

Hierarchies of legislation and standards and their interaction in controlling product safety

There are 2 hierarchies of guidelines in place that exist in parallel in the United Kingdom. These are the hierarchy of legislation and the hierarchy of standards, as seen in *Table 1*. Legislation is legally mandated by different levels of government, and so contravening it within its geographical scope constitutes a criminal offence. It is written in broad terms to apply in as many situations as possible. Standards, conversely, are guidelines for companies by non-government agencies that provide a number of very specific criteria that products and systems must meet to comply with them. There is no inherent obligation to follow standards; they are typically used to demonstrate a product's prowess in a safety or technical domain, with more cachet the higher it is in the hierarchy.

Hierarchy of legislation	Hierarchy of standards
European Law (Civil liberties etc.)	International standards bodies (ISO, NATO etc.)
European Directives (New approach directives)	European Standards (EN, ECE)
UK implementation of EU directives	Harmonised standards (BS/EN)
UK Acts of parliament	Domestic Standards (BS) - Kitemark
UK Regulations	Other National Standards (ANSI, ASTM, TNO)
Byelaws (from local councils)	Trade Standards (SAE, ACU, etc)
	Other endorsements

Table 1: The hierarchies of legislation and standards in descending order of scope of influence (Clift, 2015)

The two sets of guidelines are not intrinsically linked, however some relationships do exist between pieces of legislation and related standards. These relationships arise from the reference (or lack thereof) to standards in legislation. They can be broadly categorized as having a fixed link, a flexible link or no link, each of which have implications for their application and effect on the end user safety for the products to which they pertain.

The *Food Imitations (Safety) Regulations 1989 (SI 1989/1291)* is an example of UK regulations that do not link to a standard in any way. The legislation itself makes illegal the supply or intent to supply of any non-food "manufactured goods" (with some specified exceptions) that could be reasonably mistaken for - and attempted to be consumed as - food, whereby an attempt at consumption "may cause death or personal injury". A manufacturer or supplier familiar with this legislation should be able to determine which aspects of a proposed or existing product need to be addressed, but will not have any guidelines as to how to undertake producing a safe product or testing said product's safety, as a related standard would typically provide. Presuming that the legislation comprehensively covers all the pertinent safety concerns in its specific domain, the manufacturer should be able to create a product that is legal and safe if they can find appropriate tests of safety. This presumption is not necessarily true, however, and as the manufacturer is likely to consider the legislation comprehensive, they are correspondingly unlikely to do more than is stated in the legislation, which will lead to products unsafe in the aspects not covered.

An example of UK regulations with a fixed link to a standard is the *Pedal Bicycles (Safety) Regulations 2003 (SI 2003/1101)*. It states that "no person shall supply any bicycle unless", if the bicycle is covered by "the British Standard", "it complies with all the requirements specified in that

standard (including marking requirements)", where "the British Standard" includes "BS 6102: Part 1: 1992". While up to date, this provided suppliers with a precise system to follow to ensure their bicycles' safety. The standard was, however, revised into multiple parts including BS EN 14764:2005 (British Standards Online), leaving the regulations pointing to an outdated standard. This meant that not only were manufacturers not legally obliged to follow the latest standard, if they did comply with the latest standard but did not also comply with the obsolete one (to include being labelled as complying with it) then they would be criminally liable. This type of system serves to punish the manufacturers and suppliers who attempt to do the best thing for their consumers (but who have not read the specifics of the regulation) by ensuring their product meets at least the latest standard. For the many companies that do as little as possible to avoid legal culpability, they will assume the specified standard is sufficient and only comply with that - less than the agreed minimum requirement for safety at the time of manufacture and sale.

The *Toys (Safety) Regulations 2011 (SI 2011/1881)* contain a flexible link to standards. Essential safety requirements are laid out, which are followed by a presumption of compliance: "A toy which conforms with harmonised standards shall be presumed to comply with the essential safety requirements to the extent that those requirements are covered by those standards". This presumption is also stated to be "rebuttable", meaning that a product that conforms to the appropriate standards could be considered legally unsafe if further evidence was brought forward. The precedent for this was set in the decisive *Balding v. Lew-Ways Ltd* [1995] 159 JP 541 case, wherein it was ruled that compliance with a standard was not necessarily sufficient to be deemed safe. Standards are a first step toward safety rather than a definitive declaration of it. As a result, the responsibility lies on the manufacturer to determine what constitutes due diligence based on the size of their company and the type of product in question. This process is costly, so it benefits companies to be conservative in their design choices, trending toward a local maxima of safety at the cost of innovation. This may well be a benefit to consumer safety in the short term, but will make large step changes in design, which may lead to greater safety, less likely.

In summary, the hierarchies of legislation and standards operate at many different levels of influence. They are created and normally operate separately, however some legislation will create links to relevant standards. Each of the three connections explored above makes compromises in terms of the ease with which companies can follow them and the end user safety for the products covered.

Word Count: 1000

Bibliography

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