### **SWEDISH CHEMICALS AGENCY**

# SUPERVISION AND MARKET SURVEILLANCE PLAN 2016

# **Foreword**

This supervision and market surveillance plan describes the supervision activities that are the priority for 2016 in the Swedish Chemicals Agency's area of responsibility.

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Sundbyberg, December 2015

**Swedish Chemicals Agency** 

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# **Summary**

[Translator's note — This document contains two summaries. This, the first, is an English translation of the Swedish summary that is on page 4 of the original document. It is similar but not identical to the English summary on page 5 of the original document.]

The supervision plan provides an overview of the operational need for supervision and serves as a strategic steering document, indicating how supervision activities are prioritised in relation to available resources.

The plan describes only the Swedish Chemicals Agency's operational supervision work and market surveillance. It does not cover supervision guidelines for municipalities and county administrative boards.

The Swedish Chemicals Agency divides operational supervision into three areas: chemical products, pesticides and articles. Under each main area we will describe the current priorities and provide a summary of projects planned for 2016.

In 2016 our supervision work in respect of chemical products will focus on continued region-based systematic control. This will be supplemented with risk minimisation measures in prioritised subject or product categories, such as high-risk businesses which are repeatedly given environmental penalties or fall short in some other manner as regards the legislation we enforce. We will monitor allergens in paint and wallpaper paste and examine eyelash adhesive. We want to reach out with information on fluorinated greenhouse gases and continue to inspect product information on car and boat care products.

We will continue to inspect product information on car and boat care products.

Supervision in the field of pesticides will focus on monitoring biocidal products, information requirements for plant protection products, and the composition of plant protection products. We may also take part in an EU project on enforcement of the Biocidal Products Regulation, depending on its relevance for the Swedish market.

Supervision in the field of articles will focus on textiles and leather, toys, jewellery, low-price electrical and electronic equipment, and rubber or plastic handles. We choose our priorities on the basis of experience, where occurrences of hazardous substances have led to high exposure. We will also undertake a broad awareness-raising campaign, including subsequent inspections, in respect of products in the sex toy category, which has not previously been monitored from the point of view of the legislation on chemicals.

We will continue to allocate resources in all three areas of supervision for checking tip-offs received from businesses, other authorities and the general public.

# **Summary**

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The enforcement plan provides an overview of the operational need for enforcement and is a strategic steering document, indicating how enforcement activities are prioritised in relation to available resources.

The enforcement and market surveillance plan describes only the Swedish Chemicals Agency's operational enforcement role and market surveillance. The plan does not consider enforcement guidance, enforcement work in the EU and correlations to the development of rules.

The Swedish Chemicals Agency divides the operational enforcement into three main areas: chemical products, articles and pesticides. Under each main area we describe current priorities and a summary of planned projects in 2016.

During 2016 enforcement of chemical products will focus on continued regional-based systematic control, supplemented with risk minimisation measures in prioritised subject or product category areas, such as companies with recurring instances of environmental sanction charges or which have shortcomings in complying with the legislation under our enforcement. We will do market surveillance activities of allergens in paints, wallpaper pastes and eyelash adhesives. We will continue to check the product information on car products and car care products. The tips we receive about products suspected of not complying with applicable legislation will be evaluated by us and we will make inspections when required.

Enforcement of pesticides will focus on monitoring biocides, information requirements for plant protection products and their composition, and of imports from non-EU countries, checking that the companies' reported data to the Products Register are correct, and on chemical analyses of pesticides.

Enforcement of articles will focus on textiles and leather, toys, materials in the indoor environment, clothing and footwear, electrical and electronic equipment in the home, as well as low-cost plastic articles for consumers. Our priorities are based on experiences of occurrences of hazardous substances leading to high exposure. Another area where we will make information efforts is the product segment sex tools, which has not previously been checked from a legislative perspective.

### 1 Introduction

#### 1.1 Supervision and market surveillance plan

Under Sections 6–10 of the Environmental Supervision Ordinance (*miljötillsynsförordning* — 2011:13), any authority that has been assigned operational supervision functions must earmark sufficient resources to cover the need for supervision and have staff with sufficient skills for supervision work. Under the Environmental Code (*miljöbalken*), the authority must also have carried out a survey of the need for supervision throughout its area of responsibility.

The authority must draw up a supervision plan for its areas of operation each financial year. The plan must be based on, among other things, the assessment of needs, and describe how the supervision work should be carried out. An state supervisory authority should also describe in its supervision plan how it has balanced the distribution of resources within and between different areas of responsibility in accordance with the Environmental Code and how the resources have been adapted to the prevailing need for supervision.

There must be regular follow-up and evaluation of the supervision work. The supervision plan must be adopted by the person within the authority who decides on the use of the authority's resources.

In accordance with Article 18(5) of Regulation (EC) No 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products, Member States must establish, implement and periodically update their market surveillance programmes. These plans must be made available to the public. In line with Sections 17 and 18 of the Toy Safety Ordinance (förordning om leksakers säkerhet — 2011:703) and Chapter 1, Section 5 of the Environmental Supervision Ordinance, the Chemicals Agency must fulfil these requirements within its areas of supervision.

Under Sections 9 and 10 of the Product Safety Ordinance (*produktsäkerhetsförordning* — 2004:469), supervisory authorities must put in place a supervision programme within their area of supervision and to inform the general public of their supervisory activities. The Chemicals Agency is a supervisory authority within the meaning of the Product Safety Ordinance.

The Chemicals Agency's operational supervision is primarily concerned with placing on the market and supply and therefore constitutes market surveillance. This plan thus covers all those plans and programmes.

Operational supervision is supervision that is undertaken directly in respect of a party carrying out an activity. Other fields of work such as supervision guidance, supervision cooperation within the EU, feedback for regulatory development, etc. are not included in the supervision and market surveillance plan. The supervision guidelines are presented in a separate plan: Supervision Guidance Plan 2016–2018 (ref. H15-08152).

In Sweden, the municipalities and county administrative boards also carry out supervision in the field of chemicals. The authorities have their own supervision plans which describe chemicals supervision, among other areas. This plan describes only the Chemicals Agency's operational supervision role.

The Swedish Chemicals Agency divides operational supervision into three main areas: chemical products, articles and pesticides. Under each main area we will describe the current priorities and provide a summary of projects planned for 2016.

### 1.2 The Chemicals Agency's operational supervision

Together with the municipalities, the Chemicals Agency enforces the provisions concerning the placing on the market of chemical products, pesticides and articles.

The Agency's supervision is aimed above all at primary suppliers. These are businesses that manufacture chemical products, articles or pesticides or import them into Sweden.

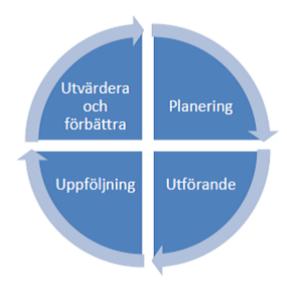
Our supervision work entails checking that products and articles supplied on the market do not contain prohibited substances, that chemical products are correctly notified to the product register, and that pesticides are approved. In addition, we check that pesticides and other chemical products are correctly classified and that the information requirements for labelling and safety data sheets are met. For articles, too, checks are carried out as to whether economic operators are fulfilling their information obligations. The checks take place by inspecting actual labels, safety data sheets, etc., by carrying out chemical analyses, and by monitoring businesses' procedures and methods of working. We provide information that makes it easier for businesses to interpret and observe the rules.

Where the legal requirements are not fulfilled, action to remedy the situation may be required, and this may also include sales bans where justified. Where an offence is suspected, the case is passed on to the Swedish Prosecution Authority, and in other cases penalties such as environmental penalties may be imposed.

### 1.3 Systematic improvement work

Supervision is carried out primarily in the form of projects. The planning of each project is documented. After it has been carried out, the work is evaluated and the results recorded. These results form the basis for improvements both in the future planning of supervision activities and in our way of working, and they are documented in the Agency's management system.

The performance of supervision and enforcement activities, including the imposition of requirements to take remedial action, is guided primarily by the provisions of the legislation.



The results of our supervision and enforcement activities are followed up and the conclusions are passed on to the outside world via news items on <a href="www.kemikalieinspektionen.se">www.kemikalieinspektionen.se</a> and sometimes in the form of publications in our series on enforcement. Articles and products posing a serious threat are communicated through Rapex, which is an information and warning system used by countries in the EU to inform each other and the public.

Key to figure:

Planering Utförande Uppföljning Utvärdera och förbättra Planning Execution Follow-up Evaluate and improve

# 2 Chemical products

#### 2.1 Brief description of the area of supervision

The Chemicals Agency is responsible for carrying out supervision of manufacturers and importers (primary suppliers) in Sweden. In its operative supervision of chemical products, the Agency checks above all that the product information (labelling and safety data sheet) meets the requirements laid down in the chemicals legislation and that the notifications to the product register have been received and are correct. The businesses that notify chemical products vary in size and also as regards the number of imported/manufactured products, the volumes concerned and how hazardous the products are to health and the environment. This means that there is considerable divergence between the businesses as regards their impact on the chemical hazards in society and the potential for minimising risks on the market.

Below is a summary of the regulated areas that may be relevant as regards supervision of chemical products on the premises of primary suppliers. Please note that the list is not exhaustive.

Regulated areas <sup>1</sup>	Description	
REACH	The European legislative act on chemicals, REACH— Regulation (EC) No 1907/2006, is a comprehensive act with different parts beginning to apply at various times up to 2018. The rules on restrictions and safety data sheets have already entered into force. The obligation to register began to apply from 1 December 2010 for high volume substances. The remaining parts will be implemented in stages until 2018. The rules on special authorisation have been entering into force successively since August 2014.	
Classification and labelling	Classification and labelling of chemical products in accordance with the criteria in KIFS 2005:7 and Regulation (EC) No 1272/2008 (CLP).	
Safety data sheets	There must be safety data sheets for chemical products, in accordance with Annex II to Regulation (EC) No 1907/2006 (REACH).	
Rules on packaging	Consumer products must, for example, have child-resistant fastenings and bear recognisable warning markings. KIFS 2008:2	
Transfer permits	Particularly hazardous products require a permit for transfer in Sweden. KIFS 2008:2	
Product register	Businesses that manufacture and import chemical products must notify them to the Chemicals Agency's product register.	
Rules on restrictions	Restrictions are laid down at both national and EU level. Some examples are:  Lead in paints CMR* substances for consumers PFOS VOCs in paints and varnishes Chlorinated solvents  * Substances that are carcinogenic, mutagenic and toxic for	

<sup>&</sup>lt;sup>1</sup> More detailed descriptions of the rules are contained in Annex 1.

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	reproduction	
Rules on detergents	These restrict the use of persistent surfactants and contain specific requirements for declarations of contents.	
<b>Product Safety Act</b>	Safety Act This Act is rarely applicable to chemical products, but it may be if there are no other rules or restrictions in place.	

Table 1. Summary of the regulated areas checked during supervision of chemical products

Businesses that manufacture, import or bring into Sweden chemical products must notify their activities and the products to the Chemicals Agency's product register. The register is a key input for the Agency's selection of businesses and simplifies the process of planning the inspection activities. There are approximately  $2\ 200^2$  active businesses and  $90\ 000$  notified chemical products in the register.

#### 2.2 Strategies for selecting supervision projects

It is necessary to have strategies for selecting projects and subjects to be supervised. The overall aim of the Chemicals Agency's supervision is to reduce risk. Below, some criteria that may be taken into account in the selection are listed:

- **Rules**, in particular new rules. The rules largely determine the type of supervision that should be carried out, since the rules are the basis for stipulating supervision requirements.
- **Products/businesses** with manufacture/import of large volumes or many products, whose products lead to high levels of **exposure** and/or are **distributed** widely.
- Businesses with **shortcomings in their reporting** to the product register (e.g. no composition data). There may be a greater need for supervision in respect of these businesses than of others.
- The **danger classification** of products. Products not classified as dangerous are considered to have lower supervision needs.
- Businesses with products that contain particularly hazardous substances.
- **Region** there are purely logistical advantages (e.g. in terms of travel) to limiting supervision to a particular geographical area.
- **Sectors** Area of use of the product group. The need for supervision may vary significantly between groups.
- **Area of use** Products that are used more frequently by, for instance, children.
- **EU requirements** for example, projects in the REACH forum, analysis of plant protection products, or reporting requirements imposed by the Commission in a particular regulated area.
- Intelligence and incoming information What is happening in the field of occupational health and safety, and what shortcomings are common? Experiences reported by e.g. the Swedish Poisons Information Centre and occupational health departments at certain hospitals.

#### 2.3 Available resources

The resources available for operational supervision of chemical products in 2016 amount to approximately 12 FTEs (calculated on the basis of an effective annual working time of 164 person

<sup>&</sup>lt;sup>2</sup> A figure of 3 200 was reported in previous years. That included businesses that were registered but had no notified products in 2015. The corresponding figure for 2015 remains stable.

days). This is an increase in comparison with previous years, owing to increased needs. It is, above all, the result of the fact that further supervision and restrictions have been added to the legislation, the number of products has increased, and also that we have identified more non-notified businesses.

### 2.4 Planned supervision activities

The Chemicals Agency's work is project-based and is prioritised on the basis of the sector, regulated area, type of products/chemicals, or geographical region. Being project-based, it facilitates cooperation with industry and provides a deeper perspective and focus on the area in question. For 2016 we have planned to undertake the following projects as part of the operational supervision of chemical products.

Supervision activity	Description of the activity
Regional inspection cycles	Businesses selected on a geographical basis. The inspections that take place under our supervisory responsibility are broad, with no focus on specific legislation or product groups. All businesses in the area are checked, and some are selected for supervision.
Car and boat care products	As a result of tip-offs, we have identified cases of inadequate product information concerning car care products. We suspect that the same problems may exist concerning boat care products.
Eyelash adhesive	Checks on allergen content. Ensure that risk and safety information is provided.
Fluorinated greenhouse gases	Dissemination of guidelines and information. Checks on restrictions.
Risk-based selection	Extracts from the product register in line with a risk-based model.
Customs project	With the help of information from Customs, identify businesses that have not notified their activities or their products to the product register.
Follow-up project	Supervision of businesses with repeated shortcomings, new businesses, businesses displaying a lack of awareness, etc.
Paint and wallpaper paste	Checks of allergens in preservatives. Ensure that risk and safety information is provided.
REACH forum pilot project	Joint EU project on how to undertake supervision in the authorisation process under REACH. Focus on authorisation phase 2.
Recovered substances	Checks on the compliance of recovered substances. Included in one of the Swedish Environmental Protection Agency's assignments from the Government.
Products in the construction trade	Together with the other Nordic countries, ensure classification and labelling, including Article 48 CLP (online advertising).
Other incident-driven supervision and intelligence	Supervision as a result of tip-offs received by the Chemicals Agency. These tip-offs are examined, and an inspection is carried out where necessary. On the basis of the tip-offs, certain product groups are selected and the whole sector will be inspected.

Table 2. Operational supervision for chemical products in 2016

# 3 Pesticides

### 3.1 Brief description of the area of supervision

Pesticides can be divided into biocidal products and plant protection products. They are chemical products that are covered by legislation laying down, among other things, requirements for approval, involving specific requirements as regards supervision. For that reason, it is practical for supervision of pesticides to be considered as its own area of responsibility.

*Pesticides* are defined as chemical or biological products intended to prevent or counteract injury or detriment to human health or damage to property caused by animals, plants or microorganisms.

All pesticides (both professional and consumer products) that are used in Sweden must be tested and approved by the Chemicals Agency, with certain exceptions. Pesticides must also be notified to the Chemicals Agency's product register, and they are covered by the rules on classification, labelling and safety data sheets. Approved pesticides are entered in the public register of pesticides. There are also further requirements concerning the labelling of and information on pesticides. The points checked by the Agency when it carries out supervision of pesticides include whether the products have been approved, that the volume of active substances corresponds to the approval, and that the products meet the requirements concerning product information.

An outline of the regulated areas in the field of pesticides is set out below.

Regulated areas	Description
Approved pesticides	Checks that only pesticides that have been approved or been granted an exemption by the Chemicals Agency are supplied on the market.
	Since 14 June 2011, pesticides have been subject to Regulation (EC) No 1107/2009, which contains rules on advertising, record-keeping, etc.
	Regulation (EC) No 528/2012 on biocidal products has applied since 1 September 2013.
Analyses	Active substances are analysed to check whether the content corresponds to the approval and that the correct active substance is included in the product.
Classification and labelling	Checks that the classification and labelling adhere to the criteria set out in KIFS 2005:7, Regulation (EC) No 1272/2008 (CLP) and the specific labelling rules for pesticides laid down in KIFS 2008:3.
Safety data sheets	Checks of the mandatory safety data sheets for hazardous chemical products in accordance with Annex II to the REACH Regulation, (EC) No 1907/2006.
Rules concerning packaging and storage	Consumer products must, for example, have child-resistant fastenings and bear recognisable warning markings. Regulation (EC) No 1272/2008 (CLP), KIFS 2008:2, and the specific packaging rules for biocidal products in KIFS 2008:3.

Table 3. Overview of the regulated areas checked during supervision of pesticides

### 3.2 Strategies for selecting supervision projects

It is necessary to have strategies for selecting projects and subjects to be supervised. The overall aim of the Chemicals Agency's supervision is to reduce risk, and this affects the selections made and the priorities set. The criteria that may be relevant to the selection are as follows:

- **Rules** In particular new rules. The rules largely determine the type of supervision that should be carried out, since the rules are the basis for stipulating supervision requirements.
- Unauthorised pesticides The majority of tip-offs received by the Chemicals Agency concern unauthorised products. Unauthorised pesticides in respect of which no assessments have been made of the health and environmental risks may give rise to unnecessary and unacceptable hazards to users, consumers and the environment.
- **Analysis** To check whether the content of an active substance conforms to the requirements in the authorisation, and to identify pesticides sold under false names

- (counterfeits).
- **Expired authorisations** Authorisations for some products have expired, although they are still available on the market.
- **Product information** Clear and accurate information is required to ensure that pesticides are handled in a manner that does not lead to harmful effects on human or animal health or unacceptable effects on the environment. It is provided primarily by means of safety data sheets and labelling.
- **Intelligence and information received** The Agency receives letters, emails and telephone calls about non-compliant products or circumstances. Those that are in priority areas are selected for inspection.
- **Knowledge transfer** Information on the rules is provided to operators.

#### 3.3 Available resources

The resources available for operational supervision of pesticides in 2016 amount to approximately 3.5 FTEs (calculated on the basis of an effective annual working time of 164 person days).

### 3.4 Planned supervision activities

For 2016 we have planned to undertake the following projects as part of the operational supervision of pesticides.

Supervision activity	Description of the activity
Plant protection products	Examination of conditions of use, labels, record-keeping, qualifications. That the conditions of use are clear. Also, advertising by the majority of businesses manufacturing or importing plant protection products.
Composition of plant protection products	Checks as regards the composition of plant protection products.
Biocidal products	Examination of biocidal products, approvals, suppliers of active substances, safety data sheets and labelling.
EU cooperation concerning biocidal products — CLEEN or the new biocides monitoring group	The European enforcement network CLEEN has planned a project on biocidal products, but it is unclear when this will begin and how relevant it will be to Sweden. There are plans to set up an EU-level group to enforce the Regulation on biocidal products. If this group launches any projects in 2016, these will be prioritised.
Pilot project	We are looking for a new direction in terms of checks of environmental monitoring data and media reporting.
Other incident-driven supervision and intelligence	The Agency receives notifications (tip-offs) in the form of letters, emails and telephone calls about 'non-compliant' products (that are suspected of failing to meet the legal requirements, smell strongly of chemicals, etc.). These are prioritised, and some are selected for inspection and checks.

Table 4. Operational supervision for pesticides in 2016

### 4 Articles

#### 4.1 Brief description of the area of supervision

The term *article* is defined in the Environmental Code and the REACH Regulation as 'an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.' For example, a treated wood panel is considered to be a chemical product, but if the panel is used as a table surface it is defined as an article.

For articles, as is the case for chemical products, there are provisions on the obligation to provide information on hazardous substances and the prohibition of particular substances. For certain groups of articles there are detailed rules restricting the use of specific chemical substances, e.g. the release of nickel from jewellery; lead, cadmium and certain brominated flame retardants in electrical and electronic equipment, and the use of certain substances in toys, e.g. plasticisers (phthalates). Currently, however, the provisions that apply to articles are less comprehensive than those that apply to chemical products. Below, examples are given of the regulated areas in which articles are monitored, and of the groups of articles that may be concerned.

Regulated areas	Regulation <sup>3</sup>	Groups of articles
Product safety	Product Safety Act (2004:451)	Articles that may constitute some kind of chemical health risk that is not covered by more specific (harmonised) EU legislation.
Safety of toys	Toy Safety Act (2011:579)	Toys, when the matter in question concerns their flammability and chemical properties.
Information on articles in accordance with REACH	REACH, Article 33	All types of articles that contain substances of the highest concern under REACH (SVHC substances entered in the Candidate List). The information must include at least the name of the substance in question.
Articles to be notified under REACH	REACH, Article 7	Since 1 June 2011, substances entered in the Candidate List in REACH and contained in articles must be notified, although there are certain exceptions.
EU rules on restrictions	Regulation (EC) No 1907/2006 (REACH), Annex XVII	Examples in articles:  Nickel in jewellery Phthalates in toys Cadmium in articles, in particular
	Directive 2011/65/EU (RoHS)	plastics PAHs in tyres Azo dyes in textiles Short chain chlorinated paraffins
	Regulation (EC) No 850/2004 (POPs)	(POPs) ■ Certain heavy metals etc. in electrical products (RoHS)

<sup>&</sup>lt;sup>3</sup> More detailed descriptions of the rules are contained in the Annex.

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Rules on	SFS 1998:944,	Examples in articles:
restrictions	KIFS 2008:2	<ul> <li>Formaldehyde in wood panels</li> </ul>
National		Mercury in articles

Table 5. Summary of the regulated areas checked during supervision of articles

### 4.2 Strategies for selecting supervision projects

In contrast to chemical products and pesticides, there are no requirements for articles to be notified to a register that can be used to prioritise supervision. The priorities for supervision work as regards articles are thus determined using a set strategy based on a systematic assessment of the following criteria:

- Risk of people or the environment being exposed to harm.
- Likelihood of a hazardous substance being present in an article.
- Possibilities for carrying out supervision, i.e. to enforce the legislation.

The strategy is described in more detail in *Strategy for the enforcement of legislation concerning environmental and health risks from chemicals in articles* — *Report of a Government assignment* (KemI Report 4/11, December 2011), which is available on our website <a href="https://www.kemikalieinspektionen.se">www.kemikalieinspektionen.se</a>.

#### 4.3 Available resources

The resources available for operational supervision of articles in 2016 amount to approximately 6 FTEs (calculated on the basis of an effective annual working time of 164 person days). The majority of supervision of articles is funded from the Action Plan for a toxic-free everyday environment.

### 4.4 Planned supervision activities

For 2016 we have planned to undertake the following projects as part of the operational supervision of articles.

Supervision activity	Description of the activity
Electrical products	Checks on various products on the premises of both larger and smaller operators, with a focus on low-price articles and the RoHS Directive, the POPs Regulation and REACH. Under the project, USB cables will also be checked as part of a joint EU project in the RoHS enforcement network.
Textiles and leather	Checks on, among other things, jackets, belts, gloves, scarves, colourful bedding, towels, and leather and artificial leather. Focus on REACH and the POPs Regulation. The project is part of a joint EU project.
Toys	Checks on various products on the premises of both larger and smaller operators, with a focus on the RoHS Directive, the POPs Regulation and REACH. Checks of shortcomings identified during earlier supervision activities. The project is part of a joint

	EU project.
Jewellery	Checks on jewellery, with a focus on the restrictions in REACH. Among other things, we will follow up the shortcomings identified during our jewellery supervision project which was carried out in cooperation with the municipalities in 2014. The project is part of a joint EU project.
Handles	Checks on handles made of rubber and similar materials, for example bicycle handlebars, hand grips and tool handles. Focus on the new restrictions on PAHs in REACH. The project is part of a joint EU project.
Sex toys	Pilot project involving checks on sex toys, with a focus on REACH and possibly also the POPs Regulation and the RoHS Directive. Broad awareness-raising campaign, including subsequent inspections.
Other incident-driven supervision and intelligence	The Agency receives tip-offs in the form of letters, emails and telephone calls about 'non-compliant' articles (that are suspected of failing to meet the legal requirements, smell strongly of chemicals, etc.). These are prioritised, and some are selected for inspection and checks.

Table 6. Operational supervision for articles in 2016

# Annex — List of legislation

Below is a list of the legislation where all or some of the provisions as at 1 January 2015 fall under the Chemicals Agency's area of supervision.

#### Act/Ordinance/Regulation/EU Regulation

#### Acts

Environmental Code (1998:808)

Product Safety Act (2004:451)

Toy Safety Act (2011:579)

#### **Ordinances**

Environmental Supervision Ordinance (2011:13)

Ordinance (2007:19) on PCBs, etc.

Ordinance (2000:338) on biocidal products containing nematodes, insects or arachnids

Ordinance (2006:1010) on pesticides containing nematodes, insects or arachnids

Ordinance (2014:425) on pesticides

Ordinance (1998:944) imposing bans etc. in certain cases in connection with the handling, import and export of chemical products

Ordinance (2008:245) on chemical products and biotechnical organisms

Product Safety Ordinance (2004:469)

Toy Safety Ordinance (2011:703)

Ordinance (2008:834) on producer responsibility for batteries

+ Ordinance (2012:861) on hazardous substances in electrical and electronic equipment

#### Regulations

Chemical Agency's Regulations (KIFS 2005:7) on the classification and labelling of chemical products

Chemical Agency's Regulations (KIFS 2008:2) on chemical products and biotechnical organisms

Chemical Agency's Regulations (KIFS 2008:3) on pesticides

#### **EU Regulations**

Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (**REACH**)

Regulation (EC) No 1272/2008 of the European Parliament and of the Council 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 (CLP)

Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants (POPs) and amending Directive 79/117/EEC

Regulation (EC) No 648/2004 of the European Parliament and of the Council on **detergents**, and the amending Regulation (EC) No 907/2006

Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of **plant protection products** on the market and Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of **biocidal products** 

Regulation (EC) No 842/2006 of the European Parliament and of the Council of 17 May 2006 on certain fluorinated greenhouse gases

Regulation (EC) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the **export and import of dangerous chemicals** 

Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer

#### **EU Directives transposed in Swedish statutes**

Directive 2004/42/CE of the European Parliament and of the Council (Directive repealed, replaced by the IED 2010/75, although probably only in respect of industrial emissions) on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain paints and varnishes and vehicle refinishing products **(VOC).** 

The Directives are transposed into Swedish law by means of the Environmental Code, Ordinance 2008:245 and the Chemicals Agency's Regulations (KIFS) 2008:2. The Swedish Environmental Protection Agency also has regulations in this field.

Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS 2).

The Directive is transposed into Swedish law by means of the Ordinance (2012:861) on hazardous substances in electrical and electronic equipment and the Chemicals Agency's Regulations (KIFS) 2008:2.

Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the **classification**, **packaging and labelling of dangerous preparations** 

The Directive is transposed into Swedish law by means of the Environmental Code and the Chemicals Agency's Regulations (KIFS) 2005:7 on the classification and labelling of chemical products. These provisions were replaced by the CLP and therefore do not need to be implemented actively, although they serve as a reference for a transitional period lasting until the end of May 2017.

Directive 67/548/EEC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions relating to the **classification**, **packaging and labelling of dangerous substances**.

The Directive is transposed into Swedish law by means of the Environmental Code, the Chemical Agency's Regulations (KIFS) 2005:7 on the classification and labelling of chemical products, and the Chemical Agency's Regulations (KIFS) 2008:2 on chemical products and biotechnical organisms. See above about the Directive on preparations.

Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys.

The Directive is transposed into Swedish law by means of the Toy Safety Act (2011:579), the Toy Safety Ordinance (2011:703) and KIFS 2008:2.

European Parliament and Council Directive 94/62/EC on packaging and packaging waste.

The Directive's provisions on heavy metals in packaging material are transposed into Swedish law by means of Ordinance 1998:944 and KIFS 2008:2.