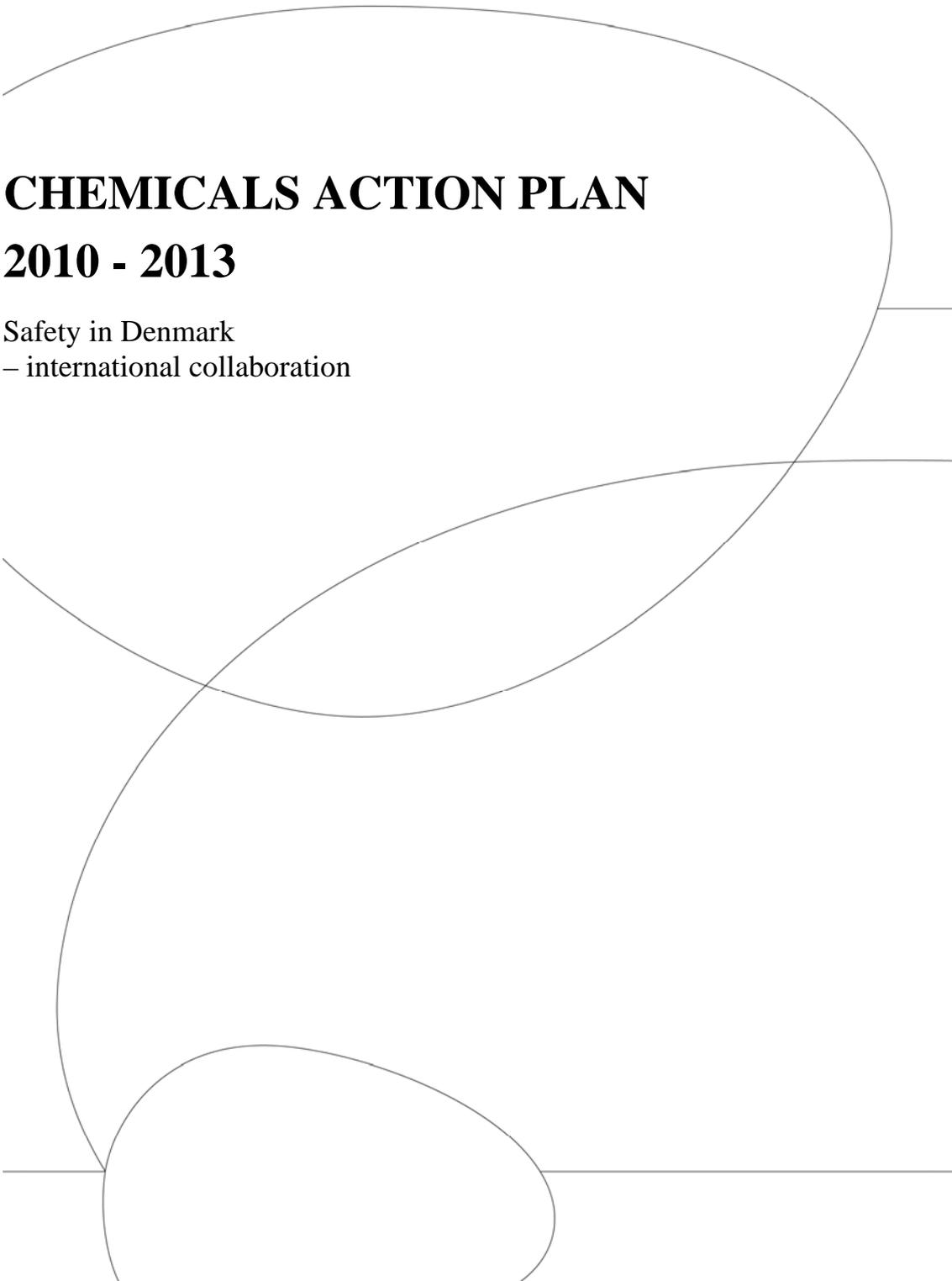


CHEMICALS ACTION PLAN 2010 - 2013

Safety in Denmark

– international cooperation

THE GOVERNMENT OF DENMARK March 2010



CHEMICALS ACTION PLAN

2010 - 2013

Safety in Denmark
– international collaboration

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Foreword

I am very proud to be presenting this new Chemicals Action Plan, which plots the course of our efforts in the field of chemicals for the next four years – from 2010 to 2013.

I am especially pleased that all the parties in the Danish Parliament, the *Folketing*, have passed the Chemicals Action Plan. It is incredibly important to achieve political unity with regard to these efforts and I am grateful for the support of all the parties in this regard.

Over the next four years we will ensure, through the Chemicals Action Plan, that people and the environment are protected to the best possible extent from harmful chemicals. Chemicals are here to stay – and we have been using them for hundreds of years. They are a part of modern society: we enjoy great benefits from many chemicals, as long as they are used correctly.

Our knowledge of chemicals and how they affect us is constantly growing. This is partly the result of the major efforts of the EU, where collaboration through REACH has resulted in the analysis and evaluation of a very large number of the chemicals that we use. It is also partly the result of Danish research, which has given us greater knowledge, in particular, about the effects that chemicals have when they are combined – what is known as the cocktail effect. Danish studies have shown that a chemical that itself is not dangerous in small doses can be dangerous on interaction with another chemical or chemicals. We have taken that new knowledge with us to Brussels, where it has helped to create a completely new outlook on how we in the European Union should regulate chemicals. Denmark must drive this development forward.

This Action Plan will result in a significant amount of new knowledge about the ‘cocktail effect’ – knowledge that, in parallel with the EU, we will be able to apply in new legislation to protect the people of Denmark and the environment to the best possible extent. At the same time, REACH and the knowledge centres for endocrine disruptors, allergens and Multiple Chemical Sensitivity also form key parts of the new Chemicals Action Plan.

We have provided an extensive economic framework to cover the next four years. DKK 173 million constitutes a significant reinforcement of the commitment. It means that we can back up our words with action and focus on a long list of important initiatives in the field of chemicals. There is still much to be done!

Minister for the Environment, Karen Ellemann

1. Introduction



1 Introduction

The Chemicals Action Plan rests on two main pillars: a strong programme of action in Denmark and an active international effort. The Action Plan also encompasses two kinds of activity, involving both general initiatives and focused initiatives concentrating on chemical substances of very high concern.

Chemicals are everywhere in our society. In many contexts they are used without causing problems for either people or the environment.

However, there exist chemicals that are problematic as well as chemicals that are used in problematic ways. It is therefore important to both the Danish Government and the *Folketing* that there should be a major focus on the risks associated with the use of chemicals.

People have been working with chemicals for years, and many chemicals with properties of concern have been banned, or their use has been restricted however, many challenges remain. There are areas where we have gaps in our knowledge and there are areas where there is a need for targeted dissemination of information to the public and to enterprises. There are areas in which international cooperation must be strengthened and there are areas which require increased monitoring.

To put it briefly, there is still a need for a major focus on chemicals.

Two main pillars of the Chemicals Action Plan

The Chemicals Action Plan is the guideline for efforts in the field of chemicals for the 2010-2013 period. Selected areas will be the object of increased efforts. The Chemicals Action Plan builds on the Danish government's Action Plan for 2006-2009. Plant protection products are now covered by the agreement on Green Growth between the Danish government and the Danish People's Party and are therefore not covered by the Chemicals Action Plan.

Chemicals Action Plan 2010 - 2013

Safety in Denmark – international cooperation

General initiatives:

Major focus on REACH

Continuation and enhancement of efforts in the consumer field

Improved international efforts

More monitoring and inspection

Prioritisation of the development of computer models and chemical substitutes

Focus on specific substances and groups:

Endocrine disruptors and the ‘cocktail effect’

Allergies

Multiple chemical sensitivity (MCS)

Biocidal products containing substances of concern

Nanotechnology

The Action Plan takes as its starting point the goal agreed at the 2002 Johannesburg World Summit on Sustainable Development: to ensure that by the year 2020 there are no goods or products on the market which have significant adverse effects on human health and the environment.

The Action Plan rests on two pillars: a strong programme of action in Denmark, and the exertion of influence at international level.

Chemical substances of concern require an international effort, since products cross national boundaries both through trade and via the environment. At the same time, this field is increasingly regulated by international conventions, the EU regulation on **Registration, Evaluation, Authorisation and Restriction of Chemical substances** (REACH) being a foremost example.

It is therefore important for Denmark to actively participate in international efforts. Only in this way can Danish environmental and commercial interests be heard. Only in this way can we ensure the proper protection of people and the environment in Denmark in the longer term.

There is much to be done at the national level. Amongst other things, we must ensure that Denmark complies with the requirements of REACH. A prerequisite here is cooperation with enterprises in Denmark.

We must also ensure that Danish citizens are well informed and we must help to build up new knowledge in those areas where information on the effects of chemicals is lacking or uncertain.

General initiatives – focused efforts

The Action Plan came about as part of a longer process involving not only the active participation of the *Folketing*, but also a dialogue with commercial, consumer and green organisations.

At the same time, the public, too, were involved. After a public meeting about a new chemicals action plan, 150 members of the public had their say and pointed out the problems that they believe it is important to solve.

The Chemicals Action Plan consists of two parts.

The first part sets out a series of general initiatives.

The second part focuses on challenges relating to specific target groups or specific substances and groups of substances.

This structure enables the Action Plan to implement a series of broad-based general activities and, for a four-year period, to place additional focus on a series of specific challenges.

2. General initiatives

2.1 Major focus on REACH

The next few years will see the registration and evaluation of 4,500 chemical substances in the European Union. This will necessitate positive cooperation amongst enterprises and Denmark shall play an active role in EU cooperation on REACH. This will include work on endocrine disruptors, combination effects and nanomaterials.

The Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is the new EU regulation on chemicals. It was adopted in 2006 and will be implemented in stages over a 15-year period. REACH will establish greater knowledge about how chemicals affect health and the environment – and will place more responsibility on enterprises with regard to ensuring that the necessary knowledge is in place and that chemicals are used responsibly.

REACH is close to completion from a purely legislative point of view. Approximately 40 directives have been repealed, and now form part of REACH. Over the next few years, the challenge is to make REACH work in practice. This will require major efforts from both industry and the authorities.

It will happen by means of the Danish authorities advising enterprises and monitoring their compliance with the obligations under REACH. In addition, the authorities will put forward proposals for EU regulation.

The Danish authorities will also actively participate in the shared EU process of evaluating chemical substances and restricting those with properties of concern. Substances of the highest concern will be prohibited or made subject to the authorisation system.

Active Danish participation in the REACH process – with consideration of endocrine disruptors, combination effects and nanomaterials

A key part of the REACH process is active participation in the work of the European Chemicals Agency (ECHA). At the Agency, representatives of EU Member States evaluate substances and company registrations and process proposals for the regulation of chemical substances.

This is also where Member States collaborate on the generation of guidance material for industry and the authorities.

Endocrine disruptors and combination effects are on the agenda in many contexts within the EU. The capacity for tackling endocrine disruptors and combined effects depends on information on the individual substances and REACH provides precisely this.

Over the next few years criteria will be developed for endocrine disruptors in the EU – at present there is different views among the various Member States on how such criterier should be. Denmark will therefore play an active role in the forthcoming establishment of uniform criteria for endocrine disruptors for the purposes of classification and regulation

within REACH. This will also have an impact on other legislation, such as legislation concerning cosmetics and plant protection products.

Denmark wants to focus particularly on how the combination effects of endocrine disruptors will be dealt with within REACH and other regulations.

REACH guidelines set out the guidelines for the work of authorities and industry on the risk assessment of industrial chemicals in the EU. The same applies to the work on combination effects.

Denmark wants to be at the cutting edge of the EU's work on revising the REACH guidelines. In 2010, Denmark also aims to help begin practical work on combination effects within the context of REACH by working to restrict the use of the phthalates of concern. It is also a Danish long-term goal to effect the amendments in REACH that will ensure adequate registration and risk assessment procedures. If necessary, further regulation must take place – for example via restrictions on use.

The Technical basis of REACH is not yet sufficiently developed with respect to nanomaterials. That basis will have to be formulated in future years and Denmark is keen to contribute active to this work. Until the necessary methods and techniques have been developed, the handling of any risk posed by nanomaterials must, where appropriate, be based on the results of somewhat limited studies and experience.

Over the next few years, 4,500 substances will be registered and evaluated

The basic principle of REACH is that industry is responsible for providing the evidence that chemical substances can be produced and used without risk to people or the environment. The use of substances of very high concern requires special authorisation within the EU.

As of 1 December 2008, EU enterprises had pre-registered 2.75 million produced or imported substances. Of these pre-registrations, 22,800 were made by 468 Danish companies. In total, the pre-registrations covered roughly 140,000 different substances. Pre-registration applies only to the production or importation of enterprises.

In the period up to 2018, enterprises must collect existing knowledge regarding the many chemical substances and they must acquire whatever knowledge is lacking. The resulting documentation is submitted to the European Chemicals Agency as part of registration.

Substantial additional effort

The initial deadline for the registration of those substances applied most extensively and those most harmful to the environment and health is 1 December 2010. The authorities must evaluate the majority of such registrations by 2013.

That means that the Danish authorities must contribute to the evaluation of 4,500 substances for registration over the next few years. That task will require a substantial extra effort.

The work will commence in 2010 and will be running at full speed as of 2011. In 2010, Denmark will contribute to the evaluation of tens of registrations and testing proposals in accordance with a detailed prioritisation of where the efforts will be of greatest significance to the protection of health and the environment.

Close collaboration between the authorities and industry

The authorities support the enterprises in the form of information in order for them to comply with the obligations under REACH. In particular small and medium-sized enterprises find it difficult to achieve this task alone, as it requires expertise that not all enterprises possess.

The registrations by enterprises will be central in the work over the coming years. Suppliers must take responsibility for the responsible use of chemical substances and enterprises must document this in registrations. Denmark and other Member States must ensure that the basis on which enterprises have evaluated chemical substances is correct.

If there is no certainty that the substances are used responsibly, Member States must put forward proposals to regulate and restrict the use of those substances.

| Initiative | Effect |
|--|--|
| Active Danish participation in the technical committees of the European Chemicals Agency (ECHA). In 2010, Danish-appointed members are expected to act as rapporteurs for proposals to restrict the use of lead and mercury. | Improved environment and health within the EU. |
| Proposals to revise the REACH guidelines in relation to the combination effects of chemicals. | Improved safety in matters affecting human health and the environment. |
| Focus on collaboration with and assistance for small and medium-sized enterprises, in particular in their work on complying with the obligations within REACH and the new rules on hazard classification and labelling. In 2010, the authorities will focus on providing companies with a single point of access for advice on REACH and on hazard classification and labelling. | Improved understanding and implementation of REACH and the new rules on hazard classification and labelling. Improved environment and health in Denmark and within the EU. |
| Active Danish participation in the Commission's working groups under REACH – including a focus on the criteria for endocrine disruptors, combination effects and nanomaterials. | Improved environment and health within the EU. |
| Drawing up of proposals for regulation at EU level of substances that are prioritised in Denmark. In 2010, for instance, Denmark aims to work to restrict the use of phthalates with properties of concern. In 2010, Denmark will aim to table two proposals concerning: 1) the candidate list, and 2) classification and labelling. | Improved environment and health. Improved competitiveness for Danish businesses. |

In 2010, it is expected that Danish rapporteurs will be responsible for drafting the European Chemicals Agency's positions on EU proposals to restrict lead and mercury when the Agency's scientific committees discuss the proposals. Moreover, Denmark will work for the restriction of the use of those phthalates of concern.

Authorities to put forward proposals

Based on the information contained in the registrations, the authorities must also produce proposals concerning substances of specific concern. These include carcinogens, endocrine disruptors and substances which are specific harmful to the environment. Typically, the authorities can propose that these substances are prohibited or included within the "candidate list" of substances subject to an authorisation requirement.

In 2010, Denmark will produce at least two proposals for substances as candidates for the EU authorisation scheme and/or subjects for harmonised classification and labelling for serious effects.

Information on the new labelling system

Alongside REACH, a new classification and labelling system for chemical substances has been adopted. The labelling system enters into force on 1 December 2010 for pure chemical substances and on 1 June 2015 for mixtures.

The system will mean that all suppliers of chemical substances and mixtures must re-evaluate classifications and produce new hazard labels for their products. At the same time, users need to become familiar with the new system. This will require considerable resources on the part of both enterprises and authorities. In 2010, the authorities will formulate the information work targeted at enterprises so as to cover both REACH and the new rules on classification and labelling.



2.2 Continuation and enhancement of efforts in the consumer field

Intensive studies of chemicals in consumer products will continue and there will be active communication to the consumers.

The consumer must be confident that toys, cosmetics, jewellery and other products do not contain chemicals which can constitute a risk. The focus on consumer products will include gathering of information, communication, monitoring and regulation.

More studies of consumer products

Danish work in respect of systematically mapping the chemical substances in consumer products represents a unique programme in the international context. It is helping to increase our knowledge of the substances used in consumer products, how products are used and whether risk for consumers are present. This programme must therefore be continued and developed.

The work covers product groups such as toys, cosmetics, hobby products, jewellery and textiles. In addition, there is also a focus on overall exposure – for example the exposure of children.

The studies often relate to products produced outside the EU. The systematic mapping of chemical substances in consumer products can reveal the presence of substances of concern. Any contravention of the rules is dealt with by the Danish EPA Chemicals Inspection Service. It may also occur, that unregulated substance reveals a problem. Where this is the case, an evaluation is carried out of the need for more specific regulation of the substance.

Results of the consumer programme shall be actively used within the EU

The results of the various studies are used to inform Danish consumers about the risks that may be associated with the use of the products in question. Where necessary, the European Commission will be called upon to tackle the risk through EU legislation.

The knowledge that is gained from the consumer projects thus helps to prioritise the efforts of both the EU and Denmark. It is important that Denmark should continue to provide the EU with this input in the future.

Targeted information campaigns

The consumer projects also provided inspiration for information campaigns. For each of the past three years, the Danish Environmental Protection Agency has carried out a major information campaign targeted at various consumer groups. The campaigns highlighted the risks inherent in various product contents and their emission of chemical substances.

Experience shows that the information campaigns are a very valuable tool for attracting the attention of consumers and communicating complex messages in an appropriate and comprehensible manner. The work on information campaigns will thus be continued and further developed, drawing on experiences from previous campaigns.

More specific, the campaign regarding nine positive habits directed at pregnant and nursing mothers and the campaign focusing on allergy which were directed at teenagers, highly effective, drawing attention to the area and persuading consumers to change their behaviour. These campaigns for particularly vulnerable or at-risk groups can also be repeated.

The way is therefore being paved for continued targeted campaigns in order to strengthen the consumer area.

In some cases, prior survey of product areas will be necessary; in others, existing campaigns can be expanded so as to increase penetration while retaining the key messages. In connection with the campaigns, the Danish Environmental Protection Agency will also continue its work on forming partnerships with the retailers, amongst others, in order to spread the message of the campaigns as effectively as possible.

| Initiative | Effect |
|---|---|
| At least five studies of groups of specific product areas per year – or fewer, but larger collated studies. | Improved safety for consumers. |
| Implementation of two major information campaigns per year in 2010 and 2011 – including a campaign on energy saving light bulbs and a campaign targeted at the “Do-It-Yourself people” in 2010 – and one campaign per year in 2012 and 2013. In relation to the campaign on energy saving light bulbs, the options for joint financing by manufacturers and importers are being examined. | Dissemination of knowledge. Improved safety for consumers. Improved protection of humans and the environment. |

| | |
|---|---|
| Use of knowledge gained from the consumer programme to legislation at national or EU level. | Dissemination of knowledge. Contribution to EU regulation. Improved protection of health and the environment in the EU. |
| Reinforcement of the Information Centre for the Environment and Health in 2010 and 2011. | Improved options for consumers to choose products with the lowest impact on health and the environment. |

The Danish Environmental Protection Agency will also be focusing on younger children by communicating information to institutions and parents. This work will pay special attention to products that may contain phthalates. In addition, guidance will also be drawn up for municipal procurement officers and childcare institutions, enabling them to make safer choices when purchasing products for kindergarten and nurseries.

Information Centre for the Environment and Health

The purpose of the Information Centre for the Environment and Health (Danish abbreviation: IMS) is to generally reinforce the opportunities of ordinary consumers to choose products with the lowest impact on health and the environment.

This is done by passing on new information in the field of chemicals and through the issues raised by IMS. The IMS thus aims to communicate expert knowledge about chemical substances relating to the environment and health, independently and reliably.

The Information Centre for the Environment and Health will continue reinforced in 2010 and 2011. Since the establishment in 2003, IMS has cooperated continuously with various organisations. Furthermore, in a number of cases IMS has entered into closer collaboration or fixed partnerships on specific subjects or events. The scene is therefore being set for the Information Centre to be evaluated before the end of 2011.

2.3 Improved international efforts with a focus on global agreements

International agreements on chemicals are important for health and the environment. It is essential that Denmark plays an active international role.

Denmark and the Nordic countries have for many years been among the few countries at the forefront of promoting the safe management of chemicals at global level. One aspect of this position is research in the Arctic which shows that chemical substances are transported and deposited far away from the places in which they are produced and used.

Numerous global agreements have been adopted and through targeted efforts Denmark has helped to provide robust material for those agreements.

There is rapid global development in the field of chemicals. Use and trade are growing and new substances are continually being introduced whilst an increasing proportion of production is shifting to developing countries and emerging economies. These tend to have less stringent environmental management practices than the OECD countries and as chemicals do not respect borders, this increases the risk of global pollution. There is still a lot of work to be done.

There is a need to ensure the effective implementation and continued development of the agreements that have been adopted and to bring about new agreements in areas where there is a risk to health or the environment. The Danish government will allocate resources to this work - including the work on incorporation of new persistent organic pollutants (POPs) in the Stockholm Convention, the reinforcement of the Strategic Approach to International Chemicals Management (SAICM) and the establishment of a convention on mercury.

A significant Danish profile at important global meetings

Improved Danish efforts will promote the safe international management of chemicals. This means, amongst other things, to improve and uniform chemicals legislation at a global level and the development and use of non-harmful chemicals.

These efforts will demonstrate that Denmark is an important driving force behind the endeavours to achieve the goals relating to chemicals set by the Johannesburg World Summit on Sustainable Development. The status with regard to achieving these goals will be reviewed by the UN in 2010-2011 and probably also at an anticipated environment and development summit in the spring of 2012, when Denmark will hold the Presidency of the European Union. The Environment and Development Summit will mark the 20-year since the 1992 UN Conference on Environment and Development in Rio de Janeiro.

| Initiative | Effect |
|--|--|
| Greater Danish efforts in global fora, especially the United Nations Environment Programme (UNEP). | Better global protection of the environment and health from harmful chemicals. |
| Implementation and further development of global conventions and the global chemicals strategy, SAICM. | Better global protection of the environment and health from harmful chemicals. |
| New convention on mercury. | Better global protection of the environment and health from harmful chemicals. |

Denmark will allocate more resources in order to more effectively influence the decisions taken in global fora on chemicals. These include the chemicals conventions, the global chemicals strategy, SAICM and meetings within the UN's environmental programme, UNEP.

The efforts will focus on enhanced Danish efforts in connection with preparing for and organizing global negotiation sessions, in order for Denmark to help bring about optimal results via Nordic cooperation, via the EU and nationally.

Denmark will play an important role when it comes to SAICM and the Montreal Protocol on Substances that Deplete the Ozone Layer. Key meetings will be held in 2012, when Denmark will be holding the Presidency of the EU for the first six months of the year and will therefore be coordinating EU efforts.

The Danish Government actively supported the adoption of SAICM in 2006. The Danish Government will continue the targeted efforts to enable the strategy to fulfil its intended role as an umbrella for initiatives that – together with the conventions – will ensure that we achieve the goals set by the 2002 Johannesburg World Summit on Sustainable Development: that by the year 2020, there are no goods or products on the market which have significant adverse impacts on human health and the environment.

The Montreal Protocol is often thought to be the most successful of all the environmental conventions, partly because a series of committees of technical experts ensures a high level of expertise. One prioritised area for Denmark will be to influence the work of a committee of experts on refrigeration systems, in order to avoid a substitution to industrial gases which have major impacts on the climate.

New convention on mercury

Following many years of targeted efforts by the Nordic countries and the EU, UNEP Governing Council decided in February 2009 to start negotiations on a new convention on mercury. This is expected to be of immense importance in solving the problems of mercury pollution. A global negotiating committee was established, which is due to finish its negotiations by 2013.

In the first part of the Action Plan period, there will be a need for special efforts by Denmark to ensure optimal preparation for the penultimate, and probably decisive, negotiation session which is scheduled to take place in 2012 during the Danish Presidency of the EU. The Danish Government will ensure that Denmark is ready to fulfil this task. In addition, Denmark will be able to provide technical input should that prove necessary in the course of the forthcoming negotiations.

2.4 More monitoring and inspection

Inspection efforts will be expanded by 50 percent in forthcoming years and numerous inspection campaigns will be carried out. One new element is that the need for inspection for all new rules will be evaluated within a year, while the same will take place for all existing rules at least every 10 years. These evaluations will take place using risk analyses.

Inspection efforts will be expanded by around 50 percent in forthcoming years due in particular to the special monitoring requirements resulting from REACH. There are also new duties to be performed as a result of a new system of classification and labelling, new rules on toys and cosmetics and an increase in the number of biocidal products requiring authorisation from roughly 300 to around 2,000.

The aim of the monitoring is to ensure public confidence in environmental and health matters with regard to the everyday use of chemical products, whilst also ensuring that we comply with EU requirements.

Targeted monitoring and consistent enforcement

Inspection is targeted at products and sectors that pose a particular risk, as determined on the basis of a technical risk analysis. The risk analysis takes into consideration the severity of the potential infringement and the likelihood of an infringement occurring. All new rules will be risk-assessed within a year, while the same will take place for all existing rules at least once every ten years.

In order to strengthen cooperation with industry, a dialogue is maintained with relevant industry organisations prior to all campaigns targeted at producers and importers and prior to relevant campaigns targeted at consumers. Expertise will be gradually improved, with a drive to acquire knowledge in cooperation with other supervisory authorities in Denmark, the Nordic countries and the EU. The results from all the inspection campaigns are made available on the Danish Environmental Protection Agency's website on an ongoing basis.

There will be consistent enforcement, with an emphasis on legal certainty and proportionality. Illegal products will be removed from the market, while enterprises that comply with the legislation will be subject to less monitoring and more guidance. This will take place in accordance with the Danish government's forthcoming plan for optimised, targeted enforcement of commercial legislation.

More inspection campaigns

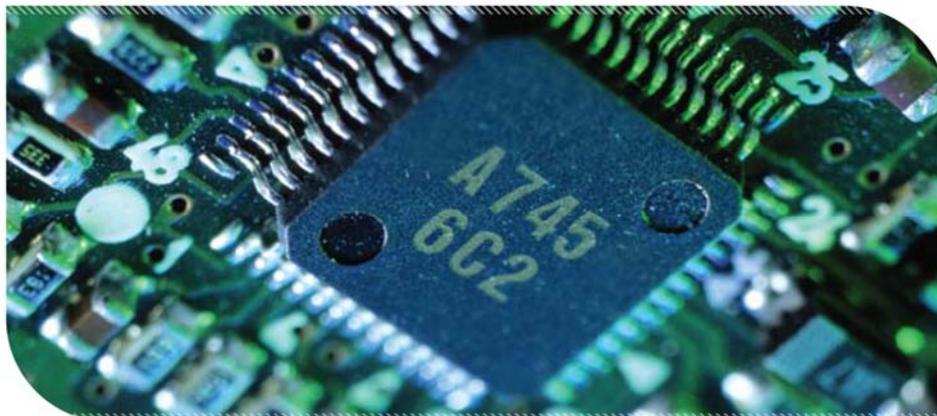
Inspection campaigns which concentrate on selected areas are an effective tool in ensuring better compliance with the rules. On average, the number of campaigns will rise from 11 to 13 per year during the period of the Action Plan. The annual campaigns are determined on the basis of a detailed risk analysis for maximum efficacy, but every year the following will be initiated:

- At least four campaigns targeted at producers and importers.
- At least eight campaigns targeted at consumer products.
- At least three REACH campaigns (except for 2010, when two will be initiated).
- At least one campaign in each of the following areas: biocidal products, joint Nordic or European campaigns, campaigns in collaboration with other public authorities, campaigns concerning the classification and labelling of chemical products, campaigns involving a large number of random samples in order to reinforce the knowledge and data bases and campaigns based on current problem areas, such as problems highlighted by political events or by the public.

Individual campaigns usually cover several of the above categories, which is why the total number of categories is more than 13. By way of example, a joint Nordic campaign targeted at the classification and labelling of consumer products would cover three categories.



| Initiative | Effect |
|---|--|
| The number of campaigns rises to 13 annual inspection campaigns (two new campaigns each year), e.g. pre-registration under REACH in 2010. | Improved safety for consumers. Improved environment and health. |
| Monitoring and inspection are targeted at products and sectors of significant risk, e.g. flea markets in 2010. | Improved safety for consumers. Improved protection of health and the environment. |
| All new rules to be risk-assessed within one year. | Improved protection of health and the environment. |



2.5 Continued prioritisation of the development of computer models and chemical substitutes

Denmark must retain its international lead when it comes to using computer models and other non-test methods. Greater use should be made of non-test methods in future and new models should be developed.

Many of the chemicals with which we surround ourselves in our daily lives have not been tested for harmful effects on humans and the environment. This is because testing chemicals is expensive and time-consuming and because there are ethical implications to animal testing.

One alternative to setting up new animal tests is the use of (Q)SAR, or (Quantitative) Structure-Activity Relationship models. These are computer models that can predict the properties of non-tested substances – including harmful effects on humans and the environment – on the basis of the structure of the chemical substances and the knowledge already gained from testing.

The data produced by such computer models is often referred to as “non-test data”. It must be stressed that the use of non-test data should not simply be seen as a cheap alternative to test data. To a great extent, it represents a very important enhancement of existing test data on individual substances.

Increased use of reliable non-test data in the future will considerably increase the overall knowledge of the harmful properties of chemicals, thus providing a significant contribution to chemical safety assessments. This was the background for the decision by the Danish Environmental Protection Agency ten years ago to give higher priority to work on (Q)SAR. Since then, Denmark has focused on becoming a world leader in the (Q)SAR field, especially in international collaboration on chemicals.

Use of computer models in REACH and the OECD

The use of non-test data is expected to increase significantly with the introduction of the new chemicals legislation, REACH. Furthermore, computer models (Q)SAR is now also highly prioritised within the OECD, which is working intensively on disseminating knowledge and use of non-test methods. This work is primarily funded by the European Commission for applications in connection with REACH.

It is important that Denmark continue to work actively in the OECD and the EU in order for (Q)SAR to be addressed satisfactorily in various guidance documents, non-test method tools and specific chemical assessments.

Especially in view of REACH, Denmark will also continue to concentrate on the further development of the use of non-test data. This applies to authorities, consultants and to small and medium-sized enterprises.

Substitution using (Q)SAR

For many years, the Danish Environmental Protection Agency has been working intensively on (Q)SAR in cooperation with the Danish (Q)SAR group at the Danish National Food Institute (DTU Food). The fruits of this cooperation include the internationally recognised Danish (Q)SAR Database and the advisory list for self-classification from the Danish Environmental Protection Agency.

These are practical tools that can be used by the industry and authorities, for example, when considering chemical substitutes.

The (Q)SAR field is developing rapidly. We must thus continue to contribute to the development of new and better models which includes a need for new endpoint objectives. At the same time, the Danish (Q)SAR Database will be updated in the next few years, in order to incorporate the most up-to-date results.

An improved and more user-friendly public version to replace the current (Q)SAR Database on the website of the Danish Environmental Protection Agency can also be developed. The advisory list for the self-classification of chemical substances from the Danish Environmental Protection Agency must also be kept up-to-date and expanded to include the latest models.

| Initiative | Effect |
|---|--|
| Updating of the Danish (Q)SAR Database. | Increased applications for the database – reduced animal testing, better options for identifying and regulating dangerous substances, increased protection of the environment and health. |
| Development of new (Q)SAR models and updating of existing models. | More reliable predictions will lead to increased recognition of the use of (Q)SAR for regulation – reduced animal testing, better options for identifying and regulating dangerous substances, increased protection of the environment and health. |

| | |
|--|---|
| <p>Updating the advisory list for the self-classification of chemical substances from the Danish Environmental Protection Agency and expanding the list to include the latest models.</p> <p>In 2010, the advisory list was updated with at least one model and the list is being expanded to include the new classification and labelling system.</p> | <p>Better options for identifying and regulating dangerous substances, increased protection of the environment and health.</p> |
| <p>Focus on giving (Q)SAR a solid footing in the EU and the OECD.</p> <p>In 2010, Denmark will evaluate a number of prioritised substances using (Q)SAR for consideration of fundamental issues within the EU and the OECD.</p> | <p>Recognition of the use of (Q)SAR in regulation – reduced animal testing, better options for identifying and regulating dangerous substances, increased protection of the environment and health.</p> |

3. Specific substances and groups

3.1 Focus on endocrine disruptors and the ‘cocktail effect’

Denmark is at the cutting edge to combat endocrine disruptors and combination effects. Our efforts must continue in order to improve knowledge and create a sound basis for legislation at both national and international levels.

Endocrine disruptors have been high on the agenda in Denmark for the past 10 to 15 years. New knowledge is constantly emerging about effects on reproduction – such as poor sperm quality, testicular cancer, malformed sexual organs and the premature onset of puberty – for which endocrine disruptors are suspected of being a contributory cause. This is the reason for continued focus on this issue. Other effects, such as cancer, cardiovascular diseases, diabetes, obesity and effects on the brain and the immune system are now increasingly being linked to exposure to endocrine disruptors.

Both in the field and in the laboratory a connection has been shown between endocrine disruptors and harmful effects in animals. Some of the changes in reproductive health which are seen in people can now be demonstrated in test animals after exposure to endocrine disruptors. It has not yet been proven whether exposure to low concentrations of endocrine disruptors in day-to-day life leads to harmful effects in people, but the conclusion is a natural one.

Denmark will continue to be at the cutting edge of knowledge acquisition

Denmark is at the cutting edge of work on endocrine disruptors. This is not least due to forward-looking and internationally-recognised Danish researchers, in combination with prompt action by the Danish Ministry of the Environment. The efforts to combat endocrine disruptors are given a high priority, starting with a national strategy that focuses on the following three elements:

- Knowledge acquisition and development of test methods
- Action-oriented studies
- Regulation

Many activities are underway both in Denmark and internationally – first and foremost in relation to knowledge acquisition and the development of test methods. These activities demand significant amounts of time and resources. Progress may seem elusive even though it is being made. Yet these activities are absolutely essential, as there is still a lack of quite basic knowledge of causes and effects. Test methods are a prerequisite for being able to identify substances that require regulation.

There is still a lack of knowledge about the specific effects of endocrine disruptors, about the specific substances that have endocrine-disrupting effects, the concentrations people and the environment are exposed to and whether low doses in day-to-day life are harmful to health and the environment.



In addition, we need to learn more about mechanisms in the hormonal system that may have a particular significance with regard to effects and about the significance of endocrine disruptors in embryonic life for the development of effects later in life.

Danish research teams are currently at the forefront of knowledge acquisition in this field and such efforts will continue in future. Current work is supplemented by a monitoring programme on the quality of young men's semen, funded by the Danish Ministry of the Interior and Health.

Continuing work of the Centre for Endocrine Disruptors

The Centre for Endocrine Disruptors opened its doors on 1 December 2008, based in Copenhagen University Hospital's Growth and Reproduction Department.

The Centre was established as a "centre without walls" – a network of related institutions. Its purpose is to gather, build up and disseminate knowledge in the field of health and the environment with a particular focus on endocrine disruptors.

For example, the Centre can help investigate the notion that endocrine disruptors may be significant in the onset of cancer, infertility, effects on the immune system and damage to the nervous system. This is a special initiative with a focus on preventive work by the authorities, including regulation.

The knowledge acquisition programmes that the Centre delivers are often long-term and resource-intensive and it is therefore necessary to secure the Centre's long-term funding in order to be able to achieve the goal of building up knowledge that can be used for preventive work, including the regulation of endocrine disruptors.

The aim is to provide a structure similar to that of the other knowledge centres, where a steering group establishes the work programme for the centre.

More knowledge on combination effects

There is a pressing need for more knowledge about the combined effects of endocrine disruptors, including pesticides. There is a lack of any major insight into what happens when the body is exposed to multiple endocrine disruptors at the same time.

In this regard research over the past few years, in which Denmark has produced groundbreaking results, has provided so much knowledge that efforts can be directed more and more towards regulation. In future more knowledge will be forthcoming on the impact of combination effects.

A group of the world's leading experts on endocrine disruptors and combination effects met in Denmark in January 2009, where they took stock of the state of knowledge on combination effects and the options for regulation. The experts point out that the risk associated with chemicals is currently underestimated, as no account is taken of the fact that people are exposed on a day-to-day basis to a cocktail of numerous different substances, including endocrine disruptors.

The experts recommend that the framework for legislation on chemicals in the EU be improved so that the legislation stipulates the inclusion of potential combination effects when risk-assessing chemicals. The experts also point out that more knowledge is still needed before the risk posed by combination effects can be fully incorporated into the risk assessment of chemicals – and this applies in particular with regard to our current exposure to chemicals, including endocrine disruptors. The experts also point out, however, that even with the current level of knowledge, it is possible to take account of combination effects when assessing the risks associated with endocrine disruptors.

A new study of the daily exposure of two-year-olds to a combination of endocrine disruptors has shown that there is cause for concern and that there is a risk of combined effects for certain endocrine disruptors.

Focus on the many substances in low concentrations in day-to-day life

The above is part of the reason why Denmark has raised the issue of combination effects in the European Union's Council of Ministers. It is also important that Denmark continues to provide new knowledge in future and back that up with active participation in the work of the EU on combination effects.

There is a particular need to investigate the combination effects of substances to which we are exposed in low concentrations in day-to-day life, which may involve abnormal functioning of both the male and female hormonal systems and other hormonal systems. Influences of this kind during embryo development should also be investigated for implications in later life.

Details of the use of the resources allocated as a special effort for 2010 and 2011 will be discussed at a meeting of the parties to the agreement behind the Action Plan before the summer of 2010. The possibility of establishing a research centre will also be discussed.

Targeted information is important

In cases in which there is insufficient knowledge for regulation, it is still possible to provide information with specific options for action. Targeted information on possible endocrine disruptors and combination effects must therefore continue to be prioritised.

The information can for example be targeted at sensitive groups where it is particularly important to be careful, or at members of the public who wish to be extra careful.

The information campaigns, “Nine tips for pregnant and nursing mothers in connection with cosmetics, baby products, and toys”(2006) and “65,000 reasons for better chemistry” (2009) are examples of information being targeted at sensitive groups. “65,000 reasons for better chemistry” provides advice on how to reduce the day-to-day exposure of two-year-olds to endocrine disruptors.

Increased efforts necessary in the EU

Denmark is one of the few countries in which endocrine disruptors are high on the agenda and where there is a focus on regulating this area. Certain endocrine disruptors are already regulated in Denmark as a result of new knowledge, for example, azole fungicides (pesticides) and phthalates.

A targeted effort within the EU is necessary in order both to provide the basis for uniform regulation of endocrine disruptors and to persuade the other EU Member States to prioritise work on endocrine disruptors and combination effects. The Commission will report on the implementation of the EU strategy for endocrine disruptors in 2010. Denmark will play an active role in the follow-up work so as to ensure that the EU prioritises its efforts in relation to endocrine disruptors.

Over the next few years the key concern will be to reach an agreement within the EU and internationally on the criteria for determining whether a substance has endocrine-disrupting properties. It is also important to reinforce forthcoming legislation with internationally accepted methods of establishing evidence of endocrine-disrupting effects.

The measures of the Chemicals Action Plan are complemented by current and ongoing work on developing test methods for endocrine-disrupting properties. This fundamental work forms part of Denmark’s contribution to the OECD’s test methods programme, which to a large extent forms the basis for regulation by the EU.

Focus on global knowledge-sharing

There is also a need for the international exchange of knowledge. Denmark is particularly active in hosting major international research workshops and national workshops disseminating new knowledge.

This role will continue in future years. New knowledge about endocrine disruptors must be used to direct international focus towards this issue and as an impetus for regulation.

Voluntary phase-out of endocrine disruptors in medical equipment

Endocrine disruptors, including phthalates, are found in a range of products including those used by particularly vulnerable groups such as small children and in medical equipment. Initiatives for effecting a voluntary phasing-out of such products will therefore be instigated.

The Danish Ministry of the Environment also aims to chart medical equipment without phthalates in collaboration with the Danish Regions, so that purchasers have a useful tool with which to avoid where possible products containing phthalates, especially where the products are used by patients who are particularly vulnerable or at risk. In this context, the

experience of Swedish hospitals will be drawn upon. A list of products and uses of medical equipment for which there are as yet no alternatives that have a lower impact on the environment and health will be drawn up by 1 December 2010. The list will detail reasons for the impracticality of substitution and proposals to promote substitution.

An attempt will be made to develop a simple environmental assessment method to help procurement officers identify the most undesirable substances. This assessment must build on environmental considerations and impacts on patients and staff. Green procurement also offers the opportunity to work on voluntarily phasing out phthalates: the Regions are happy to take a lead in this, if competitive alternatives exist on the market.

In the course of the ongoing dialogue on green public procurement with Local Government Denmark and others, the Danish Environmental Protection Agency will investigate whether experiences from the phase-out initiatives arising from green procurement by the Regions can be translated to the municipal level.

| Initiative | Effect |
|--|--|
| Knowledge acquisition. | A better basis for regulation and information. |
| Active Danish involvement in the EU's work on criteria for endocrine-disrupting effects and on combination effects. In 2010, Danish efforts will focus on ensuring that combined effects are incorporated into the report on the EU's strategy for endocrine disruptors as a key element with a view to regulation in 2012. | A better basis for regulation. Improved protection of health and the environment. |
| Knowledge acquisition in respect of the exposure of the population and the environment to endocrine disruptors. Additional studies into the exposure of the population and the environment to commonly occurring endocrine disruptors will be commenced in 2010. | Improved safety for consumers. A better basis for regulation. Improved protection of health and the environment. |
| Knowledge acquisition on possible groupings of endocrine disruptors. | A better basis for regulation and thus improved protection of health and the environment. |
| Knowledge acquisition on the potential link between certain common combinations of substances and unexpected serious effects. In 2010 studies will commence into combined effects in animals. This will include substances that lead to abnormal functioning in male and female hormonal systems and which people are exposed to in day-to-day life. | A better basis for regulation and thus improved protection of health and the environment. |
| Listing of medical equipment without phthalates will start and finish in 2010 with a view to the voluntary phasing-out of phthalates in medical equipment via green public procurement. | Instigates the voluntary phasing-out of phthalates and thus improves the protection of human health. |

3.2 Allergies to chemical substances in consumer products

Allergies are a growing problem and efforts in this area must therefore be continued and increased. This means, amongst other things, that more knowledge must be acquired.

Around 20 percent of the population is allergic to chemical substances in the immediate environment: and allergies have increased over the past 10 years.

Allergies to chemical substances occur early in life and can give rise to chronic eczema with long-term requirements for treatment, sick leave and pensions. There are many chemical substances which can give rise to allergies and occurrences remain very frequent, amongst young people, too. Certain forms of allergy are on the rise.

Continuation of the National Allergy Research Centre

The National Allergy Research Centre is engaged in the monitoring and prevention of allergies to chemical substances as well as the provision of information. The Research Centre was established in 2001 as part of the Health and environment” strategy of the Danish Government. It is located at Gentofte Hospital and is unique because the centre has a close relationship with the clinical world, through networks with hospital specialist departments and with general practitioners and specialists.

The Research Centre has received acclaim from an international panel of experts, which concluded that the centre is a unique institution in Europe. Over the years, the National Allergy Research Centre has delivered valuable scientific work which has significantly influenced the regulation of chemical substances. The Research Centre has supported the efforts of the Danish Ministry of the Environment in the field of allergies and thus helped to prioritise allergies as part of the EU agenda.

Many substances of very high concern in hair dyes, perfumes and preservatives have been prohibited or restricted on the basis of scientific documentation from the Centre. Documentation from the Centre has helped the Commission to determine that mobile phones should be covered by the legislation on nickel.

Taking adequate account of protection against allergies through legislation remains a challenge, particularly when it comes to cosmetics and other consumer products which come into close contact with the skin. Certain chemical substances, such as hair dyes, which can cause very serious allergic reactions or can provoke reactions in many consumers, are still permitted.

It is not possible to ban every allergenic agent and therefore, it is important to inform consumers about the risks associated with products such as hair dyes. The Danish Environmental Protection Agency conducts information campaigns for specific target groups. These include “Nine positive habits for pregnant and nursing mothers” and the “Teenager campaign on hair dyes, perfumes and henna tattoos” for which the Research

Centre provided the expertise. The role of the Centre to supply important knowledge to include and use in consumer campaigns will continue.

The important work of the Centre must be maintained. In 2012, an evaluation will examine the question of merging the Centre with the Danish Research Centre for Chemical Sensitivities.

| Initiative | Effect |
|---|---|
| Monitoring the prevalence of allergies to chemical substances. | Identification of focus areas. A basis for targeted preventive efforts. |
| Acquisition of knowledge on exposure to chemical allergens, risk factors in the environment and for individuals and effects on the prevalence of allergies. | The ability to regulate chemical allergens and more intensive targeting of information in order to reduce the frequency of allergies and chronic illnesses. |
| The mapping of combined effects in the event of exposure to multiple allergens. | A better basis on which to determine limit values and protect the population. |
| Analysing the correlation between allergies to chemical substances and other disorders of the immune system. | Clarification of the need for new preventive measures, regulation and provision of information. |
| Advice to public bodies and general dissemination of specialist information. | Increased level of knowledge and improved health. |

3.3 Focus on multiple chemical sensitivity (MCS)

Multiple chemical sensitivity (MCS) is a growing problem. Research must continue and be developed further.



| Initiative | Effect |
|------------------------|--|
| Knowledge acquisition. | A better basis for any regulation, information, prevention measures and treatment options. |
| Provision of advice. | Dissemination of knowledge. Improved protection of health. |

Continuation of the Danish Research Centre for Chemical Sensitivities

Multiple chemical sensitivity is a generic term for the phenomenon whereby people become ill when exposed to commonly occurring chemical influences such as perfumes and gases which are released by new furniture or new electronic equipment. This illness is not the result of allergies. It is not yet clear how and why the illness occur, nor how to treat it effectively.

The Danish Research Centre for Chemical Sensitivities was established in 2006 following a decision by the parties in the Danish Parliament (*Folketing*). This happened in connection with a proposal for a decision on financial compensation for victims of Rentolin (wood preservative). The Research Centre, based at Gentofte Hospital, has been funded by the Danish Ministry of the Environment. Since its inception, the Research Centre has collected existing knowledge and worked systematically to produce new knowledge within the following areas: the extent of the problem among the population; genetics; mechanisms of illness; and psycho-social consequences.

In addition, the Research Centre has advised patients, the authorities and the healthcare system. Insufficient knowledge means that it is not currently possible to either prevent or treat multiple chemical sensitivity. It is obvious, however, that this illness affects a large

group of people whom neither the healthcare system nor the social security system can help in a tangible way.

As it is not clear what causes this illness, we cannot say what role chemicals play, apart from causing the symptoms. Therefore, there is a need for a continued systematic gathering of knowledge in order to be able to determine prevention options and produce recommendations for the treatment of patients within the healthcare system and the social security system.

An understanding of the illness mechanisms is an important prerequisite for being able to evaluate the significance of exposure to chemicals for the development of the condition. It is also important in relation to preventing the development of multiple chemical sensitivity.

The work of the Research Centre has already shown that 45 percent of the population feel disturbed by odours and chemicals in the air, 27 percent experience clear but mild symptoms, three percent are disturbed to such an extent that it affects them either socially or at work, while 0.5 percent are so badly affected that they suffer serious consequences, both socially and in terms of work.

The Research Centre was positively evaluated in August 2008 with the recommendation that the Centre should continue within the current framework. The Centre will therefore continue its important work over the forthcoming years. An evaluation will be carried out in 2012, examining amongst other things whether the Centre might continue via a merger with the National Allergy Research Centre.

3.4 Improved efforts with regard to biocidal products containing substances of concern

In future a total of 2,000 products will require authorisation, compared to the current 300. This will provide better protection for consumers and the environment.

The EU's Biocidal Products Directive will over a few years phase in an expanded European authorisation scheme, where the active substances are assessed at EU level, and where the individual product is assessed at national level in accordance with EU rules.

When the Biocidal Products Directive has been fully implemented it will cover all biocidal products within 23 different product groups. Many of these did not previously require authorisation in Denmark. This applies, for example, to preservatives, antifouling products and certain disinfectants.

Proposals for a new Biocidal Products regulation have been tabled that would mean, in the long term, that biocides used in products such as furniture, textiles and impregnated wood would have to be authorised in the EU. One outcome would be the prevention of cases relating to allergenic biocidal products in furniture where dimethyl fumarate, for example, can be a problem.

Information and dialogue with enterprises regarding new products on the Danish market

It is estimated that the 23 product groups cover about 2,000 products. At present, authorisation takes place for such products as rodenticides, insecticides, certain wood preservatives, algicides and mosquito repellents.

In total the current system covers around 300 products. The new product groups mean that a range of enterprises that were not previously covered need to be given information and guidance in respect of applying for authorisation for their products.

Significant additional efforts will be made to inform applicants so that they are aware of the data requirements and conditions of authorisation. Early information and dialogue with applicants is important in order to secure good competitive conditions for Danish enterprises applying for authorisation for their products for the first time.

Increased efforts by the EU

Additional resources will also be used to ensure a high level of protection and active participation in the EU's work on evaluating the many new active substances and their use in consumer products.

At the same time, it will be important to gather new knowledge on exposure to biocidal products in our daily lives, in the workplace and through the environment.



| Initiative | Effect |
|---|---|
| Improved guidance and information for enterprises concerning data requirements and conditions of authorisation. | Fewer infringements. Better competitive conditions for Danish enterprises. Better quality of applications mean less time needed for processing. Lower costs and better service for enterprises. |
| Increased Danish influence on the evaluation of active substances in biocidal products in the EU. | Uniform evaluation within the EU with a high level of protection. Effective biocidal products that have no undesirable effects on the environment and health. Consideration of Danish special interests, such as the Danish requirement for training in order to use rodenticides. |
| Knowledge acquisition. | More qualified advice for enterprises. Evaluation of biocidal products according to EU principles. Greater influence on EU evaluations. |

3.5 Enhanced efforts in the field of nanotechnology

The field of nanotechnology is an important new area in respect of both securing available knowledge and reinforcing its dissemination to the public and enterprises.

Nanotechnology has been in the spotlight recently, not least because of the fear that contact with nanomaterials may have significant impacts on health and the environment. Not all nanomaterials constitute a risk. Carbon black, for example, has been used for decades in applications such as the colour black in printing ink and for car tyres and has not given rise to any known serious risks to health and the environment.

However, some nanomaterials and applications of materials may give rise to problems. Efforts will therefore be focused on fields and applications which can constitute a risk in practice. It is essential that knowledge is available so that it can be used to amend legislation and to ensure that it is possible to avoid potential risks involved in the use of nanomaterials in real-life situations.

The overall purpose of Danish efforts is to ensure that the use of nanomaterials does not give rise to risks for the environment and human health.

Important international collaboration

There is a great deal of attention on the field of nanotechnology, This has led to the establishment of international cooperation in the EU and the OECD in which Denmark also participates.

It is important that the Danish efforts are coordinated with the international work of the OECD and the EU. This will focus and ensure the progress of international work on knowledge acquisition and the adaptation of legislation. Denmark will therefore continue and expand its cooperation with the OECD and the EU.

Denmark must participate in international efforts in the field of nanotechnology in order to ensure prioritisation of Danish commercial and consumer interests.

Updated information for businesses and consumers

Since nanomaterials represent a new field in which progress is rapid, consumers, enterprises and industry require continuous and up-to-date information.

It is important, amongst other things, to inform enterprises of important considerations in respect of the nanomaterials in their products and about with the implications of nanomaterials in connection with REACH.

| Initiative | Effect |
|---|---|
| Collection of available knowledge on the use of nanomaterials and associated risks. In 2010, knowledge about the most | A better basis for handling, regulation and information to consumers and enterprises. |

| | |
|--|--|
| widespread nanomaterials will be gathered. | |
| A Danish contribution to international regulation. | Increased protection of the environment and health regionally and internationally. |
| Dissemination of knowledge and dialogue on regulation and risk factors. | Improved cooperation between authorities and enterprises ensures necessary knowledge about nanomaterials. Improved protection of health and the environment. |
| Development of methods to screen uses of nanomaterials for risks and provide guidance on special measures necessary for responsible use. This work will be instigated in 2010. | Better protection of the environment and health with the best possible utilisation of existing knowledge. |

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**Safety in Denmark – international
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