



Council of the
European Union

Brussels, 5 February 2015
(OR. en)

5848/15
ADD 1

ENV 33
MI 58
DELECT 11

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	30 January 2015
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union

No. Cion doc.:	C(2015) 328 final - Annex 1
Subject:	ANNEX to Commission Delegated Directive amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices

Delegations will find attached document C(2015) 328 final - Annex 1.

Encl.: C(2015) 328 final - Annex 1



Brussels, 30.1.2015
C(2015) 328 final

ANNEX 1

ANNEX

to

Commission Delegated Directive

amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices

ANNEX

to

Commission Delegated Directive

amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices

In Annex IV to Directive 2011/65/EU, the following point 41 is added:

"41. Lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases.

Expires on 31 December 2018."