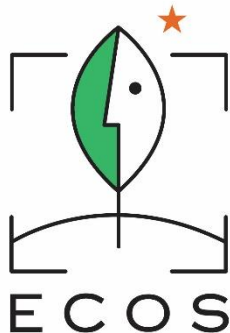


EUROPEAN ENVIRONMENTAL
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ORGANISATION EUROPÉENNE
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POUR LA NORMALISATION

THE USE OF STANDARDS IN LEGISLATION AND POLICIES

How to ensure a legally-sound and socially-acceptable use of standards by
policy-makers in view of the CJEU *James Elliott* ruling and other court cases

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Summary

In the James Elliott case in October 2016¹, the Court of Justice of the European Union (CJEU) shed some light on the legal nature of standards: standards are part of EU law. What are the implications of this ruling for the European standardisation system and the way policy-makers use standards to support legislation and policy? While the ruling has already had some minor implications, it is likely to have other impacts – direct or indirect – on the standardisation system in the longer term.

Standards are increasingly used in support of legislation and policy in the EU, across an increasing number of areas, including areas of public interest. In this context, the distinction between political and technical issues is becoming blurred and policy-makers risk delegating political decisions to the standardisation organisations. Moreover, when standards are developed in public interest areas such as health services and environmental protection, it requires that all those concerned and impacted by standards are involved in their development. This is not always the case today, and the fact that more and more European standards are developed at international level represents a threat to inclusiveness.

Combined with the growing evidence that harmonised standards produce legal effects, also confirmed in the CJEU James Elliott ruling, the increasing use of standards in policy-making requires the review of the political approach to standards, and the standardisation development process. The present paper offers a new vision for this political approach to ensure that standards serve the needs of all. In particular, ECOS argues that the development of standards should be carefully triggered and observed by legislators and be transparent and as inclusive as possible.

¹ For more information about the *James Elliott* case, see Annex I.

Foreword

The use of standards in European laws and policies has increased in the past decades, and their use is growing in areas of public interest such as services and environmental protection.² In parallel, growing evidence shows that standards have clear legal effects, despite their voluntary nature and the private status of the organisations in charge of their development, the European Standardisation Organisations (ESOs).³ In the ruling in the [James Elliott case](#), the EU Court of Justice stated that harmonised standards are *part of EU law*, thereby shedding light on the legal nature of standards.

Despite the increasing use of standards in many EU political areas and their indisputable legal effects, the European standardisation system, including the European Commission's mandating process⁴ and the standard development process, has not significantly evolved. The legal framework established by Regulation (EU) 1025/2012 on European standardisation brought a number of improvements; however, it remains insufficient to ensure the effectiveness and legitimacy of the regulatory approach to standards in the long term. The use of standards in policy is thus today the subject of many societal, scientific and political discussions.

In this paper, we propose to take a close look at the possible implications of the *James Elliott* ruling, and to explore whether the current political approach to standards in the EU is sustainable, especially from a legal and democratic perspective. The paper is not meant to question the use of standards in policy as a matter of principle, or the added value which standards can bring to our economy and society. It does, however, make recommendations to ensure that the use of standards for regulatory purposes is made with certain democratic safeguards and that there is a sufficient and effective legislative and judicial control over the standards development process. This will, ultimately, ensure that standards associated with policies meet the needs of both the market and society as a whole, and that they are developed through a truly transparent and inclusive process, in line with Regulation (EU) 1025/2012.

1. The growing importance of standards in policy

1.1. An increasing use of standards by policy-makers

In the past decades, the use of standards to support European laws and policies has increased, and today standards play a key role

² Examples of European laws supported by standards include the REACH Regulation, the Construction Products Regulation, product-specific Ecodesign and energy-labelling legislation, the EMAS Regulation, the Packaging and packaging waste Directive, the WEEE Directive, the F-gas Regulation, the Renewable Energy Sources Directive, and the Air Quality Directive.

³ H. Schepel, *The New Approach to the New Approach: The Juridification of Harmonised Standards in EU Law*, 12(4) *Maastricht J. Eur. Comp. L.* 521–533 (2013); Rob van Gestel, Hans-W. Micklitz, 'European integration through

standardization: How judicial review is breaking down the club house of private standardization bodies' (2013) 50 *Common Market Law Review*, Issue 1

⁴ Process whereby the European Commission requests the European Standardisation Organisations (ESOs) to develop and adopt European standards or European standardisation deliverables in support of European policies and legislation. About a fifth of all European standards are developed following a standardisation request (mandate).

in the governance of the European Union.⁵ Standards help remove technical barriers to trade and support innovation by stimulating dissemination of technologies. Standards are, therefore, considered as key policy tools in many areas relating to the functioning of the Internal Market, beyond the Single Market for goods, e.g. data privacy, consumer and environmental protection, and services.

The use of standards in legislation has also grown since it prevents the development of more restrictive legislation, which is more difficult to adapt to market and technological developments, while at the same time offering harmonisation. This regulatory technique is also appealing as legislators often lack time and expertise to define technical requirements in legislation. The fact that those being regulated are involved in the decision on how the legal requirements can be met is also believed to presume a higher level of compliance.

In its Communication on the role of European standardisation in the framework of European policies and legislation⁶, the Commission committed to promote the broader use of standards to support legislation, in line with its strategy on Better Regulation. Regulation (EU) 1025/2012, which forms part of general framework of European policy⁷, introduced steps to foster the development of European service standards, in addition to product

standards. The commitment to promote the use of standards was reiterated in the EC Communication *European standards for the 21st century*⁸ published in June 2016, where the Commission noted that *the EU standardisation policy features higher on the political agenda*.

In this context, the use of standards in EU legislation and policies is expected to continue increasing and to become widespread in the future. While ECOS agrees that standards can help support legislation and policies, we would also like to stress that standards are one tool among many others available to policy-makers. These include regulatory technical specifications, and any other technical tools which may be provided by other reliable, independent bodies such as EU agencies, the EU Joint Research Center or the World Health Organisation (WHO).

1.2. The risk of delegating political decisions

The increasing use of standards in legislation and policy in a broad range of policy areas means that the tasks which the legislators are delegating to the ESOs are more and more political, but also increasingly important for consumers and the general public.⁹

Experience shows that this public-private partnership can lead to undesirable, sometimes unintentional delegation of

⁵ B. Frydman and A. van Waeyenberge, *Gouverner par les standards et les indicateurs*, Ed. Bruylant, 2014; *La normalisation en France et dans l'Union européenne: Une activité privée au service de l'intérêt général?*, H. Aubry, A. Brunet, F. Peraldi Leneuf, Presses Universitaires d'Aix-Marseille, 2012; *The New Global Rulers : The Privatization of Regulation in the World Economy*, T. Büthe and W. Mattli, Ed. Princeton, 2011.

⁶ COM(2004) 674 final <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52004DC0674&from=EN>

⁷ https://ec.europa.eu/growth/single-market/european-standards/policy/framework_en

⁸ COM(2016) 358 https://ec.europa.eu/growth/content/commission-takes-steps-modernise-eus-standardisation-policy-1_en. See also EC Communication COM(2015) 215 final "Better regulation for better results - An EU agenda".

⁹ For instance, in the area of environmental protection, existing standards provide agreed definitions for nanomaterials, criteria for defining the sustainability of biofuels, methods for measuring air quality, safety and environmental requirements for refrigerating systems, and tests for measuring the energy efficiency of appliances.

political decisions to private actors. Combined with the domination of big industry in the process, this can result in poorly written standards which do not meet the needs of all stakeholders.

For instance, in the context of the Ecodesign policy framework, poorly drafted standardised methods developed to measure the energy consumption of energy-related products can impact the energy class which the products will fall in on the Energy Label, and the energy savings which will be delivered.¹⁰ An ECOS report published in June 2017 presented a number of such cases: dishwashers tested in a highly efficient but infrequently used wash programme, TVs tested with a video clip that does not reflect typical home viewing, and fridge-freezers tested without opening the doors and without any load in the fresh food compartments.¹¹ Some manufacturers and importers were also found to be exploiting a loophole in the European test methods allowing them to achieve compliance or mislead consumers on the energy performance of their products.¹² Based on these findings, the legislators decided to close this loophole through the adoption of a regulation regarding the use of tolerances in verification procedures, amending simultaneously no less than 25 Ecodesign product-specific legislations.¹³ Such situations could perhaps have been avoided if no discretionary powers had been delegated to

standardisers, and if the standards development process had involved a wider, more balanced number of stakeholders throughout, and been more transparent.

More recently, in the public health sector, the Dutch National Institute for Public Health and the Environment (RIVM) and the Dutch Food and Consumer Product Safety Authority (NVWA) have decided to step down from all tobacco committees in charge of advising on the measurement of toxic substances in cigarettes. RIVM and NVWA explained that their decision was due to the overrepresentation of the tobacco lobby in the NEN, CEN and ISO standardisation committees which did not allow to give public health sufficient emphasis.¹⁴ The organisations consider other methods, such as those developed by the WHO Tobacco Laboratory Network (TobLabNet)¹⁵, as more reliable since they have been developed and validated independently of the tobacco industry.

Luckily, successful examples also exist. Nevertheless, the increasing use of standards in political areas of general interest risks leading to growing tension between political objectives and private interests. Therefore, ECOS, calls for a rethinking of the standardisation process to make sure this public-private partnership works for all. We believe that standards should only be used as tools to provide purely technical details when

¹⁰ "How product testing practices contribute to the loss of energy savings, and how to prevent it", ECOS [paper](#), April 2016

¹¹ "Closing the reality gap – Ensuring a fair energy label for consumers. Identifying weaknesses and recommending solutions to improve critical aspects of test standards for televisions, refrigerators and dishwashers", CLASP, ECOS, EEB and Topten [report](#), June 2017

¹² See for instance on light bulbs: <https://www.theguardian.com/environment/2015/dec/17/leading-lightbulb-brands-making-false-claims-on-energy-efficiency>

¹³ <http://ecostandard.org/verification-tolerances-and-measurement-uncertainties/>

¹⁴ RIVM press statement:

https://www.rivm.nl/en/Documents_and_publications/Commun_and_Present/Newsmessages/2018/RIVM_withdraws_from_tobacco_committees; also reported in the news e.g. <https://radar.avrotros.nl/uitzendingen/gemist/07-05-2018/rivm-stapt-uit-tabakscommissies/>

¹⁵ TobLabNet is a global network of government, academic, and independent laboratories working to strengthen national and regional capacity for the testing and research of the contents and emissions of tobacco products, in accordance with Article 9 of the WHO Framework Convention on Tobacco Control (WHO FCTC).

considered necessary and effective and should in no case replace legislation or accommodate political discussions.

Legislators should pay attention to the tasks which they choose to delegate to the European Standardisation Organisations (ESOs) and should be clear about their objectives and expectations. This means that legislators should neither delegate legislative powers nor give discretion to the standardisers, especially when it comes to health, safety and environmental aspects. This should always be the case, even if it entails that the legislators set a number of technical requirements in the legal text and are prescriptive and detailed in the standardisation requests submitted to the ESOs. Combined with greater inclusiveness in the system, this will not only ensure that standards remain technical and unbiased, but also that they meet the needs of both industry and society.

1.3. The quasi-binding nature of harmonised standards

Harmonised European standards are standards adopted on the basis of a request made by the European Commission for the application of Union harmonisation legislation. While these are voluntary and the result of a private process, their quasi-binding nature is no longer disputable.

First, once their titles and references are published in the Official Journal of the European Union (OJEU), harmonised standards provide presumption of conformity with the corresponding requirements of harmonisation legislation.

While economic operators are free to use any technical means to demonstrate that their products, services or processes comply with EU legislation, the harmonised standards provide a presumption of conformity. In this context, most business operators choose to use them since it is the cheapest and safest way to ensure compliance. This holds particularly true for companies engaged in cross-border trade.

Furthermore, after the adoption of a European standard (harmonised or not), the national standardisation bodies must withdraw all conflicting national standards.¹⁶ Finally, after publication of a reference in the EUOJ, Member States are obliged to respect the presumption of conformity which arises in respect to the products which comply with the standards and can in no way limit their entry into the market.¹⁷ In the *Commission vs. Hellenic Republic Case C-489/06*, the contracting authorities of Greek hospitals were told that they could not reject CE-market medical devices even on the grounds of protection of public health without following the safeguard procedure. Thus, harmonised standards represent a de facto barrier to the further development of products and services which comply with more ambitious demands, such as greater environmental performance, at least in public procurement.

In its *Vademecum* on standardisation, the Commission also adds that (...) *the legislator may decide to make standards, or parts thereof, compulsory, for example in order to ensure interoperability, to classify the performance of products or verify compliance against limit values laid down in legislation. Most commonly, however, standards become*

¹⁶ Article 3(6) of Regulation (EU) 1025/2012 on European standardisation

¹⁷ E.g. case C-100/13, *Commission v Germany* ECLI:EU:C:2014:2293

commercially binding on the basis of private agreements between economic operators.

Evidence that harmonised standards have *de facto* binding effects on market operators, notwithstanding their voluntary nature, has also been shown in many research papers and Court cases involving standards.¹⁸ In the *Fra.Bo.* case in 2012, the CJEU stated that a national standard can be considered as capable of hindering the free movement of goods since a certification body (here the German Technical and Scientific Association for Gas and Water, DVGW) *in reality holds the power to regulate the entry into the German market of products.*¹⁹

The best evidence, however, is undoubtedly the CJEU ruling in the *James Elliott* case. In this case, the CJEU stated that harmonised standards *form part of EU law* and qualified harmonised standards as *necessary implementation measures* of EU law provisions. The Court added that the fact that compliance with essential legal requirements can be proved via other means than proof of compliance with harmonised standards *cannot call into question the existence of the legal effects of a harmonised standard* (para 42).

The fact that harmonised standards are prepared by private bodies did not influence its conclusions for the following reasons:

- the preparation of harmonised standards is governed by the essential requirements contained in the underlying EU legislation;
- the drafting process is *initiated, managed and monitored by the Commission*;

¹⁸ M. Medzmariashvili, 'Delegation of Rulemaking Power to European Standards Organizations: Reconsidered'. *Legal Issues of Economic Integration* 44, no. 04 (2017): 353–366; Hettne, Jörgen, 'Standards, Barriers to Trade and EU Internal Market Rules: Need for a Renewed Approach?'. *Legal Issues of Economic Integration* 44, no. 4 (2017): 409–420

- it is only upon official publication of the reference to a harmonised standard in a Commission's Communication that the standard acquires its peculiar effects.

ECOS welcomes the CJEU's conclusion in the *James Elliott* case that harmonised standards form part of EU law. We strongly believe that this firm statement requires that the process of developing harmonised standards, from their mandating to their referencing, and the level of transparency on both the process and its outcomes are reconsidered. This exercise will need to take place with the involvement of all European institutions, stakeholders and the general public.

1.4 The politicisation of European standardisation

While legislators have been increasingly interested in using standards, the standardisation organisations have put themselves in the front line of political discussions. After publishing a Guide for policy-makers²⁰ clarifying the benefits of using voluntary standards to support the implementation of legislation and policies, CEN-CENELEC joined the Stakeholder group of the Commission's Regulatory Fitness and Performance (REFIT) platform.

This platform aims to ensure that EU legislation delivers results for citizens and businesses effectively, efficiently and at minimum cost. In the platform, CEN-CENELEC actively promote the role of European standardisation in the Better Regulation agenda, and, in particular,

¹⁹ C-171/11, *Fra.bo SpA v Deutsche Vereinigung des Gas- und Wasserfaches eV (DVGW)* — Technisch-Wissenschaftlicher Verein, ECLI:EU:C:2012:453, paragraph 32

²⁰ CEN-CENELEC Guide 30 'European Guide on Standards and Regulation - Better regulation through the use of voluntary standards - Guidance for policy makers'

the benefits of market-driven standardisation as a means of supporting European policy objectives. They often refer to the untapped potential of using standards in key areas of public interest such as energy and consumer protection policies. In the Committee on Standards, many Member States are also directly represented by the national standardisation bodies.

In 2018, the Standards Market Relevance Roundtable ("SMARRT") was established to improve the dialogue and cooperation between the Commission and industry representatives with a view to *enhance the effectiveness of the legislators' use of the European Standardisation System*. The Roundtable meets before each meeting of the Member States' Committee on Standards to *offer market relevance opinions*. This initiative has been heavily criticised by civil society organisations as the voice of industry was already considered to be sufficiently represented through the ESOs and was thereby given another avenue of influence.

ECOS believes that this politicisation of standardisation is an additional reason for a renewed political approach to standards which can ensure that an adequate balance is found between what needs to be set in law and what can be delegated to private bodies.

This revised approach should go hand in hand with democratisation of the process of developing harmonised standards, where there is an increased transparency, as well as a greater and more effective participation of civil society organisations at all levels. Such democratisation should be seen both as a must

and an added value, and not as a threat, especially not to efficiency, flexibility or speed. It is rather the lack of democratic elements which represents a threat to the future legitimacy of the regulatory approach to standardisation.

2. The need to review the political approach to standards

2.1 Further clarifying the legal nature of harmonised standards

With the CJEU *James Elliott* ruling that harmonised standards form *part of EU law*, it is now clear that the Court of Justice has jurisdiction over the validity and interpretation of harmonised standards, and can give preliminary rulings concerning the latter, in accordance with [Article 267](#) of the Treaty on the Functioning of the European Union (TFEU), as for acts of the institutions, bodies, offices or agencies of the Union. This fact also finds confirmation in Toolbox 18 of the Better Regulation Package, where the Commission states that *Where indirectly referenced technical standards, even when voluntary, confer a legal effect, such technical standards fall under Article 267 of TFEU meaning that the Court of Justice of the European Union shall have jurisdiction to give preliminary rulings concerning the validity and interpretation of such standards.*²¹

The further legal implications of the CJEU ruling are, however, still to be clarified. In particular, clarity is needed as regards the extent to which the European standardisation

²¹ https://ec.europa.eu/info/sites/info/files/file_import/better-regulation-toolbox-18_en_0.pdf p. 114

process impacts the balance of power in the EU, and whether the process complies with fundamental constitutional principles, such as those of conferral and institutional balance.

According to these principles, the European institutions can only act within the limits of the powers conferred to them and delegation of powers is only allowed within certain limits. Today, it is not clear whether harmonised standards should be considered a product of *delegation* or *implementation*. A clarification of the legal nature of harmonised standards would be welcome as it would, at the same time, help clarify which safeguards and controls need to be applied to the process.

If harmonised standards were a product of delegation of powers from the Commission to the ESOs, the latter would need to comply with the requirements set by the CJEU for such delegation to be lawful. These requirements were referred to in the *ESMA* case²², where the Court stated that delegation of power is only lawful and respectful of the principle of institutional balance if it fulfils certain requirements, including the existence of an effective system of judicial control.

The position of the CJEU in the *James Elliott* case, on the other hand, suggests that harmonised standards should be seen as a product of *implementation* of EU law. If this be the case, then harmonised standards will need to be subject to the control procedure set out by [Article 291](#) of the TFEU, namely the Comitology procedure. This approach would be more consistent with Regulation (EU) 1025/2012, which already requires that the Comitology procedure is followed for the

adoption of Commission' Standardisation Requests to the ESOs to develop harmonised standards.

ECOS considers it urgent to have greater clarity on the exact legal nature of harmonised standards with a view to review the process and ensure that the necessary guarantees and control mechanisms are in place.

2.2 Strengthening the European Commission's control

In the *ESMA* case, the lawfulness of the delegation of tasks to the ESOs by policy-makers is conditional upon the existence not only of judicial control, but also of administrative control. In the case of harmonised standards, administrative control translates into the control exercised by the Commission on the process. However, here again, a number of questions are pending as to whether administrative law principles apply to European standardisation.²³

Harmonised standards associated with policies are generally developed as a response to a Standardisation Request submitted by the European Commission (EC) to the three ESOs, which are free to accept or reject it.

As said above, according to Regulation (EU) 1025/2012, a Request is an implementing act which is subject to the procedure laid down in Regulation (EU) 182/2011, the Comitology procedure.²⁴ The Commission should, therefore, consult the Committee on Standards, bringing together Member States, before adopting a Standardisation Request. If the Committee gives a negative opinion, the

²² Case C-270/12, *ESMA*, ECLI:EU:C:2014:18

²³ M. Gnes, "Do Administrative Law Principles Apply to European Standardization: Agencification or

Privatization?" (2017) 44 *Legal Issues of Economic Integration*, Issue 4, pp. 367–380

²⁴ Art. 10 (2) in conjunction with Art. 22(3)

Commission either appeals the decision to the Appeals Committee or submits a new version of the request within two months. The detailed rules about when and how Standardisation Requests are repealed, considered obsolete or modified are described in the Commission's staff working document known as the *Vademecum on European Standardisation in Support of Union Legislation and Policies (Part I)*.²⁵

While there is administrative control over the Standardisation Requests, questions can be raised by the fact that the Requests are drafted in close collaboration with the ESOs and interested stakeholders, sometimes involving their international counterparts ISO and IEC. The Standardisation Request on material efficiency in the area of Ecodesign (Mandate M/543) and the Standardisation Request on F-gases (M/555) are two examples where the Requests were largely redrafted by the standardisers mainly on the grounds that they would have otherwise been rejected (M/543 was actually rejected upon first submission).

While EU funding goes to the ESOs for part of their operations on the one hand, and the standardisation work requested by the Commission on the other, this does not translate into subordination of the ESOs to the European Commission. The ESOs are private entities whose income comes primarily from their membership, and whose internal rules and regulations apply whether or not work is undertaken in response to a Standardisation Request. There is no hierarchical relationship between the Commission and the ESOs (as in a principal-agent relationship), only guidelines for cooperation.

Once a Request has been accepted by the ESOs, the Commission is however meant to oversee the drafting process of the standards through the assistance of Harmonised Standards consultants (HAS consultants, formerly known as New Approach consultants). One of the main implications of the *James Elliott* judgement was that these consultants are no longer hired and managed by CEN-CENELEC, but directly by the Commission.²⁶ The main task of the HAS consultants is to ensure that harmonised standards comply with the essential requirements laid down in legislation and the related Standardisation Requests. The consultants are meant to be involved in the standardisation process from the onset and to provide comments on the compatibility of a draft standard at each stage of the process, i.e. from the establishment of a work programme by the technical body in charge of drafting the standards, up until the formal voting on the draft European standards.

The consultants, however, do not decide what technical requirements should be included in the standards. Their control is, therefore, not substantive and involves only a marginal control over the content of harmonised standards. Negative comments from the consultants may result in the suspension of further proceedings, when new version of the draft standard must be prepared. However, if a consultant and the concerned technical body cannot agree on how to address the concerns, the ESO's technical board is involved. The consultants have no veto right, and the technical body in charge is not obliged to adopt all suggestions provided by them.

²⁵ https://ec.europa.eu/growth/single-market/european-standards/vademecum_fr

²⁶ https://ec.europa.eu/growth/content/call-expression-interest-harmonised-standards-consultants_fr

Once the harmonised standards have been adopted by the ESOs, and if the Commission considers that the standards satisfy the request, the Commission published the title and reference to the standards in the C section of the OJEU through the adoption of a Commission's Communication.

ECOS believes that the administrative control over the standardisation process should be further assessed to ensure that the principles of lawful delegation are met. As regards the HAS consultants, ECOS welcomes the Commission's recent decision to handle their recruitment and management. However, we believe that the role of the consultants should be clearly defined and strengthened. Clear independence rules, such as those applying to the European Food Safety Agency (EFSA)²⁷, should be set to ensure the independence and impartiality of the consultants throughout the process.

2.3 Clarifying the extent of the judicial control

Traditionally, standards were considered immune from judicial scrutiny. Therefore, the CJEU's *James Elliott* judgement is a major step forward towards the "juridification" of harmonised standards.²⁸ From a judicial perspective, however, by stressing that the ESOs cannot be described as *institutions, bodies, offices or agencies of the Union*²⁹, the Court indirectly denied the reviewability of

standards in an annulment action under TFEU [Article 263](#).

An indirect challenge to the validity of a harmonised standard may, however, be possibly raised through a claim against the Commission's Communication which publishes the title and reference of this particular standard, thus relating to the "control function" of the Commission.³⁰ Such claim could allege that the Communication is invalid because the standard it makes reference to does not comply with the essential requirements. Nevertheless, it is unclear whether such challenging action would lead to the substantive review of the standard by the Court, as the standard is not directly referenced and remains a private document, available against payment. ECOS believes that questions around the judicial control over the standardisation process will need to be addressed in the future.

2.4 Clarifying where liability stands

Legal experts today struggle to agree on who could be held responsible for a standard that may be found to be insufficiently robust to meet essential requirements after publication, or even pose risks to e.g. consumers or the environment.³¹ Some argue that the ESOs and their members should be liable for any restrictive effects or risks posed by standards. It remains unclear, however, whether the standardisation organisations could be held responsible since the standards are being developed by the stakeholders involved, and

²⁷

https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

²⁸ H. Schepel, *The New Approach to the New Approach: The Juridification of Harmonised Standards in EU Law*, 12(4) *Maastricht J. Eur. Comp. L.* 521–533 (2013); Rob van Gestel, Hans-W. Micklitz, 'European integration through standardization: How judicial review is breaking down the club house of private standardization bodies' (2013) 50 *Common*

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²⁹ paragraph 34

³⁰ H. Schepel, *The New Approach to the New Approach: The Juridification of Harmonized Standards in EU Law*, pp. 528 ff

³¹ Verbruggen, P. (2017). "Private regulation in EU better regulation: Past performance and future promises." *European Journal of Law Reform*, 19(1-2), 121-140; "The liability of notified bodies under the EU's New Approach: the implications of the PIP breast implants case (C-219/15)", Verbruggen P. & van Leeuwen B., *Tilburg Private Law Working Paper Series No. 08/2017*

not the standardisation organisations themselves. On the contrary, others argue that it should be the European legislators, or the Member States, who should be liable for inappropriate provisions in the final standards. Legislators, however, do not have much control over the development process, and do not impose standards as they do with laws. Finally, in some cases, it was claimed that it was the notified bodies which should be made responsible.

ECOS believes that there is a need to clarify who would be liable for risks which may be posed by standards, including health and environmental risks. We also call upon the European institutions to start discussions on the reviewability of harmonised standards in actions for annulment.

2.5 Improving the standardisation process and the legal framework

With the increasing use of standards in policy and following the CJEU *James Elliott* ruling, the ESOs should review their rule-making process to introduce certain features of public rule-making, at least for standards associated with EU legislation.

In the Guidelines on the applicability of Article 101 of the TFEU to horizontal co-operation agreements, the Commission states: *With respect to transparency, the relevant standard-setting organisation would need to have procedures which allow stakeholders to effectively inform themselves of upcoming, ongoing and finalised standardisation work in good time at each stage of the development of*

*the standard.*³² Today, however, there is no difference between the process followed by the ESOs to develop European standards and that used for the development of European *harmonised* standards.

While improvements have been made in the standardisation system, the participation of civil society is not yet effective and many barriers to participation still exist, especially at national level. While the lack of expertise and resources is a frequent barrier for civil society organisations, other barriers are also common. These include the lack of information about planned or ongoing standardisation work, the low understanding of how the standards development process works, and the absence of specific participation rules and assistance tools.

The legal framework for European standardisation, including Regulation (EU) 1025/2012 contains requirements for the transparency and inclusiveness of the European Standardisation System. Nevertheless, the Regulation falls short on details and it is difficult to assess the extent to which the system has truly improved in this regard. For instance, while the Regulation requires the ESOs to encourage and facilitate the effective participation of all stakeholders, including those representing SMEs, the consumers, trade unions, and the environment,³³ there are no provisions as to how this should be done, which would allow to review progress. Moreover, while the national delegation principle prevails in CEN-CENELEC, national standardisation bodies are mainly encouraged to facilitate the participation of

³²[http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011XC0114\(04\)&from=EN,ref 282](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011XC0114(04)&from=EN,ref 282)

³³ [Regulation \(EU\) 1025/2012](#), Article 5

small- and medium-sized enterprises, and a series of measures to take is provided.³⁴

In July 2015, ECOS made a number of recommendations for a more transparent and inclusive standardisation system³⁵. Supported by the European organisations representing consumers and trade unions in standardisation, ANEC and ETUC respectively,³⁶ ECOS called for a specific category of stakeholders to be established within standardisation organisations for civil society organisations. Such separate category should include a series of specific rights (and obligations) adapted to the profile and limited means of these organisations:

- Unlimited access to technical bodies, and advisory groups;
- Unlimited access to existing standards and other deliverables (for non-commercial purposes);
- A “voting” right, even if symbolic, allowing societal organisations to provide a formal opinion on a draft standard, which would create awareness about the position of these organisations on specific topics and trigger some mechanisms;
- A right of appeal, allowing these organisations to launch an appeal against any standard that, in their opinion, could pose risks to the society or the environment.

Access to standardisation work should be without charge, and access to documents should be facilitated.

While progress has been made at the European level³⁷, civil society organisations are barely involved in standardisation at national level. Their participation is not sufficiently encouraged or facilitated, and when so, it is done inconsistently among national standards organisations. Greater efforts are, therefore, needed at national level to ensure that the process is inclusive at all levels.

While national standardisation organisations should take actions for a greater and effective participation of underrepresented stakeholders, national authorities also have a role to play in making this happen, for instance through financial support. In this context, should Regulation (EU) 1025/2012 be revised in the future, the wording should be strengthened and clarified, and the need for inclusiveness at national level should be more clearly addressed.

However, while facilitating the participation of civil society organisations in the standardisation process is paramount and will help legitimise the process, this alone cannot guarantee that the common good and public interest are taken into account in all standards. Civil society organisations will indeed not only remain weak in number within technical bodies but also they will not be able to mobilise enough resources to be represented in all relevant bodies irrespective of whether there are seats available or even funds to support them. In this context, there is a need to ensure that a mechanism is in place to safeguard societal concerns, including environmental

³⁴ Article 6

³⁵ [The future of European standardisation: ECOS' recommendations for a transparent and inclusive standardisation system, that can effectively support EU legislation and policies](#), July 2015

³⁶ [An effective contribution of societal stakeholders to ensure good quality standards: A joint proposal from ANEC, ECOS and ETUC](#), September 2015

³⁷ See joint ANEC-ECOS-ETUC-CEN-CENELEC brochure on the rights of civil society organisations in the European standardisation system: <https://www.cencenelec.eu/News/Publications/Publications/CivilSociety.pdf>

ones, to a bare minimum in the development of standards.

2.6 Making standards public and free of charge

The question around the public availability of standards has long been discussed.

In its Communication 2011/C 11/01³⁸, the Commission stated that *the standard-setting organisation's rules would need to ensure effective access to the standard on fair, reasonable and non-discriminatory terms*. As it is, standards are available for purchase from the national standardisation bodies and the price varies from one country to another. Standards are also not always available in all national languages.³⁹ The principled statements contained in Regulation (EU) 1025/2012 concerning the openness and transparency of the European standardisation process do not seem to apply in this case.

According to CEN-CENELEC, the exploitation of copyright on all European standards' contents, including harmonised ones, is a way to ensure the sustainability of the system, which is funded by the revenues from sales of standards.⁴⁰ Interestingly, however, national standardisation bodies were not able to provide figures on the sales of European harmonised standards during the impact

assessment conducted on the revision of the European Standardisation Package.⁴¹

Certain Member States have taken measures to address the public availability of standards at national level. National legislations in Austria⁴² and in the Netherlands⁴³ require that all standards made mandatory by national laws or regulations should be made publicly available free of charge. The standards referred to in legislation should be freely consultable at a defined location indicated on the organisation's website. In Belgium, in November 2017 the Federal Council for Sustainable Development (FRDO-CFDD) adopted a resolution calling for standards referred to in legislation to be made freely and publicly available, in all national languages.⁴⁴ The Council, whose role is to advise the Belgian federal government on federal policy for sustainable development, deplored the fact that national consultation councils, which also include the Central Economic Council and the Council on Consumption, are regularly asked to provide their opinions on draft legislation which refer to standards but do not have access to the contents of those standards.

While it is difficult to reconcile the fact that standards are part of EU law, as stated by the CJEU in the *James Elliott* case, with the fact that they are available only against payment,⁴⁵ it is premature to say that the ruling itself will lead

³⁸ [http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011XC0114\(04\)&from=EN](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52011XC0114(04)&from=EN)

³⁹ For example ISO 140001 is only available in English from the Estonian standardisation body

⁴⁰ https://www.cencenelec.eu/news/policy_opinions/PolicyOpinions/PositionPaper_Consequences_Judgment_Elliott%20case.pdf, p. 7

⁴¹ R. van Gestel, H.-W. Micklitz, 'European integration through standardization: How judicial review is breaking down the club house of private standardization bodies' 50(1) Common Market Law Review (2013), p. 147

⁴² Austrian Standardisation Act, January 2015 https://www.ris.bka.gv.at/Dokumente/BgblAuth/BGBLA_2015_I_153/BGBLA_2015_I_153.pdf, Ref 28

⁴³ <https://www.nen.nl/Normontwikkeling.htm>

⁴⁴ [Avis d'initiative sur la mise à disposition des normes du Conseil Fédéral du Développement Durable \(FRDO CFDD\), <http://www.frdo-cfdd.be/fr/publications/avis-dinitiative-sur-la-mise-disposition-des-normes>](https://www.frdo-cfdd.be/fr/publications/avis-dinitiative-sur-la-mise-disposition-des-normes)

⁴⁵ L. Senden, 'The Constitutional Fit of European Standardization Put to the Test', p. 352. For a different opinion, supporting the copyright of ESOs, see U. Karpenstein, 'Gefährdet der EuGH den New Approach?' (2017) EuZW, p. 321 and ff

to a change in the system of copyright of harmonised standards. Unlike the Advocate General, the Court of Justice did not qualify harmonised standards as acts of *institutions, bodies, offices and agencies*, a qualification which would have automatically brought harmonised standards under the scope of Article 15(3) TFEU and Regulation (EC) 1049/2001 on access to documents.

ECOS believes that harmonised standards should be easily accessible, free of charge, to the public and interested parties. We are convinced that greater transparency over the content of harmonised standards may also ultimately contribute to a more effective and inclusive standardisation system, with a well-balanced representation of interests.

2.7 Internationalisation of standardisation

CEN-CENELEC work in close cooperation with their respective international counterparts, ISO and IEC. The rules of cooperation are set in bilateral agreements: the Vienna agreement between CEN and ISO, and the Frankfurt agreement between CENELEC and IEC. According to these agreements, the international standardisation organisations should take the lead whenever possible when the standards are considered globally relevant, and independently of whether the standards are linked to EU legislation.

The Guidelines for the implementation of the Vienna agreement state: *ISO lead is the preferred option (...). Exceptional CEN lead is only possible if the P-members [national standards bodies who actively participate] of*

*the respective ISO committee that are not CEN national members agree by simple majority to allow the CEN committee to lead. It adds that: EC funding should not be a factor in taking decisions on lead assignment.*⁴⁶

In any case, whoever takes the lead should ensure that the other organisation is involved. This means that even in case where CEN or CENELEC leads on a standard considered of global relevance, it shall work with parallel voting in ISO or IEC at defined stages, with all comments received from the international level being addressed, adequately responded to and reported back to the international committee by the European committee in charge. According to CEN, thanks to this close cooperation, 43% of all European Standards in the chemicals sector are identical to the international standards published by ISO. This cooperation between CEN-CENELEC and their international counterparts exists beyond the strict boundaries of the standards-drafting process. ISO and IEC are indeed consulted very early in the standardisation process, including during the drafting process of the European Commission's Standardisation Requests.

In its Vademecum on standardisation, the Commission stresses that *where cooperating in standard development with other bodies (e.g. the ISO, the IEC or European sectoral standardisation bodies), the ESO that accepted the request remains fully responsible and accountable (...) for its compliance with the initial request.* It does not specify, however, whether this includes ensuring that the process by which the standards will be developed at international level should be

⁴⁶ Guidelines for the implementation of the Agreement on Technical Cooperation between ISO and CEN (the Vienna Agreement), 7th edition, 2016

equivalent to the European process, especially in terms of transparency and inclusiveness.

While international cooperation can be beneficial for the quality of the standards and is important for European companies to export their products globally, it raises questions about the actual power and control of European legislators over the mandating and development processes of harmonised standards. Moreover, the international standards development process takes place outside the boundaries of Regulation (EU) 1025/2012 and there have been examples where civil society organisations, including ECOS, were denied access to technical bodies in charge of developing future standards in relation to a Standardisation Request.

The ESOs should be responsible to ensure that the participation of Annex III organisations is encouraged and facilitated in the same way, and to the same extent, independently of whether the standards are developed at European or international level. The same institutional checks and balances should also apply at the European level. If this is not possible, no EC-commissioned standards should be allowed to be developed at international level.

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ANNEX 1 - The CJEU's ruling in the *James Elliott* case

The ruling of the Court of Justice of the European Union (CJEU) in the [James Elliott case](#) is a landmark decision: it is the first time that the Court decided upon the legal value of harmonised European standards (hENs).

The case started with a dispute between two companies in Ireland. James Elliott Construction Ltd., an Irish construction company, was in charge of the construction of a youth facility building in Dublin. The Irish Asphalt Ltd. company was contracted to provide the aggregates for use in the construction process, which were meant to comply with an Irish national standard. This national standard implements into Irish law a harmonised European standard adopted by CEN, in response to a Commission Standardisation Request given under the “New Approach” Directive on construction products. The aggregates supplied, however, did not meet the contractually required quality levels, and massive damages occurred to the building. As a result, James Elliott Construction Ltd. launched a dispute seeking financial compensation from Irish Asphalt for the remedial work it had to carry out.

The Irish Supreme Court expressed doubts regarding the interpretation of the scope and content of the standard under dispute, the relationship with the Construction Products Regulation, and the legal nature of hENs as a general principle. In particular, it inquired whether the CJEU may give a preliminary ruling about the interpretation of a hEN, in accordance with Article 267 of the TFEU. Article 267 of the TFEU states that the CJEU has jurisdiction over the validity and interpretation

of acts of the institutions, bodies, offices or agencies of the European Union. It was unclear whether this article applied in the case of harmonised European standards as the ESOs (CEN, CENELEC, and ETSI) are private organisations, and not agencies or bodies of the European Union. The Irish Supreme Court thus turned to the CJEU for a preliminary ruling.

In response to this question, the CJEU confirmed that the TFEU Article 267 applies, and that the Court has jurisdiction to give a preliminary ruling concerning the interpretation of a harmonised standard. This interpretation was based on the following arguments:

- Harmonised European standards form part of EU law;
- Harmonised European standards have legal effects.

The recognition that standards form part of EU law came from the fact that hENs are *a necessary implementation measure* of an act of EU law. In the construction products area, hENs constitute key supplements to the Construction Products Regulation which defines only the essential requirements to be complied with by construction products to gain access to the Internal Market. This is the first time the EU Court establishes a link between the hENs as voluntary acts adopted by private standardisation bodies, and EU law.

The Court added that hENs have legal effects, even if they are voluntary and developed by organisations governed by private law and which are not part the Union institutions, bodies, offices or agencies within the meaning of TFEU Article 267. The Court founded its conclusion on the fact that:

- The process of drawing up hENs is subject to the rigid control of the Commission;
- The process takes place within the strictly defined limits of a standardisation request of the Commission issued under a “New Approach” Directive;
- References to the standards are published in the EU Official Journal, thereby granting presumption of conformity to all products produced in accordance with those standards.

More generally, this judgment implied that a private regulatory act can be considered as having legal effects as part of EU law provided that:

- A close connection to an EU legislative act (here the Construction Products legislation) exists strictly governing the exercise of the delegated powers by the private body and clearly confining the scope of this exercise;
- A sufficiently strong involvement of the delegating authority (here the Commission) in the drawing up process of the private regulatory act can be evidenced, and public accessibility of such acts is guaranteed, in the case of hENs, through their publication in the EU Official Journal.