Council of the
European Union

Brussels, 25 January 2021
(OR. en)

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ENV 32
ENT 11
COMPET 34
IND 21
SAN 22
CONSOM 13
MI 23
CHIMIE 5
DELACT 8

'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)
No. Cion doc.:	13455/20 + ADD 1 - C(2020) 7980 final + Annex
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 27.11.2020 amending Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds - Intention not to raise objection to a delegated act

1. The Commission has submitted the abovementioned delegated act[1] to the Council in accordance with the procedure set out in Article 290 TFEU and in particular the second subparagraph of Article 15(1) of Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants[2]. The Commission notified the delegated act on 27 November 2020, therefore, the Council may object to it until 27 January 2021.

1 Doc. 13455/20 +ADD1.
2 OJ L 169, 25.6.2019, p. 45–77.

2. The Working Party on Environment examined the delegated act through an informal consultation procedure. Within the established deadline, the Netherlands submitted the Statement set out in the Annex to this Note.

3. After expiry of the two months period for objection, and unless the European Parliament objects to it, the delegated act shall be published and shall enter into force on the twentieth day following its publication in the Official Journal of the European Union in accordance with Article 2 of the Delegated Regulation.

4. In view of the above, the Permanent Representatives Committee is invited:
   - to confirm the intention not to raise an objection to the delegated act;
   - to take note of the Statement of the Netherlands set out in the Annex to this note and to enter the Statement in the minutes of its meeting.

ANNEX

Statement from The Netherlands

The Netherlands recognises that the proposed delegated act to relax the unintended trace contamination (UTC) for PFOA in medical devices from 25 ppb to 2 ppm is needed as industry has indicated that for now, it is not possible to produce the relevant medical devices meeting the 25 ppb standard. Yet, there are two issues that raise concern.

First, both the EU and the EC have committed themselves to eliminating to the extent possible the use and emission of PFAS. Raising the UTC now seems contradictory to these efforts even though it is proposed as a temporary measure which is to be reviewed after 2 years.

Second, the UTC for PFOA proposed in the delegated regulation deviates from the limit value set within the Stockholm Convention (that does not have an exemption for medical devices).

To ensure consistency, the Netherlands is of the opinion that the EU should also request the proposed exemption within the framework of the Stockholm Convention.

Therefore, the Netherlands abstains from the Council's non-objection to the delegated Regulation.