From: @health.fgov.be>
Sent: Thursday, April 30, 2020 5:07 PM
To: GROW CARACAL <GROW-CARACAL@ec.europa.eu>; ENV CARACAL <ENV-CARACAL@ec.europa.eu>
Cc: @health.fgov.be>; reach <reach@health.fgov.be>
Subject: CARACAL34 : BE Comments on the doc CA/18/2020 IND Paper - AP 8.1

Dear colleagues,

We have taken good note of the document *10 - a.p. 8.1_ Euromcontact_AESGP_MedTechEurope_position paper* referred to in the Open Caracal session agenda (*Doc. CA/01/2020 rev1 VERSION OF 19 MARCH DRAFT AGENDA*) as:

8.1 REACH Restrictions on CMRs used in Medical Devices (Industry position paper)	CA/18/2020 Written comments by	8 May 2020

We hereby communicate the **Belgian comments** relative to this topics:

We note the request by an industry sector (*Euromcontact_AESGP_MedTechEurope*) for the possible exemption for products falling under the scope of the *Regulation (EU) 2017/745 on medical devices* (which entry into force is delayed to 2021 – if our information is correct) relative to the Borates under the entries 28-30 of Annex XVII.

We identity a need for information to obtain the necessary clarifications on the functioning of the (future) provisions under REG 2017/745 (*MDR Annex I Chapter II Section 10.4.1.*) relative to the restrictions of the CMRs substances in substances, mixtures and articles. We therefore ask the **Commission to provide us with all necessary information to ensure how the current obligations relative to the (Consumer) substances and mixtures will be dealt with by the new regulation, in case the Borates would be exempted from the REACH /Annex XVII obligations (entries 28-30), based on a legal analysis**. This analysis should also include elements relative to the currently applicable regulation, the Medical Device Directive (MDD), as requested by the sector. We also ask the Commission to provide the REACH CAs with **any other requests received by industry to date, relative to other Substances, where issues had been identified regarding the current CMRs ban in the (Consumer) Substances and Mixtures for use in Medical Devices**. Available information relative to the absence of (non CMRs) substitutes should certainly be key for discussions on the identified substances.

We consider the **information required above would be the indispensable basis for any discussion considering an exemption from the current applicable obligations (relative to some 28-30 Annex XVII entries)**. Besides, we consider the **dialogue is necessary with the authorities in charge of the Medical Device Regulation** relative to the coherence and coordination of the corresponding obligations of the new regulation and ask the Commission for the initiative that have been taken to that aim. We would be particularly interested in learning how the industry dossiers for requiring exemption from these provisions (*10.4.2.*

Justification regarding the presence of CMR and/or endocrine-disrupting substances and ensuing *guidelines* under *10.4.3.* and *10.4.4*) will be assessed by the authorities.

Furthermore, **we are astonished** that while this topic is currently under consultation at the Caracal (based on an industry request and without any informative document from the Commission), the **Commission proposal** (due REACH Committee 13/5/2020) relative to the listing of the new classified substances (or updated classifications) under entries 28-30 of Annex XVIIalready **inserts a general exemption (i.e. for all CMRs substances) for products under the scope of the *Regulation (EU) 2017/745 on medical devices*** (which entry into force is delayed to 2021 – if our information is correct). *Reference for the proposal: COMMISSION REGULATION (EU) .../... of XXX amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), as regards carcinogenic, mutagenic or reproductive toxicant (CMR) substances, devices covered by Regulation (EU) 2017/745 of the European Parliament and of the Council, persistent organic pollutants, certain liquid substances or mixtures, nonylphenol and testing methods for azocolourants: EXTRACT: (3) In entries 28-30, the following point (f) is added in paragraph 2 of column 2: "(f) devices covered by Regulation (EU) 2017/745".*

We therefore request this topic to be discussed, both in Caracal and in the REACH Committee, based on above stated information items to be communicated by the Commission to the MSs.

Best regards

For the REACH and CLP Belgian CAs,

Eurostation | Place Victor Horta, 40/10 | 1060 Saint-Gilles | Belgique
Bureau 02C27B | **t** 02 524 | **f** 0 |

service public fédéral
Santé publique, Sécurité de la Chaîne alimentaire et Environnement
www.health.belgium.be | Contact Center +32 (0)2.524.97.97