To: Members of the REACH Committee

Brussels, 18 June 2020

Dear Sir/Madam,

We are writing to you regarding the REACH Committee Meeting that will take place next week on 23 June. At this meeting crucial discussions, and potentially votes (by written procedure), are planned on:

(1) the restriction proposal on lead in gunshot in or around wetlands

(2) the restriction proposal on substances in tattoo inks or permanent make-up

(3) the proposal to exempt medical devices from REACH annex XVII

Agenda point 4. Restriction of lead in gunshot in or around wetlands

We ask you to support this restriction as it will not only avoid deaths due to lead poisoning of over 1 million birds and other wildlife species each year, but it will also prevent impacts on the EU population, in particular on children and pregnant women, caused by the uncontrolled dispersion of lead into the EU's environment.

Ammunition industry figures estimate that a total of 18,000-21,000 tonnes of lead is being dispersed annually into the EU's environment from hunting, of which 1,432 to 7,684 tonnes are released on wetlands. Estimates from individual Member States suggest that the figures may be far greater.

Moreover, several EU countries (such as Denmark, Norway, Belgium, the Netherlands and Finland) have already banned the use of lead in shot in wetlands-.

We urge you to support this proposal during the meeting of next week, as this decision has been delayed for already almost two years.

We also invite you to read our joint letter with WWF and BirdLife International (attached) for further details.

Agenda point 5. Restriction of substances in tattoo inks or permanent make-up

We ask you to support this restriction which is a positive illustration of ECHA's and the Commission's efforts to address and regulate large groups of chemicals of concern, for which there is direct human exposure leading to well-founded short- and long-term health concerns.

European Environmental Bureau
Europe's largest network of
environmental citizens' organisations
www.eeb.org
International non-profit association –
Association internationale sans but lucratif

Boulevard de Waterloo 34, B-1000 Brussels
Tel.: +32 2 289 10 90
Email: eeb@eeb.org

EC register for interest representatives:
Identification number: 06798511314-27

You can find a detailed analysis by the EEB and HEAL in the document "Proposed European restriction on tattoo inks and permanent make-up: HEAL and EEB's updated analysis".

Agenda point 6. Draft Commission Regulation Draft (EU) amending Annex XVII to the Commission REACH Regulation (EC) No Regulation 1907/2006

This draft regulation proposes to exempt devices within the scope of Regulation (EU) 2017/745 (Medical Device Regulation (MDR)) from the restrictions laid down in entries 28-30 of Annex XVII of REACH as it is considered that the level of protection of human health provided by both Regulations are comparable.

However, as detailed in the joint Health Care Without Harm Europe, ClientEarth and EEB letter we sent you on the 8th May 2020, the MDR obligations only cover patient contact materials which are invasive, (re)administer, transport or store medicines, body liquids or other substances, including gases, to/from the body. They require substitution only when replacement is technically possible and benefits of substitution outweigh risk. Only CMR 1A and B are concerned (MDR Annex I section 10.4).

There are currently more than 500,000 medical devices available in hospitals, community-care settings and at home (The European Medical Technology Industry in figures 2019). Therefore, any general derogation from the REACH CMR Restriction (i.e. for all CMRs substances and for all products under the scope of the MDR) has a potential to exempt a high number of medical devices which safety will not be ensured under Annex I Section 10.4 of the MDR once it enters into force.

In addition, the Medical Device Regulation (MDR) will fully apply from May 2021 and not 2020. If the proposal under discussion is approved, it will result in an unacceptable gap of several months in the protection of people from CMRs via Medical Devices.

In order to avoid a reduction of the level of health protection currently ensured, we ask you to ensure that:

- the derogation should be formulated as "devices within the scope of Annex I section 10.4 of Regulation (EU) 2017/745 should be exempted from the restrictions laid down in entries 28-30 of Annex XVII to Regulation (EC) No 1907/2006".

- the entry into force of the exemption should match the entry into force of the new MDR.

Yours faithfully,

Tatiana Santos
Policy Manager: Chemicals & Nanotechnology, EEB

European Environmental Bureau
Europe's largest network of
environmental citizens' organisations
www.eeb.org
International non-profit association –
Association internationale sans but lucratif

Boulevard de Waterloo 34, B-1000 Brussels
Tel.: +32 2 289 10 90
Email: eeb@eeb.org

EC register for interest representatives:
Identification number: 06798511314-27

On behalf of:

European Environmental Bureau (EEB)

Health and Environment Alliance (HEAL)

European Environmental Bureau
Europe's largest network of
environmental citizens' organisations
www.eeb.org
International non-profit association –
Association internationale sans but lucratif

Boulevard de Waterloo 34, B-1000 Brussels
Tel.: +32 2 289 10 90
Email: eeb@eeb.org

EC register for interest representatives:
Identification number: 06798511314-27