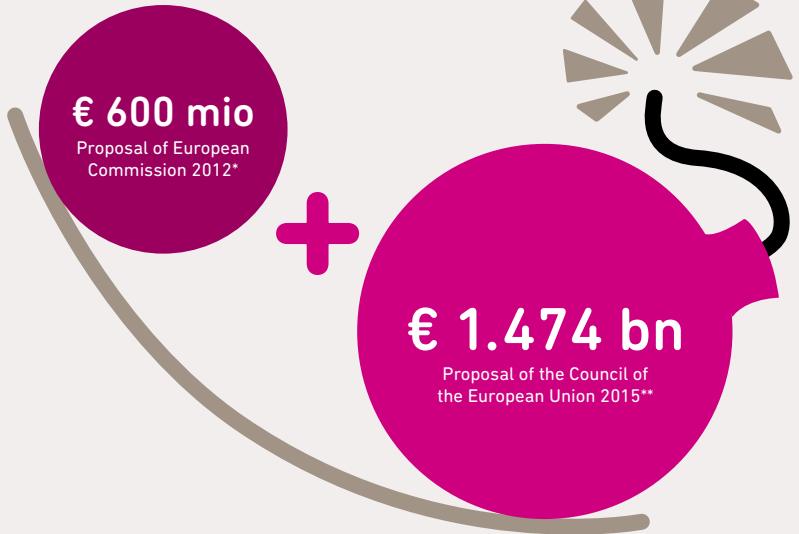


New IVD regulation

Impact on manufacturers



**Estimated additional costs for the European IVD industry
(five-year period)**

The proposed IVD regulation lays down rules concerning the placing on the market of in vitro diagnostics. The proposal of the Council would burden the industry with more than two billion euros.

Sources:

- * European Diagnostic Manufacturers Association (EDMA) 2012, European Commission 2012, VDGH member survey 12 / 2013
- ** Survey of the German Diagnostic Manufacturers Association (VDGH) after presentation of the proposals of the Council 6/2015

VDGH

Verband der Diagnostica-Industrie