FIVE-POINT PLAN OF THE FEDERAL GOVERNMENT ON PROTECTION AGAINST ENDOCRINE DISRUPTORS

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INTRODUCTION

What are endocrine disruptors?

Endocrine disruptors (ED) are substances or mixtures that interfere with hormone regulation and action. They are exogenous substances that can adversely affect one or more functions of the endocrine system. Exposure to these substances, especially during sensitive life stages, can impair human and animal health and harm the environment.[1] Due to their modes of action, endocrine disruptors in organisms can cause serious long-term effects if they interfere with endogenous feedback loops. They are potentially carcinogenic, toxic to reproduction or disruptive to development. Endocrine disruptors may cause irreversible damage to the development of organisms or even pose a threat to entire populations, for instance where they significantly skew sex ratios or decrease fertility and fecundity in wild animals.

For certain chemical substances, the harmful effects have already been well documented and acknowledged throughout the EU. Provisions have been laid down for individual chemical substances, including selected bisphenols, alkylphenols, UV-filter substances and some phthalates. For other substances, far more research is still required.

How do we come into contact with endocrine disruptors?

Endocrine disruptors can be found in packaging, toys, cosmetics and many other everyday items.

Bisphenols, for example, are used in the manufacture of polycarbonate plastics and resins which, among other applications, are used in food packaging. These substances migrate to food from packaging and other sources, and can thus enter the human body.

Phthalates are found in products such as food packaging, beverage containers, toys and personal care products. They can be absorbed orally, through inhalation or via the skin. Regulatory measures have already been taken for individual product

[1] https://environment.ec.europa.eu/system/files/2022-12/Annexes%20to%20the%20Delegated%20Regulation.pdf

groups, for instance food contact materials and articles.

Children and adolescents can be exposed to these substances to such a degree that detrimental health impacts cannot be ruled out. This is shown by the findings of the German Environmental Survey for Children and Adolescents (GerES)[2] and the European Initiative on Human Biomonitoring (HBM4EU),[3] which was concluded in June 2022. However, it is clear from the sharply falling phthalate concentrations in food and other consumer goods that legal provisions, such as those regulating plastics in food packaging, are effective for protecting human health and the environment.

One particular aspect is the uptake of endocrine active pharmaceutical substances such as thyroid hormones or contraceptives. These are components in medicines that intentionally and necessarily influence the human endocrine system. An unintended uptake via the environment seems extremely unlikely, despite the fact that endocrine active pharmaceutical substances are discharged, for example, in effluent from sewage treatment plants into surface waters, where they can be detected in trace amounts.[4]

Why have a national Five-Point Plan on Protection against Endocrine Disruptors?

This Five-Point Plan aims to provide more comprehensive information on endocrine disruptors and ensure better protection against these substances for humans and the environment. The goal is to greatly reduce the concentrations of endocrine disruptors in humans and the environment. To achieve this, the Federal Government intends to

1. further expand regulation of endocrine disruptors
2. improve public information on the risks of endocrine disruptors and on measures already in place to protect human health
3. promote joint action and bolster enforcement
4. increase knowledge on endocrine disruptors and
5. strengthen international cooperation.

The Federal Government's Five-Point Plan on Protection against Endocrine Disruptors highlights the links between regulation, information and research in the field of endocrine disruptors, and outlines options for action.

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[2] https://www.umweltbundesamt.de/sites/default/files/medien/479/publikationen/uug_02-2023_deutsche_umweltstudie_zur_gesundheit_von_kindern_und_jugendlichen_2014-2017.pdf

[3] https://www.hbm4eu.eu/result/

[4] https://www.umweltbundesamt.de/themen/chemikalien/arzneimittel/die-uba-datenbank-arzneimittel-in-der-umwelt

1. IMPROVING REGULATION

Regulation on endocrine disruptors is mainly harmonised at EU level. To this end, there are a number of EU Regulations that are directly applicable in all EU Member States. Germany is involved in improving this EU legislation.

Regulation at EU level

Chemicals regulation under REACH

Chemicals are evaluated and regulated at EU level in the REACH Regulation (Regulation (EC) No 1907/2006). Under REACH, case-by-case assessments can be used to identify endocrine disruptors EU-wide as substances of very high concern (SVHCs) and to regulate them. Producers and importers of substances identified as SVHCs are subject to information requirements if the SVHC content of an article is higher than 0.1 percent by weight. Moreover, inclusion of a substance on the candidate list can be a first step towards more extensive regulation at EU level. For example, a SVHC might become subject to authorisation, or uses of the substance could be restricted.

The procedure for regulating an endocrine disruptor at EU level under the REACH Regulation can be initiated by the competent authorities of the Member States. They can draw up proposals for classifying and regulating endocrine disruptors and launch the corresponding regulatory process at EU level. In Germany, the competent authorities are those agencies responsible for the protection of humans and the environment: the Federal Institute for Risk Assessment (BfR, responsible for consumer health protection); the Federal Institute for Occupational Safety and Health (BAuA, responsible for health protection in the workplace) and the German Environment Agency (UBA, responsible for environmental protection).

Under the Chemicals Act, the Federal Office for Chemicals (BfC) at the BAuA is instrumental in the implementation of the REACH Regulation and the CLP Regulation (Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures). The BfC coordinates the processes that involve German assessment authorities BAuA, BfR and the UBA, and is the contact point for the European institutions.

For example, the UBA is currently working on the EU-wide restriction of bisphenol A and other bisphenols subject to regulation. The use of these bisphenols is deemed a threat to the environment due to their endocrine disrupting properties and their discharge into the environment.

In keeping with this approach, instead of focussing on individual substances, the fundamental strategy under REACH is to also identify substances with a similar structure and comparable properties and regulate them together as a substance

group. This grouping approach allows a highly efficient protection of humans and the environment against substances with hazardous properties. Another aim is to ensure that in products, substances with hazardous properties are not replaced by alternatives that pose a similar potential risk. Germany's assessment strategy is thus in line with the European Commission's Chemicals Strategy for Sustainability outlined below.

Regulation of plant protection products, biocides and pharmaceuticals

Biocides, active substances in plant protection products and pharmaceuticals are exempt (in part) from the fundamental provisions on evaluation, restriction and prohibition under the REACH Regulation. These products are subject to separate provisions under European law, which stipulate comprehensive, detailed and refined risk assessments.
The following applies to plant protection products and biocides: Active substances that are identified as endocrine disrupting according to specified criteria may not be approved in the EU for use in plant protection or biocidal products. The same applies to substances that are classified pursuant to Regulation (EC) No 1272/2008 (CLP Regulation) as known or presumed endocrine disruptors (Category 1).

Exemptions for active substances in plant protection products are only possible if exposure has been proven to be negligible or if use of the active substance is deemed necessary pursuant to Article 4 (7) of Regulation (EC) No 1107/2009. The latter is only permitted in exceptional cases, subject to tight restrictions and time limits.

For biocides, too, the exemption rule applies to active substances with identified endocrine disrupting properties. However, an approval can be granted under specific circumstances, such as for certain disinfectants, if the biocidal active substance is necessary to combat serious danger to human health. In these cases, products with endocrine disrupting properties are designated candidates for substitution, i.e. as products or active substances to be replaced, the review period is curtailed and use by the general public is prohibited. This generates huge pressure to develop alternatives in order to avoid reauthorisation and to promote innovation that benefits human health and the environment.

For active substances in medicinal products for human and veterinary use, the approval process includes an environmental risk assessment. However, possible environmental risks of medicinal products for human use currently have no practical bearing on approval, even for endocrine active medicinal products, since the therapeutic effect has priority. The European Commission proposal of 26 April 2023 on the reform of the pharmaceutical legislation in the EU aims to revise the provisions on medicinal products for human use. In the case of veterinary medicinal products, on the other hand, the final risk-benefit assessment is influenced by possible environmental risks. Thus, under Regulation (EU) No 2019/6, authorisation for a veterinary medicinal product can be refused for environmental reasons.

European Commission Chemicals Strategy and zero pollution ambition

In October 2020, the European Commission published the European Chemicals Strategy for Sustainability.[5] The Chemicals Strategy is a cornerstone of the European Green Deal. It aims to make a key contribution to the goal of achieving a toxic-free environment by 2050 (zero pollution ambition). The European Commission has announced a range of measures for achieving this ambitious goal.

In the view of the European Commission, the protection of humans and the environment against endocrine disruptors should be improved. This should include making it easier to identify these substances and regulate them as appropriate. The Chemicals Strategy envisages both improving and accelerating regulation under REACH of substances or substance groups of particular concern, including endocrine disruptors, in products such as consumer goods and certain items for professional users. Substances will only be granted exemption if their use is proven to be essential for society. In addition, legally binding criteria for hazard classes and appropriate labelling pursuant to the CLP Regulation have been introduced for endocrine disruptors.

Water law provisions

The regulation of endocrine disruptors under water law depends very much on data availability and how that data is assessed under other legislation. For example, substances are prioritised and environmental quality standards laid down on the basis of ecotoxicological information – including endocrine active characteristics – which are available or can be obtained under regulations relating to substance control (REACH Regulation, Regulation on Plant Protection Products, Regulation on Biocidal Products).

The EU Water Framework Directive (EU WFD) is a key instrument under water law that promotes comprehensive water body protection. The Directive on Environmental Quality Standards and the Groundwater Directive are WFD daughter directives. They set out environmental quality standards for certain substances or substance groups in surface waters in accordance with the Water Framework Directive. These also include some endocrine disruptors such as DEHP and nonylphenol.

In addition, the 2013 amendment to the EQS Directive introduced a mechanism for a watch list. This list comprises substances to be monitored by the Member States to determine whether they represent a risk for the aquatic environment and to lay down any necessary environmental quality standards. Some substances on the watch list have now been proven to have endocrine disrupting properties.

In October 2022, the Commission presented a draft revision of the EQS Directive that

[5] https://ec.europa.eu/commission/presscorner/detail/de/ip_20_1839

contains extensive proposals on this topic, including the introduction of an effect-based monitoring to evaluate endocrine disruptors in water bodies, and proposes the introduction of environmental quality standards for synthetic oestrogens and bisphenol A.

Food contact materials and articles

For health protection reasons, some food contact materials and articles, including packaging, and specific material groups such as plastic, are now subject to special individual provisions beyond the general safety requirements. Regulation (EU) No 10/2011 includes a list of substances authorised for the manufacture of plastic food contact materials and articles. The authorisations are based on the relevant risk assessments of the European Food Safety Authority (EFSA). Where necessary, restrictions and limit values are laid down to ensure that no substances are transferred from the materials to the food in quantities that can pose a risk to human health. This is the case for bisphenol A and certain phthalates.

To promote consumer health protection, limits on the potential transfer to food were laid down at EU level specifically for the use of bisphenol A in varnishes and coatings for food contact materials and articles (Regulation (EU) 2018/213).

The EU provisions are updated continuously in line with new findings and risk assessments by EFSA.

Goal 1: Further expanding regulation of endocrine disruptors

The Federal Government supports the proposals in the European Commission's Chemicals Strategy for Sustainability aimed at facilitating the identification, labelling and regulation of endocrine disruptors. The government is supporting activities by the competent authorities in Germany to prepare and initiate European provisions on endocrine disruptors. These activities are to be further strengthened. In order to better evaluate the potential environmental impacts of pharmaceuticals, including endocrine active medicinal products, the Federal Government advocates improving the data situation and ensuring a more robust environmental risk assessment, especially as part of the reform of the pharmaceutical legislation in the EU. Chemicals concentrations in humans and the environment will continue to be monitored at national level and in Europe-wide collaborations.

Implementing the EU Chemicals Strategy and further developing the European legislative framework

The Federal Government supports the goals of the European Commission on further developing the European legislative framework for chemicals in order to strengthen protection against endocrine disruptors. In its Chemicals Strategy for Sustainability, the European Commission proposes a range of regulatory approaches, to be implemented in various legislative acts. These include the revision of the REACH Regulation, the proposals for revising the Cosmetics Regulation (EC) 1223/2009 and the revision of the Toy Safety Directive (which the European Commission announced

for 2023). The current regulations on endocrine disruptors vary across the different EU provisions. The Federal Government supports the goal of making the identification of endocrine disruptors more harmonised across the various European laws.

The EU Chemicals Strategy envisages extending the data requirements for registering substances under REACH to include endocrine disrupting properties. The aim is to accelerate and simplify evaluation and classification of these substances by the competent authorities. The European Commission is furthermore considering adding the property “endocrine disrupting” as a separate category of substances of very high concern (SVHC).

If data on the classification of a substance as endocrine disrupting is already made available on registration, the competent authorities are saved the expense and effort of researching data and implementing projects. This puts the fundamental REACH principle of “no data, no market” into practice for endocrine disruptors as well.

On 19 December 2022 a delegated regulation was adopted in the EU as part of the revision of the CLP Regulation. It introduced new hazard classes for endocrine disruptors in the areas of environment and human health.

Strengthening regulatory activities

The competent authorities in Germany work at EU level to identify endocrine disruptors, for example under the Biocidal Products Regulation, the Plant Protection Products Regulation and REACH. Due to their endocrine disrupting effect, active substances in plant protection and biocidal products have either already been banned or been declared candidates for substitution. The German authorities also work on proposals for adequately regulating substances under REACH.

Nine out of 22 substances that are on the REACH SVHC candidates list[6] due to their endocrine disrupting properties were put forward by the German competent authorities.

Once substances have been identified as SVHCs and are added to the list of candidates, manufacturers and importers are subject to information obligations, including towards consumers. This increases transparency and supports substitution of these substances. Moreover, the inclusion of a substance in the list of candidates can be the first step towards more extensive regulation, such as imposing restrictions on a substance, or making it subject to authorisation.

The intensive work and cooperation by Germany’s competent authorities (BAuA, BfR, UBA) on regulation proposals for endocrine disruptors has already improved protection against these substances. This work will be stepped up further in future. In

[6] https://www.echa.europa.eu/candidate-list-table

this framework, the German authorities collaborate with national authorities of other EU Member States to support the implementation of the Chemicals Strategy of the European Commission.

Further developing the evaluation methodology and incorporating advances in scientific knowledge into chemicals regulation

Knowledge in the field of endocrine disruptors is growing at a particularly fast and accelerating pace. Implementing the latest scientific and research findings in regulation is therefore a particular challenge.

The evaluation bodies develop guidelines for implementing the regulation of endocrine disruptors and update existing guidelines in cooperation with the competent authorities of the other EU Member States, EFSA and the European Commission.

Current gaps in knowledge that may hinder implementation of endocrine disruptor regulation are being identified and highlighted. These gaps include a lack of validated, OECD-recognised test procedures for certain endocrine effect mechanisms and an inadequate understanding of the correlation between exposure and risk of endocrine-related damage to health caused by exogenous substances.

Food contact materials and articles

The European Commission is planning a revision of EU law on food contact materials and articles. This will also consider key points of the EU Chemicals Strategy, for instance with regard to the use of certain SVHCs. The Federal Government attaches particular importance to further improving the safety of food contact materials and articles, and will therefore participate closely in the revision process.

Proposals for the environmental risk assessment under the EU Pharmaceutical Strategy

With the publication of the Pharmaceutical Strategy for Europe, the European Commission signalled the strengthening of the environmental risk assessment for pharmaceuticals in line with the European Green Deal and the Zero Pollution Action Plan. For the EU consultation, the UBA drew up proposals that also address the issue of pharmaceuticals with intended endocrine active substances.

National and Europe-wide monitoring of chemicals concentrations in humans and the environment

The German Environmental Survey (GerES) is a representative study of the population conducted at regular intervals to determine exposure of humans to chemicals by analysing blood or urine samples. In addition, the Federal Environmental Specimen Bank (UPB) enables chemicals concentrations in the

human body, environmental media and organisms to be identified, focussing particularly on their development over time. Endocrine disruptors are included in the range of substances studied.

Building on this series of reports, the European HBM4EU Initiative[7] collected data on current concentrations of selected chemicals in human samples from the European population. The new European Partnership for the Assessment of Risks from Chemicals (PARC) is continuing this work and extending it to include environmental and food monitoring.

The toxicological assessment values derived by the UBA-based HBM Commission (HBM-values) form the basis for evaluating the success of regulatory instruments and, in future, of the EU Chemicals Strategy. Data from environmental and health monitoring can also point to sources, hotspots and especially affected population groups, and help identify new substances of very high concern. In the context of restrictions, targeted monitoring of the possible substitute substance is important, as it ensures countermeasures are taken in good time if the substitutes themselves lead to new risks to the environment and human health. To that end, monitoring of the environment, feed, food and drinking water should be continuously brought into line with the latest scientific knowledge on endocrine disruptors. In 2023, a health-based parameter for bisphenol A in drinking water was introduced under the German Drinking Water Ordinance (TrinkwV). It lays down a limit value of 2.5 microgram per litre of drinking water, effective from 12 January 2024.

Since 2010, the German Chemical Industry Association VCI has worked with the BMUV in a project to develop HBM analysis methods for further substances. These methods can supplement the studies of the GerES, the UPB and the European initiatives.

[7] https://www.hbm4eu.eu/

HUMAN BIOMONITORING COMMISSION OF THE GERMAN ENVIRONMENT AGENCY (UBA)

The task of the UBA's HBM Commission is to advise the President and other UBA staff on HBM issues.

The Commission is made up of scientists, specialists from federal and Länder authorities, universities, hygiene institutes and clinics. Members were appointed to the Commission for their expertise in the field. Alongside members, there are permanent guests that include representatives of the Workng Group of the Supreme Health Authorities of the Federal Länder, the BMUV, the Federal Ministry of Health (BMG), the Robert Koch Institute (RKI), BfR and the UBA. Authorised experts can also serve as guest consultants.

The Commission derives two types of assessment values for substances in the human body: 1. Reference values from a series of measuring results of a sample taken from a defined population group and analysed according to a defined statistical method and 2. Toxicologically founded HBM values for harmless concentrations in blood or urine (HBM-I) and for concentrations in blood or urine at which adverse health effects considered relevant are possible (HBM-II), whereby these assessments refer only to the respective individual substances and not to mixtures of substances.

The Commission cautions that the HBM values do not give a level up to which "topping up" is possible. Medical history, symptoms and temporal connections must be considered when applying the values, for example in order not to hinder other preventive measures.

2 PROVIDING AND COMMUNICATING INFORMATION

The protection of the environment and human health against the impacts of certain chemicals is of great importance, especially if environmental health is threatened over several generations. For that reason, the Federal Government will supplement the assessment and regulatory measures described in the section “Regulation at EU level” with more intensive information and awareness-raising campaigns on the potential risks of endocrine disruptors. These will be aimed at both the general public and the trade and retail sectors.

Awareness raising and information campaigns are important tools for taking account of exposure to endocrine disruptors across different areas of application. Natural and synthetic endocrine disruptors occur in various ways and can be found in all areas of daily life. Up to now, consumers have had only very limited opportunities to make informed choices. Moreover, the effects of exposure to endocrine disruptors on consumers can vary from case to case. Depending on the effect mechanism of the ED substances and the life stage exposed to them, sometimes only specific population groups may be susceptible to adverse health effects, for instance children or those who are pregnant. This Five-Point Plan centres on measures that ensure consumers have comprehensive information on endocrine substances and their risks

that is tailored to specific target groups.

Information will help the manufacturing and processing industries to minimise their use of or to substitute endocrine disruptors, and make it easier for retailers to market suitable alternatives even before legal bans come into force or in cases where such bans cannot be imposed.

Goal 2: Keeping the public better informed about the risks of endocrine disruptors

The competent federal authorities, such as the UBA, BfR and the Federal Office of Consumer Protection and Food Safety (BVL), will

- facilitate access to information and increase visibility of information that the Federal Government and its authorities have already made available
- actively communicate information in order to reach consumers in their specific target groups
- explain to the public the potential risks of endocrine disruptors
- sensitise the public and protect particularly vulnerable population groups
- campaign for sustainable consumption and use, for instance returning surplus medication to pharmacies instead of disposing of it in the wastewater system.

A dialogue will also be fostered with stakeholders and multipliers who are active in the field of endocrine disruptors. The goal is to communicate information on specific risks, highlighting both the areas where action is needed and what options for action are available. By involving these multipliers, a wider public will be reached.

Information and awareness-raising measures

Using existing structures and instruments, in future the Federal Government and competent authorities will provide more extensive information on the links between human health, environmental protection and the effects of endocrine disruptors, and on the precautions already in place. To this end, the available knowledge will be prepared and used to inform especially vulnerable population groups and the general public on key aspects of endocrine disruptors.

Once a substance is identified as carcinogenic, mutagenic or toxic to reproduction, or if there is robust scientific data pointing to such an effect, the substance itself and products that contain it are disqualified from receiving the state environmental label Blue Angel.

Associations and other suitable multipliers will develop and make available information tailored to specific target groups.

Associations that are already examining endocrine disruptors can supplement the information, education and awareness-raising measures of the Federal Government and its authorities. They can particularly play a role in communication on endocrine

disruptors in products (supply chains, circular economy), sustainable consumption and vulnerable groups. Funding for associations can also support dialogues that raise the visibility of the issues of endocrine disruptors.

Using suitable channels, the competent federal authorities will intensify communication of the following topics:

- Information on substances or substance groups with endocrine disrupting properties, focussing in particular on potential uses of the substance, possible uptake paths and effects, and options for avoiding potentially risky applications.
- Education on and promotion of sustainable pharmaceuticals management (for instance careful use, environmentally sound disposal).
- Information on physical exposure of people in Germany to endocrine disruptors, its development over time following regulatory measures and on subgroups of the population exposed to particularly high levels of contamination.
- Information on how substances with endocrine disrupting properties can be, or are already being, identified and regulated in the different legal areas.
- Better dissemination of regular monitoring data and of data from the representative GerES series and analysis of UPB samples on the sources of public exposure and its development over time.
- Dissemination of suitable outreach materials from European projects such as HBM4EU on the current exposure situation in Europe, which can be tailored specifically to endocrine disruptors, and use of the data for information purposes.
- Definition of “substances with endocrine disrupting properties” / “endocrine disruptors” and classification of the different terms in circulation that are often used misleadingly – “endocrine”, “endocrine active”, “endocrine disrupting”.
- Information on activities by German competent authorities relating to classification and regulation of substances with endocrine disrupting properties.
- Cooperation with competent authorities in other EU Member States.

Information for experts

A range of newsletters, websites and other information is already available for professionals and experts. Federal authorities are supporting a wider distribution of these materials:

- Results of EFSA assessment of active substances in plant protection products and food contact materials and articles in the EFSA Journal.[8]
- Results of ECHA assessment of active substances in biocidal products presented in the opinions of the Biocidal Products Committee.[9]
- Results of the European Medicines Agency (EMA) assessment of medicinal products in the Public Assessment Reports and European Public Assessment Reports.
- ECHA's list of endocrine disruptors giving the latest assessment status of substances.
- ECHA information on the regulation of selected endocrine disruptors.
- Publications on exposure of the population to endocrine disruptors and its development over time based on comprehensive reports from projects such as GerES, UPB, HBM4EU and PARC.
- Resources on the web pages of specialist bodies BfR, the UBA, BAuA and the BVL, offering both basic information and more detailed, scientific sources for experts.
- Information compiled by the relevant national professional bodies, for instance the German Society of Endocrinology (DGE), the German Society of Epidemiology (DGEpi), the German Society of Pediatrics and Adolescent Medicine (DGKJ), the Toxicology Society (GT), the German Pharmacology Society (DGP) and the Drug Commissions.
- Newsletters of the EURION projects.
- Publications in databases and registers.

[8] https://efsa.onlinelibrary.wiley.com

[9] https://echa.europa.eu/de/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval

Information and training for multipliers

Using outreach and educational measures, and in cooperation with clubs and associations, the Federal Government will better inform especially vulnerable groups about the effects of chemicals with endocrine disrupting properties. Training offers for multipliers will be one of the means of achieving this. Associations and federal authorities will develop suitable information and training materials such as online tutorials.

3 PROMOTING JOINT ACTION

Within the Federal Government, no specific ministry has the overarching responsibility for endocrine disruptors. Given that endocrine disruptors and endocrine active substances in pharmaceuticals are regulated under the respective EU law for different sectors (for example chemicals, plant protection products, biocides, cosmetics, toys, veterinary and human medicinal products), the relevant ministries and their competent authorities hold both regular and event-specific exchange.

Using integrative approaches, the Federal Government intends to build on this exchange in those areas where this can be expected to generate new, positive momentum. The Coalition Agreement also points out the particular importance of interministerial and inter-agency cooperation. This will also include the committees required under occupational health and safety law and the committee for maternity protection.

Goal 3: Stepping up cooperation and strengthening enforcement

Processes within and between ministries and competent authorities will be designed to enable better coordination, harmonisation and cooperation.

Stepping up interministerial cooperation

Existing cooperation structures in the field of environment and health, for instance the Action Programme Environment and Health (APUG), will be used to intensify cooperation between ministries and ensure more consistent work on endocrine disruptors. APUG is a useful tool for exchange between relevant ministries and federal authorities and for inter-agency communication. APUG is therefore an appropriate framework to underpin implementation of the Five-Point Plan on Protection against Endocrine Disruptors and to support corresponding projects. For example, APUG can be used to network federal authorities on this issue.

Exchange between ministries and competent authorities will be fostered and further developed to generate positive momentum. The focus of these activities is on improving the knowledge base, networking key actors and ensuring well-coordinated,

consistent government work.

Strengthening enforcement

Enforcement must be strengthened in order to ensure that products – including imports – are prevented from entering the market if they do not meet the legal requirements. The supervisory authorities of the Länder are responsible for monitoring compliance with chemicals regulations. In the case of transboundary trade, the customs administration is also involved in monitoring goods subject to bans and restrictions, in line with the relevant provisions. It notifies the competent Länder supervisory authorities if it finds evidence of an infringement. Under Germany's Basic Law, operational cooperation between the Federation and the Länder in practical enforcement of the law is only possible within very narrow boundaries. The Federation nevertheless supports the Länder, for example in an advisory capacity or by offering Common Central Units like Control of Food, Feed, Cosmetics, Consumer Products and Tobacco Products Traded on the Internet (G@ZIELT). These units were set up through agreements between the Federation and Länder. This form of cooperation with the Länder is aimed at improving the enforcement of EU chemicals law for imported products as well. In the negotiations on the EU Regulation on general product safety, Germany worked to secure more stringent product safety provisions. The new EU Product Safety Regulation (PSR) strengthens the powers of the market surveillance authorities and entails clear product safety obligations for all actors. Online marketplaces must work with the market surveillance authorities to mitigate risks. The authorities can order online marketplaces to remove or disable access to offers of dangerous products either immediately or in any event within two working days. Products from outside the EU can only be placed on the market if there is an economic operator established in the European Union who is responsible for the safety of those products. The PSR also fleshes out the obligations of the different economic operators, such as manufacturers, importers, distributors or fulfilment service providers, and lays down their exact duties. The new EU PSR will improve the product recall procedure. If a product has to be recalled, consumers must be informed directly. The rapid alert system for dangerous products (Safety Gate Portal) is being upgraded so that unsafe products can be identified more easily. The new EU Product Safety Regulation will take effect in 2024. The Federation is holding regular exchange with the Länder in the relevant bodies to discuss such matters as how product recalls can be ordered effectively and with legal security as part of the implementation of existing horizontal regulations (Market Surveillance Act, current Product Safety Act and future EU Product Safety Regulation).

4 BUILDING ON THE KNOWLEDGE BASE

Since 1999, around 500 million euros have been spent on research into endocrine disruptors at EU level. A comprehensive evaluation and consequent prioritisation of further research needs, potentially also at national level, has not yet been carried out.

Goal 4: Improving the knowledge base on endocrine disruptors

The Federal Government is pursuing the goal of improving the knowledge base on endocrine disruptors at national and European level. The Federal Government will press for optimised use of EU research funding in priority areas previously agreed on by the Member States, and for projects to be networked more effectively.

National knowledge bases and research

For a successful European chemicals policy, it is vital to generate high-quality data on exposure in Germany and Europe that can serve as a basis for analyses and science-policy interactions.

Examples of key projects being implemented in Germany that also cover protection against endocrine disruptors are the German Environmental Survey GerES VI and the BfR projects Total Diet Study (MEAL Study), the children's nutrition survey (KiESEL Study) and the A&A study on the impacts of plant protection products on users, workers and local residents.

The GerES series collects representative data on exposure to chemical substances for the German population as a whole. These studies have been instrumental in securing Germany a leading position in the field of human biomonitoring in the EU and beyond. The Federal Government wants to make these important surveys a regular study with secured funding. It will also develop the series further.

The MEAL and KiESEL studies enable the collection of data on exposure to chemical substances in food, drink and luxury foods.

In addition, the ministries' research plans (REFOPLAN) will increase the focus on research projects that aim to identify areas where regulation on endocrine disruptors is needed, for instance developing proposals for identifying SVHC under REACH, creating a scientific basis for restriction proposals and investigating safe substitutes.

In the field of medicinal products, the development and harmonisation of test methods – preferably without animal experiments – to identify endocrine disruptors is an important research goal that the Federal Government will support financially. To reduce the impacts of pharmaceuticals in the environment, another focus will be projects on sustainable use and the promotion of more environmentally sound substitutes.

Another useful approach is for the Environmental Specimen Bank (UPB) to conduct more comprehensive environmental monitoring and gather data on the impacts of trace substances on ecosystems. An initial review is underway to determine whether it would be useful to extend the environmental section of the UPB to include further substances for assessment. In this way, UPB reserve samples can be used where necessary to study newly occurring substances for which there is currently no data or clear understanding of their distribution, but which are suspected of having an endocrine disrupting effect.

The competent authorities will carefully evaluate existing research findings and

communicate these more intensively. The results of these evaluations can be disseminated through suitable formats and channels.

Another envisaged approach are dialogues involving scientific agencies the UBA, BfR and BAuA, with a focus on stepping up support for research into endocrine disruptors. One research goal should be to enable further proposals for SVHC identification and restrictions.

Generating practical knowledge at European level

The European Commission and the Member States launched the PARC partnership under the new EU research and innovation funding programme Horizon Europe. The programme aims to support the authorities and agencies of the Member States and the EU that are tasked with risk assessment and risk management with data, new tools and methodologies.

PARC is a key EU research project and a successor to EU-ToxRisk, SEURAT-1, EuroMix, HBM4EU and other past EU projects with regulatory relevance. PARC will build on those projects to further expand the central European network in the field of chemicals regulation, environment and health. PARC plays a direct role in the implementation of the European Green Deal, especially the Chemicals Strategy for Sustainability.

The active involvement of the UBA and BfR in the European partnership PARC will also be used to expand knowledge on endocrine disruptors: The work package “Monitoring and Exposure“ (co-lead UBA) collects load data across Europe on endocrine disruptors in humans and the environment. The aim of the work package “Hazard Assessment” (co-lead BfR) is to develop new toxicological test methods for studying endocrine effects and effect mechanisms.

Identifying further research activities

The UBA and BfR are involved in EURION, the EU research cluster into endocrine disruptors funded by the Horizon 2020 programme. The UBA is a partner in the ERGO project and BfR participates in both the ATHENA and EDCmet projects.

Further research can be identified, for example, through Länder programmes on food, feed and drinking water monitoring. Findings from the national monitoring plan and monitoring under the German Food and Feed Code, including data on cosmetics, tattooing materials and consumer goods, may prompt new research activities. Both monitoring programmes are supported by the BVL. We will promote the development of standardised examination methods with the aim of generating comparable, valid results from these programmes.

5 INTERNATIONAL COOPERATION

A basic lack of capacity in chemicals management is a particular problem in emerging economies and developing countries. There are deficits above all in national competent authority and regulation structures, and in personnel, expertise and financing. There must be greater recognition of the importance of political will for building and strengthening responsible chemicals management in many developing countries and emerging economies. Equally, the challenges for industrialised countries in supporting that capacity building need to be acknowledged.

International collaboration is also important for strengthening dialogue and exchange with third countries and, since the harmful impacts of chemicals do not stop at borders, for establishing sustainable and sound chemicals management worldwide.

At international level, there are a number of initiatives which involve German authorities, for instance the OECD expert group “Endocrine Disruptor Testing and Assessment”, which explores developing and harmonising testing methods.

In addition, the Globally Harmonized System of the United Nations (UN GHS) ensures that classification and labelling of hazardous substances and mixtures are standardised worldwide on their respective markets. While the UN GHS is not legally binding, it serves as the main basis for more far-reaching provisions in individual countries and is, for example, the prerequisite for globally harmonised requirements for the transport of hazardous goods. Since 2003, the UN GHS has been reviewed every two years and updated as necessary. It has now been revised nine times. Preparations are currently underway for the adoption of the tenth revision.

The UN GHS represents a key pillar for the sound management of chemicals (and

waste), SMCW. The UNEP Global Chemicals Outlook of 2019[10] points out, however, that in many emerging economies and developing countries, the UN GHS has still not been introduced and implemented.

For this reason, it is vital that projects under international cooperation on chemicals management dealing with particular substance properties such as an endocrine disrupting effects are implemented expressly with SMCW in mind.

This Five-Point Plan describes how the example of endocrine disruptors can be used in capacity-building projects and partnerships to highlight the importance of adequate SMCW capacities for tackling the challenges of international chemicals management.

Hazard classes and criteria for classifying endocrine disruptors have not yet been laid down in the UN GHS. The coordination processes for adding new hazard classes to the UN GHS are complex and require a long time horizon. Subsequent implementation also needs long-term planning, as emerging economies and developing countries need appropriate timeframes and possibly financial assistance, especially if basic capacities are still being developed.

Goal 5: Strengthening international cooperation

Capacity building to implement sound chemicals management should be strengthened in developing countries. To this end, it is first necessary to explore the long-term acceptance for expanding the UN GHS to include endocrine disruptors, taking previous experience such as that made with the EU CLP Regulation as a basis.

Piloting in international projects and partnerships with SMCW relevance

International collaborative projects should focus more systematically on identifying the concrete challenges of establishing SMCW and what specifically is needed to do so. Endocrine disruptors, perhaps in combination with other relevant aspects, are suited to making collaborative projects and partnerships as practice-oriented as possible. Pilot projects on such issues as endocrine disruptors could be tailored to the needs and specific circumstances. If not already achieved, the first goal of these projects and partnerships should be to implement the UN GHS at national level, and to use the opportunity to highlight the benefits of gradually extending the UN GHS to other substances such as endocrine disruptors.

[10] https://www.unep.org/explore-topics/chemicals-waste/what-we-do/policy-and-governance/global-chemicals-outlook

FINANCING

All the measures arising from the Five-Point Plan on Protection against Endocrine Disruptors will be implemented in the framework of constitutional responsibilities and are conditional on availability of funds. If concrete measures or future follow-up measures lead to expenditures in the federal budget, they are conditional on the availability of budgetary funds and/or staff positions and do not prejudice any ongoing or future budget negotiations.

GLOSSARY

Abbreviation	Full title
A&A	Anwender- und Anwohner-Studie (study on the impacts of plant protection products on users, workers and local residents)
APUG	Aktionsprogramm Umwelt und Gesundheit (Action Programme Environment and Health)
ATHENA	Assays for the identification of thyroid hormone axis-disrupting chemicals: elaborating novel assessment strategies
BAuA	Federal Institute for Occupational Safety and Health
BfC	Federal Office for Chemicals
BfR	Federal Institute for Risk Assessment
BMG	Federal Ministry of Health
BMUV	Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection
BVL	Federal Office of Consumer Protection and Food Safety
CLP	Classification, Labelling, Packaging
CLP Regulation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
DGE	German Society of Endocrinology
DGEpi	German Society of Epidemiology
DGKJ	German Society of Pediatrics and Adolescent Medicine
DGP	German Pharmacology Society
ECHA	European Chemicals Agency
ED	Endocrine disruptors
EDCmet	Metabolic effects of endocrine disrupting chemicals: novel testing methods and adverse outcome pathways
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ERGO	EndocRine Guideline Optimisation

Abbreviation	Full title
EU	European Union
EURION	European Cluster to Improve Identification of Endocrine Disruptors
EuroMix	A tiered strategy for risk assessment of mixtures of multiple chemicals
EU-ToxRisk	An Integrated European ‘Flagship’ Programme Driving Mechanism-based Toxicity Testing and Risk Assessment for the 21st century
GerES	German Environmental Survey
GT	German Toxicology Society
HBM	Human biomonitoring
HBM4EU	European Human Biomonitoring Initiative
LFGB	German Food and Feed Code
KiESEL Study	The Children’s Nutrition Survey to Record Food Consumption
MEAL Study	Total Diet Study for Germany
PARC	Partnership for the Risk Assessment of Chemicals
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REACH Regulation	REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL | of 18 December 2006 | concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
REFOPLAN	Ministry research plan
RKI	Robert Koch Institute
SEURAT-1	Development of a research strategy for the replacement of in vivo repeated dose systemic toxicity testing
SMCW	Sound Management of Chemicals and Waste
SVHC	Substances of Very High Concern
TrinkwV	Drinking Water Ordinance
UBA	German Environment Agency

Abbreviation	Full title
UN GHS	United Nations Globally Harmonized System of Classification and Labelling of Chemicals
UNEP	United Nations Environment Programme
UPB	Federal Environmental Specimen Bank