Dear colleagues,

Over the past months, standardisation activities in Europe have focused mainly on the proposal for a regulation of the European Commission on the marketing of medical devices[1].

Indeed, Council Directive 93/42/EEC, which is currently applicable but will become null and void with the adoption of the proposed regulation, plans the participation of CEN TC55 in the development of harmonised standards relevant to the Directive. A harmonised standard lays down assessment procedures to demonstrate the conformity of specific restricted categories of devices with the requirements of the Directive

CEN TC55 is therefore empowered to propose amendments during parliamentary debates, particularly with regard to implantable devices and nanoparticles.

The proposed regulation introduces the requirement to provide the implanted patient with an implant card, whatever the host tissues and the level of risk associated with the device. The requirement applies to our European colleagues if we consider that "implantable device" means any device intended to be totally or partially introduced into the human body by clinical intervention and to remain in place for at least 30 days. All our dental restoration products fall into this category…

It is therefore perfectly legitimate to exclude from this requirement all the devices, except dental implants, used by our colleagues, but CEN TC55 has decided, on the contrary, to ask the European Commission to exclude dental restoration devices from the definition of implantable devices. It would be surprising that the Commission grant such a request as nothing justifies changing the definition. However, it is quite likely and most desirable that the Commission will modify the rule regulating implant carrier cards so that it excludes dental implants.

The issue of nanoparticles poses the same kind of difficulty in formulating one single rule for such a varied array of devices. The Commission considers that nanoparticles are dangerous, and would like the provisions regulating Class III devices (highest risk level, safety obligations …) to apply to all medical devices that contain or may release nanoparticles (e.g. during polishing, burring…). Here again, CEN TC55 has asked the Commission to revise the definition of nanoparticles and the rules that apply to them in order to prevent medical devices that have proven to be of low risk from becoming too expensive and, consequently, inaccessible.

Another topic, which has not been considered by CEN TC55, yet having a great impact on our colleagues' activity, is the issue of dental prostheses. The issue must be analysed and our colleagues' interests defended.

More specifically, the proposed regulation lays down rules for the marketing on the Union market of medical devices manufactured outside the European territory that should guarantee greater transparency, traceability and means of control. Greater emphasis is placed on the role of the manufacturer's authorised representative, with all non-EU manufacturers being under the obligation to designate a single authorised representative for the whole of the EU and to provide their representative with all the information and documentation required from EU-based manufacturers to demonstrate the conformity of a device. In addition, the newly-introduced

[1] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0542:FIN:EN:PDF

concept of "importer" adds an economic operator who will not be able to claim to be either a EU manufacturer or a manufacturer's authorised representative and who, as importer solely, will have an obligation of transparency towards clinicians. It will thus be easier for the notified bodies and European medical safety agencies to trace incidents and identify non-EU manufacturers through their single authorised representatives and the reports of all the importers and users.

In any case, I suggest that the European National Dental Associations read the proposed regulation and consider its consequences on our colleagues' practice.

On another matter, and although the topic goes well beyond the ERO borders, I think it is important to mention the ISO projects for dental identification. Following the natural disasters and the transport accidents that made so many victims from so many different nationalities on the same sites, and tourist sites especially, the need to improve communication and the exchange of international data relating to dental identification has become quite clear. There are many stakeholders involved, including dentists, search and rescue teams, Interpol, law enforcement services, soldiers, and software publishers, one of the major ones working on disaster victims identification being Danish.

A preliminary meeting will be held in Incheon, South Korea, in October 2013. The purpose of the meeting will be to prepare one or more dental identification standards projects. I will gladly provide further information to all interested ERO members. Registration for this event is open to all stakeholders concerned but must be completed through a standardisation agency. I will facilitate registration for any ERO delegate who would like to attend.

I will not be attending the next ERO Plenary Session in Istanbul but Roland L'Herron, if the Board so wishes, can make an oral presentation of this report and answer questions from the delegates.

Respectfully yours,

Dr. Philippe Calfon
In charge of the Standardisation unit of the ADF French Dental Association
Chairman ISO TC106 SC3 "Dentistry – Terminology"
Chairman CEN TC55 WG5 "Nomenclature and coding system for medical devices used in dentistry"
ERO/CEN TC 55 Liaison Officer