Stainless Steel for Hygienic Applications

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**Introduction**

In the European Union and, indeed, throughout the world, Regulators are increasingly concerned with the potential impact of materials and products on human health and the environment. Such concerns tend to be reinforced in the minds of the Regulators by adverse news items carried in the media, which is reflected by public unease about food safety, health and environmental issues.

In this atmosphere of concern, we must not lose sight of the fact that the stainless steel family offers a remarkable and extremely versatile range of engineering materials. This is especially important, as throughout this session of the conference, we will hear about regulatory and market access issues that provide challenges for stainless steel.

For the purposes of this paper and the accompanying presentation, the term “hygienic” will be taken to encompass the following applications.

- Beverage, dairy and food uses (in the broadest senses)
- Drinking water supply
- Medical devices
- Pharmaceutical plant and equipment

Materials suitable for these applications must meet the following common requirements; durability, adequate mechanical/physical properties, ease of fabrication and inert/easily cleaned surfaces.

This paper explores these common requirements for hygienic applications, highlights the properties of stainless steels utilised to fulfil the common requirements identified above and discusses the concerns of the Regulators.

**Beverage, dairy and food**

Materials for beverage, dairy and food preparation, processing and storage are required to maintain the integrity of the structure (ie corrosion resistant and sufficiently robust to withstand the demands of the service environment). In contrast, regulatory concerns are focused on the chemical activity of the surface in contact with the foodstuff or beverage. Although food contact surfaces must be sufficiently inert to impart neither colour nor flavour to foodstuffs, it is their level of metal release (measured in μg/cm²/day or μg/cm²/week) that is the major concern for Regulators. In particular, it is the contribution that food contact surfaces make to the total daily intake (TDI) or total weekly intake (TWI) of metals by consumers from all other dietary sources (ie from all food intake, including water/beverages and food contact materials) that is of concern. In fact, there has been sufficient regulatory interest in this topic for the Council of Europe to publish “Guidelines on metals and alloys in contact with food”.

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1. Council of Europe, “Guidelines on metals and alloys in contact with food.”
Stainless steels are selected for food contact application because they are resistant to corrosion, inert, easily cleaned and sterilized without loss of properties, and can be fabricated by a variety of techniques into robust structures. The selection of an appropriate stainless steel grade is critical to the success of any food contact application. It is vital that all aspects of the application are considered in the grade selection process (eg cleaning regimes, their associated chemicals and whether operation of the plant will be continuous or batch-type with shutdowns). In the majority of food contact applications where stainless steel is used, austenitic grades with 18% chromium provide an optimum balance of corrosion resistance (to a wide range of foodstuffs), cost and ease of fabrication. Nevertheless, ferritic, martensitic and duplex stainless steels are also used in food contact applications. Figures 1 to 4 illustrate typical food contact applications where austenitic, ferritic martensitic and duplex stainless may be used.

Martensitic stainless steels may be hardened by heat treatment and are suitable for moderately corrosive environments. For example, medium-priced cutlery often utilises grade 1.402 (AISI 420), while grade 1.4122 with a higher carbon content and molybdenum tends to be used for high quality cutlery and grade 1.4116 with high carbon, molybdenum and vanadium is used for cooks’/professional knives.

Ferritic stainless steels offer good corrosion resistance, but cannot be hardened by heat treatment and have limited formability. Typical applications for grade 1.4016 (AISI 430) include low-priced cutlery, hollowware, work surfaces and cabinets, and trim on domestic cookers.

Austenitic stainless steels provide good to excellent resistance to corrosion, a wide range of mechanical/physical properties and good fabrication characteristics. Grade 1.4301 (AISI 304) and its derivatives are used in relatively mild environments (with a chloride content less that 200 mg/l) for both domestic and professional cutlery, hollowware, and kitchen utensils and to a limited degree process/storage vessels. Grade 1.4401 (AISI 316) and its derivatives are suitable for more aggressive service environments with chloride contents up to 500 mg/l. For this reason, they represent the most widely used grades for food contact applications (eg pipework, cooking/mixing/storage vessels, ovens/heaters, preparation/work surfaces, bulk transport containers, etc). At higher chloride contents, especially if combined with stress and increased operating temperatures, duplex stainless steel grades 1.4462 (2205) and 1.4362 (2304) may be required for their resistance to stress-corrosion-cracking (eg steam heating systems and boilers). In some very aggressive applications (eg hot brines), superaustentic grades 1.4547 254 SMO) or superduplex grades 1.4410 (2506) may be required.

Stainless steels in contact with foodstuffs have been subject to a number of studies\(^2\), \(^3\). In some of these studies, the release of nickel from stainless steel saucepans was evaluated for a variety of foodstuffs and water. The studies revealed that, on first use, measurable levels of nickel were detected. It was also shown that, as the number of subsequent uses increased, the level of nickel release diminished and reached a steady state (measured in the order of \(\mu\)g/l). These observations reflect the changes that occur in the passive oxide layer on first immersion of stainless steels in aqueous media. The studies went on to show that certain acidic foodstuffs (eg rhubarb) released higher that
expected levels of release. As a result of these findings, it is recommended that such foodstuffs are not cooked in the first use of, or stored in, stainless steel saucepans.

**Drinking Water Supply**

Materials for drinking water supply, which for the purposes of this paper excludes sewage and wastewater treatment, must be corrosion resistant to both internal and external service environments and sufficiently robust to withstand the internal and external forces generated in these applications. The longevity of these materials is an additional and important factor in their selection, especially as many water supply pipes and other items of equipment are buried below ground. For such applications, water supply companies often require a design life in excess of 100 years. As may be expected, drinking water regulations are designed to ensure that surfaces in contact with drinking water impart neither colour nor flavour and prevent consumers from exceeding the maximum recommended TDI* or TWI* for specific metals from all dietary sources. This objective is achieved by setting maximum permitted limits for specific metals, which are based on WHO recommendations and measured in µg/cm²/day or µg/cm²/week. It is interesting to note that, unlike current UK Drinking Water Regulations, European Acceptance Scheme for Construction Products in Contact with Drinking Water proposes to share the maximum permitted limits for metals between contributions from natural sources and those from products.

Stainless steels are widely used in drinking water supply systems because they are resistant to corrosion, inert and can be readily fabricated by a variety of techniques. The selection of an appropriate stainless steel grade for drinking water applications depends on the composition of the drinking water (the internal environment) and the external service environment. For this reason, it is difficult to provide a list of stainless steel grades used for specific applications. Even the general guidelines for austenitic stainless steels in contact with chloride-containing waters [ie type 1.4031 (304) suitable for chloride contents less than 200 mg/l and type 1.4401 (316) for chloride contents up to 500 mg/l] are modified (lowered) for chlorinated waters. As previously mentioned the external service environmental must also be considered. For atmospheric exposure in areas of significant industrial pollution and/or coastal regions or in subterranean applications with acid and/or high chloride soils, grade 1.4401 (AISI 316) and its derivatives is favoured and, in some cases, the duplex stainless steels 1.4462 (2205) and 1.4362 (2304) may be necessary. While, in still more aggressive situations, the superaustenitic (eg 1.4547) and superduplex (eg 1.4410) grades may be required. Typical drinking water applications for stainless steel include pipework, storage tanks/vessels, valves and liners for existing (corroded) water supply pipes.

It is perhaps worthwhile mentioning that, in mainland Europe, ferritic grades 1.4510, 1.4520 and 1.4521 are used in drinking water supply applications and that hot water supplies are required to be of drinking water quality. In these circumstances, with the potential for increased chloride content due to evaporation couples with increased operating temperatures, ferritic and duplex stainless steels are recommended for their resistance to stress-corrosion-cracking.

* - It is perhaps worthwhile mentioning that, in their calculation of TDIs and TWIs, Regulators assume that consumers drink 2 litres of water per day.
Stainless steels in contact with drinking water have been subject to extensive study. Much of this work is summarized in a “Review of metal release from ferritic, austenitic and duplex stainless steel grades exposed to potable water and related adverse environments”\(^4\). This paper demonstrates that, under normal operating conditions, the release of chromium and nickel from stainless steels in contact with is at or below the limits of detection for current analytical techniques (ie 1-2 parts per billion). Furthermore, the paper shows that, in systems operated for hundreds of hours outside normal conditions, the TDiS or TWIs for chromium and nickel are not exceeded; and that such systems can be restored to the passive condition (ie with metal release measured at 1-2 parts per billion) under normal operating conditions.

**Medical Devices**

In functional terms, medical devices must possess appropriate mechanical and physical properties (eg strength, toughness, low magnetic permeability) to meet their design criteria. In addition, they must exhibit adequate corrosion resistance when exposed to body fluids, cleaning agents and disinfectants as well as withstanding a variety of sterilising techniques. In Europe, the Medical Device Directive (MDD) sets out a number of “essential requirements”, which are intended to protect both patients and professional users. The essential requirements recognise different levels of criticality for medical devices and the tiered approach of the MDD is reflected in the horizontal and vertical (product) standards that support it.

Although stainless steels have been long established in medical device applications (figure 5), it is important to distinguish between stainless steels used for implant applications and commercial grades [eg 1.4305 (AISI 303), 1.4301 (AISI 304) and 1.4401 (AISI 316)] used for other medical devices (eg dental scalers, dental explorers, dental and surgical forceps, kidney dishes, theatre tables, etc). In the EU, the MDD defines implants as medical devices that are exposed to human tissue for more than 30 days.

ISO 7153-1\(^5\) specifies stainless steels for surgical and dental instruments. It should be stressed that the grades specified in ISO 7153-1 are generic and represent typical, readily available, commercial steel compositions (ie not specifically prepared for surgical applications). This standard also provides an indication of typical applications for each grade.

Martensitic stainless steel [eg grades 1.4006 (AISI 410), 1.4021 (AISI 420), 1.4028 (AISI 429) and 1.4125 (AISI 440C)] is used extensively for dental and surgical instruments. These stainless steels can be heat treated (hardened and tempered) to develop a wide range of mechanical properties [ie high hardness for cutting instruments (figure 6) and lower hardness with increased toughness for load-bearing applications (figure 7)].

Austenitic stainless grades 1.4303 (AISI 303), 1.4301 (AISI 304), 1.4401 (316) and their directives are also used for medical devices. Grade 1.4305 (AISI 303) stainless steel is used where its free-machining properties enhance the ease of manufacture (eg medical devices with screw threads, with drilled and/or tapped holes). Handles of multi-part dental instruments are often manufactured in grade 1.4305 (AISI 303), where its lower corrosion resistance is not a disadvantage. Grade 1.4301 (304) and its directives are used where good corrosion resistance and moderate strength are
required (eg dental impression trays, hollowware, retractors, guide pins, theatre tables and storage cabinets), while grade 1.4401 (AISI 316) and its directives may be used for dental explorers and vaginal probes.

ISO standards 5832-1 and 5832-9 specify wrought stainless steel and high-nitrogen stainless steel, respectively, for surgical implants. The original development of these materials was based on grade 1.4401 (AISI 316) stainless steel. However, their chemical composition is now enhanced with higher chromium, nickel, and molybdenum and, in the latter case, nitrogen. In addition, implant grade stainless steels have specific requirements for resistance to pitting corrosion and for cleanliness that do not apply to commercial stainless steels [eg 1.4401 (AISI 316)]. Hence, special production routes (ie vacuum melting or electroslag refining) are used to produce "clean" implant steels.

The regulatory concerns for implants relate to biocompatibility, control of biological contamination and freedom from residual debris resulting from their production. For this reason, implants are subject to very specific surface finish requirements. In many cases, the surfaces are mechanically polished to a high finish and/or electropolished. Polished surfaces offer enhanced corrosion resistance and improved fatigue life. In the case of an electropolished finish, a chemically clean, smooth, surface is produced. Implants are also subject to stringent cleaning regimes designed to remove gross microbiological contamination, which if not removed, although subject to sterilisation, could compromise the health of the patient. It is perhaps worthwhile mentioning that, although implant grade stainless steels do not provide the best level of biocompatibility, the cost benefit in relation to other implant materials is such that they are favoured. In the UK, some 50% of all replacement hips are manufactured in stainless steel.

Interest in metal release from medical devices in contact with body fluids and human tissue has tended to remain an academic issue, which has mainly concerned surgeons when their patients have exhibited allergies attributable to specific metals (eg nickel). As a consequence, test methods for such studies have not been refined and remain to be validated. In addition, the quality of papers on the subject are, to say the least, variable and a frequent criticism of such studies is that test materials are not adequately characterised. For these reasons, it is difficult to provide typical values for metal release from materials in contact with body fluids and human tissue. However, test results indicate that metal release from metallic materials in contact with body fluids/human tissue is greater than that for drinking water. The ongoing EU Risk Assessment of nickel has required a greater understanding of these interactions and the proposed European New Chemicals Policy will require still more data. In response, research on stainless steels in contact with body fluids has commenced.

ISO 5832-1 compositions D and E are used for bone plates and screws, femoral fixation devices, neurosurgical implants, skeletal pins and wires, while stainless steel conforming to ISO 5832-9 may also be used for intramedullary nails and pins, ankle, elbow, finger hip, knee, shoulder, toe and wrist implants. Figure 8 illustrates a stainless steel bone plate and bone screws.
Pharmaceutical Plant and Equipment
Pharmaceutical applications, in common with food and beverage, demand that the materials of construction maintain the integrity of the structure (ie are corrosion resistant and sufficiently robust to withstand the service environment) and, once again, inert surfaces are required (ie insignificant release of contaminants into the product).

Stainless steels are widely used in the pharmaceuticals industry because of their resistance to corrosion, inert (easily cleaned) surfaces and ease of fabrication. Although grade 1.4401 (AISI 316) and its derivatives are the most widely used stainless steels in pharmaceutical plant and are considered by many as the industry standard, materials for each application are selected on the basis of their resistance to corrosion in a specific service environment. The selection of a suitable grade of stainless steel must also include consideration of the cleaning regime and cleaning agents used in the plant. Furthermore, the operation of the plant (whether continuous with a “clean in place” system or batch operation with shutdowns to clean the plant) may also influence the choice of material.

The austenitic stainless steel grade 1.4031 (AISI 304) and its derivatives are used in mild environments where the chloride content is less than 200 mg/l, while grade 1.4401 (AISI 316) and its derivatives may be used with chloride contents up to 500 mg/l. At higher chloride contents and especially if combined with increased operating temperatures, the duplex stainless steels grades 1.4462 (2205) and 1.4362 (2304) are used for their resistance to stress-corrosion-cracking. For more aggressive service environments, the superaustenitic (e.g. 1.4547) and superduplex (e.g. 1.4410) grades may be required. Typical examples of stainless steel applications in pharmaceutical production are processing and reaction vessels, storage tanks/vessels, pumps, pipelines and tubes, heat exchangers, scrubber units, taps and valves.

The author is not aware of any studies on metal release from stainless steels in contact with pharmaceutical products or, indeed, any regulations where metal release levels are specified. Pharmaceutical producers require contact materials to be sufficiently inert to protect both the efficacy of their product and the well-being of end users. However, this requirement is seldom specified.

Discussion and Summary
The stainless steel family offers a remarkable and extremely versatile range of engineering materials well adapted to hygienic applications. However, grade selection is a critical feature in achieving structural integrity, adequate corrosion resistance and protection of the product throughout the design life.

In contrast to these industrial considerations, Regulators are concerned with the potential impact of metals and alloys on human health. Metal release from stainless steels in contact with foodstuffs, drinking water, body fluids/human tissue and pharmaceutical products is determined by the presence, and integrity, of the passive oxide film. Therefore, selection of an appropriate grade of stainless steel is also critical in limiting the level of metal release. Regulators have begun to recognise that the bioavailability of metals is determined by the level of metal release and not by their chemical composition.
In applications where stainless steels in contact with drinking water and foodstuffs, Regulators are concerned with the contribution of released metals to the total daily or weekly dietary intake of consumers. Tests on stainless steels in contact with food and drinking water indicate very low levels (i.e., parts per billion) of metals release, which is below levels found in many foodstuffs.

For medical devices, especially implants, the regulatory concerns are threefold. Firstly, the potentially lethal effects from the release of cumulative poisons and secondly, the effect of an accumulation of allergens on human health. In this second concern, there is evidence to suggest that, for those not already sensitised, slow release of nickel from dental arch wires and brackets may, in fact, reduce the likelihood of future nickel sensitisation. Thirdly, the potential to increase the total body burden of metals may have a combined effect with the total daily or weekly dietary intake to generate adverse health effects.

The metal release implications for pharmaceutical products are more complex and less easily identified. The main concerns are presence of unwanted chemical species in the product that may adversely affect its efficacy or interference with metabolism of the patient. There seems to be little guidance in this area beyond the requirement that contact materials should be inert.

In summary, stainless steels have an excellent and well-established track record in hygienic applications. The various subgroups within the stainless family, which offer a unique combination of corrosion resistance (moderate to excellent) and wide variety of mechanical/physical properties, provide range of materials that meet the need of consumers and professional users. In addition, the concerns of Regulators may be satisfied by appropriate selection of a suitable grade for specific hygienic applications.


**References**

1. Guidelines on metals and alloys in contact with food; Council of Europe; published 11.10.2000.

2. Systemic nickel: the contribution made by stainless steel cooking utensils; Contact Dermatitis, Volume 32:2, 1994


4. Review of metal release from ferritic, austenitic and duplex stainless steel grades exposed to potable water and related adverse environments; M Lewus, T.Newson, B Lee and D Dulieu; 4th European Stainless Steel Science and Market Congress, Pair, June 2002.

5. ISO 7153-1 Surgery – Metallic materials - Part 1: Stainless steels


Stainless Steel for Hygienic Applications

Figure 1 – Examples of stainless steel in food contact applications

Figure 2 – Commercial kitchen using stainless steels in food contact applications
Stainless Steel for Hygienic Applications

Figure 3 – Stainless steel brewing vats

Figure 4 – Stainless steel beer barrels
Figure 5 – Surgical application of stainless steels

Figure 6 – Stainless steel dental scalers (grade 1.4028)
Figure 7– Stainless steel surgical needle holders (1.4021)
Figure 8 – Stainless steel bone plate and bone screws (Implant – Composition D)