European Regulation and Stainless Steel

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Introduction

This paper addresses European health and environmental regulation as it applies to the product, stainless steel, posing threats to the markets for stainless steel. The paper focuses on three aspects, the first two of which are closely related:

i. hazard classification;
ii. metal ion release;
iii. trace elements.

Of course, there is also regulation that applies to the workplace and the manufacturing process in relation to control of emissions etc. However, this type of regulation applies to all workplaces and causes few, if any, "excess" problems due specifically to the fact that the workplace is a stainless steel manufacturing plant.

What is European regulation?

There are several types of EU legislation. The main ones that are applicable to all Member States (unless otherwise specified) are:

- Directives
  - Council
  - European Parliament and Council
  - Commission
- Regulations

Directives are addressed to the Governments of the Member States (MS). They stipulate the results to be achieved and the deadline(s), but leave the form of the legislation and the methods to be decided by each of the MS. *Regulations* are directly applicable and binding in all MS on the date of publication in the Official Journal. There are also Council or Commission *Decisions* that apply specifically in one or more MS and are directly binding; and the Commission also publishes *Communications*, *Recommendations*, *Green Papers* and *White Papers*. European/international *standards* and/or *Technical Guidance Documents* are also important for the implementation of many Directives/Regulations.

EU legislative procedure and institutions involved
The role of the European Commission (EC) is to ensure that the objectives of the EU Treaties are attained via appropriate legislative and other policies, and to monitor and enforce the implementation and practice of the EU laws and other policies. The EC is thus the only EU institution that can propose legislation. Following adoption by the "college" of twenty Commissioners, formal proposals for Directives (other than Commission Directives) and Regulations are submitted to the European Parliament and the Council of Ministers for their adoption. Representatives of MS Governments (and

other stakeholders) are usually heavily involved during the development of the formal EC proposal.

Stainless steel - perception

General population
When most people think of stainless steel, they think of a material that is strong, safe, clean, hygienic and beautiful. Those of us with a little more knowledge will add to this list more technical properties such as, in particular, corrosion resistance. And we know that "stainless steel" is a term that describes a diverse family of alloys of which there are some 200 grades that allow selection of stainless steels to fulfil a very wide range of applications ranging from high-tech industry through the chemicals, food, wine, catering, water distribution and pharmaceutical industries, use in medical devices, architecture and transport to relatively mundane, but very important, consumer uses such as pots and pans, other kitchenware, cutlery etc. It can truthfully be said that stainless steels are vital to the infrastructure of the western world.

Regulators
When regulators in their private capacities think of stainless steel, it is highly likely that the majority of them also think of words like strong, safe, clean, hygienic, beautiful. Some of them do, or should, know that stainless steels are alloys and understand something about their more technical properties.

However, as regulators, they see stainless steel as comprising a mixture of metals that bring their own properties, including toxicity and eco-toxicity, to the material. The fact that the whole point of making alloys is to make materials that have different properties from their component elements is a concept that seems to have no place in the European regulatory framework.

European regulation and stainless steel

The following European legislation and its implications for stainless steel will be discussed, but the list is not claimed to be comprehensive. In addition, there is a constant trickle of new/amending/daughter legislation that has the potential for impact on stainless steel. Certain UN/OECD regulatory activities and recommendations of the WHO and the Council of Europe will also be addressed as they have important implications in relation to some EU legislation.

- EU Directives on the classification and labelling of "dangerous substances" (67/548/EEC) and dangerous "preparations" (1999/45/EC);
- the UN/OECD "Globally Harmonised System" of classification and labelling of chemicals (http://www.unece.org/trans/danger/publi/ghs/officialtext.html);
- the proposed new EU legislation on chemicals management policy (White Paper, February 2001);
- the EU risk assessment Regulation ((EEC) No 793/93);
- the EU marketing and use Directive (76/769/EEC) and its daughter "jewellery Directive" (94/27/EC);
- the EU water framework and drinking water Directives (2000/60/EEC and 98/83/EC respectively) and legislation on construction products in contact with drinking water;

- the EU Regulation on food safety ((EC) No 178/2002) and Council of Europe recommendations on metals and alloys (March 2001);
- EU legislation on medical devices (93/42/EEC);
- EU "end-of-life" legislation on vehicles (2000/53/EC), waste electrical and electronic equipment (2002/96/EC), and legislation on restriction of use of hazardous substances in electrical and electronic equipment (2002/95/EC);
- EU proposal on Integrated Product Policy (EC Green Paper, February 2001).

Hazard classification

In the EU, metals are subject to the same regulation as chemicals. The basic legislation under which chemicals are classified (in relation to their intrinsic hazardous properties) and labelled is the Dangerous Substances Directive (67/548/EEC). It is worth noting that the standard test methods that are used to identify the (eco)toxicity of chemicals in the EU are, in general, unsuitable for use with metals.

In the Dangerous Substances Directive, all chemicals are defined either as "substances" (e.g. sodium chloride, benzene, nickel) or "preparations" (i.e. mixtures or solutions of one or more substances). At the time that the EU list of substances on the market was being established, industry and the regulators decided jointly that metallic alloys should be considered to be preparations. This decision had little negative consequence until the publication of the first "Dangerous Preparations Directive" (DPD) in 1988 (88/379/EEC).

Under this Directive, "preparations" are classified essentially in one of two ways:

- in accordance with the amount of a classified substance they contain (the so-called "conventional method"); or
- on the basis of their own hazardous properties.

However, for certain hazards (carcinogenicity, mutagenicity and reproductive toxicity), only the conventional method is allowed (i.e. the preparation cannot be "tested out").

Classification of stainless steel
As a "preparation", stainless steel that contains a concentration of a classified metal at or above the cut-off limit defined in the DPD has also to be classified. Currently, the only metal of relevance to stainless steel that is classified is nickel. Nickel is classified as a skin sensitiser (i.e. it can cause allergy to nickel) and as a material suspected as being able to cause cancer via inhalation. As a consequence of the rules of the DPD, the Material Safety Data Sheets for stainless steels that contain more than 1% of nickel are obliged to carry the following "risk phrases":

- R43 May cause sensitisation by skin contact
- R40 Limited evidence of a carcinogenic effect

This application of simple rules, devised for simple chemical mixtures, to complex materials like stainless steels, results in unjust classification that clearly has potential to affect the market for nickel-containing grades of stainless steel. In fact, some important alloy user companies have black or grey lists of materials to be avoided simply because they carry a hazard classification. And, while we may be able to counter R43, using

evidence for the nickel-containing stainless steels themselves, showing that they cannot cause skin sensitisation, the current legislation does not allow use of test data on stainless steel to remove the R40 classification.

The alloys industry, globally, has worked for several years now to try to change the regulatory attitude to alloys and gain recognition that hazard classification on the basis of content of classified elements represents a fundamentally flawed approach to hazard assessment for such materials. Considerable progress was made in both the EU and the OECD. In the EU, a revision of the DPD was developed to take account, *inter alia*, of the need to introduce rules for the environmental classification of preparations. The alloys industry was successful in gaining recognition of the need to consider a different approach for alloys, and the following text is included in the introductory part of the revised DPD (1999/45/EC):

> *Whereas the characteristics of alloys are such that it may not be possible accurately to determine their properties using currently available conventional methods; whereas it is therefore necessary to develop a specific method of classification which takes into account their particular chemical properties; whereas the Commission, in consultation with Member States, will examine this need and submit a proposal, if appropriate, before the implementation date of this Directive;* [30 July 2002]

In parallel, the OECD was working for the UN on the development of a globally harmonized system (GHS) of classification and labelling of chemicals (and preparations). Within this forum, industry succeeded in having introduced the possibility, with certain caveats, to test out for all toxicological endpoints, including carcinogenicity, mutagenicity and reproductive toxicity; and the concept of a "weight of evidence" approach, which may be very important for alloys, is explicit in the GHS. Although implementation of the GHS will be voluntary, the EU, via both the EC and the individual Member States, has "signed up" to the GHS and has a moral obligation to implement it at some point (the UN has indicated a desire to see the GHS implemented globally by 2008).

However, the proposed all-embracing New EU Chemicals Management Policy (NCMP) has halted the progress that was expected before implementation of the revised DPD. It is hoped, but not certain, that the GHS will be implemented via the NCMP and that the non-applicability of the "conventional method" for the classification of alloys will be recognized.

This appears to be a good situation for alloys, including stainless steel, and certainly there are potential opportunities within the proposed new legislation. But it will be vitally important that a more flexible attitude than has been apparent in the past is taken in relation to basing decisions on data derived from non-standard tests. This is because the standard test methods for chemicals have been developed for use essentially with organic chemical compounds and many of them simply cannot be used to test metals/alloys. One problem with non-standard tests is that they may give more indicative than definitive results. For example, with metals and alloys, very low (sub-threshold) release rates for the metal ion(s) of concern may be submitted as part of the weight of evidence for non-classification. While metal ion release rates, with only a little other information, may be acceptable for some (eco)toxicological end-points, it is understandable that for more

"high level" toxicity, such as carcinogenicity or reproductive toxicity, considerably more information may be required to convince regulators, and ourselves, that the toxicity of a particular element is not expressed when that element is alloyed with other elements.

Is this of any significance for stainless steel?

EU Risk Assessment Regulation
Under this Regulation, a mandatory risk assessment is being conducted on metallic nickel and a number of nickel compounds, with the Danish authorities acting as rapporteur on behalf of the Member States. A component part of chemical risk assessment is to review the classification of the substance following evaluation of the hazard identification data. If the outcome of this review leads to any higher-level toxicity classification for nickel, and/or to classification for effects on the environment, it may be considerably more difficult to "prove" that the affected stainless steels need not be classified.

Other alloying elements
Currently, nickel is the only classified metal used in stainless steel. However, within the context of the Dangerous Substances Directive, the UK has proposed that molybdenum trioxide should be classified as a suspect carcinogen (R40). In preparation for its obligations under the coming NCMP, the chromium industry is supporting a voluntary risk assessment on metallic chromium – this could lead to some hazard identification. And all metals will need to have similar assessments carried out on them to fulfill the requirements of the NCMP.

Authorisation and the NCMP
Another legislative bullet will be aimed at stainless steel if any of its alloying elements are classified in certain toxicity categories: in the proposed NCMP, the use of chemicals of high concern by reason of their toxicity will have to be authorised. Authorisation is likely to be for a limited period, during which time industry will be expected to find a less dangerous substitute. Certain stakeholders want sensitisation to be included in the list of end-points of high concern; and some MEPs have expressed a desire for a complete ban on the use of sensitisers by 2012. Such action would effectively ban the production and use of nickel-containing stainless steels in the EU!

Summary – hazard classification

Only methods that are suitable should be used for the testing and hazard classification of metals and alloys. The use of unsuitable methods that lead to unjustified classification can unnecessarily damage the market and restrict the choices available to potential users.

Metal ion release

There is already a body of EU legislation that utilizes, *inter alia*, the rate/extent of metal ion release as an indicator for the potential of a metal or alloy to cause harm to either health or the environment.

Jewellery Directive
The aim of this Directive is to reduce the incidence of nickel sensitization via controls applied to articles that are intended for use in "direct and prolonged contact" with the

skin, such as jewellery, and those that are used to maintain piercings while the wound is healing ("post assemblies").

According to this Directive, articles that are for use in direct skin contact applications for prolonged periods should not release more than 0.5 μg of nickel per cm^2 per week when tested in artificial sweat in accordance with a CEN standard test protocol. Application of this test to stainless steel shows that, of all the grades tested, only the resulfurised grade 303 is likely to fail this test.

In an interesting converse criterion in relation to post assemblies, the Directive currently indicates that post assemblies must be homogeneous and that the concentration of nickel, expressed as mass of nickel to total mass, should be less than 0.05 %. This precludes the use of the preferred grade of stainless steel (316L) for post assemblies and may thereby allow the use of less well-characterised materials for this increasingly common application. However, as part of the foreseen review of this Directive, a study and risk assessment are underway that may result in an exemption from the 0.05% rule for one or more grades of stainless steel; and even the most cautious of the stakeholders involved in the discussions about this Directive now support the premise that, even for materials used for post assemblies, the rate of nickel release should be the key criterion.

Other legislation

The drinking water Directive establishes a parametric value for nickel of 20 μg/litre, based on the WHO health-based guidance value for nickel. A new European Acceptance Scheme (EAS) has been proposed for construction products in contact with drinking water. This will include a positive list of products that may be used. One of the criteria that is being addressed by the metals Working Group of the committee working on the EAS is the contribution of metal "contaminants" by metals used in construction products in contact with drinking water. With appropriate grade selection, stainless steel products are expected to meet the relevant metal release criteria. However, when considering metals in water, it should not be forgotten that there will always be a natural background concentration. If regulators, taking a more precautionary approach, wish to reduce the parametric values for "contaminants" in drinking water that are, in part, of natural origin then the margin for addition from construction products becomes smaller. This is not currently considered to be a problem for stainless steel, but it is important that we avoid unjustified reductions in the permitted values.

The water framework Directive addresses environmental issues in relation to surface and groundwater. The Directive includes a list of priority substances (i.e. substances of concern for water quality): this list includes nickel. There is therefore the potential that the increasing use of stainless steel in architectural and street furniture applications could be restricted on the grounds that such use may contribute to increased nickel concentrations in surface and ground waters. However, data are available that show that nickel release from stainless steel under normal environmental condition is negligible. There is also an OECD regulatory guideline currently undergoing validation that will provide quantitative data on the transformation of metals/alloys in water and the subsequent dissolution of the metal ions. These data will be used in the classification of metals and alloys for potential effects on the aquatic environment.

Metals and alloys, particularly stainless steels, are used in many food contact applications (e.g. in food and beverage production and storage, catering and cooking, for

cutlery). The recent EU Regulation on food safety foresees the establishment of a Panel on food additives, flavourings, processing aids and materials in contact with food. Most of the current interest on materials in contact with food is related to plastics and materials that may leach from them into foods. In March 2001, the Council of Europe published its recommendations on metals and alloys in food contact materials: with the proviso only that before first use, new stainless steel food contact items are exposed to boiling water and the water is discarded (to avoid the occurrence of undesirable levels of nickel), use of appropriate grades of stainless steels in food contact applications gives rise to no concern about excessive release of metal ions inot foods and beverages.

Stainless steels are also widely used in medical devices. Methods have been developed for the toxicological and stability testing of metallic products used in/as medical devices. The approaches taken for this application may be of value for the hazard assessment of stainless steels under other EU legislation (e.g. the proposed NCMP).

Conclusion – metal release

There are precedents in EU regulation for use of metal ion release data to demonstrate that metallic alloys may be used without risk to human health, and a test is under development that will also address identification of potential environmental hazards from metals/alloys based essentially on metal release rates. Such approaches naturally take into consideration the intrinsic properties of alloys and provide a far more realistic basis for hazard classification (and risk assessment) than the mass composition of the alloy.

Trace elements

There is increasing EU regulatory interest in the end-of-life of products/materials with a view to increasing recycling/reuse and decreasing adverse impacts on the environment. One particular objective is to restrict the permitted concentrations of certain "heavy metals" to very low levels, even zero. Current regulatory interest focuses on lead, mercury, cadmium and hexavalent chromium. A problem for metals and alloys is that traces of these restricted metals (though not, of course, hexavalent chromium) may be naturally present in the products.

Industry has been successful in gaining an amendment to the relevant Annex to the end-of-life vehicles Directive in which the following text now appears:

> *Since it is evident that a total avoidance of heavy metals is in some instances impossible to achieve, certain concentration values of lead, mercury, cadmium or hexavalent chromium in specific materials and components should be tolerated, provided that these hazardous substances are not intentionally introduced.*

Unfortunately, no such text has been included, yet, in either the waste electrical and electronic equipment or the restriction of use of hazardous substances Directives.

Finally, the proposed EU Integrated Product Policy (IPP) should be mentioned as this has the potential to apply to stainless steels or to products made from them. A Green Paper was published in February 2001 in which IPP appeared to be addressed within the three-pillar concept of Sustainable Development. A leaked text for the IPP White paper

has recently appeared in which the emphasis has shifted almost entirely to environmental aspects: the social and economic parameters seem no longer to be included. If only environmental aspects are considered, metals and alloys have the potential to "score" badly e.g. in relation to use of energy. It is vitally important therefore that industry pushes for the inclusion of social and economic factors, and for factors such as the recyclability/recycling of metals/alloys to be taken into account to avoid unjustified adverse conclusions being reached about our products.

Conclusions

There is a huge amount of EU legislation that impinges on the product, stainless steel, and that has the potential to damage our markets. In this paper, some of the technical and lobbying activities that are being used to counter the development and use of inappropriate legislation and methods for the regulation of stainless steels have been mentioned. The following paper goes further into how to ensure the future market for stainless steel.