

Second National Strategy on endocrine disruptors



2019–2022:
strategic
objectives



MINISTÈRE
DE LA TRANSITION
ÉCOLOGIQUE
ET SOLIDAIRE

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2nd National strategy on Endocrine Disruptors

2019-2022: strategic objectives

The French government is increasingly mindful of the major health and environmental challenges linked to endocrine disruptors. According to the IRSN 2018 satisfaction indicator survey, half of the French respondents consider that risks related to endocrine disruptors are high.

To better protect against and help reduce environmental contamination from endocrine disruptors, the regulatory framework, mainly established on a European scale, has to reach a satisfactory level of collective protection of the population and the environment.

Endocrine disruptor: a new approach

By means of the 1991 Wingspread statement, scientists for the first time were able to express their concerns to the international community about the consequences of human and environmental exposure to chemicals that can interact with the endocrine system. These substances are referred to as “endocrine disruptors”. The commonly accepted definition is that of the World Health Organisation, proposed in 2002 and updated in 2012: *“An endocrine disruptor is an exogenous substance or mixture that alters the function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations”*.

Health and environmental issues

Endocrine disruptors are found in many everyday objects and products (household products, detergents, crop treatment products, cosmetics, food products, etc.). They are present in the environment as a result of contamination of different media (water, sediment, soil, air, etc.).

Endocrine disruptors have an impact on wildlife (sex change in some fish populations, developmental disorders, etc.) and eco-systems, and participate in the erosion of biodiversity. They also contribute to the development of pathologies in humans. Many studies describe, for example, a link between exposure to certain families of substances and fertility and reproduction disorders (decreases in sperm quality, increased frequency of abnormalities in organ development or reproductive function, lowering of the age of puberty onset, hormone-dependent cancers such as breast cancer or prostate cancer).



Neurological disorders such as autism, decline in IQ or metabolic disorders such as diabetes or obesity, are also suspected of being associated with exposure to endocrine disruptors. There is growing scientific evidence that some people are more vulnerable than others to endocrine disruptors. The “1,000 days” period, which extends from prenatal development to early childhood is particularly critical and should be given priority attention. Puberty is also a window of vulnerability to endocrine disruptors, because several systems (reproductive system, hypothalamic pituitary axis, etc.) complete their maturation during this period under the influence of sex steroid hormones. A summary of the work undertaken by the French agency Santé publique France (“Public Health France”) on reproductive health was published in 2018¹. Some health professionals are increasingly mobilized on the issue of endocrine disruptors. For example, in 2015, at its 21st Congress in Vancouver, the International Federation of Obstetric Gynecologists launched an appeal against chemical pollution, highlighting in particular the serious impact on reproductive health and the health of future generations.

Like all the developed countries, France is facing a progression of chronic diseases (such as diabetes, respiratory diseases, inflammatory diseases and hormone-dependent cancers) and an increase in fertility and reproductive disorders, disorders for which the environmental factor is strongly emphasized but remains difficult to characterize, in a population that is also facing unprecedented ageing. The WHO estimates that 23% of global mortality is related to the environment, which represents 12.6 million deaths per year, including 1.4 million in Europe². Toxic chemicals, including endocrine disruptors, contribute to this mortality. Negative externalities related to endocrine disruptors have a cost to society, that is difficult to estimate accurately, but which some studies estimate to be at €150 billion a year for the European health system, not counting the environmental costs³.

Challenges for hazard and risk assessment

The mechanisms of action of endocrine disruptors are complex and sometimes question the paradigms of conventional toxicological analysis. Therefore, the dose/effect relationship is not always uniform: in some cases, the effect of certain endocrine-disrupting substances may be stronger at low doses than at higher doses. Moreover, establishing a causal link between the action of the endocrine disruptor and its adverse effects, according to the levels of scientific proof, is complex, just as it is for other environmental factors. Indeed, the pathologies linked to endocrine disruption are, for the most part, multifactorial. In addition, the same individual is exposed to a large number of chemical substances, including endocrine disruptors, by multiple routes (oral, cutaneous and respiratory) during his or her life. Little is still known about the cocktail effect that may result, which complicates the analysis of causal links. These cumulative and synergistic effects may challenge the overall approach to risk management with the “Acceptable Daily Intake” and the “Tolerable Daily Intake”. Moreover, the effects can be delayed

¹ <http://invs.santepubliquefrance.fr/Publications-et-outils/BEH-Bulletin-epidemiologique-hebdomadaire/Archives/2018/BEH-n-22-23-2018>

² Report “Prévenir la maladie grâce à un environnement sain”

https://www.who.int/quantifying_ehimpacts/publications/preventingdisease.pdf?ua=1

³ 2015 Study – Estimating burden and disease costs of exposure to endocrine-disrupting chemicals in the European Union – Scientific team led by Leonardo Trasnada (University of New-York-NYU-Langone Health)



over time in an individual and spread over several generations (e.g. by epigenetic modifications of genomes). Exposure during the period prior to conception, during pregnancy, and over the first 1,000 days of life is of particular interest.

When scientific data converges to demonstrate the endocrine disruption effect of a substance, as is the case for some substances, a preventive approach consist of prohibiting or limiting use of the substance. However, demonstrating an endocrine disruption effect is sometimes difficult and the scientific data is insufficient. In this case, applying the precautionary principle reduces exposure to endocrine disruptors.

Improved understanding of the mechanisms of action of endocrine disruptors is important for developing expertise and adequately protecting citizens and the environment. Basic research is therefore a priority. Epidemiological studies aimed at monitoring populations using the “exposome” approach coupled with applied health research is also essential to make progress in understanding causal relationships. They will make it possible to better take into account the effects of endocrine disruptors and better manage them to reduce exposure and risk.

Strong societal expectations

The complexity associated with endocrine disruptors is a source of scientific, political and societal debate, and opens up many perspectives in terms of epidemiological, basic, clinical and human and social science research. Beyond mobilizing the scientific community, the media interest in studies on certain substances has led public opinion to take the issue seriously. The demonstration of widespread contamination of the environment, organisms and the general population by potential endocrine-disrupting substances is a factor justifying this mobilization of society.

In this respect, the mobilization and joint efforts of all stakeholders, from the government to communities, economic actors, associations, health and education professionals, scientists and experts is needed. The French have high expectations: according to the 2018 IRSN satisfaction indicator survey cited above, half of the French respondents believe that there are high risks related to endocrine disruptors, but only 13% trust the authorities to protect them from endocrine disruptors.



Regulations, mainly European Regulations, to be improved

The regulatory framework for endocrine disruptors is insufficient and somewhat piecemeal in the way they take the endocrine-disrupting nature of substances on board. Regulations on chemicals have been set up at international and European level. As part of the United Nations Environment Program, the international panel on chemical pollution, in consultation with the United Nations Environmental Advisory Group on Endocrine Disruptors, published three new reports in June 2018. These reports focus on the different initiatives to identify endocrine disruptors and on existing scientific knowledge about life cycles, environmental exposure, effects, legislation and measures and gaps concerning substances with endocrine-disrupting properties⁴.

A roadmap was adopted during the 70th World Health Assembly in May 2017 on chemical products to **increase the participation of the health sector in the Strategic approach to the international management of chemical products**⁵.

At the European level, public health and environmental policies have, since the mid-1970s, been based on action programmes which define the priority objectives to be achieved over a period of several years. The current programme, the European Union's 7th Environment Action Programme, covers the period up to 2020 and identifies reducing exposure to endocrine disruptors as one of its priority objectives, as part of the implementation of a strategy for a "non-toxic environment".

From a regulatory point of view, recent progress has been made in taking into account the endocrine-disrupting nature of a substance in certain European regulations. Since 2008, the REACH regulation has enabled some substances to be identified as endocrine disruptors, but so far only a dozen substances have been recognized in this way. In 2018, the Commission adopted the criteria for identifying a substance as an endocrine disruptor under regulations on plant protection and biocide products. Included in the regulations, these criteria were completed in June 2018, through guidelines drawn up by the European Chemicals Agency and the European Food Safety Authority; France was very active in contributing to this work. Biocidal and phytopharmaceutical substances are now evaluated according to these guidelines and will be excluded from the market if they are recognized as endocrine disruptors. The regulation on cosmetic products should be modified to take specificities of endocrine disruptors into account and, in general, France considers that all regulations concerning substances or articles must ensure sound management of risks related to endocrine disruptors.

To prevent the majority of substances remaining unclassifiable as regards their endocrine disruption, tests and methods to identify the endocrine-disrupting nature of substances must be developed and validated and the use of these tests must be made mandatory in substance registration dossiers.

⁴ <https://www.unenvironment.org/explore-topics/chemicals-waste/what-we-do/emerging-issues/scientific-knowledge-endocrine-disrupting>

⁵ <https://apps.who.int/iris/bitstream/handle/10665/273139/WHO-FWC-PHE-EPE-17.03-fre.pdf?ua=1>



A specific national strategy since 2014, to be revised

France is active and a forerunner in Europe on the issue of endocrine disruptors. As such, in April 2014, the first National Strategy on Endocrine Disruptors (SNPE) was adopted by the Government, which was a first worldwide.

This strategy, which sets the primary objective of reducing the exposure of the population and the environment to endocrine disruptors, is structured around four axes:

1. Research, development, monitoring;
2. Expertise of substances;
3. Regulation and substitution of endocrine disruptors;
4. Training and information.

It has been evaluated by a joint mission of three general inspections (CGAER, CGEDD, IGAS), which reported on its implementation and recommendations to the government in February 2018.

The Second National Strategy on Endocrine Disruptors (SNPE2) structures national actions related to endocrine disruptors and ensures their full coherence with the European framework. On 7th November 2018, the European Commission published a communication on its strategy to minimize the exposure of Europeans to endocrine disruptors. While France welcomes the progress made by this communication, it nevertheless calls on the Commission to strengthen certain aspects of it and to specify the timetable for its implementation.

France is indeed very vigilant that its implementation should meet the challenges and commitments of the European Union and that it should sufficiently protect citizens and the environment.

The SNPE2's main objective is to reduce the exposure of populations and the environment to endocrine disruptors, which reinforces the primary objective of SNPE1.

In the short term, all levers of action must be mobilized to achieve the ambitious goal of a “non-toxic environment” according to a “one planet, one health” or “*One Health*” approach; the health of the eco-system being inseparable from human and animal health. Reducing the presence of endocrine disruptors in the environment requires collecting data on the impregnation of different media to be able to act at the source. The acceleration of substance expertise and the substances' inclusion in the European regulation framework on chemical substances, in light of scientific knowledge, will make it possible to replace and prohibit those whose endocrine disruption is known or presumed, and to control, by means of prevention and precautionary measures, the use of those whose nature is suspected, and therefore act at source.

France proposes changes to the European regulations to better take into account the specificity of endocrine disruptors. In particular, France requires a horizontal definition common to all regulations, and providing categorization based on the level of evidence, France wants all the regulations on chemical substances to enable good risk assessment and management of endocrine disruptors, by ensuring minimal exposure to endocrine disruptors by, with priority given to vulnerable people. In the current state of regulation, France will continue to mobilize the expertise of its agencies to make a strong contribution to European expertise.



In some cases, the contamination of eco-systems has already been proven. It is important to think of ways to detoxify and protect them. The SNPE2 identifies this detoxification as an axis of progress.

Initial and ongoing training of professionals (health professionals and professionals handling and/or working in contact with endocrine disruptors, for example in engineering colleges, veterinary schools, architecture schools and agricultural colleges) as well as the information given to young people at school must evolve to better take endocrine disruptors into account. Collective action is a priority on the issue of endocrine disruptors, knowing that everyone at their own level can also become involved in reducing exposure to these substances.

Finally, even if we already have the means to act, it is necessary to plan for the medium- and long- term and to reinforce knowledge on endocrine disruptors.

This strategy is a component of the future National Environmental Health Plan 4 (PNSE4, "my environment, my health"); its implementation will be monitored by the "Groupe santé environnement" or French Health Environment Group (GSE).

The SNPE2 is also consistent with the other national plans and major initiatives of public health and protection of the environment and biodiversity: Action Plan on Plant Protection Products and Agriculture Less Dependent on Pesticides, Chlordecone Plan, Health at Work Plan, National Health Strategy, National Public Health Plan, National Health and Nutrition Programme, Autism Plan, Cancer Plan, Micropollutants Plan to Preserve Water Quality and Biodiversity, National Biodiversity Strategy, Climate Plan, Biodiversity Plan, National Plan on Air, etc.

There are two main documents that make up the second National Strategy on Endocrine Disruptors:

- this document, which describes the strategic objectives;
- the action plan.



I- Train and inform

Further develop the expertise on ED substances taking into account their impact on health and the environment

The Government will strengthen the partnership between and mobilization of national agencies part of European regulatory expertise. France has a significant power of initiative (via the proposal for a substance evaluation dossier for example) as part of the European cooperation led by the European agencies ECHA and EFSA in particular.

The French national agency Anses will continue the expertise actions started with SNPE1 with at least six substances evaluated per year in 2020 (at least three under REACH and at least three biocidal or phytopharmaceutical substances) proposing, when it judges the data sufficient, recognizing substances as endocrine disruptors under the European regulations, as it did for Bisphenol A. Anses will evaluate nine substances per year from 2021.

Anses will define a method for prioritizing substances that may have endocrine-disrupting properties, in order to establish a list which will prioritize the assessments to be conducted, will inform citizens and will also be a communication tool for stakeholders.

Additionally, as regards health products and cosmetics, ANSM and Anses will strengthen their cooperation and will be entrusted with the joint mission of listing substances which may have endocrine disrupting properties for humans and the environment in cosmetics, medical devices and drugs, which particularly expose vulnerable populations and the environment. The agencies will recommend appropriate management measures under the health and cosmetic products regulations, REACH and other regulations.

Raise awareness and inform stakeholders and citizens

French people today have a strong expectation of information on exposure to chemicals via consumer goods they buy. The information unfortunately comes up fragmented, sometimes very technical and not easy to read.

The proposed information and awareness campaigns aim to:

- provide citizens and those involved in prevention with information based on the latest scientific knowledge available on the subject;
- disseminate clear, verifiable, useful and pragmatic information, particularly by setting up labelling at the European level;
- identify good practices allowing everyone to reduce their exposure to endocrine disruptors, and more broadly their exposure to chemicals;



- clarify existing regulations as well as the action of institutions in matters of safety and health;
- encourage awareness-raising actions in different jurisdictions, especially in health facilities, institutions with young children, schools, small and medium-sized businesses so as to limit the presence of endocrine disruptors in indoor environments and thus reduce the population's exposure;
- assist local communities to encourage the consideration of exposure to endocrine disruptors in public procurement.

A public information website on chemicals has been put online by Santé publique France agency (Public Health France) since september 2019 and clarifies possible preventive measures at an individual level. Public Health France will launch a campaign to promote the “Agir pour bébé” (Act for baby) website and a public communication campaign in 2020 on the issue of chemicals (endocrine disruptors will therefore be included in this campaign), with special attention to the most vulnerable populations.

Train to strengthen the prevention of exposure to endocrine disruptors

The objective is to strengthen training on endocrine disruptors:

- health and early childhood professionals who are in touch with those populations most vulnerable to exposure to endocrine disruptors and who are actors working in prevention;
- professionals who may handle or be exposed to potentially endocrine-disrupting chemicals in the course of their work (e.g. building professionals, farmers, architects, etc.).

This training, which can be part of initial training or ongoing education, will provide knowledge elements, explain the uncertainties surrounding this topic, best practices that can be passed on and substitution possibilities.



II- Protect the environment and the population

Collect data on environmental impregnation

Knowledge of environmental impregnation by endocrine disruptors differs depending on the environment; The public policy fighting against endocrine disruptors can only be effective if we improve our knowledge of the impregnation of different environmental compartments and thus of the different sources of exposure.

Regarding the monitoring of endocrine disruptors in aquatic environments, this includes continuing and improving the regular monitoring of substances characterizing the chemical and/or ecological status of waters under the Water Framework Directive (WFD) 2000/60/EC and its daughter directives (Directive 2008/105/EC, Directive 2013/39/EU), ensuring that endocrine disruptors are taken into account.

As regards other compartments, specific monitoring campaigns must be carried out in the air and soil, in particular by ADEME, CSTB for indoor air and INRA. The data gathered through these campaigns should be available on dedicated websites, following the example of the portals launched for the Water Framework Directive (WFD) (Naiades, Ades). This allows the data to be exploited and makes it possible to combine monitoring of the environments with knowledge on the sources and routes of exposure.

An updated overview of the effects of substances with endocrine-disrupting properties present in the environment will be conducted by French Office for biodiversity by the end of 2020 to understand the effects of endocrine disruptors on biodiversity, and highlight knowledge gaps that limit risk assessment and management of endocrine disruptors.

Food is also a route exposing the population to endocrine disruptors. To strengthen knowledge, a specific part will be dedicated to endocrine disruptors in the new total diet study conducted by Anses.

Protecting eco-systems from the impact of endocrine disruptors and optimizing their detoxification capabilities

When an environment is contaminated, measures should be put in place to trap pollution and thus reduce or eliminate the impregnation of the environment. Total decontamination remains difficult to achieve, and the priority remains prevention at the source of pollution. To do this, it is necessary to know the contribution of each of the sources of pollution in order to prioritize the treatments to be implemented according to the estimated impacts on public health and biodiversity. Appropriate treatment of effluents and management of ED vector or precursor waste (medicinal residues, chlorinated and brominated dioxins, spreading sludge, etc.) are essential components. The strategy will also support the implementation of protocols and



remediation techniques for environments polluted by endocrine disruptors to limit their effects on wildlife and the food chain. Several remediation technologies are already available or in development, for example bioremediation, which has the advantage of combining a depollution function with production for biomaterials, creation of refuges for biodiversity, etc.

The strategy is an opportunity to initiate cross-cutting thinking and increase vigilance on the growing dispersion in the environment of substances of artificial origin, reactive substances, which can have cumulative and synergistic effects and whose long-term impacts are poorly understood and difficult to quantify.

Adapt the regulatory framework to endocrine disruptors in order to have effective tools

France reiterates its commitment, at the highest political level, to an ambitious adaptation of the European regulatory framework on endocrine-disrupting chemical substances; it is an EU commitment via the 7th Environment Action Programme. The European regulatory framework is the adapted framework and France will continue to play a leading role.

France reiterates the need for a horizontal definition of all regulations, taking into account the one applicable to biocides and plant protection products and the experienced gained on REACH. This definition must make it possible to differentiate the levels of evidence in line with scientific knowledge into three categories (endocrine disruptors, known, presumed and suspected), in the same way as the existing categorization for carcinogenic, mutagenic and reprotoxic compounds. France will make concrete proposals to the European authorities and the Member States.

France supports a regulatory approach allowing maximum reduction of exposure to EDs; in particular, it supports the fact that the management of EDs must be identical to that of the most dangerous substances for health or the environment (carcinogenic, mutagenic, reprotoxic and persistent and bioaccumulative substances) and that all regulations must be consistent, with particular attention to limiting exposure as far as possible, particularly of vulnerable groups. To this end, France will promote the following actions:

- regulate endocrine disruptors using group approaches based on similar structures and similar properties to avoid regrettable substitutions;
- do not recycle and put products containing endocrine disruptors back on the market. Develop disposal channels for waste containing endocrine disruptors;
- revise environmental standards developed based on the classical paradigm of regulatory toxicology so as to take into account the specificities of action of endocrine disruptors and current scientific knowledge.

France will make public its contributions made at EU level.



Strengthen regulatory enforcement and assess the effectiveness of regulations

The effectiveness of regulatory action depends on a level of control that is properly proportioned to health, environmental and economic issues. To that end, it is appropriate to reinforce controls on products which may contain endocrine disruptors, in the annual monitoring programme of the bodies that prevent fraud, the Classified Installations Inspectorate and the Labour Inspectorate, and with particular attention to border controls, on the part of customs agents. Samples and measurements should also be taken to evaluate the evolution of the concentration of endocrine disruptors in the environment.

France will ask, as part of the ECHA Forum, that coordinated European control projects take place over the next few years on the subject of endocrine disruptors.

Promoting substitution

The search for safer alternative solutions is a driver for innovation for companies and the industry. The concept of functionality is to be placed at the heart of the substitution process. The European regulations that cite endocrine disruptors impose a substitution approach and controls to protect workers throughout the supply chain. By replacing endocrine disruptors, and other dangerous chemicals overall, through alternative techniques such as non-chemical alternatives or safer alternative chemicals, companies can save time and effort in managing the risks associated with their use. It is also essential to quickly eliminate the unacceptable alternatives, on the basis of their dangers or their performance, which may be considered insufficient.

ECHA has launched an initiative to promote substitution, in particular by encouraging Member States to share their experiences in this area. Thematic seminars have been organized for this purpose. France has proposed, via INERIS, that such an event be organized in 2019 on the textile sector. Annual seminars or “workshops” will be organized to promote the dissemination of knowledge and experiences on the substitution of harmful substances.

Manufacturers can already refer to several documents: the practical methodological guide for assessing alternatives, which is the result of the work of INERIS and MEDEF, several French and international websites on substitution as well as the ECHA website, which gathers the information present in the registration dossiers and requests for authorisation or restriction under REACH. In terms of information on alternatives, several portals can be useful, for example, interprofessional technical centres and CRITTs (Regional Centers for Innovation and Technology Transfer).

With this new SNPE, the aim is to target calls for projects for this topic to create a new dynamic around substitution and to finance ambitious projects, including exploring the safety or toxicity of substitutes offered by public or private research. Public funding can be mobilized to create an incentive framework for substitution, however it is worth remembering that mobilization of industrial players is crucial on this subject.



As stated in the National Public Health Plan, the government will mobilize companies in the sectors relevant to the issue of endocrine disruptors in order to encourage the voluntary withdrawal of products containing endocrine-disrupting substances, the substitution of endocrine-disrupting substances and informing the general public with prevention messages.



III- Improve knowledge on endocrine disruptors

Develop tools and methods to identify endocrine-disrupting substances and characterize their effects

In order to compensate for the lack of evaluation methods for endocrine-disrupting properties, France will continue to be involved in the work carried out at international level, particularly in the context of the OECD.

The Government will support the establishment of a public-private platform to select and support the validation of methods developed in research laboratories. This platform will coordinate the necessary financing and carry out its operations by relying on networks of scientific experts, industrials, test laboratories and non-governmental organizations.

The platform will seek international openness, for the pre-validation operations, participation in its governance and its funding. This project has been hailed by some national and international authorities.

Organize long-term research on endocrine disruptors at the national level to accelerate the acquisition of knowledge on the effects and modes of action of these substances

The national scientific community has largely mobilized in recent years on the complex issue of endocrine disruptors and is actively developing collaborations at European and international levels with institutions who have also included this issue in their research agendas.

On human health issues, scientific approaches have evolved in recent years, by combining mechanistic studies very specific to each molecule and looking for biomarkers, the notion of the exposome, in order to better understand the complexity of an individual's lifetime exposure to multiple interacting substances.

Research organizations will be encouraged and supported, in particular to:

- Develop an infrastructure for analyzing the chemical exposome. Such an infrastructure will have as its objectives: 1) to develop quantitative endocrine disruptor assay methods (biomonitoring and epidemiological studies); 2) to develop screening methods to explore the chemical exposome and identify emerging substances; 3) to be at the heart of a future infrastructure at European level.
- Set up a test validation platform. This platform must support researchers to transform the models and methods developed to test ED activities in real tests with the potential to be validated one day on the regulatory level.



- Mobilize large cohorts (CONSTANCES, Autism, E3N, Pelagie, Eden, TiMoun, etc.), targeted epidemiological studies (including national studies on pesticides near agricultural areas) to study the effects of endocrine disruptors by using approaches that allow the characterization of exposure to substances that are often not persistent in the body in the relevant developmental and life windows. Cohorts can indeed provide arguments in favour of a causal relationship between exposure to endocrine disruptors and pathologies (rare effects and great variability). These arguments can be reinforced by targeted epidemiological studies and by monitoring exposed populations.
- Develop modelization in all its components: modelization exposure pathways to identify the main path(s), modelization of eco-system contamination, modelization of kinetics and dynamics in organisms; modelization of the effects of endocrine disruptors through systems biology; ability to analyse large datasets. The modelization tools developed will also make it possible to systematically link biomonitoring (biomarkers of exposure) and exposure. All of these modelization works will provide elements on the risks of exposure, for example by accumulation in the trophic chain and in the different target tissues of organisms. They will also allow biomarkers indicative of eco-system exposure and associated hazards for biodiversity to be developed.
- Conduct experimental studies on *in vivo* models, in accordance with good laboratory practice and regulatory requirements, to define the mode and mechanisms of action of the endocrine disruptors. This work will provide material for the Anses and ANSM expert assessments and will ultimately make it possible to define a known endocrine disruptor in regulations. It is these experimental studies that demonstrate the endocrine-disrupting character of a substance, supported by *in vitro* studies.
- Propose prevention and remediation strategies.

Define and organize coordination at the national level

The complexity of the phenomena requires addressing a large number of questions about the sources of exposure in the environment, mechanisms of action, effects on health and living organisms and eco-systems, the relevance of models, effect markers, socio-economic, psychological factors of exposure and vulnerability and cost/benefit analyses of uses and alternatives.

Endocrine disruptor research has existed in France since the 1990s, the Ministry of the Environment has hosted a national research programme on the subject since 2005 (PNRPE) and Anses has supported the theme since the creation of the National Environment, Health and Work Research Programme. The ANR has also supported the theme via numerous projects. It is now a question of transforming this pioneering mobilization to create a support body on all topics related to endocrine disruptors and more generally in the field of environmental health, in a framework that favours the emergence of new ideas and approaches.

Mobilizing a multidisciplinary and multi-stakeholder approach will aim to strengthen and better coordinate existing networks among specialized research institutions and funding arrangements in this field at international, European and national levels.



It is also necessary to organize permanent interaction with the actors responsible for monitoring and expertise on the one hand and, on the other hand, with political actors, public managers, companies and civil society actors to contribute to the development of research on this theme and to promote its recognition.

Mobilizing the resources

The main developments in recent years call for:

- continuing and consolidating research on the specific issue of endocrine disruptors, which also reflect the priority given to the health environment theme;
- developing the notion of the exposome in different types of research;
- clinical research work and epidemiological studies to be better taken into account;

The resources must be mobilized around the following axes as a priority:

- taking into consideration the different aspects of the research: from understanding the mechanisms of action of substances to operational aspects in the context of translational research;
- connecting institutional action programmes and calls for projects;
- creating synergies in the resources mobilised by the institutions to promote and facilitate the emergence of research programmes that bring together research teams at the European and international level;
- implementing the open science policy with respect to research data;
- developing the link between research, monitoring devices and expertise, especially through the sharing of observational data and the use of monitoring data by researchers;
- facilitating access to data to assess risks, socio-economic impacts and enable cost and benefit approaches for decision-makers;
- developing the use of different approaches to applied health research, on human and social sciences, and new methods and tools for monitoring human health and environments;
- mobilizing human and social sciences further, by deepening approaches based on economics but also by developing other approaches, especially in psychology, sociology, anthropology and communication sciences. The idea being in particular to help decision-making by focusing on human and social sciences and life and health sciences, to determine the appropriate risk management measures based on the level of evidence;
- to propose long-term funding for these ambitious projects in all scientific disciplines, to enable research organizations to develop their leadership at the European and international level in this field.



Strengthen environmental monitoring, health monitoring and develop the clinical approach

Health and environmental monitoring allow the follow-up of spatial and temporal trends of exposures, particularly to endocrine disruptors and possible health effects. The French National Public Health Agency has been conducting two types of actions for several years:

- Monitoring the impregnation of populations through human biomonitoring studies including the determination of biomarkers of exposures to substances suspected of causing endocrine disruption, which have been identified as priorities. It would involve combining them with environmental monitoring data to understand the exposure and adjust preventative actions;
- Epidemiological monitoring actions to describe health events with known or suspected links to endocrine disruptors (occurrence of pathologies but also early detectable biological effects), in particular to monitor temporal and spatial trends and to evaluate the effectiveness of prevention policies.

The actions presented as part of this new national strategy on endocrine disruptors are a continuation of the actions already started by "Santé publique France" (the French National Public Health Agency) as part of the first strategy and thus reinforce the acquisition of monitoring data, in particular by more effectively coordinating the analysis and sharing of biomonitoring data at the national level.

The objectives associated with the continuation of the national biomonitoring programme will be defined and will aim to acquire knowledge on exposure to chemicals, in particular to endocrine disruptors. In particular, a specific focus on the impregnation of the most vulnerable populations could be considered.

This work may also help to document the existence of socio-economic inequalities of exposure.

Monitoring of reproductive health indicators will be continued and new mechanisms for monitoring pathologies suspected of being linked to endocrine disruptors will be developed.

Finally, the compilation of this monitoring data associated with investigations into mechanisms of action will best describe adverse health events possibly related to endocrine disruptors, and ultimately demonstrate the health impact. Strengthening applied health research projects to develop a clinical approach to exposure to endocrine disruptors will be implemented to better document the cause-and-effect relationship between exposure and the development of pathologies related to endocrine disruption. These research actions will integrate the identification and measurement of new biomarkers of effects in the framework of the new National Biomonitoring Programme in particular, allowing the early detection of endocrine disruption (use of libraries and molecular biology tools).



www.ecologie-solidaire.gouv.fr

