

NEWSLETTER – January/February 2021

Our first year at PEPPER!

The public-private platform dedicated to the pre-validation of endocrine disruptors characterization methods (PEPPER) was established as a non-profit association (under the French 1901 law) in December 2019.

From April to August 2020, an inventory work was conducted to identify methods which are scientifically robust, mature enough and able to bridge existing gaps in endocrine disruptors characterization.

In September 2020, three of these methods were selected to enter the pre-validation process. The first method resorts to human placental cells and aims at assessing women's exposure during pregnancy. The second method resorts to zebrafish larvae and measures the size of adipocyte (lipid storage) to identify substances which could contribute to obesity or diabetes for instance. The third method resorts to human adrenal cells to analyse substances' potential effects on hormone synthesis (this last method being an enhancement of an existing OECD Test Guideline).



PEPPER is currently in talks with the laboratories developing these methods to identify protocols and resources needed for their testing. The contractual phase has started in January 2021.

European Commission: Fitness Check and Chemicals Strategy for sustainability



Brussels, 14.10.2020
SWD(2020) 251 final

COMMISSION STAFF WORKING DOCUMENT
FITNESS CHECK
on endocrine disruptors

The Fitness Check on endocrine disruptors¹ and the Chemicals Strategy for sustainability² have been published on 14 October 2020 (the Fitness Check as an Annex).

The Fitness Check, as announced in November 2018, is a screening on how endocrine disruptors are addressed in more than 30 European regulations or directives. This covers a wide range of regulated industries: plant protection products, biocidal products, toys, cosmetics, food contact materials,

REACH, human and veterinary medicines (unintended exposure via the environment), water.

The Fitness Check addresses the coherence and global effectiveness of EU legislation in terms of protection of human health and the environment from the harmful effects of endocrine disruptors. The document conclusions include the necessity of an “horizontal” (i.e. common) approach for the identification of endocrine disruptors across the various sectorial regulations, based on the WHO definition and on criteria already established for plant protection and biocidal products. The publication also stresses the need to strengthen the data requirements on endocrine disruptors in order to facilitate their identification, including for potential effects on vulnerable groups, as well as the necessity to develop more methods which minimise the use of animals.

This analysis has been conducted by the European Commission’s Joint Research Centre, in partnership with other Directorates-General and the Secretariat-General. It relies on previous fitness checks, scientific documentation and the outcome of two public consultations (stakeholders, citizens) and a survey on a group of SMEs. Interestingly, 40% of the answers to the citizen consultation came from France³.



The Chemicals Strategy for Sustainability inventories actions to be conducted on endocrine disruptors, some of which being scheduled for 2021. Namely, The European Commission proposes to establish identification method of endocrine disruptors based on criteria existing for plant protection and biocidal products, to strengthen information requirements across regulations and to accelerate the development and

uptake of methods to generate information on endocrine disruptors. The Commission also proposes to ban endocrine disruptors in consumer products as soon as they are identified, allowing their use only where it is proven to be essential for society.

¹ <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=SWD:2020:225:FIN>

² https://ec.europa.eu/environment/strategy/chemicals-strategy_en

³ <https://ec.europa.eu/jrc/en/publication/public-consultation-context-fitness-check-eu-legislation-regard-endocrine-disruptors-factual-summary>

Second Annual Forum on Endocrine Disruptors

The European Commission had committed, in its 2018 Communication, to organising a Forum on endocrine disruptors on an annual basis. The second annual Forum was held on 17-18 December 2020. The various stakeholders (scientists, regulatory authorities, industries, NGOs) showcased their respective work on the field and expressed their concerns and expectations. PEPPER was introduced on this occasion (see the participants' presentations⁴). The French Minister for the Ecological Transition mentioned on this occasion France's historical involvement in these issues, having led to the National Strategy on Endocrine Disruptors, the creation of PEPPER and the work conducted by Anses on prioritization and classification of ED substances.



Anses' ongoing work on endocrine disruptors



In line with Action 3 of the Second French National Strategy on endocrine disruptors (prioritization and categorisation of ED substances)⁵, Anses is going to publish a report on the establishment of a list of substances with potential endocrine disrupting properties. This report will also contain a prioritization strategy for the evaluation of these substances. In a second step, Anses will establish a list of substances according to their endocrine disrupting properties: “known”, “presumed”, “suspected” - the work conducted by Anses to produce these lists being part of a wider European dynamic.

In June 2020, several Member States (including France) have launched the website <https://edlists.org/> which hosts several lists of endocrine disruptors. The main purpose of this website is to keep all stakeholders up to date on the status of endocrine disruptors or potential EDs being investigated in the EU.

The intention behind this database is to improve the level of knowledge on endocrine disruptors, to improve transparency, coordination between regulations and cooperation between agencies.

In parallel, Anses is pursuing their work on the assessment and identification of endocrine disruptors at regulatory level. Namely, Anses is about to register with ECHA a dossier on Bisphenol B and its identification as SVHC (substance of very high concern) because of its endocrine disrupting properties, case which will be examined by the Member State Committee.

⁴ https://ec.europa.eu/environment/events/second-annual-forum-endocrine-disruptors_en

⁵ <https://www.ecologie.gouv.fr/strategie-nationale-sur-perturbateurs-endocriniens#e2>

PEPPER works as an “accelerator” for the validation process; unique of its kind in Europe, PEPPER brings together public and private resources and has the support of the French government (National Strategy on Endocrine Disruptors ⁶, Investments for the Future Program⁷), the industry, NGOs, regulatory bodies, European and international organisations. PEPPER’s contribution to the quicker adoption of test methods for endocrine disruptors identification (incl. toxicity and ecotoxicity elements) is one of France’s answers to the call from the European Commission for Member States to contribute to the work of international authorities (2018 Communication “Towards a comprehensive European Union framework on endocrine disruptors”⁸): the OECD (who establishes test guidelines), ECVAM, ISO, whose budgets cannot support the pre-validation process.



<https://ed-pepper.eu/en/>

⁶ <https://solidarites-sante.gouv.fr/sante-et-environnement/les-plans-nationaux-sante-environnement/article/deuxieme-strategie-nationale-sur-les-perturbateurs-endocriniens-2019-2022>

⁷ <https://www.gouvernement.fr/le-programme-d-investissements-d-avenir>

⁸ <https://ec.europa.eu/transparency/regdoc/rep/1/2018/FR/COM-2018-734-F1-FR-MAIN-PART-1.PDF>