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Examination of *Vademecum* on European Standardisation – objection to Harmonised standards

This article examines Part II of the *Vademecum* and Final *Vademecum* Part 2/3 critically, relevant legal provisions concerning medical devices subject to Council Directive 93/42/EEC, by way of example, connexion to Commission Decision No 768/2008/EC and Commission Notice 2016/C 272/01, explores how an allegedly deficient Harmonised standard is objected and examines potential incoherence.

Vademecum on European Standardisation Part II European standardisation in support of European policies Chapter 6 Procedure for formal objections against harmonised standards 15 October 2009 was written by DG ENTR/13 European Commission. The draft *Vademecum* was revised 14 October 2014 and submitted to the Committee on Standards under Regulation (EU) No 1025/2012 and said to have been revised substantially. A final draft *Vademecum* was placed on the Notification system website (date unknown).

The *Vademecum* presents guidelines on administration of a formal objection to a harmonised standard according to Decision No 768/2008/EC.

According to §1.1. ¶2 of the *Vademecum*, a Harmonised standard does not necessarily need to fulfil all Essential requirements specified by the Directive concerned. Therefore, only deficiencies (shortcomings) against an Essential requirement may be challenged. §2.2. of the *Vademecum* confuses common understanding of Harmonisation.

Commission Notice 2016/C 272/01 presents guidance on Harmonised standards, citing the *Vademecum* (SWD (2015) 205 final 27.10.2015).

Incoherently, according to the Commission Notice, even if a manufacturer has not used harmonised standards, a change in a relevant harmonised standard could mean a change in the state-of-the-art that implies that his product may not be compliant. GROW.DDG1.B. 3 published Action plan: structural solutions to decrease the stock of non-cited harmonised standards (ARES (2017)-491 9072-09/10/2017) to improve legislative compliance of harmonised standards during their development.

Limited provisions are promulgated by and suspected informal procedures exist at the European Commission to deal with such eventualities. Instead, the Commission relies on the *Vademecum* and certain elements of Regulation (EU) No 1025/2012 – the latter invoking Commission Decision No 768/2008/EC – to control objections.

The *Vademecum* – as with Regulation (EU) No 1025/2012 and Commission Notice 2016/C 272/01 – fails to deal with consequences of pass-through normative standards and numerous problems created by Annex Z legitimation promulgated in European standards.

The *Vademecum* reveals an opaque, vague and distichous approach, whereby *sui generis* legislation mixes with non-majoritarian standards to confer or extend legitimacy. Existence of very limited case law means manufacturers continue to be left in precarious position and in the case of medical devices, patients afforded questionable protection.

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Recent events and initiatives concerning harmonised standards are discussed.

European standardisation system

The European Commission revised the *Vademecum* on European standardisation to align it with reforms brought by the Regulation and Communication for standards.

According to SWD (2016) 126 final, the *Vademecum* also sets guidelines for the European standardisation organisations to ensure transparency and inclusiveness during execution of Commission requests.

European standardisation organisations

CEN, Cenelec and ETSI are recognised by Article 2(8) of the Regulation as European standardisation organisations (ESO).

- CEN (the European Committee for Standardisation) exercises standardisation activities in all fields, except for electro-technology and telecommunications
- Cenelec (the European Committee for Electro-technical Standardisation) exercises standardisation activities in electro-technical field
- ETSI (the European Telecommunications Standards Institute) exercises standardisation activities in ICT and telecommunications fields

Each ESO is an independent, non-profit organisation consisting of two main parts: a "secretariat" and a "network".

Each ESO secretariat handles administrative and practical matters and ensures standards are developed according to agreed (open, transparent, inclusive) processes. The CEN / Cenelec Management Centre (CCMC) in Brussels is the joint secretariat of CEN and Cenelec, while ETSI secretariat is in Sophia Antipolis in the south of France.

Members of CEN and Cenelec (legal entities) are the NSBs covering 28 EU Member States, the Former Yugoslav Republic of Macedonia and Turkey and EFTA countries Iceland, Norway and Switzerland. In the case of ETSI, industry and other stakeholders on a worldwide basis (around 800 members from 64 countries) are also members of the organisation.

National standardisation bodies (NSBs)

National standardisation bodies (NSBs) are the organisations (legal entities) who develop and adopt national standards are recognised nationally and notified by the Member States to the Commission. These bodies represent the interest of national interested parties in standardisation. Usually, these bodies are also members of CEN, Cenelec and/or ETSI and ISO and/or IEC. Standardisation matters for a given country are either handled by a single NSB, or more than one NSB (within their respective fields of expertise, similar to ESO fields). NSBs may be either public or private sector organisations, or combinations of the two, and may undertake a range of related activities in addition to standards development and adoption.

According to SWD (2016) 126 final, NSBs play a pivotal role in the ESS, enabling interested parties (industry and other stakeholders) to participate in elaborating and approving standards at national, European and international (ISO/IEC) levels.

Regulation (EU) No 1025/2012, providing the legal basis of the ESS, applied since 2013. According to SWD (2016) 126 final, overall, no major issue was identified concerning application of relevant provisions of the Regulation by ESOs, their national members (National Standardisation Bodies or NSBs, and National Standardisation Organisations or NSOs) or stakeholders organisations eligible for Union financing (the Annex III organisations).

In this framework, standardisation activities supported by Union financing in 2013 – 2014 (and in the period immediately before) are explicitly and directly linked to policy objectives of the Commission, and linked with EU priorities as set out in the Annual Union Work Programme and/or the ICT Rolling Plan.

For efficiency assurance, the *Vademecum* on European standardisation in support of Union legislation and policies has been defined as a tool addressed to all parties participating in the system and aimed at clarifying mechanisms for and role of the Commission's standardisation requests.

According to SWD (2016) 186 final, standardisation is interlinked with Union policies: it is designed to play a coherent role in the development of the Single Market.

The Commission asserts development of harmonised standards targets removal of trade barriers in the Single market, representing a major added value of European standardisation. It is also asserted the ESS assumes direct EU relevance and pursues objectives that could not be achieved nationally and that companies, particularly, can benefit from reduced transaction costs, increased interoperability and development of common technical language within the European Single Market.

Commission staff working document Vademecum Part II (p40/80)

The following articles in the *Vademecum* invoke Articles 10 and 11 in Regulation (EU) No 1025/2012 to clarify constitution of a standard committee.

Article 5 *Vademecum*

A Standing Committee shall be set up consisting of representatives appointed by the Member States who may call on the assistance of experts or advisers; its chairman shall be a representative of the Commission.

The Committee shall draw up its own rules of procedures.

Whereas it is necessary to set up a Standing Committee, the members of which will be appointed by the Member States with the task of helping the Commission to examine draft national standards and cooperating in its efforts to lessen any adverse effects thereof on the free movement of goods.

The Vademecum cites Commission Decision No 768/2008/EC Annex I Chapter R3 Article R9:

Article R9 Commission Decision No 768/2008/EC Annex I Chapter R3

Formal objection to a harmonised standard

When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in … [reference to the relevant part of the legislation], the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.

In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

Article 10 Commission Decision No 768/2008/EC Annex I Chapter R3

Standardisation requests to European standardisation organisations

1. The Commission may within the limitations of the competences laid down in the Treaties, request one or several European standardisation organisations to draft a European standard or European standardisation deliverable within a set deadline. European standards and European standardisation deliverables shall be market-driven, take into account the public interest as well as the policy objectives clearly stated in the Commission's request and based on consensus. The Commission shall determine the requirements as to the content to be met by the requested document and a deadline for its adoption.

2. The decisions referred to in paragraph 1 shall be adopted in accordance with the procedure laid down in Article 22(3) after consultation of the European standardisation organisations and the European stakeholder organisations receiving Union financing in accordance with this Regulation as well as the committee set up by the corresponding Union legislation, when such a committee exists, or after other forms of consultation of sectoral experts.

3. The relevant European standardisation organisation shall indicate, within one month following its receipt, if it accepts the request referred to in paragraph 1.

4. Where a request for funding is made, the Commission shall inform the relevant European standardisation organisations, within two months following the receipt of the acceptance referred to in paragraph 3, about the award of a grant for drafting a European standard or a European standardisation deliverable.

5. The European standardisation organisations shall inform the Commission about the activities undertaken for the development of the documents referred to in paragraph 1. The Commission together with the European standardisation organisations shall assess the compliance of the documents drafted by the European standardisation organisations with its initial request.

6. Where a harmonised standard satisfies the requirements which it aims to cover and which are set out in the corresponding Union harmonisation legislation, the Commission shall publish a reference of

such harmonised standard without delay in the Official Journal of the European Union or by other means in accordance with the conditions laid down in the corresponding act of Union harmonisation legislation.

Article 11 Commission Decision No 768/2008/EC Annex I Chapter R3

Formal objections to harmonised standards

1. When a Member State or the European Parliament considers that a harmonised standard does not entirely satisfy the requirements which it aims to cover and which are set out in the relevant Union harmonisation legislation, it shall inform the Commission thereof with a detailed explanation and the Commission shall, after consulting the committee set up by the corresponding Union harmonisation legislation, if it exists, or after other forms of consultation of sectoral experts, decide:

(a) to publish, not to publish or to publish with restriction the references to the harmonised standard concerned in the Official Journal of the European Union;

(b) to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the Official Journal of the European Union.

2. The Commission shall publish information on its website on the harmonised standards that have been subject to the decision referred to in paragraph 1.

3. The Commission shall inform the European standardisation organisation concerned of the decision referred to in paragraph 1 and, if necessary, request the revision of the harmonised standards concerned.

4. The decision referred to in point (a) of paragraph 1 of this Article shall be adopted in accordance with the advisory procedure referred to in Article 22(2).

5. The decision referred to in point (b) of paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 22(3).

Council Directive 93/42/EEC adds:

Council Directive 93/42/EEC

Whereas, in accordance with the principles set out in the Council resolution of 7 May 1985 concerning a new approach to technical harmonization and standardization (2), rules regarding the design and manufacture of medical devices must be confined to the provisions required to meet the essential requirements; whereas, because they are essential, such requirements should replace the corresponding national provisions; whereas the essential requirements should be applied with discretion to take account of the technological level existing at the time of design and of technical and economic considerations compatible with a high level of protection of health and safety;

Whereas, in order to demonstrate conformity with the essential requirements and to enable conformity to be verified, it is desirable to have harmonized European standards to protect against the risks associated with the design, manufacture and packaging of medical devices;

whereas such harmonized European standards are drawn up by private law bodies and should retain their status as non-mandatory texts; whereas, to this end, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines on cooperation between the Commission and these two bodies signed on 13 November 1984;

Whereas, for the purpose of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted, on a mandate from the Commission, by either or both of these bodies in accordance with Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (1), and pursuant to the abovementioned general guidelines; whereas with regard to possible amendment of the harmonized standards, the Commission should be assisted by the Committee set up pursuant to Directive 83/189/EEC; whereas the measures to be taken must be defined in line with procedure I, as laid down in Council Decision 87/373/EEC (2); whereas, for specific fields, what already exists in the form of European Pharmacopoeia monographs should be incorporated within the framework of this Directive; whereas, therefore, several European Pharmacopoeia monographs may be considered equal to the abovementioned harmonized standards;

Article 5 Council Directive 93/42/EEC

Reference to standards

1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been publishes in the Official Journal of the European Communities; Member States shall publish the references of such national standards.

2. For the purposes of this Directive, reference to harmonized standards also includes the monographs of the European Pharmacopoeia notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, the references of which have been published in the Official Journal of the European Communities.

3. If a Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6 (2).

Article 8 Council Directive 93/42/EEC

Safeguard clause

1. Where a Member State ascertains that the devices referred to in Article 4 (1) and (2) second indent, when correctly installed, maintained and used for their intended purpose, may compromise the health and/or safety of patients, users or, where applicable, other persons, it shall take all appropriate interim measures to withdraw such devices from the market or prohibit or restrict their being placed on the market or put into service. The Member State shall immediately inform the Commission of any such measures,

indicating the reasons for its decision and, in particular, whether non-compliance with this Directive is due to:

(a) failure to meet the essential requirements referred to in Article 3;

(b) incorrect application of the standards referred to in Article 5, in so far as it is claimed that the standards have been applied;

(c) shortcomings in the standards themselves.

Regulation (EU) 2017/745 states:

Regulation (EU) 2017/745

(22) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council (2) should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality and risk management, laid down in this Regulation.

Article 10 Regulation (EU) 2017/745

General obligations of manufacturers

2. Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I.

9. ...

The quality management system shall address at least the following aspects:

(e) risk management as set out in in Section 3 of Annex I;

Annex I General safety and performance requirements Regulation (EU) 2017/745

Chapter I General requirements

3. Manufacturers shall establish, implement, document and maintain a risk management system. Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

(a) establish and document a risk management plan for each device;

(b) identify and analyse the known and foreseeable hazards associated with each device; (c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;

(d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;

(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and

(f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

4. Risk control measures adopted by manufacturers for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art.

To reduce risks, Manufacturers shall manage risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, manufacturers shall, in the following order of priority:

(a) eliminate or reduce risks as far as possible through safe design and manufacture;

(b) where appropriate, take adequate protection measures, including alarms if necessary, in relation to risks that cannot be eliminated; and (c) provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users. Manufacturers shall inform users of any residual risks.

5. In eliminating or reducing risks related to use error, the manufacturer shall:

(a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

6. The characteristics and performance of a device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.

7. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use are not adversely affected during transport and storage, for example, through fluctuations of temperature and humidity, taking account of the instructions and information provided by the manufacturer.

8. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

9. For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes

intended, does not present a risk at all or presents a risk that is no more than the maximum acceptable risk related to the product's use which is consistent with a high level of protection for the safety and health of persons.

The table of content of the Commission staff working document *Vademecum* Part II compared to the Final *Vademecum* published Part 2/3 is as follows:

	Final *Vademecum*		Staff working document
Element	Title	Element	Title
0.	Introduction	0.	Introduction
1.	Objectives	1.	Objectives
2.	Procedure for the preparation and adoption of a standardisation request	2.	Procedure for the preparation and adoption of a standardisation request
2.1	Responsibilities between the Commission services during preparation and adoption	2.1.	Responsibilities of Commission departments
2.2	Overall workflow during preparation and adoption	2.2.	Overall workflow during preparation and adoption
2.2.1	Planning phase (Article 8, Article 10(1) and Article 12 point a)	2.2.1.	Planning phase (Articles 8, 10(1) and 12(a))
2.2.2	Preparation phase (Article 10(1) to (2), Article 12 point b))	2.2.2.	Preparation phase (Articles 10(1) and (2) and 12(b))
2.2.3	Adoption and notification phases (Article 10(2) to (3), Article 22(3) to (4))	2.2.3.	Adoption and notification phases (Articles 10(2) and (3), 22(3) and (4))
2.3	Timing during preparation	2.3.	Timing during preparation
2.4	Deadline planning	2.4.	Deadline planning
2.5	Regulated consultations during the mandating process	2.5.	Regulated consultations
2.5.1	Means for consultation and information provision	2.5.1.	Consultation and provision of information
2.5.2	Importance of consulting the ESOs	2.5.2.	Consulting the ESOs
2.5.3	Importance of consulting the Annex III organisations	2.5.3.	Consulting the Annex III organisations
2.5.4	Importance of consulting sectorial experts of the Member States	2.5.4.	Consulting Member States' sectoral experts
2.6	Other consultations	2.6.	Other consultations
2.7	Possible Union financing on European standardisation activities	2.7.	Union financing of European standardisation activities
3.	General guidance for drafting a standardisation request	3.	General guidance for drafting a standardisation request
3.1	Introduction	3.1.	Introduction
3.2	Addressees of a standardisation request	3.2.	Addressees
3.3	Clarity in indicating the legal framework and in justifying a standardisation request	3.3.	Clarity in indicating the legal framework and justifying a request
3.4	Scope of requirements given in a standardisation request	3.4.	Scope of requirements in a standardisation request
3.5	Reference to the legal requirements in a standardisation request	3.5.	Reference to legal requirements in a standardisation request

Final *Vademecum*		Staff working document	
Element	Title	Element	Title
3.6	Principles to be respected for indicating legal requirement aimed to be covered by European standards	3.6.	Indicating legal requirements aimed to be covered by European standards – general principles
3.6.1	Rationale for indicating the covered legal requirements	3.6.1.	Rationale for indicating legal requirements covered
3.7	Requirements for indicating significant changes in European standards supporting application of Union legislation	3.7.	Requirements for indicating significant changes in European standards supporting the application of Union legislation
3.8	Requirements for validation of provisions in a standard	3.8.	Requirements for validation of provisions in a standard
3.9	Possible requirements asking for co-operation with other bodies	3.9.	Possible requirements for cooperation with other bodies
3.10	Co-operation with the Commission's research facilities	3.10.	Cooperation with Commission's research facilities
3.11	Deadlines for execution of a standardisation request	3.11.	Deadlines for execution of a standardisation request
4.	Model structure for a standardisation request	4.	Model structure for a standardisation request
4.1	A standardisation request as an Implementing Act	4.1.	Standardisation requests as implementing acts
4.2	Recitals of a Commission Implementing Decision	4.2.	Recitals of a Commission implementing decision
4.3	Articles of a Commission Implementing Decision	4.3.	Articles of a Commission implementing decision
4.4	Annexes of a Commission Implementing Decision	4.4.	Annexes to a Commission implementing decision
4.4.1	Annex I "Requirements for the [European]/[harmonised] standards [and European standardisation deliverables]"	4.4.1.	Annex I: Requirements for the [European]/[harmonised] standards [and European standardisation deliverables]
4.4.2	Annex II "[European]/[harmonised] standards [and European standardisation deliverables] and deadlines for adoption"	4.4.2.	Annex II: [European]/[harmonised] standards [and European standardisation deliverables] and deadlines for adoption
4.5	Guidelines for the execution of standardisation requests	4.5.	Guidelines for the execution of standardisation requests
4.6	Internal reference number and access to the texts of standardisation requests	4.6.	Internal reference number and access to the texts of standardisation requests
5.	Acceptance and execution of a standardisation request	5.	Acceptance and execution of a standardisation request
5.1	Acceptance of a standardisation request by the ESOs	5.1.	ESOs' acceptance of a standardisation request
5.2	Starting the work and agreement on the requested work programme	5.2.	Starting the work and agreement on the requested-work programme
5.3	Updates to the requested work programme	5.3.	Updates to the requested-work programme
5.4	Commission follow up during the execution phase	5.4.	Commission follow-up during the execution phase

Final *Vademecum*		Staff working document	
Element	Title	Element	Title
5.5	Communication to the Committee on Standards during the execution phase	5.5.	Informing the Committee on Standards during the execution phase
5.6	Common principles for deadlines and events during the execution phase	5.6.	Common principles for deadlines and events during the execution phase
Annex I	Checklist for planning the overall process	Annex I	Checklist for planning the overall process
Annex II	Main elements of a standardisation request	Annex II	Main elements of a standardisation request

No significant differences in table of content are evident.

The *Vademecum* presents guidelines on administration of a formal objection to a harmonised standard according to Decision No 768/2008/EC. That Decision specifies 4 elements:

- notification of deficiency in a harmonised standard identified by an EUMS or EC to the Committee founded by Article 5 Council Directive 98/34/EC
- opinion by Committee without delay
- decision on publication of harmonised standard in OJEU
- notification by the EC to European standardisation body (ESB), including request to revise standard concerned, where appropriate

According to §1.1. ¶2 of the *Vademecum*, a Harmonised standard does not necessarily need to fulfil all Essential requirements specified by the Directive concerned. Therefore, only deficiencies (shortcomings) against an Essential requirement may be challenged. The *Vademecum* accepts that correspondence between the content of a Harmonised standard and Essential requirements is preferably indicated in the standard itself. By means of example, it refers to an annex thereof (*eg*, the eponymous Annex Z).

§1.2. of the *Vademecum* originally examined legal consequences of a formal objection (Figure 1).

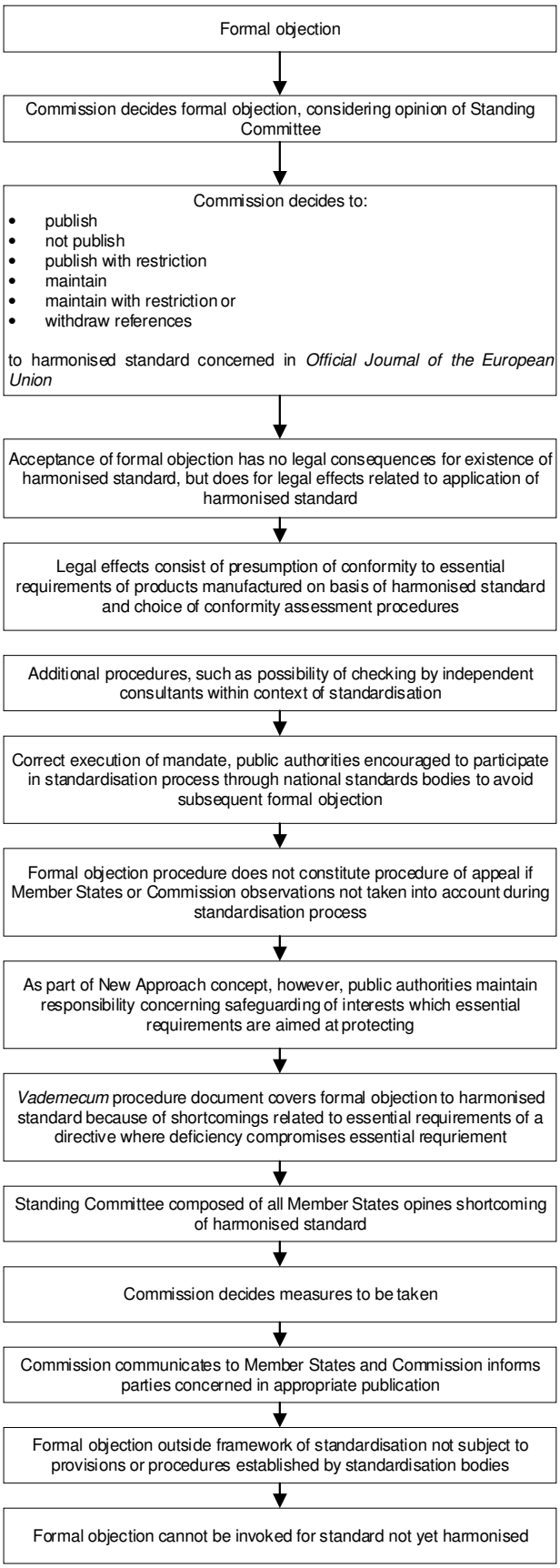

Figure 1 Legal consequences of formal objection to harmonised standard according to §1.2 *Vademecum*

Formal objection to a Harmonised standard does not create legal consequences for its existence but does for its application as a Harmonised standard, *viz*:

- presumed conformity of product manufactured on the basis of the Harmonised standard
- choice of CAP

Implications created by formal objection to a harmonised standard are not explored herein.

It is important to understand formal objection to a Harmonised standard does not constitute an appeal procedure. The *Vademecum* expressed since public authorities are encouraged to participate in standardisation processes, they would have had ample time to proffer observations and influence content on adequacy of a particular standard, including safety matters, before its publication and ultimately, Harmonisation. Formal objection only applies to a Harmonised standard, *ergo*, any standard still in draft or not published in the OJEU cannot be objected to formally by the *Vademecum*.

> *vademecum* (or *vade mecum*) — book ready for reference
>
> (deduction, Oxford English Dictionary)

§1.3. of the *Vademecum* explains that it is not necessary for a safeguard clause to be activated against a product in order to object to a Harmonised standard formally. Instead, formal objection to the Standing Committee can only be submitted when the Commission:

- considers shortcomings exist in a Harmonised standard in a product subject to justify a safeguard measure
- notes an EUMS intends to maintain a safeguard measure on a product even if un-justified because an EUMS still considers a Harmonised standard deficient but the Commission does not

Introduction of a formal objection to a Harmonised standard can be by an EUMS according to §2.1.a. or the EC according to §2.1.b. of the *Vademecum*, respectively. It is necessary for an EUMS to consult the European standardisation bodies concerned before objecting to a standard formally (Table 1).

A formal objection may be withdrawn using the same channels as for introducing the objection.

Table 1 Legal consequences according to §1.2 *Vademecum*

	Comment
The introduction of a formal objection gives rise to the obligation of the Commission to decide on the formal objection, taking into account the opinion of the Standing Committee. The Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in the Official Journal of the European Union	It is unknown if the European Commission operates documented procedures to control objections to Harmonised standards and consequent decisions
While of itself the acceptance of a formal objection has no legal consequences for the existence of the said harmonised standard, it does for the legal effects related to the application of this harmonised standard. These legal effects consist of the presumption of conformity to essential requirements of products manufactured on the basis of this harmonised standard and the choice of the conformity assessment procedures	It is unclear if judicial review relevant to medical devices exists, however, Opinion of the AG in C-613/14 James Elliott Construction seems salutory
It must be stressed that it is part of the New Approach concept that standardisation remains a voluntary process based on consensus achieved in the framework of independent bodies. In principle, the public authorities accept the results of this process, provided that certain conditions are fulfilled, such as compliance with the mandate (the mechanism by which the Commission requests the European	Opinion of the AG in C-613/14 James Elliott Construction seems salutory

	Comment
standardisation bodies to carry out some standardisation work in support of European policies and legislation) and respect for the principles embodied in the general guidelines agreed upon by the Commission and the European standardisation bodies	
What is more, additional procedures have been introduced, such as the possibility of checking by independent consultants within the context of standardisation. Similarly, to monitor the correct execution of the mandate, the public authorities may be encouraged to participate in the standardisation process through their national standards bodies, and in the case of ETSI in a different appropriate format) with a view to avoid raising a formal objection later on in the process	Credentials of independent consultants and how selected unknown. Examples whereby public authorities encouraged by European Commission to participate in standardisation process on medical device standards not found
The formal objection procedure does not constitute a procedure of appeal available to the Member States or the Commission, when the latter note that their observations were not taken into account during the standardisation process. As part of the New Approach concept, however, the public authorities maintain their responsibility concerning the safeguarding of the interests which the essential requirements are aimed at protecting. The procedure described in this document covers, therefore, the formal objection to a harmonised standard on account of the fact that it presents shortcomings in relation to the essential requirements of a directive, of a kind to harm the interests, which the essential requirements are designed to protect. To prevent later formal objections, the opinions on safety matters forwarded by national authorities participating in the standardisation work should be considered seriously	It is unknown if the European operates documented appeal procedures. Examples of national authority objections, safety matters and other dissatisfaction expressed against a Harmonised medical device standard not found publicly although known
Confirming the existence of such a shortcoming is no longer the act of a single Member State, but is based on the opinion of the Standing Committee composed of all the Member States. The consequences of this opinion have to apply at Community level according to the procedures laid down. In the light of the opinion delivered by the Standing Committee and also on the basis of all available information, the Commission will decide on the measures to be taken. This decision will be communicated to the Member States and the Commission will inform the parties concerned in an appropriate publication	Incidental shortcoming discovered by single Member State requires (overall) consensus of all Member States
A formal objection falls outside the framework of standardisation and is not subject to the provisions or procedures established by the standardisation bodies. It cannot be invoked with respect to a document that has not yet received the status of a harmonised standard	There seems no reason to suggest direct objection to a standardisation body cannot be submitted by an individual Member State or Standing Committee of all Member States. Formal objection only levelled against Harmonised standard

The Vademecum refers to safeguard clause to resolve formal objections and safeguard action against a product in the event of a deficient Harmonised standard (Table 2).

Table 2 Relationship to the safeguard clause according to §1.3 *Vademecum*

	Comment
The question arises of the relationship between the formal objection procedure and the procedure for a safeguard clause against a product, on the grounds of a shortcoming in a harmonised standard. A formal objection does not necessarily have to be preceded by an introduction of a safeguard clause,	Considering medical devices subject to Council Directive 93/42/EEC, by way of example, Article 8 thereof provides an EU Member State must alert the European Commission in the event

	Comment
however such a situation is not excluded. In this context reference must be made to the texts of the New Approach directives	health and/or safety of patients, users and other persons occurs because of certain reasons: (b) incorrect application of an applied Harmonised standard pursuant to Article 5 Council Directive 93/42/EEC (c) shortcomings in a Harmonised standard
The Commission shall bring the matter before the Standing Committee and shall initiate the procedure for a formal objection to the harmonised standard in the following two cases:	According to Article 8 2. Council Directive 93/42/EEC, the European Commission • consults parties concerned about an allegedly deficient Harmonised Standard as soon as possible • immediately informs initiating plus all other EU Member States if interim measures applied by the former to resolve a deficient Harmonised Standard are justified • immediately alerts the Committee on standards and technical regulations pursuant to Articles 5 Council Directives 93/42/EEC and 83/189/EEC • immediately informs initiating EU Member State, manufacturer or EUAR if interim measures by initiating EU Member State un-justified
- when the Commission considers that, on the grounds of a shortcoming in the harmonised standard, the safeguard measure against a product is justified	
- when the Commission notes that such a measure is not justified, but that the Member State in question intends to maintain its position	No provision for this in Article 8 Council Directive 93/42/EEC
It is obvious that in these two cases the formal objection is considered to have been introduced by the Member State in question. Thus the introduction of a safeguard clause against a product, on the grounds of a shortcoming in a harmonised standard, does not require the separate introduction of a formal objection to this harmonised standard, but nor does it exclude it	Activation of Article 8 1. (b), 1. (c) and 2. Council Directive 93/42/EEC constitutes formal

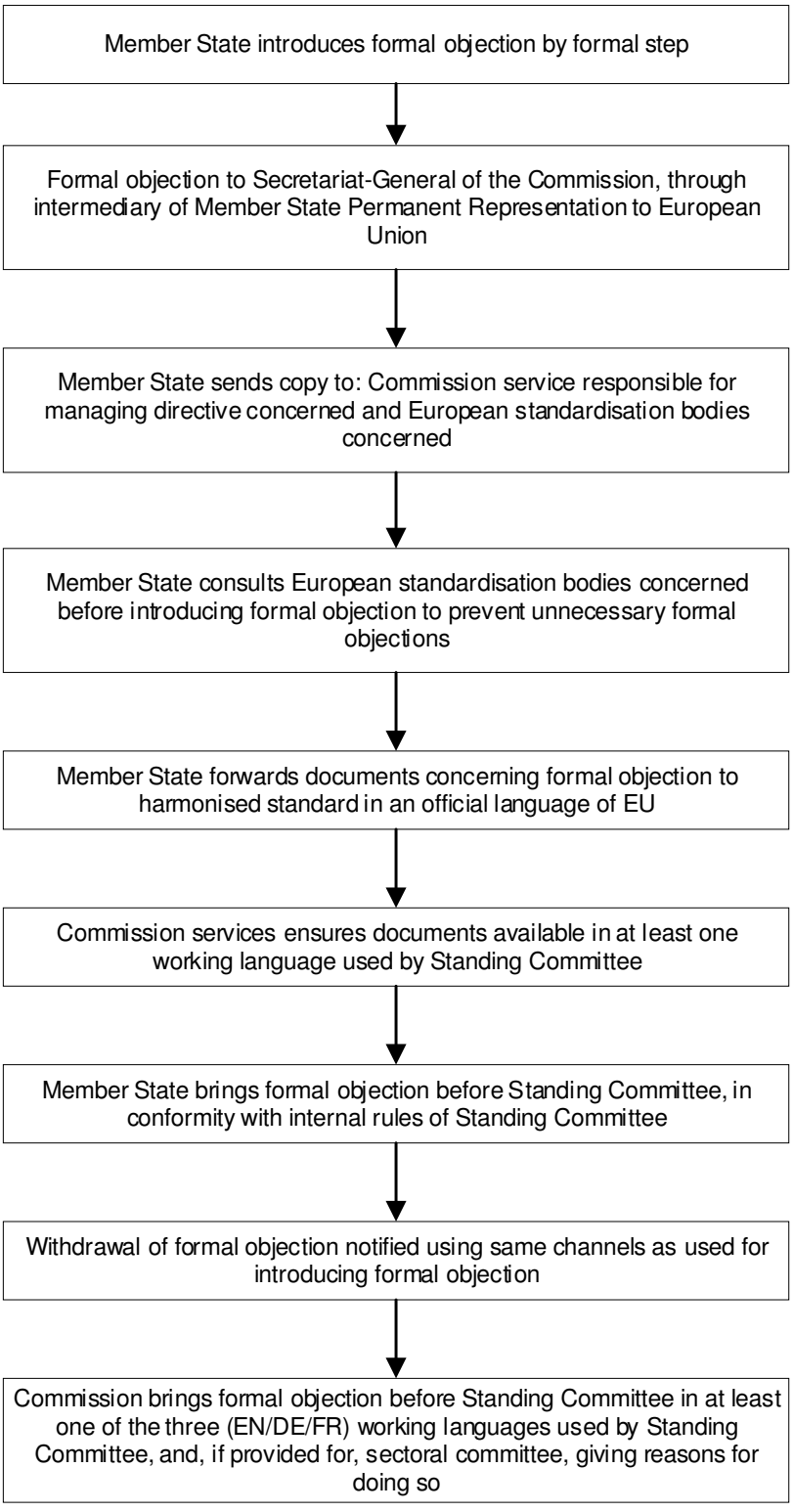

Figure 2 §2.1 Introduction of formal objection to harmonised standard, introduced by a Member State or European Commission, described by *Vademecum*

Once an EU Member State objects to a Harmonised standard formally, copies of the objection must be sent to the responsible commission service and European Standardisation organisation concerned (Figure 2), however, the *Vademecum* explains each Member State must try to resolve concerns about a Harmonised standard with the European Standardisation organisation concerned before formally objecting.

Curiously, the procedure outlined for such objection to a harmonised standard appears vague and only partly-formal (Figure §2.2 of the *Vademecum*; see Figure 3 below).

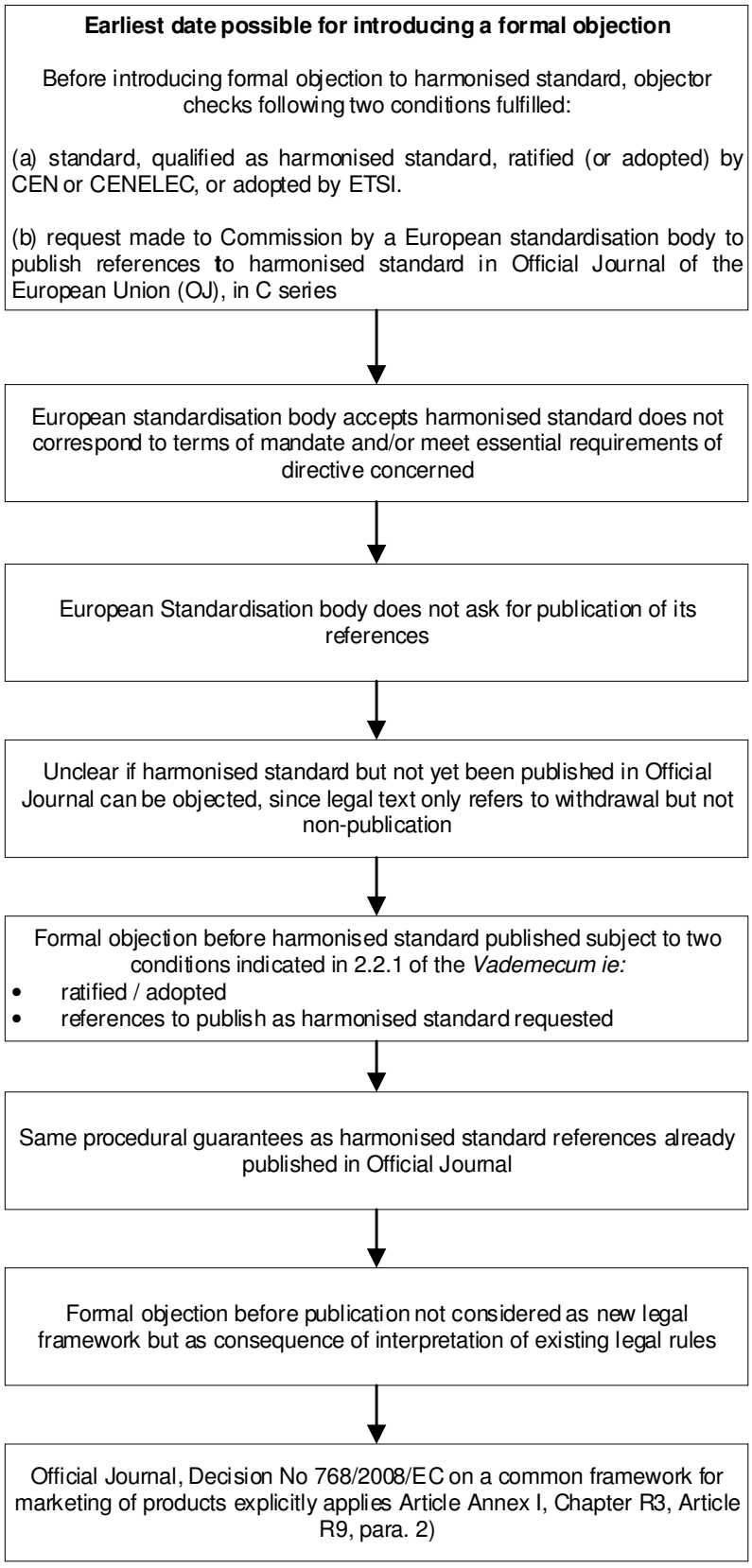

Figure 3 Earliest date possible to introduce formal objection according to §2.2 *Vademecum*

§2.2. of the *Vademecum* confuses common understanding of Harmonisation. The section concerns the earliest date possible to introduce formal objection to a harmonised standard. Actually, it does not present date line at all. Instead, the section debates whether un-ratified or un-adopted standards and absence of request by a ESB to the EC to publish a harmonised standard in the *OJEU* C series can still precipitate formal objection to a standard. According to the *Vademecum*, since Decision No 768/2008/EC explicitly permits the EC to decide … to not publish … (a) harmonised standard in the (*OJEU*) constitutes legal certainty that an un-published harmonised standard can still be objected.

This position seems somewhat perplexing and incredible, since it is understood that the act of publishing a standard in the *OJEU* constitutes the final (and confirmatory) stage of Harmonisation.

Table 3 Information to be forwarded when introducing formal objection according to §2.3 *Vademecum*

Information	Comment
A reference to the directive concerned and an explicit reference to the safeguard clause of this directive	Implies standards somehow connected to safeguard measures
The references of the harmonised standard (number, year and title)	No requirement to identify sub-ordinate normative standards invoked by Harmonised standard
Precise details as to the part of the harmonised standard which is contested and as to the related essential requirements	Aside from eponymous Annex Z, it is extremely rarely possible to relate standard to a corresponding Essential requirement
An indication of the type(s) of products concerned, where necessary	Scope of standard may assist, however, common nomenclature inexistent or incoherent with, for instance UDN schemes
Detailed arguments justifying why the harmonised standard is being contested in relation to the directive's provisions	Requires fundamental and comprehensive analysis and interpretation

Council Directive 93/42/EEC does not specify information to be submitted to the European Commission when an EU Member State objects to a Harmonised Standard pursuant to Article 8 of the Directive. Therefore, it would appear §2.3 of the *Vademecum* should be followed (Table 3).

§2.4. of the *Vademecum* concerns deadline planning, explaining an ESO can expect to receive notifications is at least 4 months but this is optimistic.

§2.5. and 2.6. of the *Vademecum* concerns regulated and other consultation during mandate process, respectively.

§2.7. Part III of the *Vademecum* explains decisions that can be taken on an objected Harmonised standard and also publications permitted. The EC publishes a decision on a formal objection in every case, once consultation procedures have been completed. The decision will be to accept or reject a formal objection. A decision is still taken even if a formal objection becomes irrelevant in the meantime. Decisions are addressed to the EUMS.

According to §2.7.3. Part II of the *Vademecum*, each decision is published in the *OJEU*. This includes decisions to not publish a Harmonised standard or to rescind harmonisation. A decision to reject a formal objection, however, is not published in the *OJEU.*

Commission Notice 2016/C 272/01 presents guidance on Harmonised standards (§4.1.2 – 4.1.3)

The notice cites the *Vademecum* (SWD (2015) 205 final 27.10.2015), explaining role of harmonised standards in context of presumed conformity and how such presumption might be withdrawn, restricted or prevented (Table 4). Explanations of how Essential requirements can be fulfilled alternatively, are given.

Table 4 Elements of Commission Notice 2016/C 272/01 relevant to *Vademecum*

Element	Title
4.1.2	Conformity with the essential requirements: harmonised standards
4.1.2.1	Definition of a harmonised standard
4.1.2.2	Role of harmonised standards
4.1.2.3	Process to harmonised standards providing presumption of conformity
4.1.2.4	The Presumption of conformity
4.1.2.5	Withdrawal, restriction or prevention of the presumption of conformity
4.1.2.6	Revision of harmonised standards
4.1.3	Conformity with the essential requirements: other possibilities

§4.1.2.2 of the notice reminds clear distinction must be made between conformity with a standard and presumption of conformity – the latter reserved to provisions relating to essential or other legal requirements … to be covered (by a Harmonised standard). The notice continues: Harmonised standards never replace legally binding essential requirements.

Figure 4 C 272/01 43 (of Commission Notice 2016/C 272/01 illustrates the following concepts when using a Harmonised standard, whereby a manufacturer assesses risk (or uses an equivalent – yet, undefined, measure) of a product against an Essential requirement (ESR) to determine if the Essential requirement must be fulfilled. (In practice, such assessment is rarely conscious in evidence presented to conformity assessment, certainly concerning medical devices).

In this illustration, a Harmonised standard used to demonstrate (fulfilment of) presumed conformity constitutes a specification. Interestingly, the concept and meaning of direct application are unexplained by the Commission Notice.

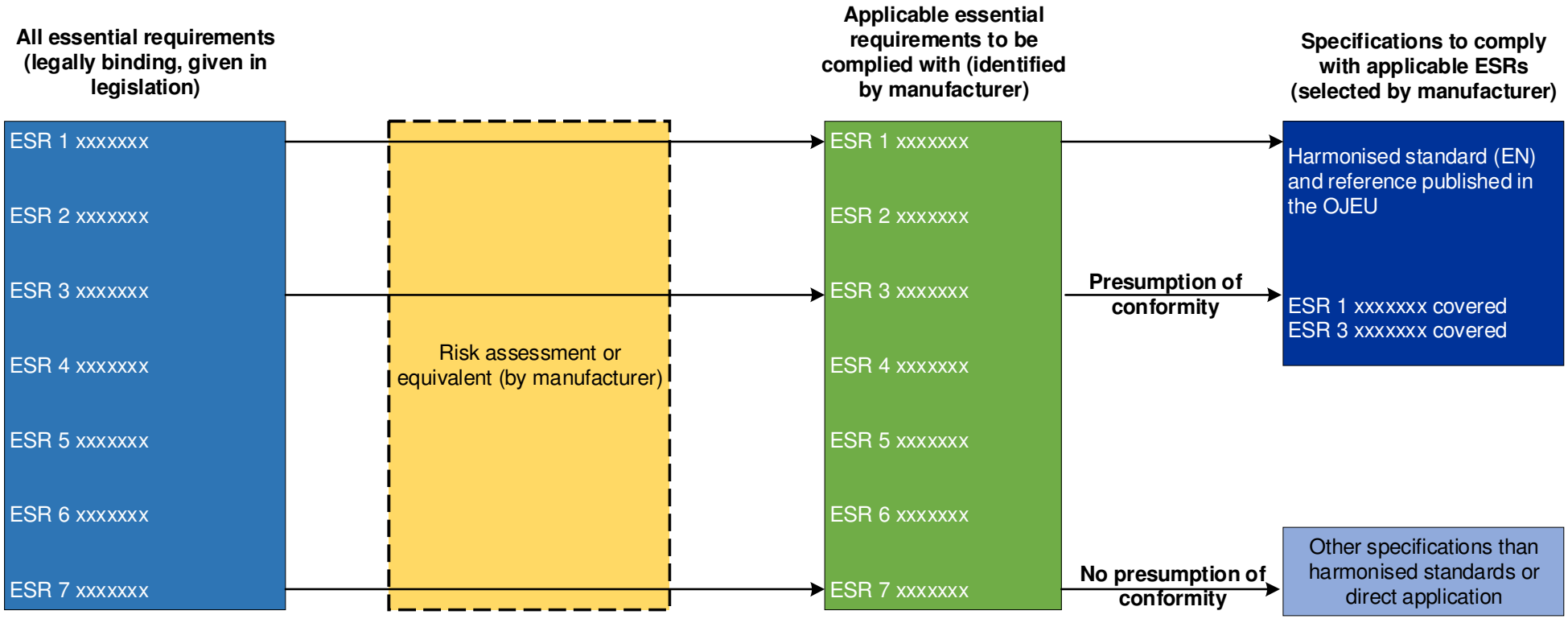

Figure 4 Conceptual use of Harmonised standard illustrated by Commission Notice 2016/C 272/01 (errors corrected)

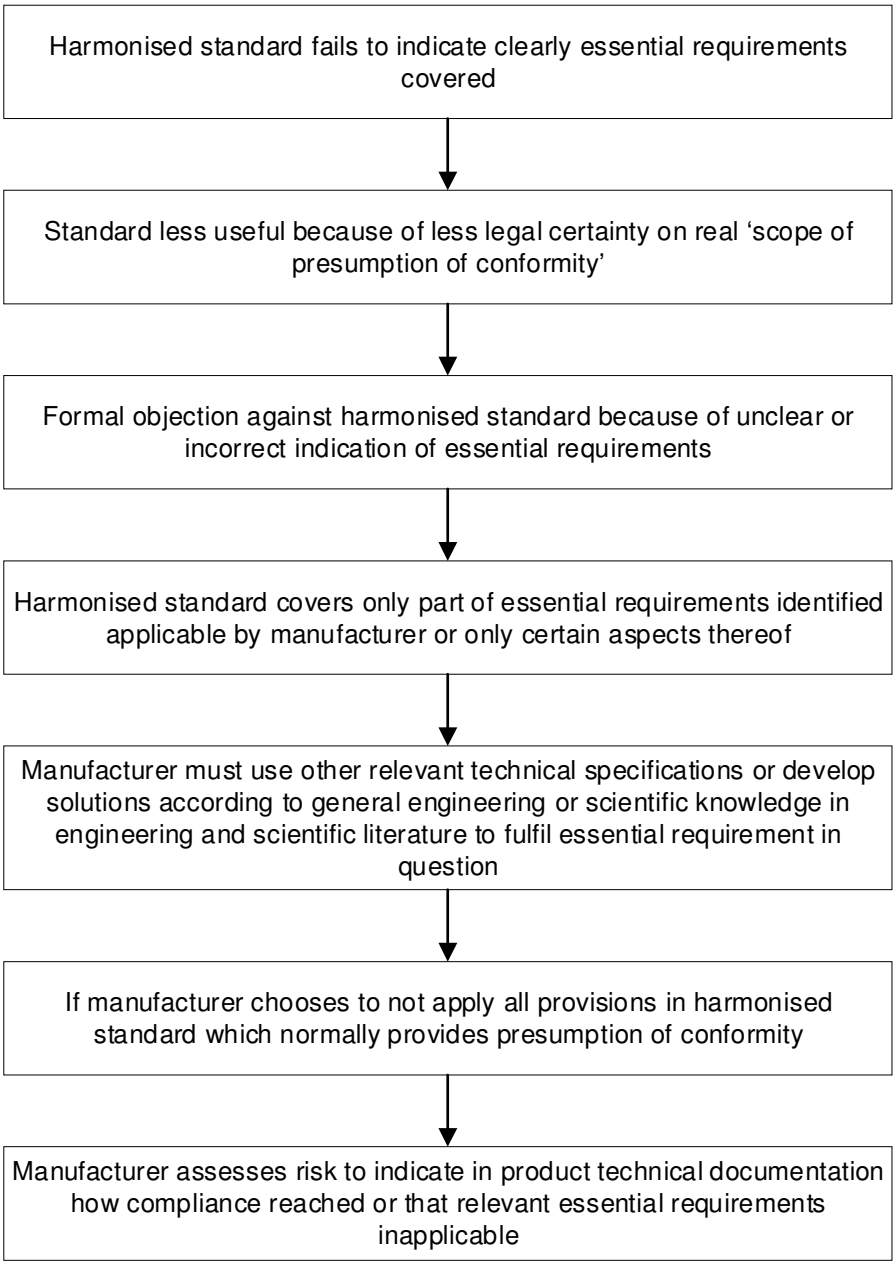

Figure 5 Criteria or factors to consider when deciding adequacy and suitability of a Harmonised Standard according to C 272/01 43 Commission Notice 2016/C 272/01

The Commission Notice explains some criteria or factors to consider when deciding adequacy and suitability of a Harmonised standard. Experience reveals the medical device sector generally does not apply such logic and simply elects to apply a Harmonised standard because it exists or when compelled by a Notified body or even a Competent authority (despite Harmonised standards being voluntary) (Figure 5).

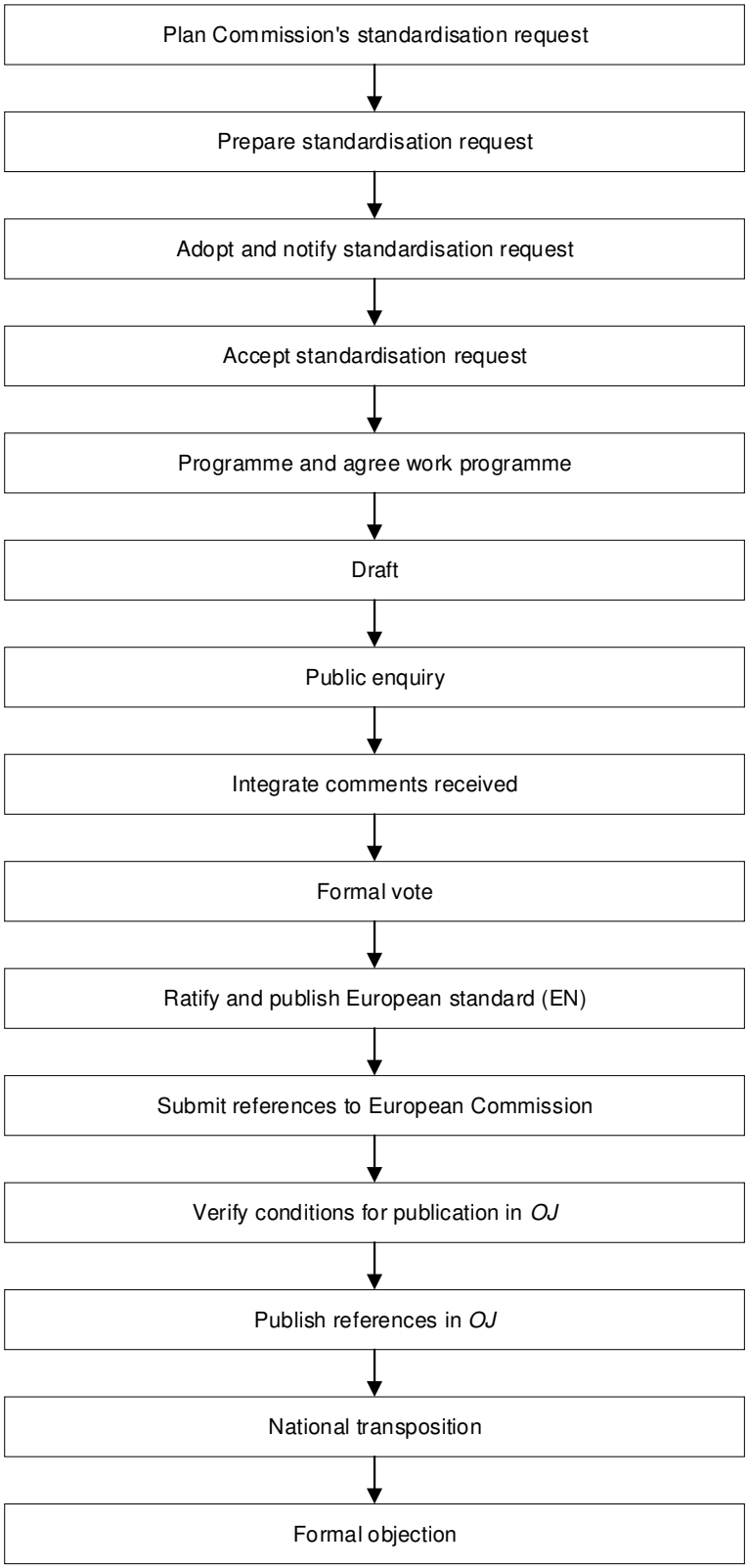

Figure 6 Process to harmonise standards providing presumed conformity illustrated by according to 1. – 15. C 272/01 43 Commission Notice 2016/C 272/01

The sequence of activities to harmonise a standard is illustrated by Figure 6.

§4.1.2.4 of the notice explains European standards, including harmonised standards, are often based fully or partly on ISO or IEC standards, however, presumption of conformity (presumed conformity) is possible only by applying the European version (because of modifications introduced necessary to harmonise a standard).

According to C 272/01 50 of the Commission Notice, if a harmonised standard contains normative references to other standards, through these references such secondary standards or parts thereof become indispensable to apply the harmonised standard. The Commission Notice explains internal rules of European standardisation organisations apply when making normative references to other standards. The Commission Notice warns against using un-dated editions of standards because of the nature of harmonised standards undated references to other standards, where relevant clauses aim to support essential or other legal requirements. Undated references may cause situations where changes in specifications contained in harmonised standards and providing presumption of conformity are uncontrolled and non-transparent — changes in normative references cannot be controlled within the meaning of Article 10(6) of the Regulation (EU) No 1025/2012 although by such changes a harmonised standard (a part of it) is *de facto* revised. This seems errant nonsense.

Incoherently, according to the Commission Notice, even if the manufacturer has not used harmonised standards, a change in the relevant harmonised standard could mean a change in the state-of-the-art that implies that his product may not be compliant.

§2.7.4. of the *Vademecum* describe how partial decisions on a formal objection must be dealt with (Table 5). Options are publication of un-contested parts of an un-published Harmonised standard, explaining what part of the standard cannot confer presumed conformity, including reasons for the decision (§2.7.4.1.) and partial removal of contested parts of a Harmonised standard, specifying the parts that can no longer confer presumed conformity, including reasons for the decision.

Table 5 Partial decision on formal objection to Harmonised standard (Table Annex *Vademecum*)

No	Case		Commission decision		
	Conclusion following consultations		Harmonised standard's references already published		Publication decision in OJ
	Formal objection	Harmonised standard deficient			
1	Objection to harmonised standard accepted	Totally	Yes	Complete withdrawal from publication of Harmonised standard's references	Yes
2			No	Harmonised standard's references will not be published	
3		Partially	Yes	Partial withdrawal from publication of harmonised standard's references	
4			No	Partial publication of harmonised standard's references	
5	Objection to harmonised standard rejected	—	Yes	Publication of harmonised standard's references not withdrawn	No

No	Case		Commission decision		
	Conclusion following consultations		Harmonised standard's references already published		Publication decision in OJ
	Formal objection	Harmonised standard deficient			
6		—	No	Publication of harmonised standard's references	

NB:

1. Partial publication means publication of harmonised standard's references indicating parts not conferring presumption of conformity
2. Partial withdrawal consists, in a single action, of complete withdrawal of previous publication and new partial publication

§3 of the *Vademecum* covers miscellaneous aspects of formal objection to a Harmonised standard.

According to review and suspension procedures stated in the *Vademecum*, a mandate to review an objected standard is sent by the European Commission to the European Standardisation body concerned (Table 6). It is unknown if such formal objections are promulgated. Absurdly, it seems if an objected standard is already under revision, formal objection might be suspended at the behest of an EU Member State. This eventuality could expose both the public and manufacturers to harm if the reason a standard was objected concerned safety or might impair performance (efficacy) of a medical device subject to the standard.

Table 6 Review and suspension procedure (§3.1 – 3.5 *Vademecum*)

	Comment
3.1. Request to review the harmonised standard	
Whenever the Commission has agreed with a formal objection to a harmonised standard, it will forward a precise mandate to the European standardisation body concerned to review the harmonised standard in question. This mandate will be the subject of an opinion delivered by the Standing Committee, if possible at the same time as its opinion on the formal objection concerned. The mandate may take the form of a simple letter or be a precise and detailed request according to the nature of the case and the standardisation work already in progress to remedy the problem that has been caused. The Commission will adopt the necessary measures to ensure the close follow-up of this mandate. The Standing Committee will be kept informed on a regular basis of progress with the respective standardisation work	It is unclear if formal objections are promulgated routinely. It is unknown if the European Commission operates documented procedures to control objections to Harmonised standards
A mandate of this kind could, moreover, also be conferred when a formal objection has been rejected, but the Commission and the Standing Committee are of the opinion that it is nevertheless necessary to (partially) review the harmonised standard	Criteria not promulgated
3.2. Suspension of a formal objection	
In the past, some Member States have proposed suspending a formal objection procedure that had already been introduced in certain cases because the standardisation revision work was making good progress	Provision seems absurd because continued violation promoted, meaning manufacturers and users might be un-protected
A suspension of a formal objection creates a situation of legal vagueness. A formal objection refers to a serious situation for either safety or health, and sometimes both,	Despite safeguard obligations, then, standard organisations can continue merrily while a serious situation created by deficient

	Comment
and hence requires urgent action. The deadlines for action and the processing of the file are no longer under the control of the public authorities but depend on the progress of standardisation work and its results, which are not guaranteed in advance. Although it has to be recognised that close cooperation between the public authorities and the European standardisation body is useful and even necessary, such situations of legal vagueness should be avoided	standards is un-mitigated by the public authorities. Judicial review seems unavoidable!
Thus there are only two possible scenarios:	
– the Member State maintains its formal objection and the Commission services are obliged as a result to pursue the procedures described in this document in order to halt a situation of legal uncertainty	Criteria not promulgated
– the Member State withdraws its formal objection in the light of a precise mandate to the European standardisation body concerned to solve the problems raised by its formal objection	Criteria not promulgated
3.3. Other communication than formal objections from the public authorities regarding a problem with a harmonised standard	
The formal objection procedure does not undermine the rights of Member States to communicate to the Commission, or directly to the Standing Committee, any problem related to the application of the essential requirements in a harmonised standard, even before it has been ratified/adopted. In some cases the problem could be serious enough for a formal objection to be introduced at a later stage. Such communications could therefore avoid a formal objection at a later stage. These communications do not have the legal consequences of a formal objection. If the harmonised standard has not been ratified yet, the Member States are invited to approach their national standards bodies – members of the European standardisation bodies - as a first step if any problem related to the application of the essential requirements in a harmonised standard arises	It is unclear if such communications are promulgated routinely
3.4. The continuous checking of the standardisation process	
The procedure for a formal objection and notification of the intention to introduce such an objection, do not preclude the Standing Committee from examining, in the framework of its work, the progress of standardisation activities, including the conformity of draft standards with the requirements of the directives and the mandates, and from informing the standards bodies of its conclusions. This type of dialogue may be useful because potential problems may be solved before the standard is ratified. The possibility for such an examination, which may occur at any moment during the process of the development of the standard, has no formal character. Communication of a position does not have legal consequences	Suggests documented procedures do not exist at the European Commission
3.5. Informing the Standing Committee	
The Standing Committee shall be informed by the Commission regularly and systematically of the way the procedure described above is progressing and its results	It is unknown if the European Commission operates documented procedures for this

	Comment
for each formal objection file. For this purpose, a reference document was established by the Commission which is presented in each meeting of the Standing Committee	
The Standing Committee shall also be informed by the Commission of every communication expressing an intention to introduce a formal objection	It is unclear if such communications are promulgated routinely

Several concerns can arise when a formal objection to a Harmonised standard is endorsed by the Commission, particularly about medical devices PoM antecedently, particularly devices implanted permanently in the body, ones that are life sustaining or utilised in emergencies and others used in chronically-ill patients or otherwise most vulnerable. In many cases, causation may be difficult to establish between deficiency in a standard and safety property of a device, or indeed its performances. Further, evidence from critical examination of numerous Harmonised standards suggests poor – even tenuous – correspondence with Essential requirements.

In these situations, it is unclear how either the EC or Standing Committee investigates accusations of inadequacy in a particular standard, since the correspondence table (typically at Annex Z of a European standard) merely records declared relation between a clause of the standard and an Essential requirement and perhaps exclusions or referral to sub-ordinate or collateral standards, without critical appraisal.

The composition of the Standing Committee is un-defined by the *Vademecum*, although §2.6. requires the responsible sectoral service to consult ministries concerned as well as all interested parties and the respective committee or group of experts of a particular Directive. Independent scrutiny by impartial experts is not provided.

Commission Decision No 768/2008/EC does not specifically deal with these issues.

Recent developments

Judicial review

Judgment of the Court (Third chamber) 27 October 2016 In case C-613/14, Request for a preliminary ruling under Article 267 TFEU from the Supreme Court (Ireland), made by decision of 19 December 2014, received at the Court on 30 December 2014, in the proceedings. James Elliot Construction Limited v Irish Asphalt Limited.

The case centred on Harmonised standard EN 13242:2002 (Aggregates for unbound and hydraulically bound materials for use in civil engineering work and road construction), must be interpreted as not binding a national court seised of a dispute concerning a contract governed by private law requiring a party to supply a product compliant with a national standard transposing that harmonised standard, either regarding the method to establish conformity of such a construction product with contractual specifications or the time when its conformity must be established.

The Court observed:

- A harmonised standard such as EN 13242:2002 at issue in the main proceedings, it must be noted that Article 4(1) of the Directive 89/106 defines harmonised standards as technical specifications adopted by CEN, Cenelec or both, on mandates given by the Commission in conformity with Directive 83/189, which give, as is apparent from the sixth and seventh recitals of Directive 89/106, concrete form on a technical level to the essential requirements defined in Annex I thereto
- According to Article 7(3) of Directive 89/106, references of harmonised standards drawn up by European standardisation organisations are subsequently published by the Commission in the 'C' series of the *Official Journal of the European Union*
- Pursuant to Article 4(2) of Directive 89/106, read in conjunction with the eleventh recital of that directive, such publication has the effect of conferring on products which are covered by that directive, and which satisfy the technical requirements defined in the harmonised standards relating to those products, the benefit of a presumption of conformity with the basic requirements of that directive (see, to that effect, judgement of 21 October 2010, *Latchways and Eurosafe Solutions*, C-185/08, EU:C:2010:619, paragraph 31), allowing the CE marking to be affixed to them
- Presumption of conformity with the essential requirements of Directive 89/106 and 'CE' marking confer on the product in question, in accordance with Article 6(1) of that directive, read considering twelfth recital of that directive, the ability to circulate, to be placed on the market and to be used freely within the territory of all Member States of the European Union
- It follows from the above that a harmonised standard such as EN

13242:2002 at issue in the main proceedings, adopted on the basis of Directive 89/106 and references to which have been published in the *Official Journal of the European Union*, forms part of EU law, since it is by referring to provisions of such a standard that it is established whether or not the presumption laid down in Article 4(2) of Directive 89/106 applies to a given product

- A product's compliance with technical requirements defined by such a standard allows presumption that product satisfies the essential requirements contained in Directive 89/106. It follows that product is authorised to circulate, to be placed on the market and to be used freely within the territory of all Member States of the European Union, with the result that, pursuant to Article 6(1) of that directive, Member States may not impose additional requirements on such products for their effective use on the market and use within the territory (see, to that effect, judgement of 16 October 2014, Commission v Germany, C-100/13, EU:C:2014:2293, paragraphs 55, 56 and 63)
- Although evidence of compliance of a construction product with the essential requirements contained in Directive 89/106 may be provided by means other than proof of compliance with harmonised standards, that cannot call into question the existence of the legal effects of a harmonised standards
- While development of such a harmonised standard is entrusted to an organisation governed by private law, it is nevertheless a necessary implementation measure which is strictly governed by the essential requirements defined by that directive, initiated, managed and monitored by the Commission, and its legal effects are subject to prior publication by reference in the 'C' series of the *Official Journal of the European Union*

European Commission Standardisation package

The European Commission published a Standardisation package in 2016 concerning services but no corresponding document was found on the medical device sector. Older strategic visions – such as COM (2011) 311 final persist therefore.

Action plan: structural solutions to decrease the stock of non-cited harmonised standards (ARES (2017)-491 9072-09/10/2017) was published by GROW.DDG1.B. 3 to improve legislative compliance of harmonised standards during their development in the most affected sectors.

The plan presents short- (Q3/2017) and medium-term (2018) goals for the most relevant sectors (tentatively agreed sectors stated therein as: medical devices, construction, emc, RED and railways), consisting of:

1. proceeding with currently non-cited harmonised standards
2. improving support from New Approach Consultants
3. developing common understanding of harmonised standards joint assessment and citation process
4. modernise Harmonised standards database

New Approach Consultants are CEN and Cenelec.

Summary

Continuing information asymmetry, incoherence and numerous examples of deficient Harmonised standards, plus criticism of fundamentals of presumed conformity by means of such standards can result in objection by an EU Member State.

Limited provisions are promulgated by and suspected informal procedures exist at the European Commission to deal with such eventualities. Instead, the Commission relies on a *Vademecum* and certain elements of Regulation (EU) No 1025/2012 – the latter invoking Commission Decision No 768/2008/EC – to control objections.

Critical examination of objection promulgated by the *Vademecum* reveals an opaque, vague and distichous approach, whereby *sui generis* legislation mixes with non-majoritarian standards to confer or extend legitimacy. Existence of very limited case law means manufacturers continue to be left in precarious position and in the case of medical devices, patients afforded questionable protection.

The *Vademecum* – as with Regulation (EU) No 1025/2012 and Commission Notice 2016/C 272/01 – fails to deal with consequences of pass-through normative standards and numerous problems created by Annex Z legitimation promulgated in European standards.

In James Elliot Construction Limited v Irish Asphalt Limited before the Third Chamber Court case C-613/14 27 October 2016 for a preliminary ruling under Article 267 TFEU from the Supreme Court (Ireland), legal effects of a harmonised standard were adjudicated. The standard was EN 13242:2002. In common with many other Harmonised standards, EN 13242:2002 states it provides for the evaluation of the products to [that] European standard EN 1744-1:1998 stating categories for maximum values of total sulphur content. The court judged that a national court is not obliged to apply presumed fitness for use of a (construction) product manufactured pursuant to a harmonised standard …

Crucially, the Court (Third Chamber) also ruled: The first paragraph of Article 267 TFEU must be interpreted as meaning that the Court of Justice of the European Union has jurisdiction to give a preliminary ruling concerning the interpretation of a harmonised standard within the meaning of Article 4(1) of Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products, as amended by Council Directive 93/68/EEC of 22 July 1993, references to that standard having been published by the Commission in the 'C' series of the *Official Journal of the European Union*.

CEN and CENELEC published a rebutting position paper (2017) on the judgement of the ECJ on the matter. Mostly, the position paper attempts to shut the door to right of public access to standards published by CEN and CENELEC contrary to Article 15 §3, TFEU or Regulation (EC) No 1049/2001. The position paper also distances implied improved control of European standards mandated by the Commission and implementing legally binding European Union obligations if a Harmonised standard is not an act adopted by the Commission but by an organisation governed by private law.

CEN and CENELEC opined despite the reluctance of the Court to clarify the debate on the qualification of and on the legal basis of the hENs, CEN and CENELEC are of the opinion that the Commission's *Vademecum on European Standardization* already offers a set of specific provisions that, if fully applied by the Commission's officials, are largely sufficient to order efficiency and consistency to the entire process, hence limiting the practical consequences of possible unclear situations.

Unsurprisingly, the position paper argues it is of paramount importance to not jeopardise successful relationship between legal use of Harmonised standards and international standardisation.

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11. Judgment of the Court (Third chamber) 27 October 2016 In case C-613/14, Request for a preliminary ruling under Article 267 TFEU from the Supreme Court (Ireland), made by decision of 19 December 2014, received at the Court on 30 December 2014, in the proceedings. Jams Elliot Construction Limited v Irish Asphalt Limited.
12. GROW.DDG1.B. 3 Action plan: structural solutions to decrease the stock of non-cited harmonised standards (ARES (2017)-491 9072-09/10/2017) www.ec.europa.eu/growth/content/european-commission-launches-action-plan-improve-publication-harmonised-standards-industry_en