

NICKEL AND METALLIC FOOD CONTACT MATERIALS

This fact sheet provides information on the exposure to nickel via food contact materials and articles, the existing state of knowledge regarding its potential impacts, and the protection offered to consumers by regulations and other means. The general public expects food for human consumption to be wholesome, nutritious, and above all, safe to eat. Indeed, food regulations across the globe that govern food contact materials and articles all share the common theme of consumer safety. Nickel-containing stainless steels are one of the most widely used food contact materials. Release of nickel is required for human exposure and toxicity to occur. Established test protocols offer a means of estimating the release (migration) of substances into food under controlled conditions. Well-designed and well-executed studies on commonly used stainless steel food contact materials and articles indicate that the amount of nickel transferred into food is very small, especially in comparison to the naturally occurring levels in many foods and within the release limits set for food contact materials and articles.



Stainless steel pots provide a safe way to prepare food

1 INTRODUCTION

The general public trusts food for human consumption to be safe and their assumption is that these expectations are delivered by the authorities via regulations related to food contact materials and articles (FCM&As), by producers of these items following guidelines, and by beverages and foodstuffs manufacturers themselves. However, inaccurate negative media reports of the impact of food, as well as food contact materials on health and well-being, can cause concerns and undermine consumers' confidence on its actual safety.

This fact sheet presents the current state of knowledge related to oral exposure to nickel via stainless steel FCM&As, its potential impacts and the protection offered to consumers by regulations and other means.

2 REGULATIONS GOVERNING FOOD CONTACT MATERIALS AND ARTICLES

There are many different regulations across the globe that govern FCM&As. [Table 1](#) provides an overview of the regulations governing FCM&As in China^{(1),(2),(3)}, the European Union⁽⁴⁾ and the United States⁽⁵⁾. It also highlights the differences in their individual approaches. Regulations can be horizontal and/or covering specific types of materials (e.g., metals, plastics, paper and board, ceramics, glass). However, they share the same common objectives of consumer and food safety [i.e., “*under normal or foreseeable conditions of use FCM&As should not transfer their constituents to food in quantities which could: endanger human health; or bring about an unacceptable change in the composition of the food; or bring about a deterioration in the organoleptic characteristics*”⁽⁴⁾].

3 TECHNICAL GUIDELINES

In addition to regulations governing FCM&As, there are globally a large number of voluntary standards. The following are some examples:

- NSF/ANSI 51 Food Equipment Materials⁽⁶⁾—applies to all commercial equipment for producing and distributing foodstuffs (food service);
- NSF/ANSI 2 Food Equipment⁽⁷⁾—sets minimum food protection and sanitation for the materials, design, fabrication, construction, and performance of food handling process equipment;
- NSF/ANSI 36 Dinnerware⁽⁸⁾—intended for use in food establishments; and
- NSF/ANSI/3-A 14159-1⁽⁹⁾—hygiene requirements for designing meat and poultry processing equipment.

Although these standards are voluntary, they are important as they are used as reference for State and Federal regulatory authorities in the United States.

At the European level, there is the Council of Europe (CoE) Technical Guide⁽¹⁰⁾ on Metals and Alloys used in FCM&As, which was developed by the European Directorate for the Quality of Medicines and HealthCare (EDQM). Though not legally binding, the Technical Guide is very influential as it serves as a reference for manufacturers and regulators, in the absence of specific European Union (EU) harmonized legislation for food contact metals and alloys. This is particularly relevant for those European countries that do not have specific national rules for metal and alloy FCM&As. The Technical Guide provides safety reviews and recommendations for metals, alloys, metal contaminants, and impurities of concern found in FCM&As, which form the basis for specific release limits (SRLs).

Table 1: A summary of FCM&A regulations in China, the European Union, and the United States

	China	European Union	Unites States
Legislation	<p>FCM&As are regulated under the China Food Safety Law to ensure quality, safety, and protection of human health.</p> <p>On 16th October 2016, 53 mandatory national standards for food contact materials and additives were approved and published by the China National Health and Family Planning Commission (NHFPC). These standards form a three-tier hierarchy:</p> <ul style="list-style-type: none"> • Level 1—basic guidelines for the Good Manufacturing Practice (GMP); • Level 2—specific product standards; and • Level 3—standards for testing methods. <p>The new regulatory system recognizes that to ensure FCM&A compliance and to guarantee food safety, all operators in the supply chain have to bear responsibility which includes, but is not limited to, the applicable provisions of <i>GB 31603⁽³⁾ National Standard for Food Safety General Hygienic Practice for Production of Food Contact Materials and Articles</i>.</p>	<p>Regulation (European Commission) No. 1935/2004⁽⁴⁾ provides a “framework” of general legislative requirements for all FCM&As, which is supported by specific measures (legislation) for groups (see Comments below) of food contact materials (FCMs) that are harmonized throughout the EU. Metals and alloys are not yet covered by specific EU measures.</p> <p>For non-harmonized FCMs, Member State regulations apply where available. For example:</p> <ul style="list-style-type: none"> • The Italian Health Ministry Decree of 21 March 1973⁽¹¹⁾ on the hygiene of packaging, recipients and utensils intended to come into contact with foodstuffs or personal-use products and its subsequent amendments. • The French Order of 13 January 1976⁽¹²⁾ relating to stainless steel materials and articles in contact with foodstuffs and its subsequent amendments. 	<p>The Federal Food, Drug and Cosmetic Act (FFDCA), administered by the Food and Drug Administration (FDA), regulates food and FCM&As. Title 21 of the United States Code of Federal Regulations (CFR)⁽⁶⁾ contains the key requirements for FCM&As.</p> <p>At State level, the main references are the Model Toxic Legislation (adopted by 19 States) and California’s Proposition 65. All components of a food contact material must comply with both the Title 21 CFR and individual State legislation for intended use before manufacturers and suppliers can market their products in a specific state.</p>
Comments	<p>The Food Safety Law also prohibits the importation, use, or purchase of food-related products not in compliance with the applicable (mandatory) Chinese Food Safety Standards.</p> <p>With regard to metallic FCM&As, the following NHFPC food-related standards apply:</p> <ul style="list-style-type: none"> • GB 4806.1⁽¹⁾ General Safety Requirements for Food Contact Materials and Articles (level 1); • GB 4806.9⁽²⁾ Metallic Materials and Articles for Food Contact Use (level 2); and • GB 31604.49⁽¹³⁾ Determination of Arsenic, Cadmium, Chromium, Nickel, Lead, Antimony and Zinc in Food Contact Materials and Articles (level 3). <p>Note: GB 4806.9 is under revision and an updated version is expected to be adopted in 2021.</p>	<p>There are EU specific measures for:</p> <ul style="list-style-type: none"> • Active and intelligent materials, Regulation (EC) No. 450/2009⁽¹⁴⁾; • Ceramics, Directive 84/500/EC⁽¹⁵⁾; • Plastics, Regulation (EC) No. 10/2011⁽¹⁶⁾; and • Regenerated cellulose film, Directive 2007/42/EC⁽¹⁷⁾. <p>The French and Italian authorities adopted different approaches to stainless steels for food contact applications. The French Order is based on chemical composition (not release), specifying a minimum of 13% chromium and maximum concentration limits for other key ingredients.</p> <p>The Italian Decree has a positive list of stainless steels suitable for food contact applications that is based on metal release tests and specific release limits for chromium, nickel, and manganese.</p>	<p>For FCM&As, it is the regulatory status of the individual ingredient substances that determines the status of the material or article. Substances intended for use as ingredients of materials used in manufacturing, packaging, transporting, or holding food (i.e., a food contact substance) and that migrate are regulated as indirect food additives in accordance with Title 21 CFR.</p> <p>Substances separated from food by a functional barrier that prevents migration (i.e., not in indirect food contact), do not require FDA approval.</p>

Chapter 3 of the Technical Guide⁽¹⁰⁾ describes analytical methods for release testing of metallic food contact materials and articles, the outcome of which can then be compared with the SRLs in Chapter 2.

4 TEST PROTOCOLS FOR FOOD CONTACT METALS AND ALLOYS

In addition to general safety requirements and release limits, test protocols play a very important role in ensuring the safety of food and FCM&As. They offer a means of estimating the release (migration) of substances into foodstuffs or food simulants under controlled conditions. Whether documented in regulations or guidelines, they represent a means of ensuring the key objectives for FCM&As are fulfilled and that they are in compliance with specified release/migration limits. Test protocols share a number of common features:

- measurement of maximum overall (for all substances combined) and specific metal release/migration limits in terms of mg/kg (ppm) food or food simulant;

- the use of different food simulants where contact with a diversity of foodstuffs is envisaged;
- overall and specific metal release/migration limits are usually expressed in terms of mg/kg (ppm) food or food simulant, but can also be expressed as mg/dm² of the FCM or article;
- unless otherwise specified, 1 kg of food or food simulant is deemed to be in contact with an area of 6 dm²;
- test conditions are selected to reflect both the actual conditions of use and a reasonable worst-case for foreseeable conditions of use; and
- test conditions should not result in changes in the physical properties of the test samples that would not occur under normal use conditions or lead to precipitation, turbidity, and other changes in the food simulants.

However, there are also differences between FCM&A test protocols, as described in [Table 2](#).

Table 2: Key test conditions from three FCM&As protocols for repeated use of stainless steel in contact with any type of foodstuff

Test Protocol					
Council of Europe Test Protocol ⁽¹⁰⁾		Italian Decree ⁽¹¹⁾		Chinese GB 4806-9 ⁽²⁾	
Simulants					
(i) 5 g/L citric acid (acidic foodstuffs) (ii) artificial tap water (all other foodstuffs)		(i) 3% acetic acid (ii) distilled water or water of equivalent quality		(i) 5 g/L citric acid (acidic foodstuffs) (ii) man-made tap water (other foodstuffs) ^a	
Test Conditions for Different Use Scenarios ^{b,c}		Test Conditions for Different Use Scenarios ^c		Test Conditions for Metallic FCM&As ^{b,c,d}	
Room temperature use	10 days at 40 °C	Prolonged contact with any food type at room temperature	3% acetic acid for 10 days at 40°C	Use at room temperature or below for >3 days	10 days at 40 °C
Hot fills and short-term storage at room temperature	2 hours at 70 °C, followed by 24 hours at 40 °C	Short-term use with heat or at room temperature with any food type	3% acetic acid at 100°C for 30 minutes	Use at room temperature or below for <3 days	40 °C, test time according to GB 31604.1 ⁽¹⁸⁾
Use with boiling contents	2 hours at simulant boiling temperature	Reusable cooking and dining cutting implements for short-term use with heat or at room temperature with any food type	3% acetic acid at 70°C for 30 minutes	Hot food at room temperature or below for <3 days	70 °C, test time according to GB 31604.1 ⁽¹⁸⁾
		Reusable articles for short-term use with heat or at room temperature, only in contact with water	Distilled water at 100°C for 30 minutes	Frying pans made of uncoated iron	Boiling 1 g/L citric acid, 1 hour
				Steaming, frying, baking, and other high-temperature contact	Boiling temperature, 2 hours
				High-temperature aluminum foil products	Boiling temperature, test time according to GB 31604.1 ⁽¹⁸⁾
				Food processing equipment and appliances	Actual time and temp 100 °C or below, Migration test according to GB31604.1 ⁽¹⁸⁾

a Described as “non-alcoholic water-based food (pH ≥5), alcoholic food, grease, and foods containing oil on the surface.”

b These test conditions apply to all food contact metals and alloys, not only stainless steels.

c Metal release is determined by analysis of the simulant from the third consecutive test.

d Chinese Standard GB 4806-9 Test Method for metallic food contact materials and articles⁽²⁾ is currently undergoing revision and the information provided herein is based on the latest draft revision. Readers are advised to check the accuracy of this information in the published standard, which is expected during early 2021.



Stainless steels are selected because of their cleanability, durability, hygienic properties, attractive appearance, and their excellent mechanical and physical properties

5 DIETARY NICKEL AND ITS HEALTH IMPLICATIONS

European Food Safety Authority (EFSA), in its 2015 Scientific Opinion⁽¹⁹⁾ on nickel in food and drinking water, concluded that exposure via the diet is likely to represent the most important contribution to the overall exposure in the general population. The highest concentrations of nickel have been measured in wild growing edible mushrooms, cocoa or cocoa-based products, beans, seeds, nuts, and grains^{(19),(20),(21)}.



Stainless steel kitchenware utensils are used in commercial and high-end kitchens

Various studies of the dietary intake indicate that 90 to 361 µg/day of nickel are consumed⁽²²⁾. The quantity of nickel absorbed from food depends on its form (i.e., soluble nickel is more readily absorbed than Ni²⁺ in organic complexes⁽²²⁾ in a food matrix). Soluble nickel is found in beverages, drinking water, soup, etc. Ni combined with organic molecules can be found in beef, poultry, pork, fish, eggs, dairy products, soy foods, nuts, seeds, many whole grains, vegetables, and legumes⁽²²⁾.

6 NICKEL TOXICITY AND TOLERABLE DAILY INTAKE

Orally absorbed nickel is distributed to the kidneys, followed by the liver, brain, lung, fat, and heart⁽¹⁹⁾. The toxicity of nickel varies depending on the chemical form of nickel and the bioavailability of the Ni²⁺ ion at target sites in humans⁽²³⁾. Nickel absorbed via the gastrointestinal tract is excreted predominantly in urine and unabsorbed nickel is eliminated with the feces.

Toxicity data is used to determine the tolerable daily intake (TDI) of substances. The TDI is an estimate of the amount of a substance in food or drinking water which is not added deliberately (naturally occurring) and which can be consumed over a lifetime without presenting an appreciable risk to health. TDIs are taken into consideration during the establishment and revision of specific migration limits (SMLs) and SRLs for substances in FCM&As.

EFSA has recently revisited its 2015 Opinion on nickel in food and drinking water⁽¹⁹⁾ taking into account newly available scientific information. The latest EFSA Scientific Opinion⁽²⁴⁾ proposes a TDI of 13 µg/kg body weight to protect from chronic effects observed in animal studies and, as a small subset of the hypersensitive nickel-allergic population also react to oral nickel exposure, EFSA recommends a lower reference value to protect this subpopulation from the for acute effects of nickel in the diet.

7 CONTRIBUTION OF NICKEL TO FOOD INTAKE FROM STAINLESS STEEL FCM&As

Nickel-containing stainless steels are one of the most widely used food contact materials; applications range from domestic utensils and kitchen equipment, through commercial catering equipment to mass food production equipment and facilities. Stainless steels are selected for these applications because of their cleanability, durability, hygienic properties, inertness, and their excellent mechanical/physical properties.

In these food contact uses, stainless steels fulfill the key regulatory requirements that constituents are not transferred to food in quantities sufficient to bring about unacceptable changes in its composition, color, odor, taste, or texture. They satisfy too the explicit requirement that substances in FCM&As should not be released in quantities that endanger human health, which is the basis of SRLs of FCM&A constituents. Indeed, experience has shown this to be the case.

Of the numerous studies that have assessed the amount of metals that are released (or migrate) into foodstuffs during the use of stainless steel FCM&As, [Table 3](#) provides a summary of four studies measuring nickel release under conditions mimicking stainless steel use as FCM&As. These studies were selected to illustrate the influence of the study design (e.g., choice of food or food simulant, the form of test samples and test conditions) on the metal release outcome.

The EFSA Scientific Opinion on nickel in food and drinking water⁽²⁴⁾ indicates that the concentrations of nickel following migration (release) are in the same order of magnitude as concentrations reported to occur in food. The studies by Flint and Packirisamy⁽²⁵⁾ and Hedberg et al.⁽²⁶⁾ in [Table 3](#) support this statement. With the exception of nickel release values reported by Guarneri et al.⁽²⁷⁾ and Kamerud et al.⁽²⁸⁾, the SRLs of 0.14 mg/kg for Ni and 0.25 mg/kg for Cr were not exceeded. These outcomes illustrate the importance of testing FCM&As in accordance with accepted national or international protocols and in an appropriate form [e.g., relevant pots and pans versus non-relevant granules as in Kamerud et al.⁽²⁸⁾].

8 NICKEL FROM NON-STAINLESS STEEL FCM&As

In times past, copper/nickel/chromium-plated food serving utensils (e.g., carving forks, serving spoons, spatulas, etc.) and nickel-plated kettle elements were common. However, over time, electroplated utensils tended to rust as the underlying steel substrate was exposed by abrasion and wear. Furthermore, nickel release from nickel-plated kettle elements, and to a lesser extent electroplated kitchen utensils, could be very high and was a cause for concern. Hence, electroplated items (particularly kettle elements) have now largely been replaced by stainless steel. In addition, electroless nickel is used for certain components in coffee making machines.

The Council of Europe has, in principle, accepted that provided the SRL for nickel is not exceeded, nickel-plated, nickel/chromium-plated, and electroless nickel plating can be used in contact with food. However, manufacturers are urged to consider carefully whether suitable alternative FCMs might be preferable to nickel plated materials.

Table 3: Summary of four studies on the contribution of nickel to food intake from FCM&As

Flint and Packirisamy ⁽²⁵⁾	Guarneri et al. ⁽²⁷⁾	Kamerud et al. ⁽²⁸⁾	Hedberg et al. ⁽²⁶⁾
Foodstuff/Simulant			
(i) Rhubarb (ii) Apricots (iii) Lemon marmalade (iv) Tomato chutney (v) Potatoes	(i) Tomato sauce (with and without EDTA ^a) (ii) Lemon marmalade (with and without EDTA ^a)	Four unspecified commercially available tomato sauces (pH 4.17-4.3)	(i) 5g/L citric acid, pH 2.4 (ii) Artificial tap water
FCM&A			
Saucepans manufactured in 304 stainless steel	18/10 stainless steel pots	(i) 316 stainless steel saucepan (ii) 321 stainless steel chips 0.5–1.18 mm (iii) 348 stainless steel granules 0.5–1.18 mm (iv) 316 stainless steel granules 0.5–1.18 mm (v) Nickel metal pellets	Stainless steel test samples cut from 2 mm thick sheet in grades: (i) EN 10083 (ii) 201 (iii) 204 (iv) 304 (v) 316L (vi) LDX 2101
Test Conditions			
Saucepans were used in a sequence of 20 cooking operations	Foodstuffs cooked for 15 minute intervals up to 1 hour	Cooking times of 2, 6, and 20 hours	In accordance with the CoE test protocol: exposure for 2 hours at 70 °C followed by 24 and 238 hours at 40°C
Outcome			
<p>After the second cooking operations:</p> <ul style="list-style-type: none"> nickel release for apricots and rhubarb was reported as 0.07 mg Ni/kg food^b and 0.01 mg Ni/kg food^b, respectively nickel pickup was below or close to the level detection for lemon marmalade, green tomato chutney, and potatoes^c chromium release was reported as 0.05 mg/kg and 0.01 mg/kg, respectively, for apricots and rhubarb <p>Abrasion had no adverse effects.</p> <p>The results showed that the use of stainless steel cooking utensils does not provide a source of dietary chromium and nickel of any significance, even for those wishing to adopt a low nickel diet.</p>	<p>The nickel and chromium release increased with cooking/boiling time, was higher with new pots, at low pH and with EDTA^a, and was sometimes remarkably different between manufacturers.</p> <p>Maximum nickel and chromium releases during food preparation were:</p> <ul style="list-style-type: none"> 0.144 mg Ni/L and 0.098 mg Cr/L, respectively, in tomato sauce 0.077 mg Ni/L and 0.074 mg Cr/L, respectively, for lemon marmalade <p>The authors concluded that nickel and chromium released from stainless steel saucepans was insufficient to elicit reactions in sensitized individuals. However, the release level of 14–17 µg Ni per 100 g of food could elicit a reaction in some highly sensitized individuals.</p>	<p>The metal release results from the 316 saucepan were similar to those reported by Flint and Packirisamy⁽²⁵⁾, as well as Guarneri et al.⁽²⁷⁾</p> <p>The large surface area/volume ratios with regard to the reference materials in granular form, coupled with up to 20 hours, were not representative of domestic cooking and represent unrealistic test conditions. The surface finish on cookware is superior to that provided by reference materials in granular form. Thus, very high levels of nickel (5.32 mg/kg for 304 stainless steel) and chromium release were reported. As a consequence, the authors concluded nickel-sensitized individual should avoid food cooked in stainless steel articles.</p>	<p>The release from all stainless steel grades investigated were below the CoE stipulated specific release limits (SRLs) for citric acid of:</p> <ul style="list-style-type: none"> 40 mg/kg for Fe 0.25 mg/kg for Cr 0.14 mg/kg for Ni 1.8 mg/kg for Mn (at the loading of 1 cm²/mL used in this study) <p>In all cases, metal releases diminished with time. Nickel release after 2 hours at 70 °C followed by 238 hours at 40°C was 0.04 mg/kg and 0.06 mg/kg for 304 and 316 stainless steel, respectively.</p> <p>The amounts of metals released into artificial tap water were below those in citric acid and close to the limits of detection.</p>

a EDTA = Ethylenediaminetetraacetic acid

b 1 mg/kg = 1 ppm

c Similar to the levels found in the same foods cooked in glass

9 SUMMARY POINTS

- Regulations and technical guidelines governing FCM&As share the same common objectives of consumer and food safety.
- Test protocols, whether in regulations or guidelines, represent a means of ensuring the key objectives for FCM&As are fulfilled and that they are in compliance with specified release/migration limits.
- Nickel-containing stainless steels are one of the most widely used food contact materials due to its durability, ease of cleaning and inert nature (corrosion resistance and low nickel ion release).
- Various studies of the dietary intake indicate that 90–361 µg/day of nickel are consumed.
- Well-constructed and well-executed studies on commonly used stainless steel FCM&As indicate that the amount of nickel and other metals transferred into food is small in comparison to the naturally occurring levels in food and within the release limits set for FCM&As.
- Stainless steels used for food contact fulfill the key regulatory requirements: they do not transfer their constituents to food in quantities that cause toxicity or bring about unacceptable changes in its composition, color, odor, taste, or texture.

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Fact Sheets on Nickel and Human Health

This is the fourth in a series of fact sheets addressing issues specific to the evaluation of risks to humans associated with nickel-containing substances and materials. The fact sheets are intended to assist the reader in understanding the complex issues and concepts associated with assessment of human health hazards, dose-response relationships, and exposure by summarizing key technical information and providing guidance for implementation.

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