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In an increasingly globalised world, standards made at the international level constitute valuable instruments to regulate complex technical issues and facilitate trade. In light of their undoubted economic advantages, the EU legislature often relies on these international standards including by making express reference to them in legislative texts. The use of international standards in regulation is expressly favoured by EU institutions. This incorporation of global standards into the EU’s legal system, however, challenges the basic tenets of public law, as the pending case *Stichting Rookpreventie Jeugd and Others* (C-160/20) blatantly exposes.

As already explained here, the Court has been asked to rule on the validity of the reference to a methodology established by an ISO standard contained in Directive 2014/40. The use of references in legislative texts is a well-established mechanism in the national legal systems and does not per se raise particular concerns. The problem lies in the fact that the ISO standards are issued by a private organisation, composed predominantly of experts and representatives of the business sector, and they are covered by copyright. Thus, is a reference to a rule which is not published in the Official Journal and is accessible only upon payment of royalties compatible with the rule of law?

The same issue was already discussed in some national cases, where the courts arrived at different conclusions (compare, for instance, this and this). Some of them held that standards cannot be considered a purely private phenomenon and it is paramount that citizens are put in a position to know the obligations they must abide by and the rights they can invoke. Therefore, when reference to standards is made in national law, the principle of legal certainty requires that the text of the standard shall be made publicly available free of charge. Advocate General Saugmandsgaard Øe, however, does not share this view.

In his Opinion, he argues that the above mentioned ISO standard does not constitute a legislative act – which would be subject to the duty of publication under Article 297(1) TFEU – but that it must still be considered an ‘element’ of the

legislative act. Then, instead of concluding that this entails the need to publish the measure, he puts forward a rather artificial distinction between technical rules which are merely technical and *accessory* to the essential requirements established in the legislative act, and the technical rules which are *necessary* to understand the scope or the content of the latter. Since the ISO standard is not directly connected to the establishment of the emission levels of cigarettes (it establishes only the method to measure them) and it does not impose obligations on producers or importers (but only to the control laboratories), it is to be considered only accessory and therefore it does not need to be published in the Official Journal.

The criteria proposed by the Advocate General are both vague and unconvincing. Clearly, in line with the principles of the New Approach and of the delegation of powers in general, essential requirements are the reserved domain of the legislature and their definition cannot be outsourced to other bodies – whether private or public, European or international. The establishment of the methodology for the calculation of emission levels has a clear effect on the legal sphere of producers and importers since, according to the method used to determine their emissions, they are allowed to include more or less substances related to tar, nicotine and carbon monoxide emissions in the composition of their products. Through the very act of referring to the ISO standard in legislation, this becomes a binding part of the legal framework governing their behaviour. If the technical and accessory character of the standard justifies its definition through a non-legislative act, it does not push it outside the fundamental guarantees of public law.

The real justification for maintaining the *status quo* emerges more clearly in the second part of the Opinion, in which the Advocate General stresses the essential and strategic role of standardisation bodies for the internal market and international trade. Free access to the text of standards would demolish the very foundations of the standardisation system, which is sustained by the royalties on the standards they create. The importance of such a system for the European economy outweighs the pecuniary burden for the citizens to obtain those standards. In balancing the conflicting interests at stake, however, the Advocate General does not consider the fact that international standards are often produced through obscure procedures, without democratic credentials or societal involvement. This system, traditionally managed as a matter of and for industry, is inevitably subject to regulatory capture by the most powerful companies in the field. The limited guarantees of transparency and participation imposed by Regulation 1025/2012 on the European standardisation bodies do not extend to the international or national systems. In fact, NGOs representing societal interests in standardisation too often face legal and practical obstacles to their effective participation in ISO technical committees. In fields strictly connected to health and consumer protection, such as the one at stake, this is particularly problematic.

National courts granting free access to standards, and the Court of Justice in *Fra.bo.* (C-171/11) and *James Elliott* (C-613/14), contributed to progressively break down 'the club house of private standardisation bodies', departing from the image and narrative of European harmonised standards as purely private, voluntary, market-driven instruments, and establishing their public law relevance for the EU legal order. This Opinion

of AG Saugmandsgaard Øe and the General Court's judgment in *Public.Resource.Org and Right to Know v Commission* (T-185/19) seem to put a halt to that judicial trend. Admittedly, the approach of the Court towards global standards and their judicial review is far from being linear (as already argued here) and a radical reform of such an important system cannot be left in the hands of the court. The issue raised in case C-160/20, however, invites the legislature to engage in careful consideration before abdicating its rule-making role in favour of international standardisation bodies, irrespective of the final outcome of the case. In this sense, the upcoming publication of the Standardisation Strategy of the Commission may also represent an opportunity to reflect on the challenges on transparency, participation and, more concretely, compliance with international obligations (in particular, the Aarhus Convention) that the increased resort to European and global standards entails.

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