0.0050	LB 0.0540 UB 0.0680	LB 0.3202 UB 0.3353	LB 1.0000 UB 1.0000	LB 20.6000 UB 20.6000	39 (14.7%)	0.1%
11.A3. Cephalopods	345	149 (43.2%)	LB 0.0000 UB 0.100	LB 0.0500 UB 0.1000	LB 0.1562 UB 0.1815	LB 0.6720 UB 0.6720	LB 2.2900 UB 2.2900	6 (1.7%)	3%
11.A4. Other	-	-	-	-	-	-	-	–	0.1%
Total 11.A. Shellfish and shellfish-based products	**1,024**	**307 (30%)**	**LB 0.0000 UB 0.0091**	**LB 0.0845 UB 0.1000**	**LB 0.2405 UB 0.2555**	**LB 0.9100 UB 0.9100**	**LB 20.6000 UB 20.6000**	**66 (6,4%)**	**3.4%**
11.B1. Fish meat excluding the species listed in the following points	829	361 (43.5%)	LB 0.0000 UB 0.0050	LB 0.0070 UB 0.0100	LB 0.0445 UB 0.0538	LB 0.2200 UB 0.2200	LB 4.0900 UB 4.0900	117 (14.1%)	43%
11.B2. Fish meat included in group 3.2.6*	643	242 (37.6%)	LB 0.0000 UB 0.0050	LB 0.0080 UB 0.0255	LB 0.0346 UB 0.0465	LB 0.1030 UB 0.1030	LB 5.5000 UB 5.5000	33 (5.1%)	52%

Table 19. Concentración de Cd (mg/kg) para la categoría de alimentos: "11. Pescados y mariscos"									
Categoría de alimentos	**N**	**<LOD**	**P5**	**Mediana**	**Media**	**P95**	**Max**	**>ML (%)**	**SAF**
11.B3. Fish meat included in group 3.2.7*	120	1 (0.8%)	LB 0.0460 UB 0.0460	LB 0.0835 UB 0.0835	LB 0.0878 UB 0.0880	LB 0.1450 UB 0.1450	LB 0.2500 UB 0.2500	1 (0.8%)	0.3%
11.B4. Fish meat included in group 3.2.8*	367	62 (16.9%)	LB 0.0000 UB 0.0100	LB 0.0530 UB 0.0600	LB 0.1319 UB 0.1389	LB 0.5679 UB 0.5679	LB 0.9520 UB 0.9520	0	0.3%
11.B5. Prepared fish based dishes	-	-	-	-	-	-	-	–	1%
Total 11.B. Fish and fish-based products	**1,959**	**666 (34%)**	**LB 0.0000 UB 0.0050**	**LB 0.0100 UB 0.0300**	**LB 0.0604 UB 0.0695**	**LB 0.2800 UB 0.2800**	**LB 5.5000 UB 5.5000**	**151 (7.7%)**	**96.6%**
Total 11. Fish and shellfish	**2,983**	**973 (32.6%)**	**LB 0.0000 UB 0.0050**	**LB 0.0180 UB 0.0500**	**LB 0.1222 UB 0.1334**	**LB 0.5322 UB 0.5322**	**LB 20.6000 UB 20.6000**	**217 (7.3%)**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake. *As defined in Table 1.

The highest cadmium concentrations are found in "shellfish and shellfish-based products", as expected. Nevertheless, the degree of non-compliance with the current legislation was less than that of "fish". Only 6.4% of the samples exceeded the ML and the mean concentrations of the three sub-classes (molluscs, crustaceans and cephalopods) were all lower than the ML (Table 19).

Eggs

The category "Eggs" is presented in Table 20. Only five results were provided for this category, therefore the sampling was obviously inadequate. Of the samples analysed, 80% were <LOD (Table 20). No maximum limits are established for this category in European legislation.

Table 20. Cadmium concentration (mg/kg) for the food category: "12. Eggs"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
Total 12. Eggs	**5**	**4 (80%)**	**LB 0.0000 UB 0.0020**	**LB 0.0000 UB 0.0020**	**LB 0.0015 UB 0.0031**	**LB 0.0060 UB 0.0064**	**LB 0.0075 UB 0.0075**	**–**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

Milk and dairy products

In this category of food, three food groups have been identified: milk, cheeses and other dairy products, although acceptable data are only available for milk, as in the other cases the samples are not very representative. The majority of the samples (90.1%) gave results <LOD. There are no maximum limits established at European Union (Table 21).

Table 21. Cadmium concentration (mg/kg or mg/l) for the food category: "13. Milk and derivatives"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
13.A. Milk	50	45 (90%)	LB 0.0000 UB 0.0004	LB 0.0000 UB 0.0030	LB 0.0007 UB 0.0058	LB 0.0068 UB 0.0300	LB 0.0100 UB 0.0400	–	57%
13.B. Dairy products	1	1 (100%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	–	30%
13.C. Cheese	4	4 (100%)	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	LB 0.0000 UB 0.0014	–	13%
Total 13. Milk and dairy products	**55**	**50 (90.9%)**	**LB 0.0000 UB 0.0004**	**LB 0.0000 UB 0.0030**	**LB 0.0006 UB 0.0054**	**LB 0.0051 UB 0.0300**	**LB 0.0100 UB 0.0400**	**–**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

Miscellaneous

The category "Miscellaneous" includes 16 categories of food (AESAN, 2011). Data is only available for vinegar and paprika, representing within the group a minimum intake (5.2% for vinegar and 2.7% for "spices"). In addition, only 18 samples were tested, therefore the representativity of this group is dubious and will not be considered in estimating the daily cadmium intake (Table 22). To estimate the cadmium contribution to the daily intake of this group, we have considered the mean European value found by the EFSA (2009a).

Table 22. Cadmium concentration (mg/kg or mg/l) for the food category: "14. Miscellaneous"

Category of food	N	<LOD	P5	Median	Mean	P95	Max	>ML (%)	SAF
14.A. Miscellaneous	18	7 (38.8%)	LB 0.0000 UB 0.0090	LB 0.0175 UB 0.0180	LB 0.1145 UB 0.1180	LB 0.3270 UB 0.3270	LB 0.4760 UB 0.4760	–	20%
14.B. Dietary products	-	-	-	-	-	-	-	–	80%
Total 14. Miscellaneous and dietary products	**18**	**7 (38.8%)**	**LB 0.0000 UB 0.0090**	**LB 0.0175 UB 0.0180**	**LB 0.1145 UB 0.1180**	**LB 0.3270 UB 0.3270**	**LB 0.4760 UB 0.4760**	**–**	**100%**

LOD: Limit of detection. LB (Lower bound): Estimation of lower bound (<LOD/LOQ=0). UB (Upper bound): Estimation of upper bound (<LOD/LOQ=LOD/LOQ). ML: Maximum established limit (Regulation (EC) 1881/2006, (EC) 629/2008 and (EU) 420/2011). –: There is no maximum established limit. SAF (Sampling Adjustment Factor): Adjustment factor by intake.

Tap water

No data is available for this food group considered in the Concise European Food Consumption Database.

2. Summary of the cadmium concentrations (observed and adjusted means) in the different food groups

For this report, the mean concentrations have been used, adjusted as necessary using the SAF, according to their contribution to diet, as mentioned above and specified for each class/category of foods in Tables 9-22. In accordance with the criteria of the EFSA (2009a), the decision to use the mean concentrations is based on the chronic toxicity of cadmium due to its capacity to accumulating in the body and assuming that lifetime consumption may involve changes in the cadmium concentrations in the foods consumed. Table 23 summarises the mean cadmium contents, adjusted by applying an adjustment factor in comparison with the observed mean concentrations for each of the food groups considered for the assessment (data collected in the period 2000-2010).

Table 23. Observed and adjusted mean cadmium content in foods at national level (Data AESAN 2000-2010)

Food group		%<LOD	Observed mean (mg/kg)		Adjusted mean (mg/kg)	
			LB	UB	LB	UB
1	Cereals and derived products	**33.6%**	0.0207	0.0286	**0.0126**	**0.0158**
2	Sugar and sweets, including chocolate	**91%**	0.0011	0.0058	**0.0007**	**0.0038**
3	Fats (vegetable and animal)	**71.7%**	0.0106	0.0177	**0.0106**	**0.0177**
4	Vegetables, nuts, pulses	**69.8%**	0.0371	0.0520	**0.0107**	**0.0300**
5	Potatoes or tubers	**26.9%**	0.0053	0.0136	**0.0053**	**0.0136**
6	Fruit	**85.7%**	0.0015	0.0215	**0.0015**	**0.0215**
7	Juices, soft drinks and bottled water	**92.9%**	0.0020	0.0048	**0.0003**	**0.0019**
8	Coffee, tea, cocoa	**66.6%**	0.0000	0.0035	**0.0001**	**0.0031**
9	Alcoholic drinks	**97.6%**	0,0016	0.0056	**0.0003**	**0.0089**
10	Meat and offal	**22.6%**	0.1913	0.1966	**0.0093**	**0.0212**
11	Fish and shellfish	**32.6%**	0.1222	0.1334	**0.0431**	**0.0541**
12	Eggs	**80%**	0.0015	0.0031	**0.0015**	**0.0031**
13	Milk and dairy products	**90.9%**	0.0006	0.0054	**0.0004**	**0.0039**
14	Miscellaneous	–	–	–	–	–
15	Tap water	–	–	–	–	–

Food intake

Daily exposure to cadmium through foods is established not only by the cadmium content in the food but also, and quite significantly, by eating patterns. Some foods with high cadmium contents have very low consumption rates in the general population and therefore have very little effect on the total intake of the element. On the other hand, other food groups with low cadmium content may be more significant due to the high levels of consumption or due to the fact that they are consumed by specific groups of the population.

The consumption of foods together with the concentration of the contaminant are the two basic pillars on which the exposure assessment is based. Therefore, it is of the most importance to have adequate available data concerning the consumption of food by the population under study, as there may be significant differences among the countries or even among the regions within the same country, due to differences in eating patterns.

When trying to assess the exposure of the population of a country to a certain contaminant through food, the necessary information, covering the general population and children, vegetarians or other sub-populations of interest, is often not available. Therefore the EFSA has established the EFSA Concise European Food Consumption Database (EFSA, 2008a) for use as a base in the assessments of exposure at European Union. Initially it included information from 16 countries, not including Spain. To obtain comparable results, the data was divided into 15 wide food groups (Table 7). The data are listed by age group and body weight and different statistical parameters are indicated in the database for the general population and for "consumers only". As recognised by the EFSA itself, this Database has certain limitations due to the size of the food groups considered and the different methodologies used by the member countries for obtaining the consumption data. The EFSA considers that this Database is suitable for estimating exposure from the concentrations of the contaminant found, taking a conservative approach, when the exposure is lower than the established levels of risk. If this is not the case, it considers that finer adjustments are necessary, using more appropriate SAF, specific intakes for the corresponding country, food sub-categories, etc. (EFSA, 2008b).

In the latest assessments, the EFSA has considered, for the intakes of each of the 15 food groups, the median of the mean values of the 16 countries which provided information to the database, which logically offers a good reference for comparison of specific assessments in a particular country.

Recently (EFSA, 2011c) the EFSA published the new "Comprehensive European Food Consumption Database" which aims to resolve some of the deficiencies in the previous database. The new database now includes data from Spain and the number of food groups has been increased to 20. In addition, data have been included from various subgroups within each of the 20 main groups. Other important change is that the new database includes intakes for children of different ages, undoubtedly a significant advance with respect to the information available to date.

As mentioned earlier in this report, we have used the food classification of 15 groups of the Concise European Food Consumption Database, for two reasons. Firstly because AESAN prepared an internal report (AESAN, 2008b) on the cadmium content in food using this classification and secondly because the latest assessment of the EFSA on cadmium (EFSA, 2009a) also followed the same criteria. In this way we can compare the results obtained in this assessment with those obtained previously by the EFSA at European level and by AESAN in Spain. Therefore, when intake data has been used from the Comprehensive Database, it has been adjusted to the 15 groups of the Concise Database.

In addition, AESAN approved (AESAN, 2006) a document on the "Model of Spanish diet for the determination of consumer exposure to chemical substances" based on an earlier study carried out by the Nuclear Safety Council (CSN, 2002) which gives a detailed list of the consumption patterns of the Spanish population, including adults and children aged 7-12 and data on the general population and "consumers only". Nevertheless, although the different foods are well represented, certain important information is missing. For example, "tap water" and although in the case of "general population" information on the intake of food groups and what each group is made up of is provided, in the section "consumers only" the information is not provided for the whole food group (it is only given for each specific food). Therefore it is impossible to use these data in the general assessment of the group if we consider "consumers only", which is the information that the EFSA uses in this type of assessment.

Recently the AESAN published a new nutritional survey for the Spanish adult population which is, undoubtedly, the most complete survey ever carried out in Spain (AESAN, 2011). However it does not include data on the child population or other sub-populations which could be of interest (vegetarians, pregnant women, etc.). This has forced us to also consider the data in the "Comprehensive Database" when necessary as mentioned above.

Tables 24 and 25 give a summary of consumption for the Spanish population according to various sources (Regulating Agencies) and which have been used in this report. As it can be seen in Table

24, there are no major differences between the different sources consulted for adult consumption considering both general population and "consumers only".

In this report we use the adult intakes from the most recent Spanish survey (AESAN, 2011), as we consider that it is the survey that best defines the current situation in Spain, and in view of the fact that the differences of the total population with respect to "consumers only" are not very significant. For the case of "extreme consumers" we use the 95 intake percentile (P95) collected in the same study. The mean adult weight has been taken from the Spanish dietary model (AESAN, 2006).

Children are always difficult to assess as the intakes vary considerably depending on the age interval considered. Although Table 25 gives the data currently listed for children in Spain in the "Comprehensive Database", and apparently much of the data found there have been taken from the study carried out by the Nuclear Safety Council (CSN, 2002), significant differences can be observed when compared to the AESAN (2006) data, which in principle come from the same source. This may be due to the grouping of data by age group used in this data base. Therefore in this study we use the data for children aged 7-12 (the whole population) listed in the "Spanish dietary model" (AESAN, 2006), where we have precise information on the mean weight of the population studied.

Table 24. Mean food intake (g/day) for adults according to different sources (Regulating Agencies)

	Food group	ENIDE (AESAN, 2011) Total population	ENIDE (AESAN, 2011) Consumers only	EFSA (2009a) Consumers only	European Comprehensive Database (España) Consumers only	(AESAN, 2006) Total population (68.48/ kg b.w.)
		g/day	g/day	g/day	g/day	g/day
1	Cereals and derived products	194.6	195.05	257	251.9	188.64
2	Sugar and sweets, including chocolate	14.97	18.94	43	19.4	18.23
3	Fats (vegetable and animal)	34.93	34.99	38	37.5	37.41
4	Vegetables, nuts, pulses	184.93	203	194	267.25	217.58
5	Potatoes or tubers	83.72	109.46	129	80	61.84
6	Fruit	213.01	240.78	153	198.4	213.88
7	Juices, soft drinks and bottled water	575.98	1,465.28	438.5	677.45	575.98
8	Coffee, tea, cocoa	95.06	111.32	601	102.4	95.06
9	Alcoholic drinks	146.64	242.92	413	188.8	69.22
10	Meat and offal	163.84	165.88	150.5	185.05	189.14
11	Fish and shellfish	89.19	99.88	62	87.7	96.07
12	Eggs	31.40	39.42	25	32.5	31.21
13	Milk and dairy products	304.88	309.95	287	411	350.52
14	Miscellaneous	43.43	82.04	14	191.8	43.43
15	Tap water	625.16	839.52	349	575.3	625.16

Table 25. Mean food intake (g/day) for children according to different sources (Regulating Agencies)								
Concise European Food Consumption Database		**Children 1-3 years old[a]**		**Other children 3-9 years old[a]**		**Adolescents 10-17 years old[a]**		**(AESAN, 2006) 7-12 years old 34.48 kg**
	Food group	**All**	**Consumers only**	**All**	**Consumers only**	**All**	**Consumers only**	**All**
1	Cereals and derived products	95	147.3	192.6	253.6	257.7	360.13	185.36
2	Sugar and sweets, including chocolate	8.8	21.4	15.75	21.9	18.56	25.3	16.29
3	Fats (vegetable and animal)	9.9	10.5	18.55	19.5	28	28.3	30.31
4	Vegetables, nuts, pulses	88	118	104.6	147.7	148.4	264.76	118.45
5	Potatoes or tubers	43.1	56.32	57.5	78.5	71.23	91.36	61.61
6	Fruit	79.4	112.5	100.35	130.2	121.56	155.26	143.36
7	Juices, soft drinks and bottled water	211.8	641.3	258.2	731.8	269.39	845,5	269.39[b]
8	Coffee, tea, cocoa	0	0	2.5	151.2	8.85	211.86	9.69
9	Alcoholic drinks	0	0	0.1	13.8	11.63	83.9	0.33
10	Meat and offal	79.5	106.3	131.3	180.4	186.3	299.86	179.55
11	Fish and shellfish	26.3	74.5	32.05	75.5	44.53	119.33	64.71
12	Eggs	24.6	34.8	24.7	49.6	30.3	52.2	24.34
13	Milk and dairy products	542.1	583.4	497.5	549.9	434.7	493	428.38
14	Miscellaneous	80.9	155.2	25.5	89.6	24.39	70.6	24.39[b]
15	Tap water	218.2	463.8	380.5	461.7	544.4	619.8	544.4[b]

[a]The EFSA Comprehensive European Food Consumption Database (EFSA, 2011c). [b]As we do not ourselves have any data we have assumed the EFSA values for adolescents.

Human exposure to cadmium

Estimation of the daily dietary intake of Cadmium is based on the observed concentrations of cadmium in foods (Table 23) using the observed and adjusted mean concentrations to obtain the lower and upper bounds in each food category. Similarly, it is based on the food intake data for adults and children listed in the AESAN studies (2006, 2011), as shown in Tables 24 and 25. Although diet is known to be the principal source contributing to the daily cadmium intake, the contribution of smoke from cigarettes and other sources should not be neglected.

1. Contribution of the different groups of food to the cadmium intake

The general presence of cadmium in all foods means that a particular group may contribute significantly to the daily intake either because it has high concentrations of cadmium or because it is consumed in large quantities even though it has low cadmium concentrations.

Table 26 shows the contribution to the daily intake of the different groups of food considered in adults (the whole population). The mean intakes (expressed in g/day) multiplied by the mean concentrations of cadmium (expressed in mg/kg) give the intake results expressed in µg Cd/day.

The food groups that most contribute to the daily intake of cadmium are "fish and shellfish" (17.3-33.9%), "meat and offal" (12.4-13.4%), "cereals and derived products" (11-21.6%) and "vegetables, nuts and pulses" (17.4-19.9%). The percentage of contribution varies according to whether the lower bound (LB) or the upper bound (UB) is considered. Nevertheless if we consider the percentage of samples below the LOD in these groups, the most reliable results correspond to the first three, as in the "vegetable, pulses and nuts" group, almost 70% of the samples are less than the LOD. According to this criterion, the first would be "fish and shellfish" and the second "cereals and derived products". These two groups are used to estimate "extreme consumers". The results reveal a somewhat different situation in Spain with respect to the European mean (EFSA, 2009a) where the groups that contribute most are "cereals and derived products" and "vegetables, pulses and nuts".

Table 26. Estimation of exposure to cadmium (adults) by different groups of food

		% <LOD	Intake (AESAN, 2011) The whole population	Intake (AESAN, 2011) Consumers only	Cd concentration Adjusted mean (mg/kg)		Daily Intake (µg Cd/day) The whole population		Daily Intake (µg Cd/day) Consumers only	
			g/día	g/día	LB	UB	LB	UB	LB	UB
1	Cereals and derived products	33.2%	194.6	195.05	0.0126	0.0158	2.4520	3.0747	2.4576	3.0818
2	Sugar and sweets, including chocolate	91%	14.97	18.94	0.0007	0.0038	0.0105	0.0569	0.0133	0.0720
3	Fats (vegetable and animal)	71.7%	34.93	34.99	0.0106	0.0177	0.3703	0.6183	0.3709	0.6193
4	Vegetables, nuts, pulses	69.4%	184.93	203	0.0107	0.0300	1.9788	5.5479	2,1721	6.0900
5	Potatoes or tubers	26.9%	83.72	109.46	0.0053	0.0136	0.4437	1.1386	0.5801	1.4887
6	Fruit	85.7%	213.01	240.78	0.0015	0.0215	0.3195	4.5797	0.3612	5.1768
7	Juices, soft drinks and bottled water	92.9%	575.98	1,465.28	0.0003	0.0019	0.1728	1.0944	0.4396	2,7840
8	Coffee, tea, cocoa	66.6%	95.06	111.32	0.0001	0.0031	0.0095	0.2947	0.0111	0.3451
9	Alcoholic drinks	97.6%	146.64	242.92	0.0003	0.0089	0.0440	1.3051	0.0729	2.1620
10	Meat and offal	22.6%	163.84	165.88	0.0093	0.0212	1.5237	3.4734	1.5427	3.5167
11	Fish and shellfish	32.6%	89.19	99.88	0.0431	0.0541	3.8441	4.8252	4.3048	5.4035
12	Eggs	80%	31,4	39.42	0.0015	0.0031	0.0471	0.0973	0.0591	0.1222
13	Milk and dairy products	90.1%	304.88	309.95	0.0004	0.0039	0.1220	1.1890	0.1240	1.2088
14	Miscellaneous[a]	38.8%	43.43	82.04	-	-	0.0000[a]	0.3400[a]	0.0000[a]	0.3400[a]
15	Tap water[b]	-	625.16	839.52	-	0.0004[b]	0.0000	0.2501	0.0000	0.3358
Total µg Cd/day							**11.3378**	**27.8852**	**12.5094**	**32.7466**
Total µg Cd/kg b.w./day (68.48 kg body weight of the adult male)							**0.165**	**0.407**	**0.183**	**0.478**
Total µg Cd/kg b.w./week (% TWI)							**1.155 (46.2%)**	**2.849 (114%)**	**1.281 (51.2%)**	**3.346 (134%)**
Tolerable Weekly Intake (TWI)							**2.5 µg Cd/kg b.w./week**			

LB: Estimation of lower bound; UB: Estimation of upper bound. [a]As no reliable values are available for this group, the daily intake is considered to be 0-0.34 µg Cd/day (EFSA, 2009a). [b]There are no results for tap water, therefore the cadmium concentration established by the EFSA (2009a) is used.

2. Cadmium intake (mean consumer and extreme consumer)

As can be seen in Table 26, the mean exposure for adults (the whole Spanish population) is 1.155-2.849 µg Cd/kg b.w. per week assuming a mean body weight for a male of 68.48 kg (AESAN, 2006) and if we consider the population "consumers only" the weekly exposure to cadmium is in the interval 1.281-3.346 µg Cd/kg b.w. per week. The differences between the total population and consumers only are not significant as the greatest cadmium contribution comes from food groups in which the percentage of consumers only is very high.

The exposure of "extreme consumers" has been estimated in accordance with the guidelines of the EFSA (2008b), by calculating the sum of the 95 percentile of "consumers only" for the two food groups that most contribute to cadmium intake and the mean exposure (total population) for the other food categories. In this case, the resultant mean exposure is 2.06-3.95 µg Cd/kg b.w. per week.

Table 27 gives a comparison of the estimated mean intake in this assessment and in the different studies published previously. The results obtained for Spain in this report are similar to those obtained by the EFSA in its assessment for 2009 (EFSA, 2009a). The differences from other studies can be attributed to greater desegregation in the food groups with more representative samples that may result in lower estimations for cadmium intake through food. In addition, the differences in the results of Table 27 may be related to the different methodology used to obtain the intake data.

With respect to the assessment carried out in 2008 by AESAN (internal report) the results are similar. With the data for the period 2000-2007 the daily intake of cadmium was 0.29 µg Cd/kg b.w./day for adults compared to the 0.165-0.407 µg Cd/kg b.w./day estimated in this report.

Table 27. Comparison of the weekly cadmium intake (adults) in different studies

Study	Mean weekly intake µg Cd/kg b.w./week
Mean exposure, consumers only(Present assessment) (Present assessment)	1.3-3.5
Extreme consumer (Present assessment)	2.1-3.9
Mean exposure (EFSA, 2009a) (Cd*)	1.9-3.0
Extreme consumer (EFSA, 2009a) (Cd)*	2.5-3.9
(FAO/WHO, 2006)	2.8-4.2
(EC, 2004)*	0.7-2.9
Sweden, 2008 (females)*	1.6
Italy, 2001, 2002 *	1.9
Germany, 2002 *	1.2
Catalonia, 2003 (Spain) *	1.5
The United Kingdom 2006 *	1.3-1.5
Canary Islands, 2006 (Spain)*	1.1
USA, 2003 *	1.5

*Taken from the EFSA (2009a).

3. Specific sub-groups of the population: children

As mentioned above, the estimation of children's intake was based on the AESAN intake data (2006), as this was the most complete information available, although it only includes children from 7 to 12 years of age. Table 28 lists the results obtained for this population in Spain.

Table 28. Estimation of exposure to cadmium (children) by different groups of food

		%<LOD	Intake (AESAN, 2006)	Cd Concentration Adjusted mean (mg/kg)		Daily intake (µg Cd/day)	
			g/day	LB	UB	LB	UB
1	Cereals and derived products	33.2%	185.36	0.0126	0.0158	2.3355	2.9287
2	Sugar and sweets, including chocolate	91%	16.29	0.0007	0.0038	0.0114	0.0619
3	Fats (vegetable and animal)	71.7%	30.31	0.0106	0.0177	0.3213	0.5365
4	Vegetables, nuts, pulses	69.4%	118.45	0.0107	0.0300	1.2674	3.5535
5	Potatoes or tubers	26.9%	61.61	0.0053	0.0136	0.3265	0.8379
6	Fruit	85.7%	143.36	0.0015	0.0215	0.2150	3.0822
7	Juices, soft drinks and bottled water	92.9%	269.39	0.0003	0.0019	0.0808	0.5118
8	Coffee, tea, cocoa	66.6%	9.69	0.0001	0.0031	0.0010	0.0300
9	Alcoholic drinks	97.6%	0.33	0.0003	0.0089	0.0001	0.0029
10	Meat and offal	22.6%	179.55	0.0093	0.0212	1.6698	3.8065
11	Fish and shellfish	32.6%	64.71	0.0431	0.0541	2.7890	3.5008
12	Eggs	80%	24.34	0.0015	0.0031	0.0365	0.0755
13	Milk and dairy products	90.1%	428.38	0.0004	0.0039	0.1714	1.6707
14	Miscellaneous[a]	38.8%	24.39	-	-	0	0.3400[a]
15	Tap water[b]	-	544.4	-	0.0004[b]	0	0.2178
Total µg Cd/day						**9.2258**	**21.1567**
Total µg Cd/kg b.w./day (34.48 kg body weight of the child)						**0.267**	**0.613**
Total µg Cd/kg b.w./week (% TWI)						**1.87 (74.8%)**	**4.29 (171.6%)**
Tolerable weekly intake (TWI) 2.5 µg Cd/kg p.c./semana						**2.5 µg**	

LB: Estimation of lower bound; UB: Estimation of upper bound. [a,b]In these cases, as we do not have sufficient information, we have assumed the values used by the EFSA (2009a).

With respect to adults, the cadmium intake in children aged 7-12 is 50-60% greater, similar to the findings of the EFSA (EFSA, 2009a) mainly due to a higher intake of food with respect to body weight.

With respect to the results of the AESAN (2008b) for the 2000-2007 period, as with the adults, estimated exposure is similar with a daily intake for the 2000-2007 period of 0.45 µg Cd/kg b.w./day compared to 0.267-0.613 µg Cd/kg b.w./day calculated for the 2000-2010 period.

Characterisation of the risk

The mean dietary intake of cadmium for adults (total population) in Spain is 1.15-2.85 µg Cd/kg b.w./week and for "extreme consumers" it has been estimated to be in the interval of 2.06-3.95 µg Cd/kg b.w./week. This mean exposure is lower than the Tolerable Weekly Intake (TWI) of 2.5 µg Cd/kg b.w./week if we consider the estimation of the lower bound (LB), but it is greater in the total population and in "consumers only" when the upper bound (UB) is considered. In extreme consumers the value of the TWI may even be double, as is the case with children aged 7-12.

The situation for the Spanish population is similar to that observed by the EFSA for the whole of the European population (EFSA, 2009a) and is also comparable to that of other neighbouring countries.

These results should be interpreted with caution as, firstly, exceeding the TWI in any particular case does not necessarily imply adverse effects. Secondly, analysis of the data used in this report has revealed that the majority of samples analysed were below the LOD for the technique and moreover a minimum percentage of these samples exceed the maximum limits (LM) established at European Union.

Taking into consideration the results used for this assessment, it is reasonable to assume that the true exposure would be nearer to the estimation of the lower bound (LB). Therefore the weekly intake of cadmium in the Spanish population would be within the limits recommended at present (PTWI), although in certain specific cases these may be exceeded.

Nevertheless, it should be noted that the recent decrease in the PTWI for cadmium from 7 to 2.5 µg/kg b.w./week clearly indicates the need to reduce, wherever possible, the population's exposure to cadmium, in particular that of children.

Uncertainties

The evaluation of uncertainties in the assessment of the dietary exposure to cadmium among the Spanish population has been carried out in accordance with the guidelines of the EFSA (2006) for the assessment of dietary exposure, and the following uncertainties have been observed:

a) Representativity of the sample. This has been one of the principal problems encountered:

- Data is available for the majority of the Autonomous Regions and therefore, in principle, could be considered representative of the whole country, although the quantity of data varies considerably from one region to another. The available data come mainly from control programmes performed by the Autonomous Regions and the PNIR. Consequently, there is no homogeneity in the distribution by groups, as these controls are essentially directed towards controlling compliance to current legislation.
- As can be seen in Table 7, only the groups "meat and offal" and "fish and shellfish" have an adequate number of samples and these two groups make up 77% of the total number of samples analysed. In all other cases, the number of samples can be considered to be inadequate. Nevertheless, it should be remembered that these two groups are the very groups that most contribute to the dietary intake of cadmium. The low number of samples in the majority of the food groups removes the validity of some of the calculated statistical descriptors (e.g. the P95).

- Some food groups include a large number of individual foods or subgroups, and the low number of samples of many of these means that the cadmium content of the group is estimated from data which are not very representative (sometimes results are available for only one specific food).

b) Analytical aspects. This is another aspect in which deficiencies have been observed:

- 34.8% of the results were provided by non-accredited laboratories or laboratories which did not provide any information in this respect. The laboratory performing the test is not usually specified, only the Autonomous Regions is given. It is possible that more than one laboratory per Autonomous Regions is used. As a result, the Autonomous Regions may specify different LOD/LOQ. It may also be due to the long period in which the samples are analysed (2000-2010), during which time techniques and/or laboratories or the methods used within the same region may have changed.
- The LOD/LOQ given in many results are unacceptably high. This is the consequence of the main objective of these tests (official control) and implies certain deficiencies when these results are used for an exposure assessment, forcing some results to be ignored, and reducing the quantity of available data in a particular food group even more.
- Another standard practice is the rejection of values which are excessively high with respect to the food in the group. The EFSA usually rejects values ten times higher than the mean for the results of the group, and the same criterion is followed in this report. Even so, some results which are over ten times higher than the group mean have been maintained, to avoid reducing the quantity of data too much. This has led to an overestimation of the cadmium content in certain groups.
- The high number of results <LOD/LOQ is also of note. In 39.2% of the total number of samples, however, in 9 of the 15 food groups the number of samples <LOD/LOQ was greater than 60%. This has resulted in the consideration, in accordance with the recommendations of the EFSA, of an estimation of the lower and upper bounds. This, of course implies some uncertainty especially when, as in the present assessment, the exposure is near to or exceeds the established reference values (TWI).
- Another factor of uncertainty to be considered is the use of the "Sampling Adjustment Factors" (SAF). Although it is essential to bear in mind the true contribution of each food or subgroup of foods in a particular category with respect to the cadmium contribution, this assessment has used the SAF from Germany (as did the EFSA in its recent assessments). Although these may be considered valid, it is not known if they accurately represent the situation in Spain.

c) Intake:

- For adults we have used the most recent food survey carried out by AESAN in Spain (ENIDE) in 2011, which we consider perfectly representative of the current situation of the Spanish population. Nevertheless, for children reliable data are only available for the 7-12 year old age group (AESAN, 2006), and therefore other age groups in which the intake/body weight ratio is more significant are not well represented in this report. Similarly, there is no available data from Spain for other subgroups of the population (pregnant women, vegetarians, etc.).
- Another problem is the adjustment of the intake data to the data on the presence of cadmium in the different food groups, as the criteria used for grouping the foods do not usually coincide with the classification used for the analyses. This requires certain adjustments which may of course have an effect on the estimation of exposure.

Conclusions of the Scientific Committee

The Scientific Committee of the AESAN has performed a risk assessment of the exposure of the Spanish population to cadmium from the intake of food, considering the cadmium content in food and eating patterns. Specifically, cadmium content data have been taken from 5,493 samples from different food groups collected during the 2000-2010 period, from 14 Autonomous Regions and other Government laboratories, classified into 15 groups or food categories.

Considering the uncertainties observed in the assessment process, the Committee considers that more specific data are necessary (analytic and intake data) in order to adequately assess the cadmium dietary intake in the Spanish population. The following conclusions can be drawn from the available data:

1. For the majority of foods, a high percentage of the samples analysed were below the maximum limits (ML) established for cadmium at European Union. The highest levels of non-conformity were observed in kidneys, horse liver and crustaceous (all foods with a fairly insignificant intake in the general population). In any case, the mean cadmium concentrations of the different food groups (except horse liver) were always lower than the ML.
2. The main food groups contributing to dietary exposure to cadmium are in descending order "fish and shellfish", "cereals and derived products", "meat and offal", and "vegetables, nuts and pulses".
3. The mean dietary intake for adults in Spain is 1.15-2.85 μg Cd/kg b.w./week for all the population, 1.28-3.35 μg Cd/kg b.w./week for consumers only and 2.06-3.95 μg Cd/kg b.w./week for extreme consumers. The mean exposure for children (7-12 years old) is estimated at 1.87-4.29 μg Cd/kg b.w./week.
4. Exposure to cadmium in adults is lower than the Tolerable Weekly Intake (TWI) of 2.5 μg Cd/kg b.w./week, if the Lower Bound (LB) estimation is considered, but it exceeds the TWI if the upper bound (UB) is considered. In children (7-12 years of age) the estimation of the lower bound (LB) is below the TWI, but may be almost double if the upper bound (UB) is considered. These results are very similar to those observed for the European population by the EFSA in 2009.
5. Taking into consideration the results used for this assessment, it is reasonable to assume that the true exposure to cadmium would be nearer the estimation of the lower bound (LB). Therefore the weekly intake of cadmium in the Spanish population could be considered to be within the limits recommended at present (TWI).

Final remarks

A "conservative" position is normally adopted in risk assessments, and many assumptions are made which, if in the end the tolerable daily (or weekly) intake is not exceeded, are accepted. Nevertheless, when these intake levels are exceeded, as is the case with cadmium, a more detailed analysis is necessary. This requires much more accurate information on the concentrations of the contaminant in the maximum possible number of foods, analytical results appropriate for this purpose and detailed and reliable intake data.

In our case, and considering all the deficiencies observed (the majority of which are listed in the section on uncertainties), although the final result indicates that the Spanish population may be exposed to cadmium levels higher than the currently established TWI, this does not necessarily imply a significant risk for the population. Some arguments in this respect are as follows:

- Lack of representativity of analytical data.
- Very high percentage of samples <LOD/LOQ implying that the real situation would be closer to the lower bound estimation and therefore would not exceed the TWI.
- No unanimous agreement with respect to said TWI. The EFSA has recently accepted the TWI of 2.5 μg Cd/kg b.w./week but nevertheless, JECFA continue to maintain a TWI of 5.8 μg Cd/kg b.w./week. If we consider the latter TWI, the results of the assessment are totally different.
- Only a small percentage of samples exceed the maximum limits (ML) established at European Union and the mean values of the different food groups never exceed these limits. It is not reasonable to assume that if the food analysed complies with current legislation (established at certain levels to safeguard the health of the population), its intake represents a risk for health, especially when the situation in Spain is similar to that in any other Member State (according to the EFSA data).

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