Council of the European Union

Brussels, 7 October 2016
(OR. en)

12959/16

ENV 637
CONSOM 234
SAN 347
CHIMIE 55
AGRI 537
MI 620

NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Identification of endocrine disrupting substances - Information from the Danish, Netherlands and Swedish delegations, supported by the Luxembourg delegation

Delegations will find in the Annex an information note from the Danish, Netherlands and Swedish delegations, supported by the Luxembourg delegation on the above subject, to be dealt with under "Any other business" at the Council (Environment) meeting on 17 October 2016.

ANNEX

Identification of endocrine disrupting substances

- Information from the Danish, Netherlands and Swedish delegations, supported by the Luxembourg delegation -

The European Union's 7th Environmental Action Programme (7th EAP) provides a long-term vision to achieve a non-toxic environment. Developing harmonised criteria for the identification of endocrine disruptors is one of the key points of the 7th EAP to meet that objective.

Clear scientific criteria for the determination of endocrine disrupting properties, combined with adequate information requirements, are the prerequisite for proper identification of endocrine disrupting substances. They also form the basis for the subsequent assessment of the risk that may be associated with the uses of such substances.

The establishment of scientific criteria is also to facilitate:

- clarity and predictability for industry, promoting responsible behaviour, investments and sustainable growth,
- improved basis for regulation of endocrine disrupting substances,
- better protection of consumers, workers and the environment, thus boosting confidence,
- consistency in the approach to chemicals across relevant regulations.

Under the Biocidal Products Regulation (BPR), and the Regulation for placing Plant Protection Products on the market (PPPR), the European Commission (Commission) was to adopt a delegated act no later than 13 December 2013 and to draft an implementing act, by 14 December 2013, specifying scientific criteria for the determination of endocrine disrupting properties. On 15 June 2016, the Commission presented its Communication on criteria for endocrine disruptors [*], including two draft acts setting out scientific criteria for endocrine disrupting properties in the context of EU legislation on biocidal products and plant protection products.

[*] Docs 10442/16 - COM(2016) 350 final + ADD 1 to ADD 17.

These draft Commission regulations follow comitology procedures. The topic of criteria for endocrine disruptors, however, is at the heart of public and political interest and therefore merits attention at Council level. This is further illustrated by the fact that the Commission proposals for criteria have already been questioned by several parties. During the first round of comments in the June Council, questions were raised as to whether the criteria meet the objectives of the respective regulations and whether they are within the legal mandate of the Commission.

The BPR and PPPR refer to substances that are considered as having endocrine-disrupting properties that may cause adverse effects in humans. This includes both substances that lead to and are presumed to lead to adverse effects due to endocrine disruption.

The criteria to identify endocrine disruptors must be consistent with the legal text in the BPR and PPPR and also with the globally accepted approach for identification of hazardous substances according to the GHS and the CLP regulation. Furthermore, the criteria should also be in line with the Commission's better regulation initiative (REFIT) that aims at consistency and coherency across legislation.