

Human blood and blood components: quality and safety for the collection, testing, processing, storage and distribution

2000/0323(COD) - 15/11/2001 - Modified legislative proposal

The Commission has made a number of amendments to its original proposal bearing in mind parliamentary amendments proposed following the first reading. The main amendments have been grouped into three categories namely, scope of the Directive, establishment of technical standards and voluntary, unpaid donation. Concerning the first category, scope of the Directive, this has now been extended to the collection and testing of blood and blood components for all purposes, including the manufacturing of medicinal products. Council Directive 89/381/EEC has been amended accordingly. In terms of the establishment of technical standards new solutions have been introduced as far as technical implementing provisions are concerned. Rather than including a list of technical annexes to the Directive, the Commission shall develop and up-date the technical implementing provision through the use of a regulatory committee procedure. Lastly, a new amendment has been included which urges Member States to encourage the voluntary and unpaid donation of blood and blood components.