

Pepper – Association Charter

One role

PEPPER is a non-profit association (under the French 1901 law) and a public-private platform dedicated to the pre-validation of endocrine disruptors characterization methods.

The project, formally launched at the very end of 2019, had been already considered under the first French National Strategy on Endocrine Disruptors in 2014. It was already established that the European Union (EU) should have a set of test methods for chemical substances, "acknowledged" by all stakeholders and allowing to identify whether a substance should be considered an endocrine disruptor.

The aim of the association is thus to identify and pre-validate endocrine disruptors characterization methods. Pepper accelerates their recognition, especially through established validation processes, so that all stakeholders can have confidence in their use.

In practice, it is about identifying mature methods, then building the required elements of proof and submitting them to the authorities carrying out internationally recognised validation (OECD, ECVAM, ISO). Hence the term "**pre-validation**".

Pepper is however not a test method developer (this is the role of upstream research), nor a test provider testing substances, nor an expert organisation classifying substances (this is the role of national and international expert authorities).

Four challenges

A confusing situation which is detrimental to everyone.

The lists of substances which can potentially have endocrine disruption properties and which must therefore be assessed are long, much longer (thousands in one case, dozens in the other) than the lists of "identified" endocrine disruptors; and they generate controversies.

Health and environmental safety, the reliability of technological innovation, product guarantees and trust in the responsible authorities and economic stakeholders suffer from this confusing situation.

A lack of test methods

The national and international observation is that there is a lack of recognised and usable test methods allowing for the characterization of endocrine disruptors in regulatory frameworks.

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A missing link to accelerate methods validation

Research efforts are made in order to improve our knowledge in the field. However, both at national and EU levels, there is a lack of support for the transfer of "experimental protocols" to the stage where "test methods" can receive the level of mutual recognition offered by official validation.

The necessity of pooling resources

Validation is costly. But the lack of validated methods also generates high direct and indirect costs (environmental and health impact, credibility of industry and authorities, consumer confidence), the weight of which is shouldered by all the players involved: health or biodiversity agencies; operators who produce or market substances or products containing these substances, etc.

It is our collective interest to have tools which are mutually accepted and acknowledged by international authorities; hence the need to pool financial contributions towards validation, in a way that, beyond the multi-sector and public/private approach, involves the various EU countries.

Pepper members consider that they must contribute to the pre-validation of characterization methods according to their means, and with regard to the impact of endocrine disruptors on their activity.

Five ambitions

Improving evaluation through stakeholder dialogue

Tools and solutions must meet expectations in a realistic way. Between environment, biodiversity and human protection, between scientific progress and practical needs and according to the various health concerns, assessments and choices must be made and priorities established. They must be shared. Pepper brings together a range of stakeholders: authorities, scientists, operators (test operators etc.), producers as well as environment, consumer and health stakeholders, from different countries.

Members commit, when participating in Pepper's activities and governance, and in the respect of the interests protected by law, to expressing their views in a frank and open manner.

Supporting the testing laboratory and biotechnology sectors and direct them towards endocrine disruptors related issues.

The call to laboratories to propose test methods and/or to participate in the testing of these methods contributes to supporting this industry, which is an important part of the country's innovation ecosystem.

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Members commit to promoting Pepper to these stakeholders and to promoting Pepper to them.

Protecting innovation

The platform will help protect innovation by providing developers with tools to ensure the health and environmental safety of products and processes.

Members take into account endocrine disruptors in their sustainable innovation and environmental policies.

Triggering a European dynamic

France is very active and a pioneer on the subject of endocrine disruptors in Europe. The creation of the Pepper platform is a key element in the French Strategy. It draws its European outreach from the participation in its governance of stakeholders coming from other countries and European or global organisations. Moreover, Pepper's work involves other European countries both through the origin of the methods to be pre-validated and the laboratories participating in the tests on those methods.

As the first platform of its kind, Pepper aims at becoming a European organisation contributing to accelerating the validation process.

Members approve the goal of creating a European organisation contributing to accelerating the validation process. They commit to making Pepper known to their counterparts in their respective fields and to advocating for their contribution.

Bringing scientific developments closer to the needs of regulatory science

Public policies must be based on "scientifically established" facts. But the tools to this end must be available and recognised as "valid". It is therefore necessary to make developers aware of the needs and expectations of authorities and citizens in terms of operational tools.

Pepper's activity, by creating an outlet for operational applications but also by surveying the academic community, is creating the necessary dynamic for research teams to produce suitable methods to fill the gaps in regulatory assessment.

Pepper members are committed to making their scientific partners (and of course their own research teams) aware of Pepper's approach and to suggesting that they make potential methods known to Pepper. Pepper members commit to making known to Pepper the mature and openly accessible methods of which they have knowledge and to working to remove possible obstacles of a legal nature to their entry into pre-validation.

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Six values

PEPPER is built on the principle that it is possible to collaboratively build tools allowing to objectively characterize endocrine disruptors. This translates into six values.

Members support Pepper's commitment to these values and commit to applying the principles thereof in their activities.

Accepting a plurality of points of view

Pepper's work is based on a partnership which brings together a range of stakeholders with various professions, disciplines, responsibilities and commitments to health and the environment.

Each member of the association and of its governance accepts that others may express different points of view and commits to respecting these points of view. He or she is committed to contributing whatever input is necessary to advance a meaningful dialogue within Pepper bodies, namely the Relevance Committee.

Implementing the principles of scientific integrity

Pepper commits to the approach to scientific integrity defined by the academies of the European countries in the <u>ALLEA</u> group, <u>The European Code of Conduct for Research Integrity</u>, including in particular the imperatives of reliability, honesty, respect, accountability and vigilance to avoid the "fabrication" of results, falsification and plagiarism.

Pepper members are committed to respecting these rules in their own activities when disseminating information on endocrine disruptors.

Staying within its role

Pepper is committed to the development of open and shareable tools for objective substance assessments and risk management rules. It should not conduct substance assessments nor take positions on risk management rules themselves.

It is acknowledged that Pepper members carry out work and take positions outside the association. They cannot do so by referring to their Pepper membership.

Adopting a "One Health" perspective

Pepper's work on endocrine disruptors does not consider humans in isolation from the environment and ecosystems. Test methods are aimed at one or the other and preferably both.

Members share this "one planet, one health" concern in their environmental strategies.

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Adopting an "open science" approach

Pepper adheres to the principle of "open science" as identified by the <u>OECD</u> and is committed to providing access to the results of its work while respecting intellectual and material property rights.

Pepper members support the open science approach in their respective fields of work.

Supporting a governance ensuring independent decision-making

The multiple and even divergent stakes that exist on endocrine disruptors (producer/consumer, producer/regulator, human health/biodiversity) do not prevent the need for mutualisation on validation, quite the opposite.

Limiting Pepper's role to the work on assessment tools avoids conflicting positions. There are still choices to be made when selecting a method (e.g. favouring a method on obesity rather than on neurological development, on humans rather than on an animal species, resorting to animal testing or not, etc.).

The fact that the selection of methods to be pre-validated is entrusted to a Relevance Committee where all stakeholders are represented, whether they are members or not of the association, allows for collective, transparent and pluralistic choices.

Members support this governance.

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