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Accession Advice
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For the transposition of EU Chemicals regulations (CLP-REACH) and the Biocidal Products Regulation

Final report
Recommendations and reviews
29/09/2016

Approximation of legislation
in the field of Chemicals and Biocides with EU regulations

TAIEX Expert missions to Bosnia & Herzegovina
organised in co-operation with
Ministry of Civil Affairs of Bosnia and Herzegovina,
the Ministry of Health of Republika Srpska and
the Ministry of Health of the Federation of BiH

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Introductory note

This is the compilation of advice that was presented to the ministries of health in the Federation of BiH and Republika Srpska and the Ministry of Social Affairs of the B-H state during five TAIEX Expert visits in May, June and September 2016.

These expert visits have been completed according to proposals from the Conference for the Health Sector in Bosnia and Herzegovina the highest advisory and coordinating body in the health care area. This institution consists of the Minister of Civil Affairs of Bosnia and Herzegovina, Federal Minister of Health, Minister of Health and Social Welfare of the Republic of Srpska and the Head of Department for Health and other services of the Brčko District BiH.

The advice covers rules which are at the heart of legislation on biocidal products and chemicals in the EU, referring to Chapter 27 of the acquis communautaire and in the case of chemicals legislation also to the Chapter 1.

The comments and recommendations regarding the implementation of the Biocidal Products Regulation are presented by Helena Casabona. Comments and recommendations when it comes to the coordinated implemention of EU Chemicals legislation in the BiH (the CLP Regulation and the REACH Regulation) are presented by Torbjörn Lindh. Both experts are members of the International Unit of the Swedish Chemicals Agency (KemI), the Member State competent authority in Sweden in the areas of biocidal products and chemicals.

Content

Chapter 1: Review of possibilities for non-EU members to align to EU Chemicals legislation

Expert review with comments on scope and features, main obligations, main components and single elements of the CLP-REACH system.[1] It explores the possibilities for Bosnia-Herzegovina and other non-EU countries to harmonise national legislation to the chemicals legislation in the EU.

Introductory comment

The CLP-regulation (1272/2008/EC) and the REACH-regulation (1907/2006/EC) build up the EU-system for chemicals risk management. In this review we call it "CLP-REACH". That is one system for the entire Community / the European Economic Area (EEA) / supposed to work in the same way all over this vast market: Fully harmonised in this regard. So the two regulations both concern, besides Chapter 27 (Environment), also Chapter 1 (Internal market) of the UE acquis communautaire.

The following review concentrates on how industry obligations under these regulations are to work in the EU from 2018 and onwards, beyond the phase-in period of REACH once this new chemicals legislation entirely has entered into force.

You should note that Chemicals management in the EU will in 2018 be fully based on the CLP-REACH system for communication and information between actors in the supply chains and on REACH regulatory control of substances that are found to be too hazardous to admit to access freely and openly. Communication and information requirements will steer risk management regarding at least 98 percent of all commercially and industrially used substances.[2]

The access to very high concern hazardous substances is already with the REACH Regulation in place governed by clear principles and procedures, with authorisation requirement and with restrictions for the production, marketing and use.

In this review we explore to what extent an EU-candidate country reasonably ought to make its chemicals manufacturers and importers subject to REACH-alike obligations in order to achieve the harmonisation to the EU-legislation. What provisions are necessary and doable to implement? What provisions do you have to prepare for but cannot transpose because they are too EU-specific or too EU-member specific?

[1] CLP: Classification, Labelling and Packaging of chemicals; REACH: Registration, Evaluation, Authorisation and restrictions of CHemicals.

[2] The number of commercially used substances on the market has been estimated to around 110,000 in the EU. The substances to which the access is limited by EC-chemicals legislation are less than 1,500. About 1,100 of them are carcinogens, mutagens and repro-toxic substances forbidden to use in consumer chemicals.

So this review is about Industry obligations and preparations in the Candidate country. The EU-candidate has to prepare for Member state duties as well. You have to establish an efficiently working institutional solution. You have to strengthen your core administration. We will present a separate review on that matter when we discuss the implementation of CLP-REACH more in details.

Main features of chemicals legislation

Chemicals legislation controls the supply and circulation of chemicals

The scope of CLP-REACH is to eliminate adverse effects on health and the environment from placing chemicals on the market and from the production, circulation and use of substances as such, in mixtures or in other products (articles[3]).

This makes the scope of chemicals legislation differ from the legislation where the use of chemicals at the physical site is the basic concern – not the obligations of manufacturers and importers placing chemicals on the market / on your territory.

Compare how obligations do address Industry in various capacities in the various areas of legislation:

The prevention and control of major chemical accidents addresses the obligation of *the operator of hazardous installations* (Seveso-establishments). Work environment legislation addresses *the employer's obligations to protect workers* from chemical agents (also hazards in the meaning of burning metals, mists of unhealthy dust etc.). Environmental legislation addresses *the producer's prevention and control of pollutants from the production site, the disposal of hazardous waste, contamination of the soil at the spot* etc.

Chemicals legislation (the control of chemicals placed on the market) is complementary to the legislation concerning special chemicals: Cosmetics, food, medical products, plant protection products, toys…. Chemicals legislation regulates the overall general supply and circulation of chemicals, with special legislation you regulate the content, shape and use of the special chemical in its finished state for the given special purposes (product control).

Features to keep in mind

Note in particular the following features of EU-chemicals legislation:

- It is a Community system designed for the whole EEA (the EU plus Iceland, Lichtenstein and Norway), counting on the strength of its Chemicals industry, vast market, international position and joint resources
- It is an industry-based system that primarily works through obligations on the actors of the supply chains of chemicals to interact in the development of chemicals risk management, providing chemical safety assessment, communication and information

[3] The EU-term for other products than chemicals is "articles"

tools for this aim (Classification and labelling, SDS, Exposure scenarios, Chemicals safety assessment method)
- It makes it possible for the Community (the Commission, the European Chemicals Agency and the Member states together) to strictly control the access within the EEA to substances of very high concern because of their hazards (Carcinogens, mutagens etc.)

CLP-REACH is a fully Community-based system

When you look at the prospects for implementation you find that CLP-REACH is *a Community system* aimed for the whole European Community and the large European Economic Area connected to the EU. It is a system supposed to work for an important share of the world market of chemicals and the global production of goods. You will conclude that this is not a system designed for the single member state or single EU accession country with their most often limited national chemical industry, national market and administrative resources.

Firstly there are the pure EU-Industry obligations and Member state obligations and tasks which do stipulate that you already are the EU-member to apply them or to comply with them. These are the obligations to undertake REACH-registration, CLP-notifications etcetera and the Member state's obligations, among these its various national competent authority' tasks at Community level. It is indispensable that you prepare your industry and your administration for these obligations and tasks until accession comes but you cannot implement it beforehand.

I.e. you cannot transpose this kind of rules into your legislation saying that your industry shall have the corresponding REACH-assessment, REACH-registration and CLP-notification obligations as in the EU already before accession or you cannot oblige your competent authority to carry out Community tasks already before you are the EU-member.

Secondly there are several important CLP-REACH elements that are dimensioned and tailored only to work in the whole Community / on the market of the European Economic Area. These are elements (Chemical safety assessment; Communication on exposure scenarios in the supply chain; Etcetera) that presuppose that industry operates within the Community and on the EEA-market – mechanisms of cost sharing and data-sharing, possibilities of innovation, availability of less hazardous chemicals and techniques; and so forth. This side of the CLP-REACH system fully counts on the many substance producers we have in the EU (in Germany, France, Italy and the UK), the well-developed and highly capable Chemicals Industry, the all-round variety of use of chemicals and the joint EU-resources, for example when it comes to available expertise.

These elements are designed for EU-aims. They do not fit into the context of the relatively small, fragmented and internationally dependent market of single countries. You cannot install them given the always scarce resources of administration and industry in a normal-sized or small national state with its sparse and unevenly developed manufacture, trade and use of chemicals.

You have to make your industry aware of these CLP-REACH elements during the period of pre-accession but you are not supposed as the EU-candidate or accession country to have all of it in place on your own. It is impossible. To try would mean the waste of time and resources.

Note also the following:

- In the EU there are producers of a big lot of the commercially and industrially used substances as well as chemicals import of all kind
- EU Chemicals industry represents all kind of manufacture and use. It is strong, able and mature for this kind of legislation
- The EU may place demands on the actors in the supply chains since these chains are most often more or less complete in the EU and the actors in the chains are subjects under the common jurisdiction
- Risk communication demands and risk management recommendations may through the supply chains of the EU involve and benefit suppliers and users of chemicals within the whole EEA
- Safety data, test data and costs of data may be shared among the high number of EEA-manufacturers, importers and downstream users
- Costs for complying with chemicals legislation may become easily distributed and shared by industry within the whole EEA; e.g. costs for providing risk management recommendations based on exposure scenarios can easily be diluted by the manufacturers and importers by passing on their costs on their clients down the chain of supply with the help of the price mechanism; and
- Industry is accustomed to classification, labelling and safety data sheets because systems similar to CLP have existed for long in the EU member states.

Together these remarks indicate quite clear why a system similar to CLP-REACH would not work on the market of a normal-sized or small country.

CLP-REACH shall ensure knowledge on risks in all areas

The CLP Regulation and the REACH Regulation are together seen as the EU Chemicals management regime based on knowledge generation and dissemination of information on hazards, potential risks, precautions and appropriate risk management measures.

Responsibilities fall fully on the chemicals manufacturers and importers when it comes to classification. Providing safety data sheets and labelling is the responsibility of all suppliers. Downstream users are involved in the development of adequate risk management measures and recommendations.

Chemicals legislation is meant to serve all other areas of legislation where chemicals are a concern (Environment, Workers' health and safety, Consumer protection etc.) It is to ensure the gathering of knowledge on hazards, exposure, risks and risk management measures and the exchange of knowledge and information on chemicals through-out the supply chains. It is to support informed decisions and choices on chemicals and enhance the continuous development of chemicals risk management. (See Figure 1 at the next

page). The knowledge and information generated through this system should enhance precautionary action on risks in all other areas of legislation where chemicals' exposure is at stake.

The two regulations direct also the classification, labelling, safety data sheets requirements and certain restrictions regarding the placing on the market of chemicals that are biocidal products and plant protection products.

CLP-REACH is an industry-based risk management development system

Chemicals management is meant to become integrated into industry management on an everyday basis. Demands are of the kind that endorses chemicals management activities (daily use of safety data, practice of risk management, the phasing out of the too hazardous chemicals to be safely handled..).

The country that prepares for EU-membership should place obligations on manufacturers, importers and other actors in the supply chain in accordance to the principles and the allocation of responsibilities used in the EU. The obligations of chemicals manufacturers and importers in chemicals legislation is as indispensable as the obligations of the employer in the area of labour or the polluter in the area of environment. Your harmonisation to general principles and to the basic division of responsibilities in the EU is at least as important as your harmonisation to detailed requirements. Systems do continue to differ very much the way they work in practice if they differ a lot when it comes to general principles and the division of responsibilities.

Obligations in the candidate country could repeat the basic obligations in CLP-REACH regarding chemicals placed on the market, classification, labelling, safety data sheets and restrictions.

The introduction of CLP-rules and rules on safety data sheets could better be done stepwise first applying to substances and some years later to mixtures, because the access to data on substances makes industry able to apply the rules also to mixtures.

CLP-REACH means the continuous action for aims of very high concern

Regulatory action, to limit the free access to chemicals or prescribe certain classification and labelling, is considered necessary regarding substances and groups of substances presenting hazards of very high concern (Substances that show to be CMRs, PBTs or vPvBs or substances presenting hazards of the equal concern).

The REACH Regulation stipulates for this purpose authorisation demands and substitution demands (REACH-authorisation) or limited access through general restrictions (REACH-restrictions) as another route.

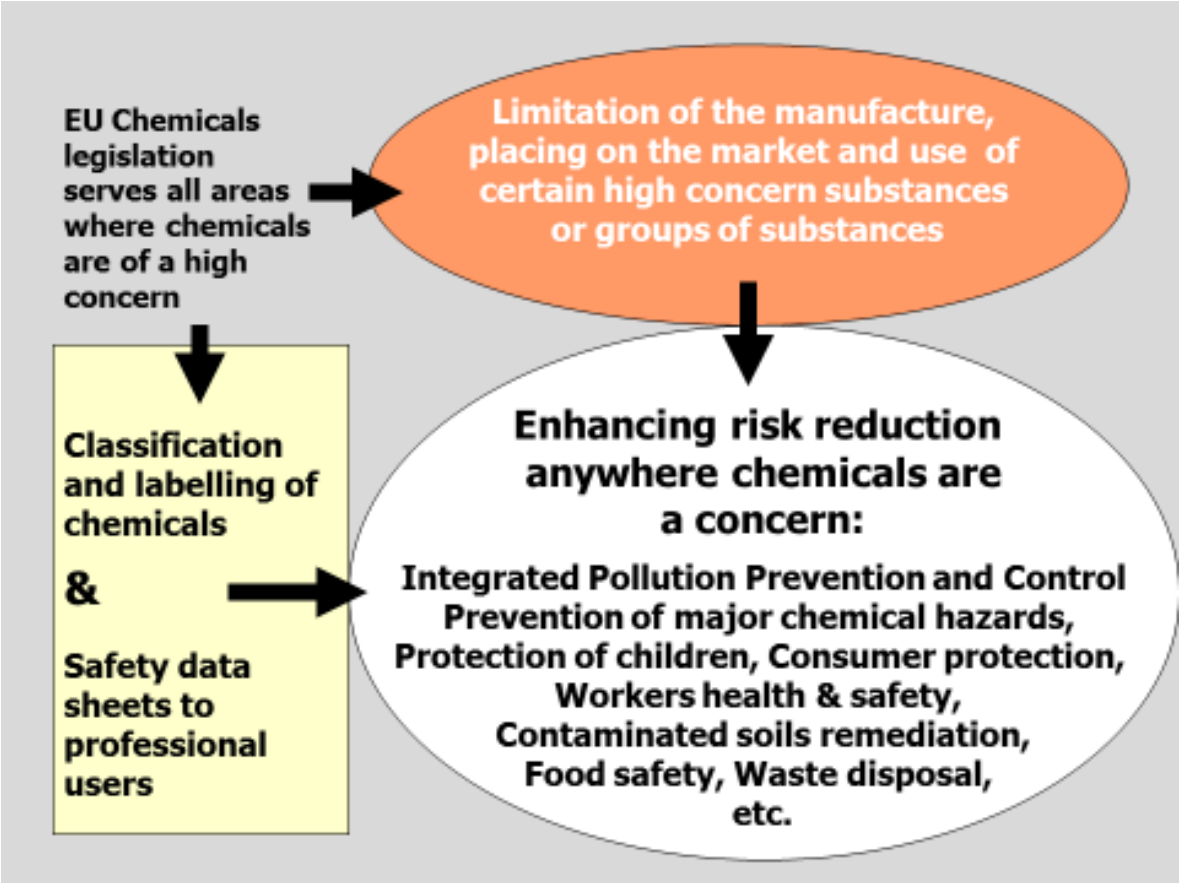

Figure 1: Through Chemicals legislation, knowledge becomes available on hazards, exposure, risks and risk management. Regulatory action is undertaken at Community level on substances of very high concern. It altogether enhances risk reduction in all areas.

The CLP Regulation stipulates a mandatory classification for carcinogenic, mutagenic and repro-toxic substances (Categories 1A and 1B) and for sensitizers of allergy to the respiratory tract.

You should regard these means of Community level regulatory action by authorisation demands and restriction decisions as necessary complementary means to the industry based risk management development system implementing the GHS in the EU. Hazards do in these cases of substances of very high concern pose such severe risks that safe management cannot be left to the individual manufacturer, importer or user of the substance.

Main industry obligations

Most EU-Industry obligations under CLP-REACH concern the placing on the market of substances as such or in mixtures.

How heavy REACH-obligations are depends on the volume of the substance that the company places on the market yearly, the kind of hazard it represent, whether it could be

considered a substance of very high concern because of its hazardous properties (SVHC) and whether it is possible to achieve the adequate control of its hazardous effects.

The obligations may be listed in the following way:

- The manufacturer or importer shall classify the chemicals they place on the market according to the CLP requirements

- All suppliers shall provide the labelling and packaging of the chemicals they place on the market according to the CLP requirements

- Suppliers of chemicals shall provide safety data sheets (SDSs) to their clients / the downstream users / according to the REACH requirements (REACH Title IV / Annex II)

- Manufacturers and importers of substances at an individual annual tonnage level from 1 tonne shall comply with the rules to register in the EU (REACH-registrations).

- Manufacturers and importers of substances at an individual annual tonnage level of 10 tonnes or more shall comply with the requirements (REACH Title 1 / Annex I) to:

- perform a chemical safety assessment,

- provide a chemicals safety report with the REACH-registration,

- draw up the exposure scenario, and

- identify, apply and recommend management measures assuring adequate control of the risks

- The downstream user of a chemical shall under certain conditions perform a chemical safety assessment and make a REACH-registration on his own (REACH Annex XII)

- Chemicals users in the supply chain have rights to make their manner of use identified and communicate data on use and exposure to their supplier (manufacturer or importer) possibly to make their use subject to the supplier's risk management recommendations (REACH Title V)

- Anyone has to comply with the authorisation rules and decisions (REACH Title VII), the bans and restrictions (REACH Title VIII), the mandatory classification and labelling (CLP Annex VI, EU-harmonised Classification and labelling) and

- Anyone placing other products than chemicals on the market (EU term "articles") has to inform on the content/use of the REACH Candidate list-substances in the product (article) (REACH Title IV).

Application rules and detailed requirements are laid down in the annexes to the two regulations.

ECHA publishes the exhaustive guidance material and the member states have organised official helpdesks in order to facilitate industry compliance.

Some working components stipulates membership

To better understand the EC-alignment options and possibilities of a candidate country it could be useful to distinguish the following three components of CLP-REACH. It would help you to consider in which way you may align to the various side of the CLP-REACH system: What kind of rules should you transpose to your law during pre-accession, which should you transpose promptly and/or better incorporate and which are rules that you - instead of transposing them - have to prepare industry and administration for up to the day of accession?

1. Regulation addressing industry for the generation and communication of knowledge up and down the supply chain for chemical safety assessment and for the elimination of adverse effects

Chemicals safety assessment, based on a standard data regime referring to the volume of the substance placed on the market per year and per company, the identification of uses, the scenario of exposure and appropriate risk management measures (REACH); Classification of chemical substances (CLP); Identification demands regarding CMRs[4], PBs[5] and vPvBs[6] (REACH)

Comments in regard to your alignment:

This group of provisions shall ensure the mobilisation of knowledge needed under REACH. The component is overall highly EU-specific. You may not achieve the same or similar gathering of knowledge of this kind by these means in a single normal-sized or small country since the knowledge possible to gather will show too sparse and fragmented. See the characteristics given above of CLP-REACH as a Community-based system. To enable us to come ahead with legislation of this kind is one of the reasons why we have the EU.

2. Regulation addressing industry for the dissemination of safety information

Providing the appropriate classification, labelling and packaging of chemicals placed on the market for the access of the general public or for industrial use (CLP), safety data sheets, exposure scenarios and risk management recommendations to the downstream user (REACH); Demands to inform the general public about the content of substances of very

[4] Substances classified as carcinogenic, mutagenic or toxic to human reproduction
[5] Substances regarded bio-accumulative and persistent against degradation. Ref. REACH Annex XIII
[6] Substances regarded very bio-accumulative and very persistent against degradation. Ref. REACH Annex XIIII

high concern in articles / i.e. other products than chemicals / placed on the market (REACH)

Comments in regard to your alignment:

These provisions are indispensable to implement at the earliest possible point of time in order to lay the ground for chemicals legislation in the country and for its approximation to the EU in the area. They provide the general instruments for CLP-REACH, the communication and information tools.

The provisions are basically the EU-implementation of the Globally harmonised system (GHS) for the Classification and labelling of chemicals, promoted by the UN and the OECD.

Implementing these provisions thus mean that you also implement GHS - if you haven't already done it. It makes you part of a worldwide system of knowledge mobilisation and dissemination based on the GHS-classification of chemical substances, transmitted and enlarged by trade relations and through the progress of chemicals legislation in all regions.

3. Joint community regulatory action - authorisation demands, restrictions, mandatory classification

Demands for authorisation to use substances which properties cause a very high concern to the Community (REACH, Annex XIV)
Restrictions on certain dangerous chemicals (REACH, Title VIII, Annex XVII);
EC-harmonised classification and labelling of CMR-substances and substances sensitive to the respiratory tract (CLP, Annex VI);

Comments in regard to your alignment:

It is necessary for your EU-harmonisation to implement the EU-bans and restrictions, the list of SVHC, the list of SVHC-candidates and the EU Classification and labelling list.

It is advisable to incorporate these provisions exactly as they read in CLP and REACH. It also means that you take advantage of the EU-results so far from regulatory action on particularly hazardous substances.

Community systems work differently from national control systems

The way a fully harmonised Community-based system works is very different from how it works with nationally based systems in the Member states steered by EU minimum-requirements like the Prevention and control of major chemicals accidents (the Seveso-directive) or the Prevention and control of Industry emissions (the IED):

When there is a Community-system you have to prepare for entering it. You cannot fully implement it beforehand since it is not nationally based. Harmonisation means that you prepare to enter it during the period of pre-accession.
When it comes to nationally based systems like Seveso and IED it is the reverse situation. Member states are supposed to set up the national systems for these aims. So the candidate country can set up its national EU-harmonised Seveso- or IED-system under the period of pre-accession and then enter the EU with that system already in place according to EU minimum requirements already implemented as it is supposed to be implemented in a Member state.

Necessary pre-accession elements

Necessary to incorporate into the legislation of the non-member are the following EU-provisions:

- General obligations regarding classification, labelling and safety data sheets.

  These ought to be issued by parliamentary law. Violation of the general obligations ought to be described and made subject to sanctions

- EC-harmonised classification, the "Classification list" (CLP, Annex VI);

  The country may incorporate the results of the EC-harmonised classification and labelling into its own legislation and make this classification and labelling mandatory for its industry. This way its industry gets access to the ready-made classification for about 4,000 substances, among them the most currently used substances and a high number of the CMRs

- Restrictions (REACH Annex XVII);

  The country may introduce the same provisions as in the EU. It is advisable to offer generous but effective periods of grace before the provisions enter into force

- Candidate list of substances of very high concern (SVHC) for authorisation; Information on the content of SVHC in articles

  The country may adopt the Candidate list and introduce the same information requirement as in the EU regarding articles that contain SVHC

- EC-decisions on substances subject to authorisation demands (REACH Annex XIV);

  The country may adopt the Annex XIV-list. It is advisable to offer generous but effective periods of grace before the provisions enter into force

- EC-decisions on authorisation. The country could adopt the decisions as decisions of its own and possibly admit holders of permits to use the substance for the same aim also in

the candidate country, under strictly the same exposure conditions and with strictly the same risk elimination requirement as in the EU.

EU-specific elements, necessary to prepare for

EC-rules for chemicals safety assessment, test-data demands, sharing and exchange of data, contacts and communication in the supply chains should be considered EC-specific and not reasonable to impose on chemicals industry in a non-EU country normal-size national state / for reasons already given above.

EU-specific elements are:

- The obligation to perform chemical safety assessments of substances placed on the market, in accordance to the method established in the EU (REACH Annex I) and referring to the corresponding minimum data demands (The so called "Standard testing regime" laid down in REACH Annexes VII-XI)

  The method could however be introduced in practice in the country, also fully introduced – or made mandatory just to the extent found feasible and necessary. It is advisable that the EU candidate country makes this method known and recommends it, preparing the grounds for its industry to enter in the EU.

  The method may be introduced under the law in the non-member country as an available tool and its methodology made mandatory just for those who apply the method voluntarily.

- The obligations on the actors in the supply chains to identify uses of chemicals and to communicate data on substances, on exposure and on chemicals use up and down the supply chain; the compilation of exposure scenarios as the outcome of this communication, recommendations for adequate risk management measures based on such scenarios - and the further communication demands on the actors in the supply chain

  What the candidate country could ensure is that these EC- rules become well-known in most ranks and files of its industry. Being familiar with these rules would certainly facilitate for its industry to integrate in the practice of the CLP-REACH system although still operating outside the Community.

- The specific EU-decision systems for authorisation (REACH Annex XIV); amending the Candidate list; restrictions (REACH Annex XVII); and mandatory "harmonised classification & labelling" (Listing of substances on the Classification list, CLP Annex IV)

  You are supposed to adopt the EU-restrictions, EU-authorisation and candidate lists of SVHC and the EU-mandatory classification and labelling list.

To introduce national decision-making systems of this kind in parallel to the EU (procedures for investigations, assessments, proposals and decisions on your own) in parallel to the EU would not fit into the harmonisation scheme. It is very costly for anyone to run such systems. Industry would not be able to feed you with the required data. Etcetera.

The main point here however is that any step of running such procedures aside of the EU Community-based system would, at least formally, mean that you alien yourself from the EU-system. It would not suit if you set up your own national decision-making systems running the similar procedures in parallel to the EU. It would rather compete with harmonising your legislation to the EU-regulations. Candidate countries are supposed to prepare for joining the common system. CLP-REACH is not about creating national systems in the Member states that you may set up in the pre-accession period and enter the EU keeping them in place like you are supposed to do when it comes to the Seveso-directive or the IED.

In case an authorisation demand for SVHC has already reached sunset date in the EU you may give provisional exemptions to companies in your country that depend on that SVHC to continue to use it until accession day but no longer.

Note that companies in a candidate country which like to receive authorisation to use SVHC before your accession can register activity in the EU and give in application as EU-legal entities. They could also call upon their importers in the EU to make them apply for authorisation.

Chapter 2: Proposals for the legal scheme

Comments on the possibilities to use primary and secondary legislation for the aim of EU-harmonisation in the area of chemicals (Acquis communautaire, Chapter 1 and Chapter 27)

Legislation regarding the placing of chemicals on the market and restrictions on chemicals in Bosnia-Herzegovina will be harmonized to the legislation in the EU (CLP, REACH, Export-import of chemicals). The proposed legal scheme refers to the practice of framework law by some of the member states at the time before REACH when EC-chemicals legislation was based on directives. Other member states issued those EC-directives directly as Governmental ordinances / decrees with referring to administrative law or law in another area where chemical safety is a concern.

Recommendations

- Base the implementation of EC-chemicals legislation on a framework parliamentary law. The existing Law on Chemicals and Draft chemicals law are good points of departure for developing law proposals although they refer very much to the situation when the EU-legislation was launched ten years ago
- Make the aim and scope of your parliamentary law embrace the general scopes of the CLP-regulation and the REACH-regulation
- Refer to the scope of the Rotterdam convention regarding Export-import
- Make the exemptions from the scope which are common exemptions to all components of CLP and REACH
- Include the definitions which are useful to and used in the law. When it comes to provisions that are supposed to harmonise to the EU Export-import Regulation refer to definitions in the Rotterdam convention
- Include the more detailed CLP- and REACH-definitions with secondary legislation, in the one or other ordinance where the definition belongs and is useful
- Appoint the competent authorities under the law and mention briefly their main tasks or issue the appointment with a Governmental decree based on a mandate in the law
- Gather the capacity and competences of central staffs in core administration dedicated to chemicals legislation and seated in or very close to the lead Ministry for chemicals legislation, that is to say the ministries of health in the two parts of the country
- Appoint the inspection bodies with tasks under the law and mention briefly their main tasks, or issue the appointment with a Governmental decree based on a mandate in the law
- Transpose the general obligation from the CLP-regulation to classify, label and package chemicals
- Transpose the general obligation to provide safety data sheets from the REACH-regulation

- Add the obligations that labelling and safety data sheets shall be provided in either of the official languages of the BiH, that is to say in equally in any part of BiH.
- Implement by secondary legislation application rules and other detailed contents of the EC-regulations that are applicable to a non EU-country
- Issue the restrictions by the law deemed necessary concerning manufacture, placing on the market, use and export of chemicals; or give a clear mandate to the Ministry in charge to issue such restrictions
- Issue total bans on SVHC (substances of very high concern because of their intrinsic properties) by the law; or give a clear mandate to the Ministry in charge to issue the bans
- Transpose general obligations from the EC-export and import regulation that are applicable to a non EU-country
- Transpose the prohibition concerning advertisement from the CLP-regulation
- Introduce rules from the EC-regulations ensuring transparency, information to the general public and information to workers
- Describe the cases which are regarded violations to the law and the corresponding penalties
- Lay down enforcement provisions giving the sufficient powers to inspectorates under the law
- Describe the cases which are considered contraventions by the inspection and the corresponding sanction fees
- Violations and contraventions should be the very clear cases, obvious and easy to judge

Because of special matters of the state of BiH I advise you also to undertake something alike the following measures:

- Issue a national state decree that says that the provisions that are issued in parallel in the BiH through the laws on chemicals also is law in the municipalities of the BiH that prevail outside the jurisdiction of these laws
- Appoint by a decree at national state level the inspection in charge under chemicals legislation in the municipalities of BiH outside the jurisdiction of the laws on chemicals

Comments on the proposed legal frame work scheme

Scope and content of chemicals legislation

You may consider the general scope of the EC-chemicals legislation as the scope that is common to the CLP Regulation and the REACH Regulation. Exempted from this scope are the radioactive substances, non-isolated isomers and products under customs' control or for transit.

CLP and REACH exempt all transport of chemicals as dangerous goods on rail, road, waterways, by sea and by air, except for a provision in CLP regarding transport-packages and the labelling of those transport-packages (outer packages).

Definitions and exemptions are normally few and general when it comes to framework law. More specific definitions and exemptions suit better to issue with the pieces of secondary legislation where they belong and apply.

Basic conditions, obligations and arrangements

General obligations to provide classification and safety data sheets for hazardous chemicals are in the EU mainly placed on the chemicals manufacturers and importers. Labelling, the provision of safety data sheets down the supply chain and packaging rules are on all suppliers.

EC-restrictions limit in various ways the access to certain chemicals. These are all provisions which regulate the free access to and use of property and limit the free movement of goods for aims of health and environment. They are typical matters for the legislator under the rule of law. So are also the accompanying provisions – mandates to issue secondary legislation pursuant to the law, the delegation of powers and the provision of means for the enforcement as well as the necessary penalty provisions in case of violation of the law.

Contents of framework law[7]

A framework law normally contains the following:

- The aim to eliminate adverse effects from the production and placing on the market of chemicals
- The scope covering the use of substances as such or in mixtures in chemicals and in articles containing or treated with hazardous chemicals placed on the market.
- General exemptions from the scope
- General definitions for the interpretation of the framework
- The obligations on chemicals industry (manufacturers and importers; other suppliers; downstream users) to classify, label, package and provide safety data sheets in compliance with the law when it comes the chemicals they place on the market
- Restriction on the manufacture, placing on the market, use or export of certain substances
- The appointment of the minister/ministry in charge for competent tasks pursuant to the law (Lead ministry, core administration)
- Mandates to the government / lead minister or lead ministry to issue pursuant regulation
- Mandates for supervision/inspection of compliance to the rules; and the delegation of powers of enforcement
- Provisions which guarantee public access to information
- Descriptions of law violations and issuing of the corresponding penalty provisions

[7] A template for a framework law regulating the placing of chemicals on the market is presented in Annex 1 to LIRA Guidance (On the development of legal and institutional infrastructures for sound management of chemicals….), UNEP 2015

It also offers the frame for the implementation of multilateral chemicals conventions[8] to the extent that conventions are not implemented through special ratification acts making the text of the convention national law.

Scope and definitions of the Rotterdam convention

Since your laws on chemicals are also to implement the EU Export-import Regulation you ought to add matters of the aim and scope of this convention to the laws, aside of what is the common aim and scope of the CLP Regulation and the REACH Regulation. The objective of the Convention is "to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties."

You also have to make clear that your law provisions referring to the Rotterdam convention are in tune with this convention when it comes to its definitions. The Convention says for example that a "Chemical means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial". That is a literally different definition from your definition of "chemical" that you have based on the definitions of "substance" and "mixture" given by the CLP Regulation and the REACH Regulation.

Contents of secondary legislation

The country that aligns its legislation to the EU should better use secondary legislation to transpose the big mass of administrative, technical and scientific definitions, application rules and detailed requirements found in the CLP-regulation and the REACH-regulation.
These provisions have the character of administrative, technical and scientific demands of the kind that concerns politicians the less. There are also the continuous technical amendments to the EU-regulations that you may be supposed to incorporate into your legislation as the candidate country. To issue the mass of such rules through secondary legislation thus makes sense. It also makes it easy for you to accommodate to the technical amendments and update your harmonised rules.

Basic allocation of costs

Primary legislation lays the base for the allocation of costs for chemicals management between industry and public administration, as well as within industry and within administration. It is achieved since the basic cost allocation follows from the division of obligations under the law. EC-chemicals legislation makes everyday costs for chemicals

[8] In the context of EU-alignment it would be the Export-import regulation, bans issued with the POPs-regulation and bans issued with the Mercury regulation.

management internalised to industry costs[9] where principal obligations are placed on chemicals manufacturers and importers.

Also joint Community regulatory action – the processes and procedures of authorisation, mandatory classification and restrictions – are to some extent based on industry obligations. The companies concerned have to take on costs for the evaluation work and consequences of the decisions. The member states' competent authorities' contribution to this work is financed by their state treasuries.

Helpdesk service provided by administration at member state level is supposed to be free of charge. So helpdesks are subject for public funding.

Enforcement combines in some member states inspection with fees, in others not.

Special legislation for the control of specific product groups

Certain special legislation works as *product control* referring to the aim, the composition, the design of the special chemical or the special product containing or treated with the substance.

In a few cases legislation establishes product approval procedures / for the permission of the special product before it is allowed to be commercialised, like with biocidal products and plant protection products. Legislation also works with restrictions referring to the intentions of the special product placed on the market as in the EU-directive on toys or referring to the particular fate (e-waste) of the product as with the directive on hazardous substances in electric and electronic equipment (the EU RoHS Directive).

REACH-restrictions make no exemptions for any group of chemicals or other products aside of radio-active substances - and cosmetics from the purely health point of view. Restrictions may be issued regarding all manufacture, placing on the market and use. At the other hand, chemicals that are ready made medical products, veterinary products, cosmetics, food or feedstuff are exempted from the CLP Regulation and from the SDS-rules as they are subject to special legislation also in this regard.
So the Governmental ordinance to implement REACH-restrictions in the country that harmonise its legislation to the EU should not make any exemptions, the ordinance to implement CLP should exempt the groups exempted in the CLP-regulation etc.

Detailed CLP- and REACH-rules apply to chemicals that are biocidal products, detergents and plant protection products, although special legislation adds to assessment requirements and labelling requirements.

[9] It means in this case that the costs for chemicals management become part of industry overall management costs – and have to be carried by the manufacturer, importer and downstream user, not the tax-payers.

Institutional set-up

I recommend you to gather the capacity and competences in a unit dedicated solely to chemicals legislation and placed on the ministerial level (Lead ministry, core administration), within or beneath the ministry in charge for chemicals legislation, in your case the ministries of health.

Experience from Member States shows that the number of full-time staffs independent of the size of the country ought to be at least 10 if the unit is supposed to keep also the CLP-REACH helpdesks asked for in the regulations. It is like a critical number, not to make the competent authority too vulnerable and too dependent on each individual staff.

Penalty provisions and enforcement means

When it comes to penalise infringements I recommend you to lay down well motivated, easily distinguished and easily understood cases of heavy infringements that qualify as being violations of the law, cases where black is black and white is white. Possibly give titles and descriptions with requisites in the law on these violations.

Here are three examples of that kind:

<u>"Violation of the information duty</u>

The one who omits the general obligation of this law to provide a client with a safety data sheet shall be sentenced to the *Violation of a principal information duty under the Law on Chemicals*.

<u>Illicit choice of handling a substance of very high concern</u>

The one who unauthorised uses a substance banned under this law as a substance of very high concern because of its hazardous properties, shall be sentenced to the *Illicit choice of handling chemicals under the Law on Chemicals.*

<u>Violation of a restriction</u>

The one who manufactures, places on the market, use or export a chemical in breech with a restriction pursuant to this law, shall be sentenced to *Violation of a restriction issued under the Law on Chemicals. "*

The inspection may be empowered to enforce all rules deemed needed

Place the tasks of enforcement on experienced inspection bodies.

Inspection should be enabled to force anyone to accomplish anything that the inspection finds necessary and reasonable when it comes to the provisions of the law as such and the total of application rules, requirements and requests issued pursuant to the law.

When you formulate particular contraventions and corresponding sanctions decided by the inspection body, do not extend the list too much. Choose also in this regard the cases which are clear and easy to determine (black and white-cases). For example:

"Infringement to information duties

The one who does not provide his safety data sheet to his client in the prescribed language shall be sanctioned for the *Infringement of information duties under the Law on Chemicals*."

Proposals because of particular matters of jurisdiction

Depending on the construction of the national state I advise you also to undertake measures that establish your EU-harmonised chemicals legislation in the separately directed municipalities. This may be done by a national state decree that says that the provisions that are issued in parallel in the two main parts of the country through the laws on chemicals also present the law in the municipalities that prevail territories outside the jurisdiction of these laws.

Additionally I advise you to appoint by a decree at national state level the inspections in charge under chemicals legislation in these municipalities that are outside the jurisdiction of the laws you will prepare on chemicals.

Chemicals legislation in the broader context

Legislation in the areas of chemicals safety works in parallel

Chemicals legislation in the EU work in parallel to other legislation on the basis of the EU-treaty. It makes each and one legislation of concern for chemical safety interact with and support the others (environment, workers' health and safety, prevention and control of major chemical accidents etc.). Note that chemicals safety in most areas of legislation concerns *the use of chemicals.* Figure 1 shows regulation in various areas.

The allocation of responsibilities to ministries

If you look at the wider legal scheme many ministries have regulatory responsibilities concerning the field of chemicals safety:

- Responsibility for the prevention and control of major hazardous accidents is normally placed on a minister/ministry of interior, civil protection, industry, physical planning and/or defence,
- Responsibility for the product control of pharmaceuticals, cosmetics and hygiene products is normally placed on a minister/ministry of social affairs or health;
- Responsibility for the regulation of workers´ health and safety is placed on ministries of health or labour; Etc.

It is crucial to an effectively and efficiently working administration that there is a lead regulatory ministry in each case of legislation, the sufficient inter-ministerial co-ordination and access to the necessary technical and scientific competence in each area. This is also internationally recognised and emphasised:

"Clarity and coherence in the allocation of mandates between public bodies is key to the efficiency and cost effectiveness……. Clear legal mandates establish the basis for the overall organization of institutional arrangements for chemicals management, while provision of adequate powers to responsible authorities ensures their ability to fulfill their mandate." [10]

Primary legislation: Main obligations, mandates and other basic provisions	**Chemicals law** **Concerning knowledge, restrictions and information on hazards and foreseen potential risks, when chemicals are placed on the market**	Environmental law Concerning the use of chemicals from the point of view of environmental protection and waste	Work environment Concerning the use of chemicals from the point of view of workers' health and safety	Other areas of legislation: Concerning the prevention of major chemical hazards; consumer protection; cosmetics; Pharmaceuticals Etcetera……
Secondary legislation: Application rules Detailed requirements	**Requests for classification labelling and packaging** **Requests regarding safety data** **(Making GHS binding)**	Pollution prevention Emission control Waste disposal etcetera; Permits ; Limitations on use	Risk prevention at work; Permits; Limitations on exposure and use	Emergency plans; Public information requirements etcetera

Figure 1: Scope of Chemicals legislation (chemicals placed on the market) and examples of the scope of other legislation where chemicals safety is a concern

[10] UNEP 2015, Ibid page 24

Chapter 3: Recommendations to Chemicals law

The point of departure of these comments is that legislation referring to chemicals placed on the market in Bosnia-Herzegovina will be harmonised to EC-rules in a coordinated way. The recommendations concern the revision, to the sufficient extent, of already existing EU-harmonised rules in Republika Srpska and the issuing of the corresponding rules in the Federation of Bosnia and Herzegovina and hopefully also in the District of Brčko.

Introductory comment

EC chemicals legislation is a fully harmonized area. Rules are so called maximum rules. The legislation is built on regulations. It is issued under Chapter 1 and Chapter 27 of the Acquis communautaire.

The regulations that make up the management system are Regulation 1272/2008 on Classification, labelling and packaging (CLP) and Regulation 1907/2006 on Registration, Evaluation and Authorisation of Chemicals (REACH). Among other regulation in the area, is the Export-import regulation 689/2008 implementing the Rotterdam convention and Regulation 850/2004 on persistent organic pollutants implementing the Stockholm convention.

This piece of recommendations does not include any recommendations regarding the implementation of the EU Regulation 648/2004 on detergents.

The system for chemicals legislation (CLP-REACH) in the EU builds on communication and information demands in the supply chain (CLP-rules; SDS-rules) at the one hand and rules for limiting the access to substances posing hazards of very high concern and certain particularly hazardous chemicals as such or articles containing such chemicals (Authorisation; Restrictions). This is meant to be enough for the chemicals management system to work within industry, for the supervision and inspection to care for and for the further regulatory action on Community level. It makes the Commission and the Member State able to concentrate their joint efforts and resources on the substances of most high concern because of adverse effects and potential risks.

The Member States are not supposed to have systems of their own, in parallel to the EU-system but may keep complementary and supporting domestic rules for example to ensure the enforcement of the EU rules, and if not competing or in conflict with the content of EU-rules .

Once you become the EU-member

When you enter the EU, the chemicals legislation and the legislation on biocides will come into force directly since the rules are regulations. You have to have the implementation law(s) in place at accession day with appointments of competent authorities, inspection

provisions, penalty provisions, decisions on helpdesks, and some further provisions that you find in the regulations when it comes to Member State obligations. See the broader background in this regard given in Chapter 1.

The legal (formal) way of implementation is your independent sovereign consideration as the Member State. It may for example be done by implementation law(s) per each EU-regulation or within the framework of laws which contain also the purely domestic provisions, in terms of EU-legislation truly complementary and supportive ones. The EU Commission is not empowered to intervene in how you do it, but that you do it in the satisfactory way as the EU-member. The weakest link breakes the chain the first.

You have chosen to delegate the administrative and technical-scientific tasks of chemicals legislation to the Ministry of Health. Many EU Member States have done this as well. The other most common ministerial realm is Environment, like the EU-chemicals legislation is issued under the Environmental chapter.

Revise the content of domestic rules

You have a lot of domestic rules. It is like if you do not believe in the Classification, labelling and safety data sheets rules but need to steer Industry by other means.

Reconsider in particular the domestic provisions that place very specific educational and training demands on the companies subject to the law demands. Such formal and precise qualification requirements may be deemed to work as obstacles of trade.

For the complementary purpose and for the support to the implementation and enforcement of EU-harmonised rules I suggest:

- that you keep the rules on the chemicals registry
- that you gather the rules on storage in the storage chapter. Possibly you move the more detailed storage requirements to a Rulebook on storage.
- that you keep rules on permits for selling hazardous chemicals but just referring to classes and categories of particularly hazardous substances and chemicals which may cause severe problems if openly accessible (like methanol).

You could also keep, at least for a considerable period of time, the system of chemicals advisers pointing at the usefulness of it when it comes to the enforcement of the EU-harmonised rules.

Possibly add GHS and the conventions to the Scope

You will implement GHS in the whole of BiH the way it is implemented in the EU. You also harmonise your implementation of the chemicals conventions to the way the EU did it (in the case of your Chemicals law: Minamata, Rotterdam, Stockholm, possibly also Vienna).

That you under this law implements the GHS and the conventions may be underscored in the scope, although it might be impossible at this stage of pre-accession to refer to the EU Regulations.

Be aware that with the ratification of conventions normally the convention text becomes national law. In the Rotterdam convention there is an amount of procedural rules. Look for these rules not to be repeated in your law or differently written there. It should be enough that the rules are already given by the convention.

Go for far less definitions

Do just include here the definitions which are used in the law and deemed necessary for the understanding of it. Considering this, I would suggest that you at least omit the following definitions in Article 2.1:

d, e, g, i, j, k, m, q, r, s, t, u, y, z, aa, ab, ah, ai, ar, as and au

Correct the definition of chemical supplier.

Refer to the UN when it comes to the GHS.

When it comes to the Rotterdam convention you gather the necessary implementation rules in one law chapter. So you ought to say in a new paragraph (Article 2.2) that the convention's definitions are to be applied in that particular chapter.

Make exemptions where they belong in Rulebooks

For the applicability of the REACH-restriction rules there are no other exemptions than the general REACH-exemptions: For radioactive matter; and for chemicals under custom control for re-export. So you are supposed to transpose these restriction rules making no other exemptions in your turn.

Regarding the transposition of CLP-rules you may preferably make the corresponding REACH-exemptions in the Rulebook implementing them, stating that these rules are not applicable on medical products, veterinary products etcetera…

Comments to C&L-rules and SDS-rules

Ref Article 6:
Note that requirements to provide labelling and provide safety data sheets are on all suppliers in the supply chain.

Avoid to speak about "legal person". Speak about "the manufacturer", "the importer" etcetera as you do further down in other chapters.

Ref Article 7:
Look for how the duties are spelled in the EU Export-import Regulation when it comes to providing classification, labelling and safety data sheets with the export of chemicals from the EU.

Ref Article 9-12:
Possibly adopt the EU Classification and labelling list as your list and speak about as your own list.

Make the ECHA C&L Inventory normative to use. It could be done by requiring that the one who use another classification or labelling (deviating from the inventory) has to notify this classification and labelling to the Competent authority / core administration.

Emphasise that C&L is supposed to be done based on available data.
The paragraph 9.4 is misleading in this way because it adds the wording on testing this way "i.e. (id est) /based/ on new testing".
The same in Article 10: "i.e. direct experimental testing".
And Article 12 says: "New testing…since they (substances) are not on the List…".

It would be much better saying this in a way where it stands clear that companies normally are supposed to search for existing data, not undertake testing when they shall find out a classification.

However, making use of the ECHA C&L Inventory will minimize the situations when a company itself has to find out the classification by searching for and assessing the laboratory data.

Ref Article 17:
I think the word "advertising" shall be replaced by "packaging" in this key article.

You do not have to be more precise on advertising than in the EU (the CLP Regulation).

Ref paragraph 19.6:
Reconsider this paragraph.

i) SDSs are not presented for articles.
ii) To gather SDSs in the Ministry is a heavy duty just to receive them,
iii) Although the Ministry is not to check and correct the SDSs it might very well be perceived as if it were doing precisely this, taking over the responsibility for the sheets

Ref paragraph 23.4
Omit this paragraph. SDS recommendations shall be understood just as recommendations. They are result from law demands (namely the REACH-demands that recommendations shall be provided) but they are not law demands themselves formally or by nature. You cannot become obliged to follow it. For sure the SDS and the risk management recommendations may be of very poor quality or they may even be wrong. However and at the other hand: The company that does not follow the recommendations in a SDS would

normally have to explain what other measures (s)he applies and why these are at least as good as the recommended ones.

Omit this para also since it regards the use of chemicals. Use of chemicals is governed by other legislation in which areas the SDS is a helping tool.

On the introduction of Chemical Safety Assessment

Ref Articles 19 and 21:
Omit what is said about chemicals safety assessment and exposure scenario in the paragraphs 19.2. and 21.1. Demands for performing the CSA cannot possibly be enforced in the meaning of REACH in BiH and reasonably not in any other candidate country as well. See what is said about this in Chapter 1 of this report (Review of possibilities for non-EU members to align to EU Chemicals legislation).

Chapter 5
What you do here is to launch CSA as the recommended tool to lay down risk management recommendations based on laboratory data (DNEL; PNEC).

It could be clearly said in the law that the one who apply this method does it voluntarily but once applying it (s)he is supposed to strictly follow the CSA-method (as it is described).

You then can introduce the description of it (REACH Annex I), present the data requirements (REACH Annexes VII to XI) – or if possible simply refer to the REACH Regulation.

However: You'll make CSA mandatory with the "Conditional authorisation for the use of SVHC" if you go for the proposal to establish this as a possibility through the pre-accession period. See what proposals about this in Chapter 4 of this report (Recommendations for the transposition of REACH)

On your need for alternative names

Reconsider whether you need the possibility of giving alternative names to substances.

Consider also if BiH should accept the alternative names for substances already given to applicants in the EU. See what is said about this in Chapter 5 of this report (Recommendations for the transposition of the CLP Regulation)

GLP

Good Laboratory Practice is a monitoring system that shall be based on a monitoring programme, a monitoring unit and GLP-inspectors. Member States are obliged to arrange for the access of labs to such programme. It is for toxicological labs mainly. The system is

run by the OECD. It takes a considerable time to establish in countries. You may try to cooperate with neighbour countries on this.

Gather storage provisions

Ref Chapter 6:
These are purely domestic provisions. Storage provisions are often found in national domestic chemicals legislation.

I think you should gather all your law level storage provisions of in this chapter or possibly issue a special Rulebook on storage requirements. Better keep the provisions together one way or another. In the present law there are storage provisions also further down here and there in the following chapters.

Storage provisions do not compete with EU-chemicals legislation since there are no storage provisions there. I cannot say if there are any competing storage provisions in other areas of EU-legislation where chemicals safety is a concern..

National Registry

I suggest that you have the registration of all chemicals placed on the market yearly, not just the hazardous ones. I also suggest that you have the coordinated or integrated registry covering the whole of the BiH.

Consider that Chemicals legislation in the EU (CLP-REACH) is applicable on chemicals whether falling for any hazard criteria or not. The duty to classify regards all chemicals.

Registration of chemicals regardless of being hazardous or not would engage the whole chemicals industry in the work of the national registry. It would make you able to follow trends of use of substances in chemicals and chemicals in society, replacement of hazardous chemicals and the results of the phasing out of particularly hazardous substances due to bans and restrictions. It could make you capable to publish good statistics. The registry would turn into "your national registry on chemicals". You may anyhow make exemptions from registration demands, for example for substances like sodium chloride, sucrose and other well-known substances.

Ref Article 35
Omit the Ministry verification of SDSs in paragraph 35.1 since it rather turns into an approval of the SDS contents. It makes administration appear as responsible for the appropriateness of the content and for its compliance to the rules.

Regarding "Restrictions and prohibitions"

Consider a short title that covers rules approximating both to the REACH Authorisation system and to the REACH-restrictions.

Consider how to proceed with Annex XIV-substances where there were no substances at all listed at the time that you issued the present law on chemicals in Republika Srpska.

Should Annex XIV-substances become banned before accession? Is it a good option to introduce possibilities for companies depending on any of these substances to appeal for the "Conditional authorisation of the use of SVHC" until accession? That would be a provisional purely domestic authorisation that must expiry at accession day, once your companies are entitled to apply for authorisation in the EU. Most important is that you get a good grasp on issues of use and national dependence of SVHCs. The provisions you choose for "Conditional authorisation…" may be a further development of conditions given in Article 44.

Ref paragraph 41.2:
Note that CMR-categories are renumbered. The former categories 1 and 2 you now call categories 1A and 1B.

Ref Article 46:
When it comes to restrictions consider also your bans that harmonise with bans in the EU POPs Regulation, Export-import Regulation and Mercury Regulation

I think it should be said clearly in the law which bans there are and when bans enter into force. In combination with that the Ministry could be entitled to decide on prolonged periods of transition in individual cases.

I also suggest that you change paragraph 46.5 into a clear mandate to the Ministry to issue the restrictions and prohibitions.

Export and import

Consider whether rules for the procedures for Prior consent and others possibly are issued already in BiH with the incorporation of the Rotterdam convention to your law with the ratification of it (with the Ratification act). If so, avoid duplicating the rules. From the EU Export-import Regulation however there is not much to implement for an EU candidate, since the regulation mostly just adds EU-MS coordination provisions to the procedures already given by the convention.

To harmonise to the EU do establish the export notification also of the PIC-candidates listed in the EU Export-import Regulation and the additional EU-notification regarding articles.

However, I advise you not to enlarge the number of countries to whom you send export notification to the whole world as the EU has done. Keep to the parties of the conventions. EU has the resources and organisation to make notifications to all countries. For a sole country to head for this level of ambition would become far too difficult to it. Many countries outside the group of parties to the convention are rather ignorant about the intentions and the procedures asked for, so the correspondence around the notifications could in many cases turn really complicated and time-consuming.

Workers' health and safety-provisions

Certain provisions are provisions to consider under Labour law / Workers' health and safety rules - as such or in terms of EU-harmonisation. It seems for example clear in the case of the provisions in Article 74 and Article 75.

MS Competent authorities and their tasks in the EU

You are supposed to appoint MS competent authorities once you are the member. It refers to BPR, CLP and REACH. In the case of the Export-import Regulation it is named Designated National Authority like under the Rotterdam convention.

You will through the screening and later negotiations with the EU Commission/ EU Delegation during pre-accession be asked which these will be. Normally it is prepared for in the chemicals law of the EU accession country / candidate country. It is taken for granted that the authorit(y)(ies) given these tasks then will stay the competent authority of the country when it enters the union. In the case of several MSs the competent authorities are two, both of them representing the national level, one the political-administrative level (ministry), the other the technical level (institute) or they represent two different ministerial realms (agriculture and environment, respectively).

I suggest that you in the legislation introduce the clear appointment of the competent authorities. Right now it is clearly given by the law/draft law that it is the Ministry of Health but the appointment in itself is missing.

The EU has no power to intervene in which realm of ministries that you place the competent authority (health, environment, industry..). The EU-concern is that Member States appoint their competent authorities and provide the necessary conditions, capacity of human resources and material resources for them to fulfil their tasks. In this regard, see what the REACH Regulation says about supporting the ECHA-Committees. See also what is written about this in the Chapter 1 of this report.

It is important that the staffs taking part in the progress reporting, screening and ECHA-trainings are the staffs most engaged in the harmonisation of rules, competent authority tasks and inspections. For this aim, do put emphasis on coordinating the contacts with the EU Commission (on screening of membership negotiation possibilities, etcetera) and do further develop the contacts with ECHA (on IPA-supported activities designed for candidate countries).

Strategy and the establishment of task forces

Ref Article 97
Do develop also the joint BiH national strategy and set up the joint BiH national task force in this area. It would certainly be useful given the situation that exists of delegation of powers to the separate parts of the BiH state.

It is important to establish a working relation and dialogue with industry all through the preparatory efforts to become the EU-member.

Poison information guided by the WHO

In all main respect the set-up and activities of so called poison information centres are guided by the Worlds Health Organisation: Monitoring of incidences of poisoning; Logistics of mobilising the most needed anti-dots; 24 hours telephone service; Network contacts countrywide with physicians; etcetera.

The Member States according to the CLP Regulation (and BPR referring to CLP) have to ensure that the health emergency response service get the prescribed data from Industry (Ref: The CLP Annex VIII that is underway to become issued) and that it does not make use of these data for any other aim than for health emergency response. The set-up and the activities of poison information might be regulated by purely national domestic law in the MSs but under the EU Biocidal products legislation and the EU Chemicals legislation these centres are not further involved in the legal systems.

MS reports

Reports that you have to give in each five years under BPR, CLP and REACH are of the kind of monitoring the breakthrough of the rules, compliance, operating matters etcetera, This you may achieve with enforcement data (for example inspection reports) but also by narrative reports on helpdesk services, statistics from helpdesk operations and/or statistics based on national registry information.

You are not supposed to provide reports of this kind through the pre-accession period although the information wanted for accession progress reports are of the same or very similar kind.

Remember that laying the legal ground is not just about the transposition of EU-rules as such – on the paper – nor solely the incorporation when it comes to key regulation provisions – but the readiness in practice of your industry and your administration, the entering into force in due time before accession of crucial rules, the acquaintance to the rules within the ranks and files of Industry, your institutional capacity and so forth.

Regarding penalty provisions and enforcement of compliance

Ref Chapter XII:
Consider to establish a rather short list of descriptions of violations of the law which are apparently serious violations easy to judge (in terms of white and black): Like when someone does not provide the classification and labelling, or does not provide the SDSs, or does not provide it in the official languages, all the clear material breaches with the law.

Ref Chapter XI:
I think inspectors should be entitled to order the correction of behaviour when it comes to the total of rules in the law. Any rule under the law should be possible for an inspector to enforce on others, as long as (s)he points at the clear reason why it should be obeyed.

Chapter 4: Recommendations for the transposition of the REACH Regulation

The point of departure of these comments is that legislation referring to chemicals placed on the market in Bosnia-Herzegovina will be harmonised to EC-rules.

Introductory comment

The REACH-regulation contains provisions for the registration, evaluation, authorisation and restriction of chemicals including rules on safety data sheets. The safety data sheet rules build on the Globally harmonized system for classification and labelling (GHS).

Industry and administration have to regard the importance of these rules and get acquainted to them.

Fully to adopt the REACH-system is not possible for an EU Candidate country. The design of the REACH-system stipulates to a large extent that you are the member to participate in it. Furthermore, to adapt to the system presupposes the access to and support from the common market (EEA). The knowledge generation demands, the communication demands, the cost-sharing and data-sharing, the compilation of safety data sheets with joint contributions from suppliers and downstream users are typical features that do not fit into a normal-sized country standing outside the Community, with normally a very limited chemicals sector, high dependence on imports and lacking experience in this area that is a virgin area to most countries.

Additionally, a candidate country cannot rely on the cooperation with the Commission, ECHA and the Member States in the way that full participation in the REACH-system stipulates.

General recommendations

- Align to the REACH-regulation in a way that ascertains:

i) the satisfactory and reasonable transposition of the rules into your legislation,
ii) the necessary capacity development within industry and administration; and
iii) the sufficient degree of implementation of the rules in practice

Crucial to your implementation will be that you transpose components of REACH to the extent that is necessary, possible and otherwise desirable. The transposition has to be balanced. At least as important as the transposition as such are that:

- The transposition is based on the Rule of law,

- The implementation starts in real within the ranks and files of manufacturers, importers and users of chemicals during the pre-accession period, and that
- Preparations include the strengthening of your institutional capacity in the area (your core administration / competent authority and inspections).

The following REACH-obligations presuppose membership and are not possible to implement before accession. They will thus enter into force on accession day. The sole option for your industry is to prepare for managing them at that time in the future:

- Duties to perform the Chemicals safety assessment and make REACH-registrations,
- Obligations and rights to communicate in the supply chain on conditions of use of substances, exposure scenarios and risk management recommendations,
- Possibilities to apply for REACH-authorisation to use substances of very high concern (SVHC; the substances included to Annex XIV of the REACH-regulation)

Recommendations for the route of transposition

Concerning the legal scheme

- Base the transposition of the regulation on framework parliamentary law (the identical laws on chemicals to be prepared in the entities of BiH)

- Issue the necessary general obligations, mandates to the executive powers, appointments of competent authorities and inspections, penalty provisions and enforcement provisions by the parliamentary law / the laws on chemicals. See the recommendations in the Chapters 1 and 2.

- Adopt the further REACH-definitions needed in secondary legislation in addition to those REACH-definitions which are proposed to be issued with the laws on chemicals

- Prescribe tasks of competent authorities and inspection in your decrees provided that such tasks will not become prescribed directly through parliamentary law and to the extent that such tasks are deemed needed to specify on the secondary level of legislation

- Incorporate with your decrees the annexes of the REACH Regulation with the necessary changes of references or incorporate these annexes into Ministry rulebooks

- Incorporate to your decrees as far as possible the wordings from the REACH Regulation and maintain as far as possible the same numbering of articles, paragraphs and annexes

- Regarding my proposal to you to provide possibilities for “conditional authorisation of continued use of SVHC” during the period of accession: Do consider to borrow administrative-technical requirements from REACH as far as it suits the purpose of these purely domestic provisions in support of the REACH-implementation

Recommendations for achieving the satisfactory and most reasonable alignment

Concerning REACH-registration

- Your industry has to get prepared for REACH-registration. There is no reason to establish a kind of national registration with the same or very similar purpose during the pre-accession period. For the purpose of preparation to manage REACH-registration, it would be really good to establish a REACH-helpdesk and start REACH-information activities on a continuous basis as soon as possible and focussing on needs of SMEs

- If you establish a registry, do base this registry on the pre-accession needs and future member state needs for having an overview of your joint manufacture and import of chemicals (BiH national market), with details on the active companies, the chemicals on the market, the use of substances in these chemicals etc. Such a registry should be considered a highly relevant complementary and REACH-supporting activity, facilitating the implementation and enforcement of REACH-harmonised rules today and industry compliance to the REACH-regulation once BiH becomes the EU-member.

- You can work with a national registry run through dual command on equal terms in the two main entities of the BiH and where the allocation of data between the entities is based on where your chemical manufacturers and importers are seated (where the company's head office is situated)

Concerning Safety Data Sheets (SDS)

- Adopt the REACH-SDS rules so far as these are GHS-rules are made mandatory in the Community but not yet in the BiH. Let first the rules enter into force for substances. Let them enter into force for mixtures with the sufficient period of grace

- Coordinate the entering into force of SDS-rules with the time schedule for CLP-rules becoming compulsory for substances and mixtures respectively

- Omit to implement the REACH-SDS rules that are additional to the GHS-standard. Those are the rules referring to communication demands, the contribution of exposure data from downstream users, compilation of exposure scenarios and demands for risk management measures that ensure no adverse effects from chemicals on health and the environment

Concerning Substances of Very High Concern (SVHC)

- Adopt the EU Candidate list as part of your legislation, although it is not a legal text of the EU but an instrument produced and used in the centralised REACH-substance evaluation procedures. The reason for my proposal is that this list has a regulatory role in the provision that says that the supplier of an article shall inform the recipient of this

article on the presence of 0.1 percent or more of a candidate list substance in the article (Ref: Article 33 of the REACH Regulation)

- Make the general ban on the handling of substances listed in REACH Annex XIV for which the sun-set date is reached, enter into force close to accession day

- Accept REACH-authorisations and extend these authorisations to your country for the companies given the REACH-authorisation in the EU, provided that the EU-company uses the substance under the same strict conditions in your country and applies the rigorous risk management measures stipulated by the EU REACH-authorisation

- Consider to provide the possibility of "conditional authorisation for the continued use of SVHC" for the period from when such a general BiH-ban on SVHC enters into force up to accession day in order to have a controlled use of these substances until you become the EU-member and the users have to follow the REACH-authorisation rules. With "continued use.." should be understood that only those who are already users who are dependent on this use can apply for the "conditional authorisation….."

- The domestic provisions for "conditional authorisation…." should be issued so that it is clearly and easily seen that these rules are complementary and supportive to the implementation and enforcement of EU-harmonised rules

- Ensure that "conditional authorisation….." may only be considered when the applicant

- presents a Chemical safety assessment (based on the method and requirements prescribed in the REACH-regulation),
- has no access to alternatives for the same aim, and
- is able to assure the adequate control of the risks (specific conditions for the use and the corresponding risk management measures that make the actual exposure equal to or below the no effect exposure level /or concentration

Concerning REACH-restrictions

- Adopt the REACH-restrictions. Let them enter into force generally within a period of at least three years but in due time before accession, where they not already are in force as in the Serbian republic

- Provide for mandates to the ministries to issue further exemptions from the restrictions within the limit of the period of pre-accession

- You may get an overview of national needs for further exemptions from restrictions by establishing the possibility for chemicals manufacturers and importers to notify the competent authorities about their actual use-dependence on chemicals subjects to the forth-coming restrictions

Concerning the Chemical safety assessment method

- Make it mandatory for anyone who performs a Chemical safety assessment to follow the method described in REACH Annex I and apply the "REACH-standard data regime" - depending on the yearly volume of the substance per company and whether the substance is regarded a SVHC

Comments and background to the recommendations

It is important in order to get ready for EU-membership, that Bosnia-Herzegovina with its transposition gets rules that it may implement in real within the ranks and files of its industry.

Prepare Industry now for REACH-registration at accession

REACH became for several years in people's minds often synonymous to REACH-registration. Most people's eyes turned to that. Doing this people focussed very much on the huge number of substances to be registered, the many potential registrants and the large amounts of data to get registered in the EU during the system's phase-in period 2010 to 2018. It is the so called "phasing-in-period" of REACH-registrations that still has two years left to become completed in 2018.

This phasing-in period will be over when BiH enters the EU. Your chemicals manufacturers and importers have to register in the same way as any newcomer-registrants in the REACH-system to the extent that your companies have not already registered on-going activities as being active also on the EU-market with a seat in any of the member states. I have not suggested that you should prepare for the registration of your companies by any special rules enforced on them during the pre-accession period. However, companies with strong incentives to enter the EU may use a short-cut by already before accession establish themselves in a Member State and register to ECHA.

Generally speaking the best way to get industry to prepare for REACH-registration is to implement EC-harmonized legislation as soon as possible, regarding classification, labelling and safety data sheets. The organisation of an official REACH helpdesk will be a decisive instrument for information about the precise REACH-registration demands. REACH-registration demands may also be the subject for information campaigns and trainings organised by the Chamber of commerce, industry branch institutes etc.

Foresee that Industry establishes the practice and routines of using safety data sheets

The system of safety data sheets is key to modern industry-driven chemicals risk management. Safety data sheets may establish and maintain close relations between suppliers and users of chemicals. It is the main way to disseminate and exchange information within industry on the hazards from chemicals placed on the market.

You should try to establish the practice of these sheets as soon as possible in all of the BiH. First the obligation should concern sheets on substances, in a somewhat later step sheets on mixtures, because industry needs sheets on substances to develop sheets on mixtures. You should coordinate this stepwise introduction in the federation with the introduction of classification and labelling requirements for substances and for mixtures.

To a large extent your industry will be helped by sheets stemming from industry in the member states and from Serbia and which are entering BiH together with your import.

A proposal on how to regulate SVHC up to accession day

The Candidate list (http://echa.europa.eu/regulations/reach/authorisation/the-candidate-list) will prove to be an important tool for the implementation in real of EU chemicals legislation in your country. (Keep the name of the list as it is, or try another name that might more clearly say what this list is all about. Call it possibly the "Observation list")

The Candidate List is published at the ECHA-website in accordance to article 59.10 of the REACH-regulation. The ECHA-publication is the only deemed authentic version of this list. The inclusion of substances to the list may place immediate legal obligations on companies referring to Articles 7 (Registration), 31 (Safety data sheet duties) and 33 (information on substances in articles) of the REACH Regulation. For the time being there are 168 substances /groups of substances listed.

You should spread the information about candidate substances widely. Which substances that are subject to regulatory action has a huge impact on the choice of chemicals and on investments in chemical techniques today and for the future.

The Authorisation list (List of SVHC the use of which requires authorisation) contains at present 31 entries. The list is issued as Annex XIV to the REACH-regulation and continuously updated at the ECHA-website (http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list). The use of these substances / groups of substances has so far in 14 cases passed the sun-set date which means that the substance from that date is not allowed to handle any longer without a REACH-authorisation.

Make the substances and groups of substances on the Authorisation list subject to a general ban so far the sun-set date of their allowed use is passed. The sun-set date of each substance is given in the annex XIV / authorisation list. So when you issue your SVHC-list there could be a common date of prohibition issued for the SVHC the use of which has passed sun-set. You may decide on a later date than the EU sun-set date as long as the date you choose is within your pre-accession period.

If deemed necessary you should provide for the generous periods of grace from this general ban. It will make bans enter into force more vigorously. It could facilitate very much both for your industry and for your administration.

REACH-authorisation is an individual concession, granted on a case-by-case basis. You are able to adopt decisions on REACH-authorisations if you like and make them valid also in BiH for the companies granted the authorisation in the EU under the same strict conditions and applying the same rigorous risk management measures as in the EU.

Your domestic use of SVHC becomes a different matter. If companies in BiH are not on the EU-market but head for REACH-authorisation on accession, they may be stuck in the meantime, as struck by the general ban.

You could provisionally handle Bosnian-Herzegovinian companies heading for EU-authorisation on accession by launching the proposed, purely domestic, "conditional authorisation for continued use of SVHC". If you do this, you may include the following requisites for the authorisation:

- the use of an alternative substance, chemical or technique has to be the first choice. Continued use of the SVHC is admitted only when the search for available less hazardous alternative for the same aim on the market is exhausted; and that
- the conditional authorisation may only consider use conditions where the SVHC is adequately controlled (the actual exposure for the substance has to be equal to / or be below the no-effect level).

Make it obligatory for applicants for "conditional authorisation…." to perform and present a Chemical safety assessment according to the rules in REACH.

I think such a provision could be really supportive to the implementation of REACH. It could help to enable companies that are dependent on the use of SVHC today to head for a REACH-authorisation once BiH enters the EU.

It is important that you include only already existing cases of use in the country.

Make it possible for the ministries to repeal "conditional authorisations…" when this is in the national interest. For example when it is in the interest of your "economic and social development". There are certainly many possible wordings which serve as metaphor for demands and needs due to EU-accession.

Have restrictions enter into force in due time in the whole of BiH

The REACH-restrictions concern at the time being 64 entries of substances or groups of substances (March 2016). You find them in the Annex XVII of the REACH Regulation. All together the number of substances restricted through these entries is over 1100, the vast majority of these are CMRs (listed in appendices to the Annex XVII) which are prohibited to use in chemicals intended for the general public.

Further important restriction on chemicals are found in the POPs Regulation, the Export-import Regulation, the RoHS-directive, the Mercury Regulation and the so called products directives, like the Toys-directive.

Since restrictions are general and exemptions from restrictions and other conditions in this regard also are general, this REACH-title brings no difficulties of the kind we see with REACH-authorisations.

Many of the REACH-restrictions refer to substances that are "obsolete" in the meaning that they are already phased out of commercial and industrial use because of their dirty history and the ease by which they could be technically replaced and switched out of use. The restriction works to hinder these substances to come back in use.

Restrictions on substances that you are dependent on in BiH are another matter. You may make it possible for companies to make notifications of those uses. On the base of such notifications you could decide on exemptions from the restrictions beyond the general date on which the restrictions are supposed to enter into force.

Restrictions in general could enter into force close to accession. The exemptions may be given for periods of time that do not exceed the pre-accession period.

Possible transposition schemes

I have done the schemes on the following pages with the will to high-light some of the above proposals.

See also the questions posed in italics regarding transposition issues that I included with these schemes and which I regard as still outstanding.

<table>
<tr><th colspan="2">Transposition scheme 1: Chemicals safety assessment (CSA)</th></tr>
<tr><th>REACH Regulation
Title II, Annex I, Annexes II-XIII</th><th>BiH framework chemicals law and decrees transposing REACH</th></tr>
<tr><td>For all registrants, all substances on the market ≥ 10 tonnes per company and year or CMR, save the exemptions regarding substances in Annex III and IV</td><td>For applicants for having conditional authorisation to handle SVHC
/ For others voluntary to undertake /</td></tr>
<tr><td colspan="2">Comments and questions
This may prepare Bosnian-Herzegovinian users of SVHC for REACH.
The general EU-obligation to report on CSA is not reasonable to transpose.
The pre-conditions of the EU-market, making knowledge generation, data sharing and cost recovery possible, do not exist in single normal-sized countries outside the Community

How to prepare other BiH-companies for CSA / REACH-registration?</td></tr>
</table>

Transposition scheme 2: Safety data sheets (SDS)	
REACH Regulation Title IV, Annex II	**BiH framework chemicals law and decrees transposing REACH**
Improved with exposure scenarios considering identified use based on communication in the supply chain and Demands for risk management recommendations if substance is placed on the market	Same demands for all volumes, GHS-implementation
Comments and questions GHS-rules will be fully introduced. Communication in supply chains including exposure scenarios is not reasonable to introduce in the single country, much dependent on international supply chains *How to prepare BiH-industry for exposure scenario and communication demands? When should obligations to provide SDS enter into force in the Federation part of BiH – for substances? – for mixtures?*	

Transposition scheme 3: Substances of very high concern (SVHC)	
REACH Regulation Title VI-VIII, Annexes XIII-XVII	**BiH framework chemicals law and decrees transposing REACH**
Candidate list, information about listed substances in articles; and List of SVHC (Annex XIV)	Lists are introduced, information in articles provided for
Comments and questions *When should the general ban on SVHC (those that have passed sun-set) enter into force?*	

Transposition scheme 4: REACH-authorisation and domestic conditional authorisation of the use of SVHC	
REACH Regulation Title VII, Annex XIV	**BiH framework chemicals law and decrees transposing REACH**
Decisions for individual authorisation	"Conditional authorisation…" if applications are given in before a certain dates. To be repealed at accession day
Comments Lists will be adopted. The provision for information about listed substances in articles will be adopted. Bosnian-Herzegovinian users of SVHC will be better prepared for entering the EU. Conditional authorisation is a domestic provision to be withdrawn at the time BiH becomes an EU-member	

Transposition scheme 5: Restrictions	
REACH Regulation Title VIII, Annex XVII	**BiH framework chemicals law and decrees transposing REACH**
Restrictions in force	Restrictions enter into force with a period of grace in certain cases, when justified
Comments and questions	
Amended restrictions: - Do include transition periods	*Should there be a deadline for companies to notify dependence on use of chemicals subject to forth-coming restrictions?* *Period of grace in the law?*

Chapter 5: Recommendations for the transposition of the CLP-regulation

The point of departure of these comments is that legislation referring to chemicals placed on the market in Bosnia-Herzegovina will be harmonised to EC-rules. The recommendations concern the revision, to the sufficient extent, of already existing EU-harmonised rules in Republika Srpska and the issuing of the corresponding rules in the Federation of Bosnia and Herzegovina and hopefully also in the District of Brčko.

Introductory comment

Classification of chemicals hazards is fundamental to the EC chemicals management system.

The rules on classification, labelling and packaging are crucial to have in place in due time and implemented in practice to a sufficient extent to prepare for accession in the area of chemicals. Both industry and administration have to regard the importance of these rules and get acquainted to them.

The proposed transposition of the regulation refers to experiences from Croatia and Serbia.

Recommendations

- Base the transposition of the regulation on framework parliamentary law. Issue the scope of the legislation, basic definitions, general obligations, mandate to the executive powers, appointments, penalty provisions and enforcement provisions by this law. See the recommendations in the Chapters 1 and 2 (Review of possibilities for non-EU members to align to EU Chemicals legislation; and Legal scheme proposals)

- Issue also the following important CLP/REACH-provisions by parliamentary law:

    i) Rules to reduce demands for testing and tests on vertebrates and prohibitions to perform tests on primates; and
    ii) Prohibition to advertise hazardous chemicals without mentioning their hazards.

- Make the obligations to classify and label substances and mixtures enter into force stepwise. First the obligations concerning substances, a few years later concerning mixtures

- Issue the application rules to the general obligations to classify, label and package chemicals by secondary legislation with the necessary changes of references

- Adopt the List of so called EU-harmonised classification and labelling (CLP Annex VI) as mandatory in the BiH as it is in the EU

- Introduce the ECHA Classification and labelling inventory as an existing useful tool. Make it normative to use this inventory

- You must of course omit to implement CLP-provisions which stipulate that you are already the EU-member, i.e. the demand on manufacturers, importers and downstream users of substances to notify their classification and labelling of substances to the above mentioned inventory at ECHA. You could possibly let them notify it to your competent authority in the area but make sure that such procedure is not perceived as your approval of their classifications

- Listen if it would be possible for BiH through an agreement with ECHA to get access on a case by case basis to the chemical identities of substances given "alternative names" in the EU

- Issue by secondary legislation on the level of the Government / provincial governments / the tasks deemed needed to be given to the competent authorities for the sake of EU-alignment and which are tasks that do not follow in a clear way from tasks directly issued by the parliamentary law

- Incorporate the CLP-annexes into secondary legislation, possibly Rulebooks, with the necessary changes of references

- Update your CLP-harmonised rules as the EU amends the CLP Regulation

- Literally incorporate the wordings of EC-obligations, requirements and tasks to the highest possible extent. Maintain as far as possible also the numbering of articles and paragraphs of the CLP-regulation

Comments to the recommendations

Base the transposition on framework parliamentary law

The EC-regulation is issued both by the EU Parliament and the Council. It contains the general principles and obligations as well as detailed precise application rules and technical annexes.

Under the rule of law and the separation of powers in a country that aligns to the EU, it becomes constitutionally normal to place the general EU-provisions in parliamentary law and transpose detailed application rules as secondary legislation. See the recommendations in the Chapters 1 and 2.
I suggest that you also state directly by parliamentary:

- That CLP-classification is supposed to build on available toxicological data and does not demand new toxicological testing
- The CLP-REACH prohibitions on animal testing

- The CLP-prohibition on advertising hazardous chemicals without mentioning the hazards

Make obligations to classify and label enter into force stepwise

First you should let the general obligations concerning substances enter into force. The general obligations concerning mixtures could enter into force a few years later when classification of substances is established in practice. Go for the corresponding stepwise introduction of SDS-rules with the transposition of the REACH Regulation.

This stepwise approach is strongly advisable because your industry will need the classification of the substances / ingredients / in the mixture to be able to classify the mixture.

It is also so that the obligation concerning substances will address comparatively few companies and a minor number of chemicals on the market – the importers and manufacturers of substances are few. The vast majority of chemicals on the market are mixtures and the vast majority of manufacturers and importers are suppliers of mixtures, not of substances. So the stepwise approach also gives time for the majority of the companies concerned to adopt to the new rules and adapt them.

The time period for the obligation regarding substances could be brief. See below the possibilities to easily find out the classification of a substance from the ECHA Classification and labelling inventory. The usefulness of that inventory also makes it possible to admit a rather short period of transition until the obligation enters into force concerning mixtures.

Incorporate CLP-application rules

Transpose by secondary legislation the application rules and the CLP-annexes I-IV on how to classify, label and package chemicals in detail. Do just undertake necessary changes of references where the EC-regulation refers to the Commission, to ECHA, to other pieces of EC-chemicals legislation etcetera.

Adopt the EU Classification and labelling list

I recommend you to adopt the EU Classification and labelling list of so called harmonised classification and make the classifications on this list mandatory as they are in the EU. It would give your industry the access to ready-made, ready-to-use classifications: Complete classifications of about 3000 substances which had a mandatory classification already under the former EU-system for chemicals control; and about 1000 classifications of substances that are assessed to be carcinogens, mutagens, toxic to human reproduction (CMRs) or sensitive to the respiratory tract.

The classification of CMRs and of sensitizers to the respiratory tract in this list are not the complete classifications. The further kinds of possible hazards from these substances

adding to their classification and labelling have to be searched for in the ECHA Classification and labelling inventory - or must be assessed by industry according to hazard criteria in the CLP-annexes I and II.

If you issue a mandatory classification and labelling list of your own, based on your own industry's assessments, it would mean that you place a tremendous load of work on yourself but catch comparatively few classifications on your list (those of hazardous substances on the BiH market). Moreover and not less important, you would run the risk that mandatory classifications of substances in the BiH could deviate from the EU mandatory classifications.

Make maximum use of the ECHA Inventory

I strongly recommend you to introduce the ECHA Classification and labelling inventory as an existing useful operation tool.

Make it normative to use this inventory. Refer to it as an available asset to your industry (as it is a useful and used tool worldwide). The inventory is a product of the CLP-regulation but constitutes no legal piece as such in the EU-system. You find the database at this site: https://echa.europa.eu/regulations/clp/cl-inventory. So as a helpful existing tool you may easily refer to it without having to refer to the EU-legislation.

With the use of this inventory your industry will get access to the classification of all registered substances on the EU-market. Situations will be few where a company in your country has to undertake the complete hazard assessment, come up with a classification and find out the labelling requirements itself. Although, anyone placing a chemical on your market should respond for the choice to make use of an already existing classification, for example originating from the EU-inventory. (S)he should stand responsible, regardless of how a classification has been derived, for judging that the classification – as well as the labelling – is appropriate.

If you set up an inventory of your own for the classification and labelling of substances it will contain just the substances commercially and industrially used in BiH. It will not be as useful as the ECHA inventory. It may also come to include classifications which are contradictory to the classification provided by the ECHA inventory.

Pass by provisions presupposing membership

Some CLP-provisions stipulate that you are already the EU-member, that the manufacturer or importer is seated within and operates on the European Economic Area of the EU or that the competent authority is a Member State body directly contributing to EC procedures or ECHA-tasks. You should pass by such provisions when it comes to the transposition since they are not possible to establish in the period of pre-accession. Do prepare industry for these future obligations and do build the capacity of the competent authority to manage these future tasks.

Of this kind is the obligation already discussed above that manufacturers, importers and users of substances shall notify their classification and labelling to an ECHA-inventory. Of this kind are also the tasks placed on the Member state to contribute to this "harmonised classification and labelling" in the procedures to amend new entries to the list / CLP Annex VI.

Do not try to copy such EC-procedures by setting up parallel copies of them during pre-accession. Running such copies of procedures would most probably result in decisions that deviate from EU-decisions. It would also be a waste of costs and time since you can already take advantage from the existing EU-procedures, you can use the ECHA-inventory, etcetera.

Consider to accept "alternative names" on substances given in the EU

The option to apply for an "alternative name" for the chemical substance is a CLP-provision that makes industry able to keep a certain use and usability of a substance secret in order to protect a commercial advantage. Each company that likes to use this provision in the EU can apply for the alternative name.

It could be problematic for you as a Member candidate if your legislation would not accept that EU-companies operating in BiH do use such alternative EU-names for their substances.

So consider to allow companies to use their alternative names as decided in the EU also in BiH. Listen if it may be possible for you, for example through an agreement, to get the confidential information from ECHA on what an alternative name stands for, when justified by your competent authority's needs to know on the case-by-case level.

All in all: You implement GHS the way the EU does it

About forty countries in the world have implemented GHS as the UN-recommended standard making it mandatory or voluntary. Now you are preparing to launch it in all of BiH. You do this implementation in the same manner as the EU does.

You may include to the scope of your legislation that it implements the GHS. If you do not refer to the CLP Regulation in your legislation, you may inform in other ways that BiH implements the GHS the way the EU implements it.

GHS; What we add and exempt

Requirements for classification and labelling that are additional to the GHS-standard are found in CLP Annex II. These are certain statements of hazards and precautions, requirements for child-safe fastenings, requirements for tactile warnings to persons with eye-damages…and some further requests. (Safety data sheets communication requirements that are additional to the GHS-standard are presented in REACH Title IV)

The following least hazardous GHS-categories are exempted from classification and labelling requirements in the EU:

- Acute toxicity cat 5;
- Skin irritation cat 3;
- Eye irritation cat 2b;
- Aspiration toxicity 2;
- Flammability of liquids cat 4; and
- Environment toxicity cat 2 and 3

The EU intends this way to direct risk management measures towards the use of hazardous substances of higher concern. Environment toxicity (cat 2 and 3) are in the EU considered just for transport labelling in the case of bulk transports.

Update your CLP-harmonised rules as the EU amends the CLP Regulation. Next will be the update of CLP to the 6th and 7th GHS-revisions.

Keep to EC-formats

To implement a regulation is different from implementing a directive. The wordings of the regulation will enter into force on accession. Thus, when transposing EC-regulations for the period of pre-accession better maintain the text as such or find the very similar wordings. Maintain as far as doable also the numbering of annexes, articles and paragraphs.

Chapter 6: Recommendations for the transposition of the Biocides Regulation

The point of departure of these comments is that legislation referring to biocides placed on the market in Bosnia-Herzegovina will be harmonised to EC-rules.

Introductory comment

Biocidal products are necessary for the control of organisms that are harmful to human or animal health or the environment and for control of organisms that cause damage to natural or manufactured materials. However, biocidal products can pose risks to humans, animals and the environment due to their intrinsic properties and associated use patters.

The purpose of the EU Regulation[11] on biocides (BPR) is to improve the free movement of biocidal products within the Union while ensuring a high level of protection. The BPR contains a number of provisions and instruments to achieve these purposes. The BPR lays down rules for the establishment of a list of active substances which may be used in biocidal products, rules for the authorization of biocidal products, the mutual recognition of authorizations within the Union, the making available on the market and use of biocidal products within one or more Member States or the Union, and the placing on the market of treated articles.

The responsibility for the different activities stipulated in the BPR is divided between the companies wishing to place biocidal products on the market, Members State´s competent authorities, the Agency (ECHA) and the Commission. It is highly important that all parties has acknowledged where the responsibility lies and allocates the requested resources so that the obligations laid down in the BPR can be carried out efficiently and effectively.

To fully adopt the provisions laid down in the BPR is not possible for a candidate country due to the fact that the system envisages work sharing between different parties, access to specific information and tools as well as participation in certain procedures with the purpose of placing biocidal products on the market. To implement such system presupposes membership and is not considered manageable in just one country.

[11] 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

General recommendations

Alignment to the BPR should ascertain:

- the satisfactory and reasonable transposition of the rules into your legislation,
- the necessary capacity development within industry and the administration; and
- a sufficient degree of implementation of the rules in practice

Only components which are considered necessary should be transposed into the new law in order to be manageable and to facilitate approximation. Crucial components in addition to the transposition is that:

- the implementation starts in practice according to the obligations laid down in the legislation
- the preparations include the strengthening of your institutional capacity in the area (your core administration / competent authority and inspections)

The transposition should be based on the Rule of law. The existing law of Republika Srpska and the draft law of the Federation Bosnia and Herzegovina (FBiH) are both based on the previous EU directive on biocides. This is considered a good starting point and together with certain aspects included in the BPR it will serve as a suitable basis for the development of the new legislation.

To fully implement the requirements laid down in the BPR for authorization of a biocidal product is not considered possible before accession into the EU since the system is based on cost and system sharing. Time and resources should rather be allocated for preparation of industry and the administration. Below, a number of recommendations within different areas are found which are in line with the above mentioned approach, taking into consideration the fact that the current legislation needs to be updated in accordance with the BPR, where possible.

Recommendations for the route of transposition

Below are some general aspects concerning the legal scheme and lists of recommendations for a number of more detailed areas included in the BPR. The order of the areas does not reflect their degree of importance, rather are they mentioned, for the sake of clarity, according to the structure of the BPR.

Concerning the legal scheme

The Law on Biocides in the Republika Srpska and the draft law of the Federation of BiH aim to ensure a high level of protection of human and animal health and the environment and to establish unified requirements for the placing of biocides on the market across BiH. The Law also aims to enhance and improve the conditions of trade in biocides with EU states and other countries, while being an incentive to safer manufacturing and ensuring competitiveness of economy. This can be achieved by basing the transposition of the

regulation on framework parliamentary law (the identical laws on biocides to be prepared in the entities of BiH) as proposed, while taking the provisions of the BPR into consideration.

It is important to ensure that the transitional measures concerning the adaptation to the different procedures laid down in BPR are feasible, especially when it comes to timelines, extent and volume. Please also consider the following:

- It is considered necessary to issue the general obligations, mandates to the executive powers, appointments of competent authorities and inspections, fees and charges, compliance with requirements and penalty provisions. Prescribe tasks of competent authorities and inspection in secondary level of legislation when deemed necessary to specify in detail.

- Incorporate as far as possible the BPR definitions and wording both in the Law on biocides and when necessary in secondary legislation in order to be as clear and consistent as possible.

- Set up a program for the biocidal products on the BiH market with the purpose to establish the transitional measures required. The program should set up a structure and establish working routines to support a stepwise approach for the necessary adaptations that need to be made in order to fulfil the requirements in the BPR on accession day. The program should help the administration to prioritize and aim at being as smooth, transparent and simple as possible.

- Regarding the matter of access to justice it is suggested that the Charter of Fundamental Rights of the European Union (2000/C 364/01) art. 47 is consulted.

Definitions and scope

Consider to use the definitions as stipulated in the BPR and ensure that the application of the definitions are consistent and relevant throughout the legal text. Due to the extended scope of the BPR (amended by Regulation (EU) No 334/2014) art. 93 and 94 lay down transitional measures for biocidal products not covered by Directive 98/8/EC, such as biocidal products for which the active substance is generated *in situ* and transitional measures concerning treated articles.

In situ generates active substances

An in-situ generated active substance can be defined as an active substance that is not directly supplied to the user. The in-situ generated active substance is intended to exert a biocidal activity during its application. Different methods of generating such active substances in-situ have been identified within the EU, although technical issues related with the in-situ generation of biocidal active substances will have to be addressed on a case by case basis in the evaluation dossier. A guidance note has been developed by the Competent Authorities on how to interpret and handle the concept of active substances generated in situ. Consider to extend the scope of the law on biocides and include derogations in line with the approach taken in art. 93 with reasonable application dates.

Treated articles

A treated article shall not be placed on the market unless all active substances contained in the biocidal product that it was treated with are approved for the relevant product type. The BPR applies to newly manufactured, treated articles but also to used and second-hand treated articles imported from a third country when they enter the Union market for the first time. This applies even to used and second-hand treated articles imported from a third country that were manufactured before the BPR became applicable.

Up to 1 March 2017, treated articles placed on the EU market may still have been treated with biocidal active substance neither approved/included in Annex I of BPR, nor under evaluation in the review programme. Art. 94 lays down the transitional measures for treated articles according to the following:

From 1 March 2017, treated articles may only be placed on the EU market if all the biocidal active substances they have been treated with are either approved/included in Annex I of BPR, and thus comply with Article 58(2), or are under evaluation in the review programme.
In case a decision is taken after 1 September 2016 not to approve the active substance for the relevant PT, the treated article can only be placed on the market for another 180 days after this decision. Consider to extend the scope of the law on biocides and include derogations in line with the approach taken in art. 94 with reasonable application dates.

Biocidal products families (BPF)

The concept of frame formulations in the previous biocides directive has been replaced by biocidal products families in the BPR. The BPR defines a biocidal product family as a group of products with similar use, the same active substances, similar compositions with specified variations and similar level of risk and efficacy. Consider to replace the old concept of frame formulations with the new concept. However, in order to establish the highest level of risk for a product of the family in question, a thorough risk assessment for human health and the environment should be requested as part of the application for authorization. If this requirement is currently not suggested to be part of the data requirements for an application, derogations may be introduced. For further options to place a BPF on the market, please see what is said about **Same biocidal product** below. For further guidance the discussion and guidance notes developed by the Commission regarding biocidal product families are available.

Data requirements

The data requirements for a dossier for an active substance and for a biocidal product are set out in Annex II and Annex III of the BPR. The data requirements are extensive, however the BPR allows for the possibility of waiving, owing either to the exposure associated with the proposed use of the biocidal product, or whether it is scientifically necessary or technically possible to generate the data. Consider a derogation with regard to the data requirements for active substances and biocidal products, please see below in the context of approval and authorization requirements.

Approval of active substances

For each active substance which is approved within EU an implementing Regulation is adopted, including the conditions under which the active substance is approved as well as dates of approval and expiry. In a case when an active substance is not approved an implementing decision is adopted. Approved active substances are included in a Union list which is electronically available to the public. Active substances which may be included in products which are under the scheme of a simplified authorization procedure are listed in Annex I to the BPR. Continue to refer to the decisions for active substances including relevant provisions taken within the EU. The decisions for approval or non-approval of active substances for a specific product type should be taken into consideration when either granting or withdrawing an authorization or removing a biocidal product from the market of Bosnia-Herzegovina.

Art. 95 lays down the transitional measures concerning access to the active substance dossier. Derogations with regard to these measures may be introduced in BiH, however industry should already now be made aware of the fact that they will have to abide to the requirements on accession day. Unless access to accepted data for the active substance can be shown the product can no longer be placed on the market. Information campaigns encouraging the manufacturers of biocidal products to consult their suppliers of active substances in order to ensure that their source is supported by data is strongly recommended.

Conditions for granting an authorization

National authorization

Revise the two-step approach which is laid down in the proposal of the law of the FBiH and included in the law of the Republika Srpska and replace it with a scheme which is in line with the procedure for national authorizations of biocidal products in the BPR. Introduce derogations under a transitional period which allow for requirements which are achievable while still considered satisfactory with regard to the safety to man and the environment. Lay down the principles for a programme which will ensure that the products, on accession day, are authorized in accordance with the BPR. Introduce expiry dates which reflect the programme.

Simplified authorization procedure

Refer to the active substances included in Annex I of the BPR and introduce requirements in accordance with the BPR for authorizations of products.

Same biocidal product

The Commission implementing regulation (EU) No 414/2013 specifies the procedure for the authorisation of same biocidal products. Where applications are submitted to the same receiving competent authority for two or more authorisations of biocidal products with the same properties, the authorisations may be granted based on one single product evaluation.

This is meant to be a simple way of placing identical products on the market, please consider the introduction of this concept in the Law on biocides.

Mutual recognition and union authorization

Introduce an alternative optional[12] scheme for applicants who wish to place a biocidal product or a biocidal product family on the market of BiH with reference to a decision taken in another country. The principles laid down in art. 33 in the BPR are partly of relevance, however consider revising the timeframe for different steps, if necessary. The application shall at least contain the draft assessment report from the evaluating country, the summary products characteristics (in case of a decision made by an EU member state), and a translation of the decision. An assessment whether there are reasons to refuse the application or adjust the terms and conditions should be made as part of the overall assessment. The decision taken for authorization of a product to be placed on the BiH market should be considered as a decision made in accordance with the BPR and require just a formal adjustment on accession day. If there are differences between the terms and conditions in the summary products characteristics compared to the one in the EU member state, this should be changed in accordance with the requirements in Art 37 and/or the Implementing regulation (EU) No 354/2013 on changes of biocidal products.

The authorization of a BPF which has already been granted an authorization in an EU member state may be made in line with the EU principles for mutual recognition i.e. the assessment made by another country could serve as a basis for the registration in BiH, provided that the company who wishes to place the product on the market submits the relevant information. In case a company wishes to place an additional product on the BiH market, the procedure described in art. 17.6 in the BPR may be adopted.

A union authorization is issued by the Commission and shall be valid throughout the Union unless otherwise specified. No product authorization at Member State level is required before placing the product on the market in a Member State. The concept may be defined in the law, however, the applicability before accession might be difficult unless there is a possibility to refer to the authorization issued by the Commission as part of the requirements for placing the product on the BiH market. Possible access to the Commission decision as well as to relevant background documents shall therefore be investigated.

Changes to existing authorizations

Implementing regulation (EU) No 354/2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council lays down a detailed procedure for the amendment of authorizations, in accordance with art. 51 of the BPR. You may consider, as a stepwise approach, to introduce the classification of different types of changes. With regard to the introduction of timelines for different procedures please make sure that they are feasible.

[12] Optional in the sense of not requiring the same information for applications handled within other procedures in the law. In case of reference to a decision from a Member State within the EU, the requirements stipulated in the BPR need to be fulfilled in order for the reference MS to be able to grant an authorization.

Transposition of national authorizations

On the day of accession into EU, biocidal products placed on the market of BiH need to be authorized in accordance with the requirements laid down in the BPR. A programme including a stepwise approach is suggested, preferably where products belonging to the same product types are grouped together. Products containing active substances not approved for that specific product type need to be removed from the market. A suitable point of departure could be to start reviewing products in product types already finalized within the EU such as rodenticides and wood preservatives. Make sure that applications for renewal is submitted in due time for the Ministry to be able to handle them. The programme may also consider aspects typical for the BiH market with regard to type of industry and the need for certain products. The program should aim at practical and simple solutions and should help the administration to prioritize and set up a structure for the adaptation to the requirements of the BPR. All products on the BiH market which include an active substance approved for that specific product type will have to fulfil the requirements in the BPR in the future. Products for which the active substance is not yet approved but where the active substance is included in the review programme or where the products were not within the scope of the biocides directive may stay on the market according to current national provisions. In case of products containing new active substances, others than the ones covered by art. 93 of the BPR, a provisional authorization may be issued in accordance with art. 55(2). In case of products containing an existing active substance not yet approved, the substance supplier or the product supplier need to be included in the list referred to in paragraph 1 in art. 95 of the BPR.

Period of grace

In case an authorization is cancelled or amended a period of grace shall be granted for the making available on the market and use of existing stocks. Consider whether the time of 180 days for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal product, as stated in the BPR, may be extended in the BiH biocidal law. Rather than having to destroy the existing stock it may be advisable to continue to use it, especially in cases where the product has not proved to cause any harm to human health or the environment. It will most likely also contribute to fewer applications for exemptions for selling out stock.

Parallel trade

The introduction of parallel trade will be limited to products authorized in accordance with the provisions in the BPR. In case a product is authorized and placed on the BiH market according to the optional mutual recognition scheme it may be possible to grant a parallel trade permit for a biocidal product that is authorized in another member state if it can be determined that the product authorized in the other member state is identical to the biocidal product already authorized in BiH. Since this is a fairly simple way to place identical products on the market it may be worth considering whether it is feasible to include the possibility to a limited extent in the new law.

Derogations

Please consider to introduce the derogations from the requirements for making available and use of non-authorized products in accordance with art. 55 and 56 in the BPR including exemptions from the information requirements where the competent authority issuing the permit shall inform the other competent authority and the Commission.

Placing on the market of treated articles

Art. 94 contains transitional measures concerning treated articles, see what is written about treated articles above. It applies to treated articles which are not biocidal products. A treated article shall not be placed on the market unless all active substances contained in the biocidal products that it was treated with or incorporates are included in the union list of approved active substances, for the relevant product type and use. The Commission has developed a number of discussion and guidance notes. The main requirements from the authority refer to inspection and enforcement tasks. Please consider the introduction of the concept of treated articles but include derogations for the applicability depending on the capacity of mainly the inspectors of the BiH.

Data protection and data sharing

It is stated in art. 59 in the BPR that data submitted for the Directive 98/8/EC or of the BPR shall not be used by the competent or the Agency for the benefit of a subsequent applicant unless a letter of access has been submitted or the relevant time limit for data protection has expired. The data protection periods are laid down in art. 60. Data protection rules will have to be followed on the day of accession. Although it is not mandatory to abide to the BPR data protection rules before accession it may be wise to at least consider the inclusion of an article on data protection in a similar way as is already included in the Law and in the draft law on biocides as well as a way to keep track of which data have been used for the authorization of a product and when it was used. Until the rules apply the data protection issues are considered a civil matter between the companies.

Register

Art. 21 of the Law on Biocides lays down the provisions for a Registry of biocides. Please ensure that the register is operational and updated. EU member states have, in addition to their own registers access to the Register for biocidal products (R4BP) which include information on both products and active substances. The intention of the R4BP is also to be a mean for communication between MS, the Agency and the Commission.

Fees and charges

According to art. 80 of the BPR on fees and charges member states shall directly charge applicants fees for services that they provide. Member states may also levy annual fees with respect to biocidal products made available on their market. The rules on fees shall respect the principles such as levels sufficient to cover the cost, the possibility of partial reimbursement, instalments and waivers, fixed deadlines and specific needs of SMEs.

The matter of fees is of great importance for the ability of the competent authority to perform their tasks. A dysfunctional authority is of no gain for companies wishing to place biocidal products on the market, neither for the protection of human health and the environment. A step forward may be to consider levels and structures in different member states before establishing a national fee system.

Competent authorities

Capacity

It is stated in art. 81 of the BPR that member states shall ensure that competent authorities have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in the BPR can be carried out efficiently and effectively. Introducing the requirements of the BPR stepwise may enable the BiH authorities to build their own competence and optimize their structure. Experiences from several competent authorities from their work on biocides show that there may mainly be a lack of competence with regard to knowledge about the specific use of biocides, exposure assessments for different product types and feasible risk mitigation measures whereas there is more knowledge about intrinsic properties of the active substances and other compounds included in the product. A way to build competence is to take part of other member states´ assessments, which have been scrutinized and discussed in different technical working groups before agreed. There is also a great number of guidance documents to consult which are publically available. A different source of information lays within industry which is responsible for placing the products on the market and which should thereby have the knowledge about the specific use of the product, about the persons who will be exposed and about the exposure to the environment.

Helpdesk and information

According to art. 81 of the BPR competent authorities shall also provide advice to applicants and particular to SMEs. This may be done by providing a helpdesk. A helpdesk may actually be a structured way of organizing the information to applicants and also to the general public by introducing the possibility of written questions and specific telephone hours. A written procedure will facilitate the development of FAQs which can be posted on the webpage and also to ensure consistent replies from the authority to the same question. Telephone hours will leave room for other important tasks of the authority.

Information campaigns in order to update and prepare industry and to gather questions are also an efficient way to provide information. These campaigns should preferably be organized in collaboration with industry associations and the chamber of commerce. It is important to encourage industry to organize themselves and to contribute to the practical implementation of the rules.

Chapter 7: Review of Member State tasks under EU Chemicals legislation

Chemicals legislation is an area of fully harmonised legislation in the EU, of importance under Chapter 1 of the acquis since obligations interfere with the free circulation of goods. Community systems are set up for this aim: the system for the control of biocidal products (BPR), the system for classification and labelling of chemicals (CLP), the system for registration, evaluation, authorisation and restrictions of substances (REACH), the system to implement the Rotterdam convention on export and import of hazardous chemicals (Export-import).

Community systems based on EU-regulations work differently from national member state systems based on EU-directives as for example the prevention and control of industrial emissions or the prevention and control of major chemicals accidents. Entering a Community system like REACH stipulates that the country becomes an EU-member. Because REACH and other Community systems are constructed to work over the whole European Economic Area with the capacity and competences of the EU chemicals industry and the whole set of industrial branches using chemicals, with the EU-institutions for this aim and with the joint resources of Member State expertise and competent authorities.
The EU-candidate country must therefore prepare for entering the Community systems under EU chemicals legislation, but may not and should not waste its efforts and time on trying in vain to set up copy-systems on its own.

BiH needs some years to prepare for entering the working Community systems in the chemicals area, strengthening the capacity to comply with obligations and tasks within the chemicals industry, within the core administration / competent authority in the area and when it comes to the enforcement / inspection capabilities.

During the forthcoming five years' period industry, the competent authority, the official helpdesks and the responsible inspection under chemicals legislation in BiH ought to prepare themselves for complying with obligations and tasks in the following areas of rules and procedures:

- Review of active substances for biocidal use under the BPR
- Authorisation of biocidal products under the BPR
- EU-harmonised classification under the CLP
- Classification and labelling inventory under the CLP
- REACH-registration
- Chemicals safety assessment and the standard test data regime, including the practice of exposure scenarios and risk characterisation ratios under REACH
- Substance evaluation, authorisation demands and restrictions under REACH
- EU export-import rules, i.e. export-notification of substances subject to REACH-restrictions

Chemicals legislation in the EU is one of the most crucial areas under Chapter 27 of the acquis communautaire since it supports the protection of environmental health and the environment anywhere in society. Knowledge and information on hazards from chemicals placed on the market and measures to eliminate the adverse effects from chemicals serve chemicals safety in all other areas of legislation (prevention and control of environmental pollution, public health, chemical agents at work, major chemical accidents, hazardous waste etc).

With the importance placed on chemicals risk management in the EU and the development of Community systems for this aim follows a high number of EU-tasks on the Member states and on their competent authorities. The Member state is obliged to contribute to the Community work within the frames of BPR, CLP, REACH and Export-import and thus allocate the necessary resources for these contributions.

The authorities responsible for chemicals legislation in BiH have to prepare to be able to take on all these EU-tasks at accession. In this regard you have to invest both in the core staffs of the competent authority and in the cluster of national expertise seated elsewhere in society.

Membership duties and Community tasks directly placed on the MS

The kind of Member state obligations

The demands on the Member State to organise competent authorities are found in article 43 of the CLP Regulation, in article 121 of the REACH Regulation, in article 81 of the Regulation on biocidal products and in article 4 of the Regulation on export and import of dangerous chemicals. In the latter regulation the competent authority is named "the designated national authority" which is the term taken from the Rotterdam convention.
Definitions of competent authority in the CLP Regulation and the REACH Regulation are identical and say as article 2.19 in REACH that it "…. means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation".

To underscore that the demand on the EU-member to appoint a competent authority is not just a literally demand, the article 121 of the REACH regulation says that "Member States shall place adequate resources at the disposal of the competent authorities to enable them, in conjunction with any other available resources, to fulfil their tasks under this Regulation in a timely and effective manner".

The four EC-regulations state also obligations for the national competent authorities to co-operate with the authorities who carry out enforcement tasks under these regulations in the country and to support each other between the Member States. This demand is expressed in the following way in article 43 of the CLP Regulation: "The competent authorities and the authorities responsible for enforcement shall cooperate with each other in the performance

of their tasks under this Regulation and shall give the corresponding authorities of other Member States all necessary and useful support to this end."

National competent authority tasks of Member States in the EC-regulations are of the following kinds:

- Obligations directly placed on the competent authorities by the EC-regulations to be carried out in the own country;
- Requirements on the competent authorities to co-operate within the Community; with the European Chemicals Agency (ECHA), the Commission and the other Member States;
- Further Member State obligations, likely to involve the competent authorities

Obligations directly placed on the competent authority

The establishment of member state helpdesks is of this kind. The helpdesks should be established to provide advice to manufacturers, importers, distributors, downstream users and any other interested parties on their respective responsibilities and obligations (Article 44 in the CLP Regulation; Article 124 in the Reach Regulation; Article 71 in the Council proposal for a regulation of biocidal products). The helpdesks does not have to be seated with the competent authority. In some Member States they were from start seated at the EU information offices. Helpdesks do often use an "expert-tree" of experts scatted here and there within the administration, to provide the appropriate information and help the questioner to navigate through the detailed rules and requirements.

Obligations directly placed on the Member States' competent authorities are also the obligations concerning national authorisations of biocidal products and the procedures for mutual recognition of national authorisations among the Member States (Chapters V and VI of the BPR).

Direct obligations are also the demands to provide information to the public in the Article 123 of the REACH Regulation (Communication to the public of information on risks of substances) and in Article 15.5 (3rd paragraph) of the Regulation on biocidal products. The REACH- article says that the competent authorities of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The article in the Regulation on biocidal products says that Member States shall take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use.

This is likely to be information about the limiting of the access to substances of very high concern within the Community because of their adverse effects, the restrictions on other particularly hazardous chemicals (the procedures under the titles VII and VIII of the REACH Regulation) and active substances regarded by the EU as urgent to replace in biocidal products.

When it comes to EC-harmonization of the classification of chemical substances some direct mandates are given to the competent authority in the CLP Regulation:

- to submit proposals for harmonised classification and labelling to the ECHA for further consideration (Article 37.1);
- to receive such proposals from industry in the own country (Article 37.6);
- to require that suppliers seated in the own country submit information used for purposes of classification and labelling to the competent authority (Article 49.3)

Requirements for co-operation within the Community

Demands to take active part in ECHA-tasks

First to mention here are the demands on the competent authority to take direct part in ECHA-work and the demands on the authority to facilitate this work.

National competent authorities have a supporting role in the procedures for registration, substance evaluation and authorisation/restrictions set up by the REACH Regulation and even more so in the system for control of biocides and biocidal products under the BPR.

In article 85.6 of the REACH Regulation is stated that " The members of the Committees shall be supported by the scientific and technical resources available to the Member States. To this end, Member States shall provide adequate scientific and technical resources to the members of the Committees that they have nominated. Each Member State competent authority shall facilitate the activities of the Committees and their working groups." This does not say to which extent the competent authority will be involved in the work of the ECHA committees but it certainly admits a considerable affirmative support. The similar demand is placed on the Member State regarding the work of its committee member in the Biocidal Products Committee (Article 65 of the proposal).

The competent authority will most probably become more practically involved than otherwise in the committees work in case that your members in these committees already are staffers of the competent authority. Whether such unions of personnel are to recommend is however a secondary issue. In the proposed regulation on biocidal products it is mentioned that it is allowed. Representatives in the committees shall however be nominated and elected on their individual merits.

All Member States and the Commission shall be entitled to participate in the work of the Biocidal Products Committee (Draft article 66) and in the coordination group for the authorisation of biocidal products (Draft article 27). The Agency shall provide the secretariat. The load of work on the one or other competent authority in the area of biocides will vary. Anyhow each MS competent authority will need to participate in these fora to the extent that the issues dealt with in there become important to all.

Substance evaluation under the REACH Regulation

Second to mention in this regard is the requisition for competent authority support to ECHA prescribed within the procedure of substance evaluation in the REACH Regulation. It says that ECHA shall rely on the competent authorities of Member States in carrying out evaluations (Article 45).

Tasks within the decision system for biocide control

Third to mention is the role that the MS competent authority plays and is likely to play in the future within the control of biocidal products placed on the market in the EU. Any Member State competent authority could become proposed and designated as the evaluating competent authority in case of an application for approval of an active biocidal substance or in the review of an application, ref articles 7-8 and 11-12 of the Council proposal. It can also become the evaluating competent authority in the procedure of granting EU union authorisations of biocidal products, ref articles 34-37 of the proposal.
In the case of a new application for an active biocidal substance the chosen MS authority has to validate the application within a month and to complete the substance evaluation within a year. The competent authority could find that a full evaluation is not needed in the case of a review. If so it is supposed to submit its recommendation on the renewal to ECHA within 180 days.

Note also that it is on the Member State competent authority that receives an application for an approval of a biocidal product to perform a comparative risk assessment if the active substance in the product is considered by the EU as a candidate for substitution. This obligation is placed on the competent authority as part of a Community procedure. The assessment may lead to a decision by the EU Commission to prohibit or restrict the use of the substance.(Article 21).

Tasks of co-operation for the purpose of the Rotterdam convention

Fourth to mention is the demands for a close co-operation with the Commission and other Member States for the purpose of the Rotterdam convention. The Regulation on export and import of dangerous chemicals establishes a complete organisation for how the Member State and the European Commission shall act within the frame of this multilateral convention, as ratified by both individual Member States and the EU Commission. This organisation for close co-operation between the Member States and the Commission serves also for performing notifications to third countries of exports of chemicals that are subject to bans and severe restrictions in the EU but which are not listed for prior consent to imports under the convention.

There is a data-base system in the Community to achieve a smoothly working co-operation and co-ordination between the Member States and the EU Commission. It concerns export notifications and prior consents to imports both under the Rotterdam convention and when it comes to the further bans and severe restrictions issued by the EU.
To what extent your designated national authority will get deeply involved in the procedures under this regulation depends on the art and the frequency of export

notifications and import consents relating to companies seated within your national territory.

Examples of obligations possibly to involve the competent authority

Most likely examples of Member State tasks under these regulations that could be placed on the competent authorities are the various Member State reports to ECHA. Those are the reports required in Article 46.2 of the CLP Regulation and Articles 117 and 127 of the Reach Regulation.

Regularly tasks not to be over-looked

The provisions to communicate with the EU Commission or the European Chemicals Agency within regulatory processes have to be high-lighted. This kind of demands on the competent authority may not be seen as simple tasks and become forgotten by the EU-member; although the competent authority's participation in the procedure sometimes is not given much space by the wordings in the EC-regulations. Often it is just mentioned briefly at the end of an article.

An example of this kind is Article 24.5 in the CLP Regulation about requests for using alternative chemical names. Here it says that ECHA shall inform the competent authorities about the outcome of such requests and provide them with the information submitted by the applicant. It means that the competent authority has to receive this information in an active and responsible manner. The information has to be taken good care of. It has to become appropriately filed. It has to be taken into account when needed. Etc.

All participation of this kind in the EC-procedures is important to incorporate among requirements or requisitions placed on the competent authority. There must never be the weak link of working in the lines of any Community-based regulatory procedure. The competent authority's contribution could very well become decisive for the outcome.

Requirements stemming from EC-directives

We have to keep in mind also the obligations and tasks placed on competent authorities by domestic law because of EC-directives and which are not listed below. There are chemicals-related EC-directives regarding the prevention and control of major accidents, chemical agents at work and chemical risks for the environment from the use and spread of certain chemicals or groups of chemicals.

Inventory of membership tasks

MS obligations, role and tasks under the CLP Regulation

Article number	Article name and wording
24.5	*Request for use of an alternative chemical name* The Agency shall inform **competent authorities** of the outcome of the request in accordance with paragraph 3 or 4 and provide them with the information submitted by the manufacturer, importer or downstream user.
37.1	*Procedure for harmonisation of classification and labelling of substances* A **competent authority** may submit to the Agency a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits or M-factors, or a proposal for a revision thereof. The proposal shall follow the format set out in Part 2 of Annex VI and contain the relevant information provided for in Part 1 of Annex VI.
37.6	*Procedure for harmonisation of classification and labelling of substances* Manufacturers, importers and downstream users who have new information which may lead to a change of the harmonised classification and labelling elements of a substance in Part 3 of Annex VI shall submit a proposal in accordance with the second subparagraph of paragraph 2 to the **competent authority** in one of the Member States in which the substance is placed on the market.
43	*Appointment of **competent authorities** and enforcement authorities and cooperation between authorities* Member States shall appoint the **competent authority** or competent authorities responsible for proposals for harmonised classification and labelling and the authorities responsible for the enforcement of the obligations set out in this Regulation. The **competent authorities** and the authorities responsible for enforcement shall cooperate with each other in the performance of their tasks under this Regulation and shall give the corresponding authorities of other Member States all necessary and useful support to this end.
44	*Helpdesk* Member States shall establish national helpdesks to provide advice to manufacturers, importers, distributors, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation.
45.1	*Appointment of bodies responsible for receiving information relating to emergency health response* Member States shall appoint a body or bodies responsible for receiving information relevant, in particular, for formulating preventative and curative measures, in particular in the event of emergency health response, from importers and downstream users placing mixtures on the market. This information shall include the chemical composition of mixtures placed on the market and classified as hazardous on the basis of their health or physical

	effects, including the chemical identity of substances in mixtures for which a request for use of an alternative chemical name has been accepted by the Agency, in accordance with Article 24.
45.2	*Appointment of bodies responsible for receiving information relating to emergency health response* The appointed bodies shall provide all requisite guarantees for maintaining the confidentiality of the information received. Such information may only be used: (a) to meet medical demand by formulating preventative and curative measures, in particular in the event of an emergency; and (b) where requested by the Member State, to undertake statistical analysis to identify where improved risk management measures may be needed. The information shall not be used for other purposes.
45.3	*Appointment of bodies responsible for receiving information relating to emergency health response* The appointed bodies shall have at their disposal all the information required from the importers and downstream users responsible for marketing to carry out the tasks for which they are responsible.
46.1	*Enforcement and reporting* Member States shall take all necessary measures, including maintaining a system of official controls, to ensure that substances and mixtures are not placed on the market, unless they have been classified, labelled, notified and packaged in accordance with this Regulation.
46.2	*Enforcement and reporting* Member States shall submit a report to the Agency every five years by 1 July on the results of the official controls, and other enforcement measures taken. The first report shall be submitted by 20 January 2012. The Agency shall make those reports available to the Commission, which shall take them into account for its report under Article 117 of Regulation (EC) No 1907/2006.
47	*Penalties for non-compliance* Member States shall introduce penalties for non-compliance with this Regulation and shall take all measures necessary to ensure that this Regulation is applied. The penalties must be effective, proportionate and dissuasive. Member States shall notify the Commission of the provisions for penalties by 20 June 2010 and shall notify it without delay of any subsequent amendment affecting them.
49.1& 3	*Obligation to maintain information and requests for information* 1. The supplier shall assemble and keep available all the information used by that supplier for the purposes of classification and labelling under this Regulation for a period of at least 10 years after the substance or the mixture was last supplied by that supplier. The supplier shall keep this information together with the information required in Article 36 of Regulation (EC) No 1907/2006. 3. The **competent authority** or the enforcement authorities of a Member State in which a supplier is established or the Agency may require the supplier to

	submit to it any information referred to in the first subparagraph of paragraph 1. However, where that information is available to the Agency as part of a registration pursuant to Regulation (EC) No 1907/2006 or a notification pursuant to Article 40 of this Regulation, the Agency shall use that information and the authority shall address itself to the Agency.
50.1	*Tasks of the Agency* The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with this Regulation.
50.2 b	*Tasks of the Agency* The Secretariat of the Agency shall: (b) provide competent authorities with technical and scientific guidance on the operation of this Regulation and provide support to the helpdesks established by Member States under Article 44.
51	*Free movement clause* On grounds relating to the classification, labelling or packaging of substances and mixtures within the meaning of this Regulation, Member States shall not prohibit, restrict or impede the placing on the market of substances or mixtures which comply with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.
52.1	*Safeguard clause* Where a **Member State** has justifiable grounds for believing that a substance or a mixture, although satisfying the requirements of this Regulation, constitutes a serious risk to human health or the environment due to reasons of classification, labelling or packaging, it may take appropriate provisional measures. The **Member State** shall immediately inform the Commission, the Agency and the other **Member St**ates thereof, giving the reasons for its decision.
52.2	*Safeguard clause* Within 60 days of receipt of the information from the **Member State**, the Commission shall in accordance with the regulatory procedure referred to in Article 54(2) either authorise the provisional measure for a time period defined in the decision or require the Member State to revoke the provisional measure.
52.3	*Safeguard clause* In the case of an authorisation of a provisional measure related to classification or labelling of a substance as referred to in paragraph 2, the competent authority of the **Member State** concerned shall in accordance with the procedure laid down in Article 37 submit a proposal to the Agency for harmonised classification and labelling, within three months of the date of the Commission decision.

53.2	*Adaptations to technical and scientific progress* **Member States** and the Commission shall, in the manner appropriate to their role in the relevant UN fora, promote the harmonisation of the criteria for classification and labelling of persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) substances at the level of the UN.

MS obligations, role and tasks under the REACH Regulation

Article number	Article name and wording
44.1	*Criteria* In order to ensure a harmonised approach, the Agency shall in cooperation with the **Member States** develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria shall consider: (a) hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate; (b) exposure information; (c) tonnage, including aggregated tonnage from the registrations submitted by several registrants
44.2	*Criteria for substance evaluation* The Agency shall use the criteria in paragraph 1 for the purpose of compiling a draft Community rolling action plan which shall cover a period of three years and shall specify substances to be evaluated each year. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment. The Agency shall submit the first draft rolling action plan to the Member States by 1 December 2011. The Agency shall submit draft annual updates to the rolling action plan to the Member States by 28 February each year. The Agency shall adopt the final Community rolling action plan on the basis of an opinion from the Member State Committee set up under Article 76(1)(e) (hereinafter referred to as the Member State Committee) and shall publish the plan on its website, identifying the Member State who will carry out the evaluation of the substances listed therein as determined according to Article 45.
45	**Substance evaluation; *Competent authority*** 1. The Agency shall be responsible for coordinating the substance evaluation process and ensuring that substances on the Community rolling action plan are evaluated. In doing so, the Agency shall rely on the **competent authorities** of Member States. In carrying out an evaluation of a substance,

	the **competent authorities** may appoint another body to act on their behalf. 2. A Member State may choose (a) substance(s) from the draft Community rolling action plan, with the aim of becoming a **competent authority** for the purposes of Articles 46, 47 and 48. In the event of a substance from the draft Community rolling action plan not being chosen by any Member State, the Agency shall ensure that the substance is evaluated. 3. In cases where two or more **Member States** have expressed an interest in evaluating the same substance and they cannot agree who should be the **competent authority**, the **competent authority** for the purposes of Articles 46, 47 and 48 shall be determined in accordance with the following procedure. The Agency shall refer the matter to the Member State Committee, in order to agree which authority shall be the **competent authority**, taking into account the **Member State** in which the manufacturer(s) or importer(s) is located, the respective proportions of total Community gross domestic product, the number of substances already being evaluated by a **Member State** and the expertise available. If, within 60 days of the referral, the Member State Committee reaches unanimous agreement, the **Member States** concerned shall adopt substances for evaluation accordingly. If the Member State Committee fails to reach a unanimous agreement, the Agency shall submit the conflicting opinions to the Commission, which shall decide which authority shall be the competent authority, in accordance with the procedure referred to in Article 133(3), and the **Member States** concerned shall adopt substances for evaluation accordingly. 4. The **competent authority** identified in accordance with paragraphs 2 and 3 shall evaluate the allocated substances in accordance with this Chapter. 5. A **Member State** may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. The Agency shall decide whether to add this substance to the Community rolling action plan on the basis of an opinion from the Member State Committee. If the substance is added to the Community rolling action plan, the proposing **Member State**, or another **Member State** who agrees, shall evaluate that substance.
59	*Identification of substances referred to in Article 57* 1. The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 83(3)(e). 2. The Commission may ask the Agency to prepare a dossier in accordance with relevant Sections of Annex XV for substances which in its opinion meet the criteria set out in Article 57. The dossier may be limited, if appropriate, to a reference to an entry in Part 3 of Annex VI to Regulation (EC) No 1272/2008. The Agency shall make this dossier available to the **Member States**. 3. Any **Member State** may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to the Agency. The dossier may be limited, if appropriate, to a reference to an entry in Part 3 of Annex VI to Regulation (EC) No 1272/2008. The Agency shall make this dossier available within 30 days of receipt to the

	other **Member States**. 4. The Agency shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. The Agency shall invite all interested parties to submit comments within a specified deadline to the Agency. 5. Within 60 days of circulation, the other Member States or the Agency may comment on the identification of the substance in relation to the criteria in Article 57 in the dossier to the Agency. 6. If the Agency does not receive or make any comments, it shall include this substance on the list referred to in paragraph 1. The Agency may include this substance in its recommendations under Article 58(3). 7. When comments are made or received, the Agency shall refer the dossier to the Member State Committee within 15 days of the end of the 60-day period referred to in paragraph 5. 8. If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, the Agency shall include the substance in the list referred to in paragraph 1. The Agency may include that substance in its recommendations under Article 58(3). 9. If the Member State Committee fails to reach a unanimous agreement, the Commission shall prepare a draft proposal on the identification of the substance within three months of receipt of the opinion of the Member State Committee. A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article 133(3). 10. The Agency shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.
64.5	*Procedure for authorisation decisions* The Agency shall send these draft opinions to the applicant by the end of the deadline set out in paragraph 1. Within one month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. The draft opinion shall be deemed to have been received seven days after the Agency has sent it. If the applicant does not wish to comment, the Agency shall send these opinions to the Commission, the **Member States** and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment. If the applicant wishes to comment, he shall send his written argumentation to the Agency within two months of the receipt of the draft opinion. The Committees shall consider the comments and adopt their final opinions within two months of receipt of the written argumentation, taking this argumentation into account where appropriate. Within a further 15 days the Agency shall send the opinions, with the written argumentation attached, to the Commission, the **Member States** and the applicant.
69.4-5	**Authorisation***; Preparation of a proposal* **/……../** 4. If a **Member State** considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed it shall notify the Agency that it proposes to prepare a dossier which conforms to the requirements of the relevant sections of Annex XV. If

	the substance is not on the list maintained by the Agency referred to in paragraph 5 of this Article, the Member State shall prepare a dossier which conforms to the requirements of Annex XV within 12 months of the notification to the Agency. If this dossier demonstrates that action on a Communitywide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in the format outlined in Annex XV, in order to initiate the restrictions process. The Agency or **Member States** shall refer to any dossier, chemical safety report or risk assessment submitted to the Agency or **Member State** under this Regulation. The Agency or **Member States** shall also refer to any relevant risk assessment submitted for the purposes of other Community Regulations or Directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Agency or **Member State** concerned on request. The Committee for Risk Assessment and the Committee for Socioeconomic Analysis shall check whether the dossier submitted conforms to the requirements of Annex XV. Within 30 days of receipt, the respective Committee shall inform the Agency or the **Member State** suggesting restrictions, as to whether the dossier conforms. If the dossier does not conform, the reasons shall be given to the Agency or the **Member State** in writing within 45 days of receipt. The Agency or the **Member State** shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Chapter shall be terminated. The Agency shall publish without delay the intention of the Commission or of a **Member State** to instigate a restriction procedure for a substance and shall inform those who submitted a registration for that substance. 5. The Agency shall maintain a list of substances for which a dossier conforming to the requirements of Annex XV is planned or underway by either the Agency or a **Member State** for the purposes of a proposed restriction. If a substance is on the list, no other such dossier shall be prepared. If it is proposed by either a **Member State** or the Agency that an existing restriction listed in Annex XVII should be re-examined a decision on whether to do so shall be taken in accordance with the procedure referred to in Article 133(2) based on evidence presented by the **Member State** or the Agency.
70	**Restrictions;** *Agency opinion: Committee for Risk Assessment* Within nine months of the date of publication referred to in Article 69(6), the Committee for Risk Assessment shall formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the **Member State** dossier or of the dossier prepared by the Agency at the request of the Commission, and the views of interested parties referred to in Article 69(6)(a).
72	**Restrictions;** *Submission of an opinion to the Commission* 1. The Agency shall submit to the Commission without delay the opinions of the Committees for Risk Assessment and Socio-economic Analysis on restrictions suggested for substances on their own, in mixtures or in articles. If one or both of the Committees do not formulate an opinion by the deadline set in Article 70 and Article 71(1) the Agency shall inform the Commission accordingly, stating the reasons.

	2. Without prejudice to Articles 118 and 119 the Agency shall publish the opinions of the two Committees on its website without delay. 3. The Agency shall provide the Commission and/or **Member State** on request with all documents and evidence submitted to or considered by it.
73.2	**Restrictions;** *Commission decision* A final decision shall be taken in accordance with the procedure referred to in Article 133(4). The Commission shall send the draft amendment to the **Member States** at least 45 days before voting.
79.1	*Composition of the Management Board* The Management Board shall be composed of one representative from each **Member State** and a maximum of six representatives appointed by the Commission, including three individuals from interested parties without voting rights and in addition two independent persons appointed by the European Parliament. Each **Member State** shall nominate a member to the Management Board. The members thus nominated shall be appointed by the Council.
85.1-3; 5-7	*Establishment of the Committees* 1. Each **Member State** may nominate candidates to membership of the Committee for Risk Assessment. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Members shall be appointed for their role and experience in performing the tasks specified in Article 77(3). 2. Each **Member State** may nominate candidates to membership of the Committee for Socio-economic Analysis. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website, without prejudice to Article 88(1). The Management Board shall appoint the members of the Committee from this list, including at least one member but not more than two from the nominees of each **Member State** that has nominated candidates. Members shall be appointed for their role and experience in performing the tasks specified in Article 77(3). 3. Each Member State shall appoint one member to the Member State Committee. /…./ The members of each Committee may be accompanied by advisers on scientific, technical or regulatory matters. /…./ Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of the Committee members, or the Management Board. 5. The members of each Committee appointed following nomination by a **Member State** shall ensure that there is appropriate coordination between the tasks of the Agency and the work of their Member State competent authority. 6. The members of the Committees shall be supported by the scientific and technical resources available to the **Member States**. To this end, **Member States** shall provide adequate scientific and technical resources to the members of the Committees that they have nominated. Each Member State **competent authority** shall facilitate the activities of the Committees and their working groups. 7. The **Member States** shall refrain from giving the members of the

	Committee for Risk Assessment or of the Committee for Socio-Economic Analysis, or their scientific and technical advisers and experts, any instruction which is incompatible with the individual tasks of those persons or with the tasks, responsibilities and independence of the Agency.
86	*Establishment of the Forum* 1. Each **Member State** shall appoint, for a three-year term, which shall be renewable, one member to the Forum. Members shall be chosen for their role and experience in enforcement of chemicals legislation and shall maintain relevant contacts with the Member State **competent authorities**. The Forum shall aim to have a broad range of relevant expertise among its members. /…./ These members shall be appointed for a term of three years, which shall be renewable. /…./ The members of the Forum may be accompanied by scientific and technical advisers. /…./ Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of Forum members, or the Management Board. 2. The members of the Forum appointed by a **Member State** shall ensure that there is appropriate coordination between the tasks of the Forum and the work of their Member State **competent authority**. 3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the **Member States**. Each Member State **competent authority** shall facilitate the activities of the Forum and its working groups. The **Member States** shall refrain from giving the Forum members, or their scientific and technical advisers and experts any instruction which is incompatible with the individual tasks of those persons or with the tasks and responsibilities of the Forum.
87.1-2	*Rapporteurs of Committees and use of experts* 1. Where, in accordance with Article 77, a Committee is required to provide an opinion or consider whether a **Member State** dossier conforms with the requirements of Annex XV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing. A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. /……./ 2. **Member States** shall transmit to the Agency the names of experts with proven experience in the tasks required by Article 77, who would be available to serve on working groups of the Committees, together with an indication of their qualifications and specific areas of expertise. /……./
103.3	*Staff rules and regulations* The Agency's staff shall consist of officials assigned or seconded by the Commission or **Member States** on a temporary basis and of other servants recruited by the Agency as necessary to carry out its tasks. The Agency shall recruit its personnel on the basis of a staffing plan to be included in the multiannual work programme referred to in Article 78(d).
111	*Formats and software for submission of information to the Agency* The Agency shall specify formats and make them available free of charge, and software packages and make them available on its website for any

	submissions to the Agency. **Member States**, manufactures, importers, distributors or downstream users shall use these formats and packages in their submissions to the Agency pursuant to this Regulation. In particular, the Agency shall make available software tools to facilitate the submission of all information relating to substances registered in accordance with Article 12(1). For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation.
117	*Reporting* Every five years, **Member States** shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127.
127	*Enforcement reporting* The report referred to in Article 117(1) shall, in relation to enforcement include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken pursuant to Articles 125 and 126 during the previous reporting period.
121	**Competent authorities;** *Appointment* **Member States** shall appoint the **competent authority** or competent authorities responsible for performing the tasks allotted to competent authorities under this Regulation and for cooperating with the Commission and the Agency in the implementation of this Regulation. **Member States** shall place adequate resources at the disposal of the **competent authorities** to enable them, in conjunction with any other available resources, to fulfil their tasks under this Regulation in a timely and effective manner.
122	*Cooperation between **competent authorities*** The **competent authorities** shall cooperate with each other in the performance of their tasks under this Regulation and shall give the **competent authorities** of other **Member States** all the necessary and useful support to this end.
123	*Communication to the public of information on risks of substances* The **competent authorities** of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment. The Agency, in consultation with competent authorities and stakeholders and drawing as appropriate on relevant best practice, shall provide guidance for the communication of information on the risks and safe use of chemical substances, on their own, in mixtures or in articles, with a view to coordinating Member States in these activities.
124	*Other responsibilities;* Helpdesks **Competent authorities** shall submit electronically to the Agency any available information that they hold on substances registered in accordance with Article 12(1) whose dossiers do not contain the full information referred to in Annex VII, in particular whether enforcement or monitoring activities have identified suspicions of risk. The competent authority shall update this information as appropriate. **Member States** shall establish national helpdesks to provide advice to

	manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation, in particular in relation to the registration of substances in accordance with Article 12(1), in addition to the operational guidance documents provided by the Agency under Article 77(2)(g).
125	**Enforcement;** *Tasks of the Member States* **Member States** shall maintain a system of official controls and other activities as appropriate to the circumstances.
126	*Penalties for non-compliance* **Member States** shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The **Member States** shall notify those provisions to the Commission no later than 1 December 2008 and shall notify it without delay of any subsequent amendment affecting them.
127	**Enforcement;** *Report;* Content The report referred to in Article 117(1) shall, in relation to enforcement, include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures taken pursuant to Articles 125 and 126 during the previous reporting period. The common issues to be covered in the reports shall be agreed by the Forum. The Commission shall make these reports available to the Agency and the Forum.
128	*Free movement* 1. Subject to paragraph 2, **Member States** shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a mixture or in an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation. 2. Nothing in this Regulation shall prevent **Member States** from maintaining or laying down national rules to protect workers, human health and the environment applying in cases where this Regulation does not harmonise the requirements on manufacture, placing on the market or use.
129	*Safeguard clause* 1. Where a **Member State** has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance, on its own, in a mixture or in an article, even if satisfying the requirements of this Regulation, it may take appropriate provisional measures. The **Member State** shall immediately inform the Commission, the Agency and the other **Member States** thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based. 2. The Commission shall take a decision in accordance with the procedure referred to in Article 133(3) within 60 days of receipt of the information from the **Member State.** This decision shall either: (a) authorise the provisional measure for a time period defined in the decision; or (b) require the **Member State** to revoke the provisional measure. 3. If, in the case of a decision as referred to in paragraph 2(a), the provisional measure taken by the **Member State** consists in a restriction on the placing on the market or use of a substance, the **Member State** concerned shall initiate a Community restrictions procedure by submitting to the Agency a

	dossier, in accordance with Annex XV, within three months of the date of the Commission decision. 4. In the case of a decision as referred to in paragraph 2(a), the Commission shall consider whether this Regulation needs to be adapted.

MS obligations, role and tasks under the BPR[13]

Article number	Article name and wording
2.8	*Scope* **Member States** may allow for exemptions from this Regulation in specific cases for certain biocidal products, on their own or in a treated article, where necessary in the interests of defence.
3.1 (m)	*Definitions* 'national authorisation' means an administrative act by which the **competent authority of a Member State** authorises the placing on the market and the use of a biocidal product in its territory or in a part thereof
3.3	The Commission may, at the request of a **Member State**, decide in accordance with the examination procedure referred to in Article 72(3) whether a specific product or group of products is a biocidal product or a treated article or neither.
7.	Approvals of active substances*; Submission and validation of applications* 1. The applicant shall submit an application for approval of an active substance, or to make subsequent amendments to the conditions of approval of an active substance, to the Agency, informing it of the name of the **competent authority** of the **Member State** that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating **competent authority**. 2. The Agency shall inform the applicant of the fees payable under Article 80(1). It shall reject the application if the applicant fails to pay the fees within 30 days and shall inform the applicant and the evaluating **competent authority** accordingly. Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly indicating the exact date of the acceptance of the application and its unique identification code. 3. Within 30 days of the Agency accepting an application, the evaluating competent authority shall validate the application if the data required in accordance with points (a) and (b) and, where relevant, point (c) of Article 6(1) have been submitted. In the context of the validation referred to in the first subparagraph, the evaluating **competent authority** shall not make an assessment of the quality or the adequacy of the data or justifications submitted. The evaluating **competent authority** shall, as soon as possible after the Agency has accepted an application, inform the applicant of the fees payable

[13] We have used the consolidated version from 25.04.2015

	under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. 4. Where the evaluating **competent authority** considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days. The evaluating **competent authority** shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 3. The evaluating **competent authority** shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant and the Agency accordingly. In such cases, part of the fee paid in accordance with Article 80(1) and (2) shall be reimbursed. 5. On validating an application in accordance with paragraph 3 or 4, the evaluating **competent authority** shall without delay inform the applicant, the Agency and other **competent authorities** accordingly and indicate the exact date of the validation. 6. An appeal may be brought, in accordance with Article 77, against Agency decisions under paragraph 2 of this Article.
8	Approvals of active substances; *Evaluation of applications* 1. The evaluating **competent authority** shall, within 365 days of the validation of an application, evaluate it in accordance with Articles 4 and 5, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 6(3), and send an assessment report and the conclusions of its evaluation to the Agency. Prior to submitting its conclusions to the Agency, the evaluating **competent authority** shall provide the applicant with the opportunity to provide written comments on the assessment report and on the conclusions of the evaluation within 30 days. The evaluating **competent authority** shall take due account of those comments when finalising its evaluation. 2. Where it appears that additional information is necessary to carry out the evaluation, the evaluating **competent authority** shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. As specified in the second subparagraph of Article 6(2), the evaluating **competent authority** may, as appropriate, require the applicant to provide sufficient data to permit a determination of whether an active substance meets the criteria referred to in Article 5(1) or 10(1). The 365-day period referred to in paragraph 1 of this Article shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances. 3. Where the evaluating **competent authority** considers that there are concerns with regard to the cumulative effects from the use of biocidal products containing the same active substance, it shall document its concerns in accordance with the requirements of the relevant parts of Section II.3 of Annex XV to Regulation (EC) No 1907/2006 and include this as part of its conclusions. 4. Within 270 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the approval of the active substance having regard to the conclusions of the evaluating

	competent authority.
13.3	*Submission and acceptance of applications* The applicant shall also submit the name of the **competent authority** of the Member State that it proposes should evaluate the application for renewal and provide written confirmation that that **competent authority** agrees to do so. That **competent authority** shall be the evaluating competent authority. The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating **competent authority** accordingly. Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating **competent authority** accordingly, indicating the date of the acceptance.
14.	Reviews of approvals; *Evaluation of applications for renewal* 1. On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for approval or, as appropriate, the previous renewal, the evaluating **competent authority** shall, within 90 days of the Agency accepting an application in accordance with Article 13(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested. 2. Where the evaluating **competent authority** decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1, 2 and 3 of Article 8. Where the evaluating **competent authority** decides that a full evaluation of the application is not necessary, it shall, within 180 days of the Agency accepting the application in accordance with Article 13(3), prepare and submit to the Agency a recommendation on the renewal of the approval of the active substance. It shall provide the applicant with a copy of its recommendation. The evaluating **competent authorit**y shall, as soon as possible after the Agency has accepted an application, notify the applicant of the fees payable under Article 80(2). The evaluating competent authority shall reject the application if the applicant fails to pay the fees within 30 days of the notification and shall inform the applicant accordingly. 3. Within 270 days of receipt of a recommendation from the evaluating **competent authority**, if it has carried out a full evaluation of the application, or 90 days otherwise, the Agency shall prepare and submit to the Commission an opinion on renewal of the approval of the active substance.
15.1	*Review of approval of an active substance* The Commission may review the approval of an active substance for one or more product-types at any time where there are serious indications that the conditions laid down in Article 4(1) or, where relevant, 5(2) are no longer met. The Commission may also review the approval of an active substance for one or more product-types at the request of a **Member State** if there are indications that the use of the active substance in biocidal products or treated articles raises serious concerns about the safety of such biocidal products or treated articles.

17	*Making available on the market and use of biocidal products* 1. Biocidal products shall not be placed or made available on the market or used unless authorised in accordance with this Regulation. 2. Applications for authorisation shall be made by, or on behalf of, the prospective authorisation holder. Applications for national authorisation in a Member State shall be submitted to the **competent authority** of that Member State (hereinafter referred to as 'the receiving competent authority'). Applications for Union authorisation shall be submitted to the Agency. 3. An authorisation for a biocidal product may be granted for a single biocidal product or a biocidal product family. 4. An authorisation shall be granted for a maximum period of 10 years. 5. Biocidal products shall be used in compliance with the terms and conditions of the authorisation stipulated in accordance with Article 22(1) and the labelling and packaging requirements laid down in Article 69. Proper use shall involve the rational application of a combination of physical, biological, chemical or other measures as appropriate, whereby the use of biocidal products is limited to the minimum necessary and appropriate precautionary steps are taken. **Member States** shall take necessary measures to provide the public with appropriate information about the benefits and risks associated with biocidal products and ways of minimising their use. 6. The authorisation holder shall notify each **competent authority** having granted a national authorisation for a biocidal product family of each product within the biocidal product family before placing it on the market, except where a particular product is explicitly identified in the authorisation or the variation in composition concerns only pigments, perfumes and dyes within the permitted variations. The notification shall indicate the exact composition, trade name and suffix to the authorisation number. In the case of a Union authorisation, the authorisation holder shall notify the Agency and the Commission.
20.2	*Requirements for applications for authorisation* The receiving **competent authority** may require that applications for national authorisation be submitted in one or more of the official languages of the Member State where that competent authority is situated.
23	*Comparative assessment of biocidal products* 1. The receiving **competent authority** or, in the case of evaluation of an application for a Union authorisation, the evaluating competent authority, shall perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1). 2. The results of the comparative assessment shall be forwarded, without delay, to the **competent authorities** of other Member States and the Agency and, in the case of evaluation of an application for a Union authorisation, also to the Commission. 3. The receiving **competent authority** or, in the case of a decision on an application for a Union authorisation, the Commission shall prohibit or restrict the making available on the market or use of a biocidal product containing an active substance that is a candidate for substitution where the

	comparative assessment performed in accordance with the technical guidance notes referred to in Article 24, demonstrates that both of the following criteria are met:: (a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human and animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages; (b) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism. 4. By way of derogation from paragraph 1, a biocidal product containing an active substance that is a candidate for substitution may be authorised for a period of up to four years without comparative assessment in exceptional cases where it is necessary to acquire experience first through using that product in practice. 5. Where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular where it is relevant to two or more competent authorities, the receiving **competent authority** may refer the question to the Commission for a decision. The Commission shall adopt the decision in accordance with the examination procedure referred to in Article 82(3). 6. Notwithstanding Article 17(4), and without prejudice to paragraph 4 of this Article, an authorisation for a biocidal product containing an active substance that is a candidate for substitution shall be granted and renewed for a period not exceeding five years. 7. Where it is decided not to authorise or to restrict the use of a biocidal product pursuant to paragraph 3, that cancellation or amendment of the authorisation shall take effect five years after that decision. However, where the approval of the active substance which is a candidate for substitution expires on an earlier date, the cancellation of the authorisation shall take effect on that earlier date.
26	Simplified authorisation procedure; *Applicable procedure* 1. Applicants seeking the authorisation of a biocidal product meeting the conditions of Article 25 shall submit an application to the Agency, informing it of the name of the competent authority of the Member State that it proposes should evaluate the application and providing written confirmation that that competent authority agrees to do so. That **competent authority** shall be the evaluating competent authority. 2. The evaluating **competent authority** shall inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. Upon receipt of the fees payable under Article 80(2), the evaluating **competent authority** shall accept the application and inform the applicant accordingly, indicating the date of the acceptance. 3. Within 90 days of accepting an application, the evaluating **competent authority** shall authorise the biocidal product if satisfied that the product meets the conditions laid down in Article 25. 4. Where the evaluating **competent authority** considers that the application is incomplete, it shall inform the applicant as to what additional information is required and shall set a reasonable time limit for the submission of that

	information. That time limit shall not normally exceed 90 days. The evaluating **competent authority** shall, within 90 days of receipt of the additional information, authorise the biocidal product if satisfied, on the basis of the additional information submitted, that the product meets the conditions laid down in Article 25. The evaluating **competent authority** shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, where fees have been paid, part of the fees paid in accordance with Article 80(2) shall be reimbursed.
27	*Making available on the market of biocidal products authorised in accordance with the simplified authorisation procedure* 1. A biocidal product authorised in accordance with Article 26 may be placed on the market in all **Member States** without the need for mutual recognition. However, the authorisation holder shall notify each **Member State** before placing the biocidal product on the market within its territory and shall use its official language or languages in the product's labelling, unless that **Member State** provides otherwise. 2. Where a **Member State** other than that of the evaluating **competent authority** considers that a biocidal product authorised in accordance with Article 26 does not meet the requirements of Article 25, it may refer that matter to the coordination group established in accordance with Article 35(1). Article 35(3) and Article 36 shall apply *mutatis mutandis*. Where a **Member State** has valid reasons to consider that a biocidal product authorised in accordance with Article 26 does not meet the criteria laid down in Article 25 and a decision pursuant to Articles 35 and 36 has not yet been taken, that **Member State** may provisionally restrict or prohibit making available on the market or use of that product on its territory.
29	National authorisations of biocidal products; *Submission and validation of applications* 1. Applicants wishing to apply for a national authorisation in accordance with Article 17 shall submit an application to the receiving **competent authority**. The receiving **competent authority** shall inform the applicant of the fees payable under Article 80(2), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. Upon receipt of the fees payable under Article 80(2), the receiving **competent authority** shall accept the application and inform the applicant accordingly, indicating the date of the acceptance. 2. Within 30 days of acceptance, the receiving **competent authority** shall validate the application if it complies with the following requirements: (a) the relevant information referred to in Article 20 has been submitted; and (b) the applicant states that it has not applied to any other competent authority for a national authorisation for the same biocidal product for the same use(s). In the context of the validation referred to in the first subparagraph, the receiving competent authority shall not make an assessment of the quality or the adequacy of the data or justifications submitted. 3. Where the receiving **competent authority** considers that the application is incomplete, it shall inform the applicant as to what additional information is required for the validation of the application and shall set a reasonable time

	limit for the submission of that information. That time limit shall not normally exceed 90 days. The receiving **competent authority** shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirements laid down in paragraph 2. The receiving **competent authority** shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. 4. Where the Register for Biocidal Products referred to in Article 71 shows that a competent authority other than the receiving competent authority is examining an application relating to the same biocidal product or has already authorised the same biocidal product, the receiving **competent authority** shall decline to evaluate the application. In that event, the receiving **competent authority** shall inform the applicant of the possibility of seeking mutual recognition in accordance with Article 33 or 34. 5. If paragraph 3 does not apply and the receiving **competent authority** considers that the application is complete, it shall validate the application and without delay inform the applicant accordingly, indicating the date of the validation.
30	*Evaluation of application* 1. The receiving **competent authority** shall, within 365 days of the validation of an application in accordance with Article 29, decide whether to grant an authorisation in accordance with Article 19. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable. 2. Where it appears that additional information is necessary to carry out the evaluation, the receiving **competent authority** shall ask the applicant to submit such information within a specified time limit. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances. The receiving **competent authority** shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. 3. Within the 365-day period referred to in paragraph 1, the receiving **competent authority** shall: (a) draft a report summarising the conclusions of its assessment and the reasons for authorising the biocidal product or for refusing to grant an authorisation (the 'assessment report'); (b) send an electronic copy of the draft assessment report to the applicant and provide it with the opportunity to submit comments within 30 days; and (c) take due account of those comments when finalising its assessment.
31	*Renewal of a national authorisation* 1. An application by or on behalf of an authorisation holder wishing to seek the renewal of a national authorisation for one or more product-types shall be submitted to the receiving **competent authority** at least 550 days before the expiry date of the authorisation. Where renewal is sought for more than one

	product-type, the application shall be submitted at least 550 days before the earliest expiry date. 2. The receiving **competent authority** shall renew the national authorisation, provided that the conditions set out in Article 19 are still satisfied. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable. 3. When applying for renewal, the applicant shall submit: (a) without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and (b) its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information. 4. The receiving **competent authority** shall inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. Upon receipt of the fees payable under Article 80(2), the receiving **competent authority** shall accept the application and inform the applicant accordingly, indicating the date of the acceptance. 5. On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for authorisation or, as appropriate, the previous renewal, the receiving **competent authority** shall, within 90 days of accepting an application in accordance with paragraph 4, decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary taking account of all product-types for which renewal is requested. 6. Where the receiving **competent authority** decides that a full evaluation of the application is necessary, it shall decide on the renewal of the authorisation after carrying out an evaluation of the application in accordance with paragraphs 1, 2 and 3 of Article 30. Where the receiving **competent authority** decides that a full evaluation of the application is not necessary, it shall decide on the renewal of the authorisation within 180 days of accepting the application in accordance with paragraph 4 of this Article. 7. Where, for reasons beyond the control of the holder of a national authorisation, no decision is taken on the renewal of that authorisation before its expiry, the receiving **competent authority** shall grant a renewal for the period necessary to complete the evaluation.
32.2	Mutual recognition procedures; *Authorisation through mutual recognition* 2. Without prejudice to Article 37, all Member States receiving applications for mutual recognition of a national authorisation shall, in accordance with and subject to the procedures set out in this Chapter, authorise the biocidal product under the same terms and conditions.
33	*Mutual recognition in sequence* 1. Applicants wishing to seek the mutual recognition in sequence, in one or more **Member States** ('the Member States concerned'), of the national authorisation of a biocidal product already granted in another **Member State** in accordance with Article 17 ('the reference Member State') shall submit an application to each of the **competent authorities** of the Member States

	concerned containing, in each case, a translation of the national authorisation granted by the reference **Member State** into such official languages of the **Member State** concerned as it may require. The **competent authorities** of the Member States concerned shall inform the applicant of the fees payable under Article 80 and shall reject the application if the applicant fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under Article 80, the **competent authorities** of the Member States concerned shall accept the application and inform the applicant indicating the date of acceptance. 2. Within 30 days of acceptance referred to in paragraph 1, the **Member States** concerned shall validate the application and inform the applicant accordingly, indicating the date of the validation. Within 90 days of validating the application, and subject to Articles 35, 36 and 37, the **Member States** concerned shall agree on the summary of biocidal product characteristics referred to in Article 22(2) and shall record their agreement in the Register for Biocidal Products. 3. Within 30 days of reaching agreement, each of the **Member States** concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics. 4. Without prejudice to Articles 35, 36, and 37, if no agreement is reached within the 90-day period referred to in the second subparagraph of paragraph 2, each **Member State** that agrees to the summary of biocidal product characteristics referred to in paragraph 2, may authorise the product accordingly.
34	*Mutual recognition in parallel* 1. Applicants wishing to seek the mutual recognition in parallel of a biocidal product which has not yet been authorised in accordance with Article 17 in any **Member State** shall submit to the **competent authority** of the Member State of its choice ('the reference Member State') an application containing: (a) the information referred to in Article 20; (b) a list of all other Member States where a national authorisation is sought ('the Member States concerned'). The reference **Member State** shall be responsible for the evaluation of the application. 2. The applicant shall, at the same time as submitting the application to the reference **Member State** in accordance with paragraph 1, submit to the **competent authorities** of each of the **Member States** concerned an application for mutual recognition of the authorisation for which it has applied to the reference **Member State**. This application shall contain: (a) the names of the reference **Member State** and of the **Member States** concerned; (b) the summary of biocidal product characteristics referred to in Article 20(1)(a)(ii) in such official languages of the **Member States** concerned as they may require. 3. The **competent authorities** of the reference **Member State** and of the **Member States** concerned shall inform the applicant of the fees payable in accordance with Article 80 and shall reject the application if the applicant

	fails to pay the fees within 30 days. They shall inform the applicant and the other competent authorities accordingly. Upon receipt of the fees payable under Article 80, the **competent authorities** of the reference **Member State** and of the **Member States** concerned shall accept the application and inform the applicant indicating the date of acceptance. 4. The reference **Member State** shall validate the application in accordance with Article 29(2) and (3) and inform the applicant and the **Member States** concerned accordingly. Within 365 days of validating an application, the reference **Member State** shall evaluate the application and draft an assessment report in accordance with Article 30 and shall send its assessment report and the summary of biocidal product characteristics to the **Member States** concerned and to the applicant. 5. Within 90 days of receipt of the documents referred to in paragraph 4, and subject to Articles 35, 36 and 37, the **Member States** concerned shall agree on the summary of biocidal product characteristics, and shall record their agreement in the Register for Biocidal Products. The reference **Member State** shall enter the agreed summary of biocidal product characteristics and the final assessment report in the Register for Biocidal Products, together with any agreed terms or conditions imposed on the making available on the market or use of the biocidal product. 6. Within 30 days of reaching agreement, the reference **Member State** and each of the **Member States** concerned shall authorise the biocidal product in conformity with the agreed summary of biocidal product characteristics. 7. Without prejudice to Articles 35, 36, and 37, if no agreement is reached within the 90-day period referred to in paragraph 5, each **Member State** that agrees to the summary of biocidal product characteristics referred to in paragraph 5 may authorise the product accordingly.
35	*Referral of objections to the coordination group* 1. A coordination group shall be set up to examine any question, other than matters referred to in Article 37, relating to whether a biocidal product for which an application for mutual recognition has been made in accordance with Article 33 or 34 meets the conditions for granting an authorisation laid down in Article 19. All **Member States** and the Commission shall be entitled to participate in the work of the coordination group. The Agency shall provide the secretariat of the coordination group. The coordination group shall establish its rules of procedure. 2. If any of the **Member States** concerned considers that a biocidal product assessed by the reference **Member State** does not meet the conditions laid down in Article 19, it shall send a detailed explanation of the points of disagreement and the reasons for its position to the reference **Member State**, the other **Member States** concerned, the applicant, and, where applicable, to the authorisation holder. The points of disagreement shall be referred without delay to the coordination group. 3. Within the coordination group, all **Member States** referred to in paragraph 2 of this Article shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its

	point of view known. Where they reach agreement within 60 days of the referral of the points of disagreement referred to in paragraph 2 of this Article, the reference **Member State** shall record the agreement in the Register for Biocidal Products. The procedure shall then be considered to be closed and the reference **Member State** and each of the **Member States** concerned shall authorise the biocidal product in accordance with Article 33(3) or 34(6) as appropriate.
36	*Referral of unresolved **objections** to the Commission* 1. If the **Member States** referred to in Article 35(2) fail to reach agreement within the 60-day period laid down in Article 35(3), the reference **Member State** shall immediately inform the Commission, and provide it with a detailed statement of the matters on which **Member States** have been unable to reach agreement and the reasons for their disagreement. A copy of that statement shall be forwarded to the **Member States** concerned, the applicant and, where applicable, the authorisation holder. 2. The Commission may ask the Agency for an opinion on scientific or technical questions raised by **Member States**. Where the Commission does not ask the Agency for an opinion it shall provide the applicant and, where applicable, the authorisation holder with the opportunity to provide written comments within 30 days. 3. The Commission shall adopt, by means of implementing acts, a decision on the matter referred to it. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3). 4. The decision referred to in paragraph 3 shall be addressed to all **Member States** and reported for information to the applicant and, where applicable, the authorisation holder. The **Member States** concerned and the reference **Member State** shall, within 30 days of notification of the decision, either grant, refuse to grant or cancel the authorisation, or vary its terms and conditions as necessary to comply with the decision.
37	*Derogations from mutual recognition* 1. By way of derogation from Article 32(2), any of the **Member States** concerned may propose to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted, provided that such a measure can be justified on grounds of: (a) the protection of the environment; (b) public policy or public security; (c) the protection of health and life of humans, particularly of vulnerable groups, or of animals or plants; (d) the protection of national treasures possessing artistic, historic or archaeological value; or (e) the target organisms not being present in harmful quantities. Any of the **Member States** concerned may, in particular, propose in accordance with the first subparagraph to refuse to grant an authorisation or to adjust the terms and conditions of the authorisation to be granted for a biocidal product containing an active substance to which Article 5(2) or Article 10(1) applies. 2. The **Member State** concerned shall communicate to the applicant a detailed statement of the grounds for seeking a derogation pursuant to paragraph 1 and shall seek to reach an agreement with the applicant on the

	proposed derogation. If the **Member State** concerned is unable to reach agreement with the applicant or receives no reply from the applicant within 60 days of that communication it shall inform the Commission. In that case, the Commission: (a) may ask the Agency for an opinion on scientific or technical questions raised by the applicant or the **Member State** concerned; (b) shall adopt a decision on the derogation in accordance with the examination procedure referred to in Article 82(3). The Commission's decision shall be addressed to the **Member State** concerned and the Commission shall inform the applicant thereof. The **Member State** concerned shall take necessary measures to comply with the Commission's decision within 30 days of its notification. 3. If the Commission has not adopted a decision pursuant to paragraph 2 within 90 days of being informed in accordance with the second subparagraph of paragraph 2, the **Member State** concerned may implement the derogation proposed pursuant to paragraph 1. 'While the procedure under this Article is ongoing, the **Member Sta**tes' obligation to authorise a biocidal product within three years of the date of approval, referred to in the first subparagraph of Article 89(3), shall be temporarily suspended. 4. By way of derogation from Article 32(2), a **Member State** may refuse to grant authorisations for product-types 15, 17 and 20 on grounds of animal welfare. **Member States** shall without delay inform other **Member States** and the Commission of any decision taken in this respect and its justification.
39	*Application for mutual recognition by official or scientific bodies* 1. Where no application for a national authorisation has been submitted in a **Member State** for a biocidal product that is already authorised in another **Member State**, official or scientific bodies involved in pest control activities or the protection of public health may apply, under the mutual recognition procedure provided for in Article 33 and with the consent of the authorisation holder in the other **Member State**, for a national authorisation for the same biocidal product, with the same use and the same conditions for use as in that **Member State**. The applicant shall demonstrate that the use of such a biocidal product is of general interest for that **Member State**. The application shall be accompanied by the fees payable under Article 80. 2. If the competent authority of the **Member State** concerned considers that the biocidal product fulfils the conditions referred to in Article 16 and the conditions under this Article are met, the competent authority shall authorise the placing on the market and use of the biocidal product. In that case, the body that made the application shall have the same rights and obligations as other authorisation holders.
43.1-5	**Granting of Union authorisations**; *Submission and validation of applications* 1. Applicants wishing to apply for Union authorisation in accordance with Article 42(1) shall submit an application to the Agency, including a confirmation that the biocidal product would have similar conditions of use across the Union, informing the Agency of the name of the competent authority of the Member State that they propose should evaluate the

	application and providing written confirmation that that **competent authority** agrees to do so. That **competent authority** shall be the evaluating competent authority. 2. The Agency shall inform the applicant of the fees payable under Article 80(1), and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating **competent authority** accordingly. Upon receipt of the fees payable under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating **competent authority** accordingly, indicating the date of acceptance. 3. Within 30 days of the Agency accepting an application, the evaluating **competent authority** shall validate the application if the relevant information referred to in Article 20 has been submitted. In the context of the validation referred to in the first subparagraph, the evaluating **competent authority** shall not make an assessment of the quality or the adequacy of the data or justifications submitted. The evaluating **competent authority** shall, as soon as possible after the Agency has accepted an application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. 4. Where the evaluating **competent authority** considers that the application is incomplete, it shall inform the applicant what additional information is required for the evaluation of the application and shall set a reasonable time limit for the submission of that information. That time limit shall not normally exceed 90 days. The evaluating **competent authority** shall, within 30 days of receipt of the additional information, validate the application if it determines that the additional information submitted is sufficient to comply with the requirement laid down in paragraph 3. The evaluating **competent authority** shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly. In such cases, part of the fees paid in accordance with Article 80(1) and (2) shall be reimbursed. 5. On validating the application in accordance with paragraph 3 or 4, the evaluating **competent authority** shall, without delay, inform the applicant, the Agency and other competent authorities accordingly, indicating the date of the validation.
44	**Granting of Union authorisations;** *Evaluation of applications* 1. The evaluating **competent authority** shall, within 365 days of the validation of an application, evaluate it in accordance with Article 19, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 21(2), and send an assessment report and the conclusions of its evaluation to the Agency. Prior to submitting its conclusions to the Agency, the evaluating **competent authority** shall provide the applicant with the opportunity to provide written comments on the conclusions of the evaluation within 30 days. The evaluating **competent authority** shall take due account of those comments

	when finalising its evaluation. 2. Where it appears that additional information is necessary to carry out the evaluation, the evaluating **competent authority** shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. However, the suspension shall not exceed 180 days in total other than in exceptional cases and where justified by the nature of the information requested. 3. Within 180 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product. If the Agency recommends the authorisation of the biocidal product, the opinion shall contain at least the following elements: (a) a statement on whether the conditions laid down in Article 19(1) are fulfilled, and a draft summary of biocidal product characteristics, as referred to in Article 22(2); (b) where relevant, details of any terms or conditions which should be imposed on the making available on the market or use of the biocidal product; (c) the final assessment report on the biocidal product. 4. Within 30 days of submitting its opinion to the Commission, the Agency shall transmit to the Commission, in all the official languages of the Union, the draft summary of the biocidal product characteristics, as referred to in Article 22(2), where applicable. 5. On receipt of the opinion of the Agency, the Commission shall adopt either an implementing regulation granting the Union authorisation to the biocidal product or an implementing decision stating that the Union authorisation of the biocidal product has not been granted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3). The Commission shall, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1).
45	Renewal of Union authorisations; *Submission and acceptance of applications* 1. An application by or on behalf of an authorisation holder wishing to seek the renewal of a Union authorisation shall be submitted to the Agency at least 550 days before the expiry date of the authorisation. 2. When applying for renewal, the applicant shall submit: (a) without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and (b) its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information. 3. The applicant shall also submit the name of the **competent authority** of the Member State that it proposes should evaluate the application for renewal

	and provide written confirmation that that **competent authority** agrees to do so. That **competent authority** shall be the evaluating competent authority. The Agency shall inform the applicant of the fees payable to it under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating **competent authority** accordingly. Upon receipt of the fees payable to it under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating **competent authority** accordingly, indicating the date of acceptance. 4. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.
46	*Evaluation of applications for renewal* 1. On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for Union authorisation or, as appropriate, the previous renewal, the evaluating **competent authority** shall, within 30 days of the Agency accepting the application in accordance with Article 45(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary. 2. Where the evaluating **competent authority** decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 and 2 of Article 44. Where the evaluating **competent authority** decides that a full evaluation of the application is not necessary, it shall, within 180 days of the Agency accepting the application, prepare and submit to the Agency a recommendation on the renewal of the authorisation. It shall provide the applicant with a copy of its recommendation. The evaluating **competent authority** shall, as soon as possible after the Agency has accepted the application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. 3. Within 180 days of receipt of a recommendation from the evaluating **competent authority**, the Agency shall prepare and submit to the Commission an opinion on the renewal of the Union authorisation. 4. On receipt of the opinion of the Agency, the Commission shall adopt either an implementing Regulation to renew the Union authorisation or an implementing decision to refuse to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3). The Commission shall renew a Union authorisation, provided that the conditions set out in Article 19 are still satisfied. 5. Where, for reasons beyond the control of the holder of the Union authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Union authorisation for the period necessary to complete the evaluation by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

47	*Obligation for notification of unexpected or adverse effects* 1. On becoming aware of information concerning the authorised biocidal product, or the active substance(s) it contains, that may affect the authorisation, the holder of an authorisation shall without delay notify the **competent authority** that granted the national authorisation and the Agency or, in the case of a Union authorisation, the Commission and the Agency. In particular, the following shall be notified: (a) new data or information on the adverse effects of the active substance or biocidal product for humans, in particular vulnerable groups, animals or the environment; (b) any data indicating the potential of the active substance for the development of resistance; (c) new data or information indicating that the biocidal product is not sufficiently effective. 2. The **competent authority** that granted the national authorisation or, in the case of a Union authorisation, the Agency, shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 48. 3. The **competent authority** that granted the national authorisation or, in the case of a Union authorisation, the Agency, shall without delay notify competent authorities of other Member States and, where appropriate, the Commission of any such data or information it receives. **Competent authorities** of Member States that have issued a national authorisation for the same biocidal product under the mutual recognition procedure shall examine whether the authorisation needs to be amended or cancelled in accordance with Article 48.
48	*Cancellation or amendment of an authorisation* 1. Without prejudice to Article 21, the **competent authority** of a **Member State** or, in the case of a Union authorisation, the Commission, shall at any time cancel or amend an authorisation it has granted if it considers that: (a) the requirements referred to in Article 16 are not satisfied; (b) the authorisation was granted on the basis of false or misleading information; (c) the authorisation holder has failed to comply with its obligations under the authorisation or this Regulation. 2. Where the **competent authority** or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give it the opportunity to submit comments or additional information within a specified time limit. The evaluating **competent authority** or, as appropriate, the Commission shall take due account of those comments when finalising its decision. 3. Where the **competent authority** or, in the case of a Union authorisation, the Commission, cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder, the **competent authorities** of other Member States and, where relevant, the Commission. **Competent authorities** that have issued authorisations under the mutual recognition procedure for biocidal products for which the authorisation has been cancelled or amended shall, within 120 days, cancel or amend the authorisations and shall notify the Commission accordingly.

	In the case of disagreement between **competent authoriti**es of certain Member States concerning national authorisations subject to mutual recognition the procedures laid down in Articles 27 and 28 shall apply *mutatis mutandis*. 4. As soon as the **competent authority** or the Commission in the case of a Union authorisation, has taken a decision to cancel or amend an authorisation, it shall update the information referred to in Article 23(5) relating to the biocidal product concerned in the Register for Biocidal Products.
49	*Cancellation of an authorisation at the request of the authorisation holder* 1. Without prejudice to Article 23, the **competent authority** of a Member State or, in the case of a Union authorisation, the Commission shall at any time cancel or amend an authorisation it has granted where it considers that: (a) the conditions referred to in Article 19 or, where relevant, in Article 25 are not satisfied; (b) the authorisation was granted on the basis of false or misleading information; or (c) the authorisation holder has failed to comply with its obligations under the authorisation or this Regulation. 2. Where the **competent authority** or, in the case of a Union authorisation, the Commission, intends to cancel or amend an authorisation, it shall inform the authorisation holder thereof and give it the opportunity to submit comments or additional information within a specified time limit. The evaluating **competent authority** or, in the case of a Union authorisation, the Commission, shall take due account of those comments when finalising its decision. 3. Where the **competent authority** or, in the case of a Union authorisation, the Commission, cancels or amends an authorisation in accordance with paragraph 1, it shall without delay notify the authorisation holder, the competent authorities of other Member States and, where relevant, the Commission. **Competent authorities** that have issued authorisations under the mutual recognition procedure for biocidal products for which the authorisation has been cancelled or amended shall, within 120 days of the notification, cancel or amend the authorisations and shall notify the Commission accordingly. In the case of disagreement between competent authorities of certain Member States concerning national authorisations subject to mutual recognition the procedures laid down in Articles 35 and 36 shall apply *mutatis mutandis*.
50	*Amendment of an authorisation at the request of the authorisation holder* 1. Amendments to the terms and conditions of an authorisation shall be made only by the **competent authority** that authorised the biocidal product concerned, or in the case of a Union authorisation, by the Commission. 2. An authorisation holder seeking to change any of the information submitted in relation to the initial application for authorisation of the product shall apply to the **competent authorities** of relevant Member States having authorised the biocidal product concerned, or in the case of a Union authorisation, the Agency. Those **competent authorities** shall decide, or, in the case of a Union authorisation, the Agency shall examine and the Commission decide whether the conditions of Article 19 or, where relevant, Article 25 are still met and whether the terms and conditions of the authorisation need to be amended.

	The application shall be accompanied by the fees payable under Article 80(1) and (2).
52	*Period of grace* Notwithstanding Article 89, where the **competent authority** or, in the case of a biocidal product authorised at Union level, the Commission, cancels or amends an authorisation or decides not to renew it, it shall grant a period of grace for the making available on the market and use of existing stocks, except in cases where continued making available on the market or use of the biocidal product would constitute an unacceptable risk to human health, animal health or the environment. The period of grace shall not exceed 180 days for the making available on the market and an additional maximum period of 180 days for the use of existing stocks of the biocidal products concerned.
53	*Parallel trade* 1. By way of derogation from Article 17, a **competent authority** of a Member State ('Member State of introduction') shall, at the request of the applicant, grant a parallel trade permit for a biocidal product that is authorised in another **Member State** ('Member State of origin') to be made available on the market and used in the **Member State** of introduction, if it determines in accordance with paragraph 3 that the biocidal product is identical to a biocidal product already authorised in the **Member State** of introduction ('the reference product'). The applicant who intends to place the biocidal product on the market in the **Member State** of introduction shall submit the application for a parallel trade permit to the **competent authority** of the **Member State** of introduction. The application shall be accompanied by the information referred to in paragraph 4 and all other information necessary to demonstrate that the biocidal product is identical to the reference product as defined in paragraph 3. 2. Where the **competent authority** of the Member State of introduction determines that a biocidal product is identical to the reference product, it shall grant a parallel trade permit within 60 days of receipt of the fees payable under Article 80(2). The **competent authority** of the Member State of introduction may request from the **competent authority** of the Member State of origin additional information necessary to determine whether the product is identical to the reference product. The **competent authority** of the Member State of origin shall provide the requested information within 30 days of receiving the request. 3. A biocidal product shall be considered as identical to the reference product only if all the following conditions are met: (a) they have been manufactured by the same company, by an associated undertaking or under license in accordance with the same manufacturing process; (b) they are identical in specification and content in respect of the active substances and the type of formulation; (c) they are the same in respect of the non-active substances present; and (d) they are either the same or equivalent in packaging size, material or form, in terms of the potential adverse impact on the safety of the product with

	regard to human health, animal health or the environment. 4. An application for a parallel trade permit shall include the following information and items: (a) name and authorisation number of the biocidal product in the **Member State** of origin; (b) name and address of the **competent authority** of the Member State of origin; (c) name and address of the authorisation holder in the **Member State** of origin; (d) original label and instructions for use with which the biocidal product is distributed in the **Member State** of origin if it is considered as necessary for the examination by the **competent authority** of the Member State of introduction; (e) name and address of the applicant; (f) name to be given to the biocidal product to be distributed in the **Member State** of introduction; (g) a draft label for the biocidal product intended to be made available on the market in the **Member State** of introduction in the official language or languages of the Member State of introduction, unless that **Member State** provides otherwise; (h) a sample of the biocidal product which is intended to be introduced if it is considered as necessary by the **competent authority** of the Member State of introduction; (i) name and authorisation number of the reference product in the **Member State** of introduction. The **competent authority** of the Member State of introduction may require a translation of the relevant parts of the original instructions for the use referred to in point (d). 5. The parallel trade permit shall prescribe the same conditions for making available on the market and use as the authorisation of the reference product. 6. The parallel trade permit shall be valid for the duration of authorisation of the reference product in the **Member State** of introduction. If the authorisation holder of the reference product applies for cancellation of authorisation in accordance with Article 49 and the requirements of Article 19 are still fulfilled, the validity of the parallel trade permit shall expire on the date on which the authorisation of the reference product would normally have expired. 7. Without prejudice to specific provisions in this Article, Articles 47 to 50 and Chapter XV shall apply *mutatis mutandis* to biocidal products made available on the market under a parallel trade permit. 8. The **competent authority** of the Member State of introduction may withdraw a parallel trade permit if the authorisation of the introduced biocidal product is withdrawn in the Member State of origin because of safety or efficacy reasons.

54	*Assessment of technical equivalence* 1. Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ('the applicant') shall submit an application to the Agency. 2. The applicant shall submit all data that the Agency requires to assess technical equivalence. 3. The Agency shall inform the applicant of the fees payable under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly. 4. After giving the applicant the opportunity to submit comments, the Agency shall take a decision within 90 days of receipt of the application referred to in paragraph 1 and shall communicate it to Member States and to the applicant. 5. Where, in the opinion of the Agency, additional information is necessary to carry out the assessment of technical equivalence, the Agency shall ask the applicant to submit such information within a time limit specified by the Agency. The Agency shall reject the application if the applicant fails to submit the additional information within the specified time limit. The 90-day period referred to in paragraph 4 shall be suspended from the date of issue of the request until the information is received. The suspension shall not exceed 180 days except where justified by the nature of the data requested or in exceptional circumstances. 6. Where appropriate, the Agency may consult the **competent authority** of the Member State which acted as the evaluating competent authority for the evaluation of the active substance. 7. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraphs 3, 4 and 5 of this Article. 8. The Agency shall draw up technical guidance notes to facilitate the implementation of this Article.
55	*Derogation from the requirements* 1. By way of derogation from Articles 17 and 19, a **competent authority** may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the **competent authority**, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means. The **competent authority** referred to in the first subparagraph shall, without delay, inform the other **competent authorities** and the Commission of its action and the justification for it. The **competent authority** shall, without delay, inform the other **competent authorities** and the Commission of the revocation of such action. On receipt of a reasoned request from the **competent authority**, the Commission shall, without delay and by means of implementing acts, decide whether, and under what conditions, the action taken by that **competent authority** may be extended, for a period not exceeding 550 days. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3). 2. By way of derogation from point (a) of Article 19(1) and until an active

	substance is approved, **competent authorities** and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance. Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the evaluating **competent authority** has submitted a recommendation for approval of the new active substance and the **competent authorities** which received the application for the provisional authorisation or, in the case of a provisional Union authorisation, the Agency, consider that the biocidal product is expected to comply with points (b), (c) and (d) of Article 19(1) taking into account the factors set out in Article 19(2). If the Commission decides not to approve the new active substance, the **competent authorities** which granted the provisional authorisation or the Commission shall cancel that authorisation. Where a decision on the approval of the new active substance has not yet been adopted by the Commission when the period of three years expires, the **competent authorities** which granted the provisional authorisation, or the Commission, may extend the provisional authorisation for a period not exceeding one year, provided that there are good reasons to believe that the active substance will satisfy the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2). **Competent authorities** which extend the provisional authorisation shall inform the other **competent authorities** and the Commission of such action. 3. By way of derogation from point (a) of Article 19(1), the Commission may, by means of implementing acts, allow a **Member State** to authorise a biocidal product containing a non-approved active substance if it is satisfied that that active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2). A **Member State** wishing to obtain such a derogation shall apply to the Commission, providing due justification.
56.1-3	*Research and development* 1. By way of derogation from Article 17, an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal product or a non- approved active substance intended exclusively for use in a biocidal product ('experiment' or 'test') may take place only under the conditions provided for in this Article. Persons carrying out an experiment or test shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. They shall make this information available to the **competent authority** on request. Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the **competent authority** of the Member State where the experiment or test will occur. The notification shall include the identity of the biocidal product or active substance, labelling data and quantities supplied, and all available

	data on possible effects on human or animal health or impact on the environment. The person concerned shall make available any other information requested by the **competent authorities**. In the absence of an opinion from the **competent authority** within 45 days of the notification referred to in the first subparagraph, the notified experiment or test may take place. 3. If the experiments or tests could have harmful effects, whether immediate or delayed, on the health of humans, particularly of vulnerable groups, or animals, or any unacceptable adverse effect on humans, animals or the environment, the relevant **competent authority** of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The **competent authority** shall, without delay, inform the Commission and other competent authorities of its decision. /……/
59.1-3	*Protection of data held by **competent authorities** or the Agency* 1. Without prejudice to Articles 62 and 63, data submitted for the purposes of Directive 98/8/EC or of this Regulation shall not be used by **competent authorities** or the Agency for the benefit of a subsequent applicant, except where: (a) the subsequent applicant submits a letter of access; or (b) the relevant time limit for data protection has expired. 2. When submitting data to a **competent authority** or to the Agency for the purposes of this Regulation the applicant shall, where relevant, indicate the name and contact details of the data owner for all data submitted. The applicant shall also specify whether it is the data owner or holds a letter of access. 3. The applicant shall, without delay, inform the **competent authority** or the Agency about any changes to the ownership of the data. /……/
60	*Data protection periods* 1. Data submitted for the purposes of Directive 98/8/EC or of this Regulation shall benefit from data protection under the conditions laid down in this Article. The protection period for the data shall start when they are submitted for the first time. Data protected under this Article or for which the protection period under this Article has expired shall not be protected again. 2. The protection period for data submitted with a view to the approval of an existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type. The protection period for data submitted with a view to the approval of a new active substance shall end 15 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type. The protection period for new data submitted with a view to the renewal or review of the approval of an active substance shall end five years from the first day of the month following the date of the adoption of a decision in

	accordance with Article 14(4) concerning the renewal or the review. 3. The protection period for data submitted with a view to the authorisation of a biocidal product containing only existing active substances shall end 10 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5). The protection period for data submitted with a view to the authorisation of a biocidal product containing a new active substance shall end 15 years from the first day of the month following the first decision concerning the authorisation of the product taken in accordance with Article 26(3), 30(1), 33(3), 33(4), 34(6), 34(7), 36(4), 37(2), 37(3) or 44(5). The protection period for new data submitted with a view to the renewal or amendment of the authorisation of a biocidal product shall end five years from the first day of the month following the decision concerning the renewal or amendment of the authorisation.
62	*Data sharing* 1. . In order to avoid animal testing, testing on vertebrates for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrates shall not be repeated for the purposes of this Regulation. 2. Any person intending to perform tests or studies ('the prospective applicant') (a) shall, in the case of data involving tests on vertebrates; and (b) may, in the case of data not involving tests on vertebrates, submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency or to a **competent authority** in connection with a previous application under this Regulation or Directive 98/8/EC. The Agency shall verify whether such tests or studies have already been submitted. Where such tests or studies have already been submitted to the Agency or to a **competent authority** in connection with a previous application, under this Regulation or Directive 98/8/EC, the Agency shall, without delay, communicate the name and contact details of the data submitter and data owner to the prospective applicant. The data submitter shall, where relevant, facilitate contacts between the prospective applicant and the data owner. Where the data acquired under those tests or studies are still protected under Article 60, the prospective applicant: (a) shall, in the case of data involving tests on vertebrates; and (b) may, in the case of data not involving tests on vertebrates, request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.

63.1-2	*Compensation for data sharing* 1. Where a request has been made in accordance with Article 62(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order. 2. Where such agreement is reached, the data owner shall make all the scientific and technical data related to the tests and studies concerned available to the prospective applicant or shall give the prospective applicant permission to refer to the data owner's tests or studies when submitting applications under this Regulation. /……../
64	*Use of data for subsequent applications* 1. Where the relevant data protection period according to Article 60 has expired in relation to an active substance, the receiving **competent authority** or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the active substance is technically equivalent to the active substance for which the data protection period has expired, including the degree of purity and the nature of any relevant impurities. Where the relevant data protection period according to Article 60 has expired in relation to a biocidal product, the receiving **competent authority** or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can provide evidence that the biocidal product is the same as the one already authorised, or the differences between them are not significant in relation to the risk assessment and the active substance(s) in the biocidal product are technically equivalent to those in the biocidal product already authorised, including the degree of purity and the nature of any impurities. An appeal may be brought, in accordance with Article 77, against decisions of the Agency under the first and second subparagraphs of this paragraph. 2. Notwithstanding paragraph 1, subsequent applicants shall provide the following data accordingly to the receiving **competent authority** or the Agency, as applicable: (a) all necessary data for the identification of the biocidal product, including its composition; (b) the data needed to identify the active substance and to establish technical equivalence of the active substance; (c) the data needed to demonstrate the comparability of the risk from and efficacy of the biocidal product to that of the authorised biocidal product.
65	Monitoring and reporting; *Compliance with requirements* 1. **Member States** shall make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products (1) shall apply accordingly.

	2. **Member States** shall make the necessary arrangements for official controls to be carried out in order to enforce compliance with this Regulation. In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain, in relation to the manufacturing process, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market and shall store production batch samples. The documentation shall include as a minimum: (a) safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product; (b) records of the various manufacturing operations performed; (c) results of internal quality controls; (d) identification of production batches. Where necessary in order to ensure uniform application of this paragraph, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 82(3). process Measures taken pursuant to this paragraph shall avoid causing disproportionate administrative burden to economic operators and **Member States**. 3. Every five years, from 1 September 2015, **Member States** shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include in particular: (a) information on the results of official controls carried out in accordance with paragraph 2; (b) information on any poisonings and, where available, occupational diseases involving biocidal products, especially regarding vulnerable groups, and any specific measures taken to mitigate the risk of future cases; (c) any available information on adverse environmental effects experienced through using biocidal products; (d) information on the use of nanomaterials in biocidal products and the potential risks thereof. Reports shall be submitted by 30 June of the relevant year and shall cover the period until 31 December of the year preceding their submission. The reports shall be published on the relevant website of the Commission. 4. On the basis of the reports received in accordance with paragraph 3, and within 12 months from the date referred to in the second subparagraph of that paragraph, the Commission shall draw up a composite report on the implementation of this Regulation, in particular Article 58. The Commission shall submit the report to the European Parliament and to the Council.
66	*Confidentiality* 1. Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (1) and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) of Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation. 2. The Agency and the **competent authorities** shall refuse access to

	information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned. Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or the privacy or safety of the persons concerned: (a) details of the full composition of a biocidal product; (b) the precise tonnage of the active substance or biocidal product manufactured or made available on the market; (c) links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product; (d) names and addresses of persons involved in testing on vertebrates. However, where urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph. 3. Notwithstanding paragraph 2, after the authorisation has been granted, access to the following information shall not in any case be refused: (a) the name and address of the authorisation holder; (b) the name and address of the biocidal product manufacturer; (c) the name and address of the active substance manufacturer; (d) the content of the active substance or substances in the biocidal product and the name of the biocidal product; (e) physical and chemical data concerning the biocidal product; (f) any methods for rendering the active substance or biocidal product harmless; (g) a summary of the results of the tests required pursuant to Article 20 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance; (h) recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards; (i) safety data sheets; (j) methods of analysis referred to in Article 19(1)(c); (k) methods of disposal of the product and of its packaging; (l) procedures to be followed and measures to be taken in the case of spillage or leakage; (m) first aid and medical advice to be given in the case of injury to persons. 4. Any person submitting information related to an active substance or a biocidal product to the Agency or a **competent authority** for the purposes of this Regulation may request that the information in Article 67(3) and (4) not be made available, including a justification as to why the disclosure of the information could be harmful for that person's commercial interests or those of any other party concerned.

67.3	*Electronic public access* */...../* 3. From the date on which the Commission adopts an implementing Regulation providing that an active substance is approved, as referred to in point (a) of Article 9(1), the Agency shall, except where the data supplier submits a justification in accordance with Article 66(4) accepted as valid by the **competent authority** or the Agency as to why such publication is potentially harmful for its commercial interests or any other party concerned, make publicly available, free of charge, the following up-to-date information on that active substance: */...../*
68	*Record-keeping and reporting* 1. Authorisation holders shall keep records of the biocidal products they place on the market for at least 10 years after placing on the market, or 10 years after the date on which the authorisation was cancelled or expired, whichever is the earlier. They shall make available the relevant information contained in these records to the **competent authority** on request. 2. To ensure the uniform application of paragraph 1 of this Article, the Commission shall adopt implementing acts to specify the form and content of the information in records. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).
69.3	*Classification, packaging and labelling of biocidal products* */……../* 3. **Member States** may require: (a) the provision of models or drafts of the packaging, labelling and leaflets; (b) that biocidal products made available on the market in their territories be labelled in their official language or languages.
71.1-6,8-9	*Register for Biocidal Products* 1. The Agency shall establish and maintain an information system which shall be referred to as the Register for Biocidal Products. 2. The Register for Biocidal Products shall be used for the exchange of information between **competent authorities**, the Agency and the Commission and between applicants and competent authorities, the Agency and the Commission. 3. Applicants shall use the Register for Biocidal Products to submit applications and data for all procedures covered by this Regulation. 4. Upon submission of applications and data by applicants, the Agency shall check that these have been submitted in the correct format and notify the relevant **competent authority** accordingly without delay. Where the Agency decides that the application has not been submitted in the correct format, it shall reject the application and inform the applicant accordingly. 5. Once the relevant **competent authority** has validated or accepted an application, it shall be made available via the Register for Biocidal Products to all other competent authorities and to the Agency. 6. The **competent authorities** and the Commission shall use the Register for Biocidal Products to record and communicate the decisions they have taken in

	relation to the authorisations of biocidal products and shall update the information in the Register for Biocidal Products at the time such decisions are taken. The **competent authorities** shall, in particular, update the information in the Register for Biocidal Products relating to biocidal products which have been authorised within their territory or for which a national authorisation has been refused, amended, renewed or cancelled, or for which a parallel trade permit has been granted, refused or cancelled. The Commission shall, in particular, update the information relating to biocidal products which have been authorised in the Union or for which a Union authorisation has been refused, amended, renewed or cancelled. The information to be introduced into the Register for Biocidal Products shall include, as appropriate: (a) the terms and conditions of the authorisation; (b) the summary of the biocidal product characteristics referred to in Article 22(2); (c) the assessment report of the biocidal product. The information referred to in this paragraph shall also be made available to the applicant through the Register for Biocidal Products. 8. The Commission may adopt implementing acts laying down detailed rules on the types of information to be entered in the Register for Biocidal Products. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2). 9. The Commission shall be empowered to adopt delegated acts in accordance with Article 83 laying down supplementary rules for the use of the Register.
75	*Biocidal Products Committee* 1. A Biocidal Products Committee is hereby established within the Agency. (g) at the request of the Commission or of Member States' **competent authorities**, any other questions that arise from the operation of this Regulation relating to technical guidance or risks to human health, animal health or the environment. 2. Each **Member State** shall be entitled to appoint a member of the Biocidal Products Committee. **Member States** may also appoint an alternate member. In order to facilitate its work, the Committee may, by a decision of the Management Board of the Agency in agreement with the Commission, be divided into two or more parallel committees. Each parallel committee shall be responsible for the tasks of the Biocidal Products Committee assigned to it. Each **Member State** shall be entitled to appoint one Member for each of the parallel committees. The same person may be appointed to more than one parallel committee. 3. Committee members shall be appointed on the basis of their experience relevant to performing the tasks specified in paragraph 1 and may work within a competent authority. They shall be supported by the scientific and technical resources available to **Member States**. To this end, **Member States** shall provide adequate scientific and technical resources to Committee members that they have nominated. 4. Article 85, paragraphs 4, 5, 8 and 9, and Articles 87 and 88 of Regulation (EC) No 1907/2006 shall apply *mutatis mutandis* to the Biocidal Products Committee.

79	*Formats and software for submission of information to the Agency* The Agency shall specify formats and software packages and make them available free of charge on its website for submissions to the Agency. The competent authorities and applicants shall use these formats and packages in their submissions pursuant to this Regulation. The technical dossier referred to in Article 6(1) and Article 20 shall be submitted using the IUCLID software package.
80.2-3	*Fees and charges* /……/ 2. **Member States** shall directly charge applicants fees for services that they provide with respect to the procedures under this Regulation, including the services undertaken by Member States' **competent authorities** when acting as evaluating competent authority. Based on the principles set out in paragraph 3, the Commission shall issue guidance concerning a harmonised structure of fees. **Member States** may levy annual fees with respect to biocidal products made available on their markets. **Member States** may collect charges for other services they provide. **Member States** shall set and publish the amount of fees payable to their competent authorities. 3. Both the implementing Regulation referred to in paragraph 1 and **Member States**' own rules concerning fees shall respect the following principles: (a) fees shall be set at such a level as to ensure that the revenue derived from the fees is, in principle, sufficient to cover the cost of the services delivered and shall not exceed what is necessary to cover those costs; (b) partial reimbursement of the fee if the applicant fails to submit the information requested within the specified time limit; (c) the specific needs of SMEs shall be taken into account, as appropriate, including the possibility of splitting payments into several instalments and phases; (d) the structure and amount of fees shall take into account whether information has been submitted jointly or separately; (e) in duly justified circumstances, and where it is accepted by the Agency or the competent authority, the whole fee or a part of it may be waived; and (f) the deadlines for the payment of fees shall be fixed taking due account of the deadlines of the procedures provided for in this Regulation.
81	*Competent authorities* 1. **Member States** shall **designate a competent authority or competent authorities** responsible for the application of this Regulation. **Member States** shall ensure that **competent authorities** have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation shall be carried out efficiently and effectively. 2. **Competent authorities** shall provide advice to applicants, in particular to SMEs, and to any other interested parties on their respective responsibilities and obligations under this Regulation. That shall include the provision of

	advice about the possibility of adapting the data requirements of Articles 6 and 20, the grounds on which such an adaptation can be made, and on how to prepare a proposal. It shall be in addition to the advice and assistance that the Secretariat of the Agency shall provide in accordance with Article 76(1)(d). **Competent authorities** may in particular provide advice by establishing helpdesks. Helpdesks already established under Regulation (EC) No 1907/2006 may act as helpdesks under this Regulation. 3. **Member States** shall inform the Commission of the names and addresses of the designated competent authorities and, where they exist, helpdesks by … [*]. **Member States** shall, without undue delay, inform the Commission of any changes to the names and addresses of the competent authorities or helpdesks. The Commission shall make publicly available a list of competent authorities and helpdesks.
87	*Penalties* **Member States** shall lay down the provisions on penalties applicable to infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The **Member States** shall notify those provisions to the Commission no later than …[*] and shall notify the Commission without delay of any subsequent amendment affecting them.
88	*Safeguard clause* Where, on the basis of new evidence, a **Member State** has justifiable grounds to consider that a biocidal product, although authorised in accordance with this Regulation, constitutes a serious immediate or long-term risk to animal or human health, particularly to vulnerable groups, or to the environment, it may take appropriate provisional measures. The **Member State** shall without delay inform the Commission and the other **Member States** accordingly and give reasons for its decision based on the new evidence. The Commission shall, by means of implementing acts, either permit the provisional measure for a time period defined in the decision or require the **Member State** to revoke the provisional measure. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).
89.2-4	*Transitional measures* /……../ 2. By way of derogation from Articles 17(1), 19(1) and 20(1) of this Regulation, and without prejudice to paragraphs 1 and 3 of this Article, a **Member State** may continue to apply its current system or practice of making available on the market or using a given biocidal product for up to three years after the date of approval of the last of the active substances to be approved in that biocidal product. The **Member State** concerned may, in accordance with its national

[*] OJ: Insert the date referred to in the second subparagraph of Article 85.
[*] OJ: Insert the date referred to in the second subparagraph of Article 85.

	rules, authorise the making available on the market or use in its territory only of a biocidal product containing only: (a) existing active substances which: (i) have been evaluated under Commission Regulation (EC) No 1451/2007 but which have not yet been approved for that product-type; or (ii) are being evaluated, under Regulation (EC) No 1451/2007, but which have not yet been approved for that product-type; or (b) a combination of active substances referred to in point (a) and active substances approved in accordance with this Regulation. By way of derogation from the first subparagraph, in the case of a decision not to approve an active substance, a **Member State** may continue to apply its current system or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with the third subparagraph of paragraph 1, and may continue to apply its current system or practice of using biocidal products for up to 18 months after that decision. 3. Following a decision to approve a particular active substance for a specific product-type, **Member States** shall ensure that authorisations for biocidal products of that product-type and containing that active substance are granted, modified or cancelled, as appropriate, in accordance with this Regulation within three years of the date of approval. To that effect, those wishing to apply for the authorisation or mutual recognition in parallel of biocidal products of that product-type containing no active substances other than existing active substances shall submit applications for authorisation or mutual recognition in parallel no later than the date of approval of the active substance(s). In the case of biocidal products containing more than one active substance, applications shall be submitted no later than the date of approval of the last active substance for that product-type. Where no application for authorisation or mutual recognition in parallel has been submitted in accordance with the second subparagraph: (a) the biocidal product shall no longer be made available on the market with effect from 180 days after the date of approval of the active substance(s); and (b) use of existing stocks of the biocidal product may continue for up to 365 days after the date of approval of the active substance(s). 4. Where a Member State's **competent authority**, or where relevant, the Commission, decides to reject an application submitted in accordance with paragraph 3 for authorisation of a biocidal product already made available on the market, or decides not to grant an authorisation or to impose conditions for the authorisation making it necessary to change such a product, the following shall apply: (a) a biocidal product which has not been authorised or, where relevant, which does not comply with the conditions of the authorisation, shall no longer be made available on the market with effect from 180 days after the date of the decision of the authority; and (b) use of existing stocks of the biocidal product may continue for up to 365 days after the date of the decision of the authority.

78	*Transitional measures concerning active substances evaluated under Directive 98/8/EC* /……./ 2. Applications submitted for the purposes of Directive 98/8/EC for which the **Member States**' evaluation in accordance with Article 11(2) of Directive 98/8/EC has not been completed by 1 September 2013 shall be evaluated by the **competent authorities** in accordance with the provisions of this Regulation and, where relevant, Regulation (EC) No 1451/2007. That evaluation shall be carried out on the basis of the information provided in the dossier submitted under Directive 98/8/EC. Where the evaluation identifies concerns arising from the application of provisions of this Regulation which were not included in Directive 98/8/EC, the applicant shall be given the opportunity to provide additional information. Every effort shall be made to avoid additional testing on vertebrates and to avoid causing delays to the review programme laid down in Regulation (EC) No 1451/2007 as a result of these transitional arrangements. Notwithstanding paragraph 1, the Agency shall also be responsible for coordinating the evaluation process of dossiers submitted for the purposes of Directive 98/8/EC for which the evaluation has not been completed by 1 September 2013 and shall facilitate the preparation of the evaluation by providing organisational and technical support to the **Member States** and the Commission from 1 January 2014.

MS obligations, role an tasks under the Export-Import Regulation 689/2008

Article number	Article name and wording
4	*Designated national authorities* Each Member State shall designate the authority or authorities, hereinafter 'the designated national authority' or 'the designated national authorities', to carry out the administrative functions required by this Regulation, unless it has already done so before the entry into force of this Regulation.
5.1-3	*Participation of the Community in the Convention* The participation of the Community in the Convention shall be a joint responsibility of the Commission and the Member States, in particular as regards technical assistance, the exchange of information and matters relating to dispute settlement, participation in subsidiary bodies and voting. With regard to the Community's participation in the Convention, for the administrative functions of the Convention with reference to the PIC procedure and the export notification, the Commission shall act as a common designated authority on behalf of and in close cooperation and consultation with all the designated national authorities of the Member States. /……../ A network of Member State rapporteurs shall be established, as appropriate,

	to deal with the preparation of technical documents such as decision guidance documents as referred to in Article 7(3) of the Convention. The Commission and the Member States shall take the necessary initiatives to ensure appropriate representation of the Community in the various bodies implementing the Convention.
7.1-2; 5-8	*Export notifications forwarded to Parties and other countries* 1. In the case of substances listed in Part 1 of Annex I or preparations containing such substances in a concentration that could trigger labelling obligations under Directive 1999/45/EC irrespective of the presence of any other substances, paragraphs 2 to 8 shall apply. 2. When an exporter is due to export a chemical referred to in paragraph 1 from the Community to a Party or other country for the first time on or after the date on which it becomes subject to this Regulation, the exporter shall notify the designated national authority of the Member State in which he is established, no later than 30 days before the export of the chemical is due to take place. Thereafter the exporter shall notify the designated national authority of the first export of such chemical each calendar year no later than 15 days before the export takes place. The notification shall comply with the requirements set out in Annex II. The designated national authority shall check compliance of the information with Annex II and promptly forward the notification received from the exporter to the Commission. /……./ Each export notification shall be registered and assigned an export reference identification number in a database at the Commission, and an updated list of the chemicals concerned and the importing Parties and other countries for each calendar year shall be kept available to the public and distributed to the designated national authorities of the Member States as appropriate. /……../ 5. Where the export of a chemical relates to an emergency situation in which any delay may endanger public health or the environment in the importing Party or other country, the requirements of paragraphs 2, 3 and 4 may be waived wholly or partly at the discretion of the designated national authority of the exporting Member State, in consultation with the Commission. 6. The obligations set out in paragraphs 2, 3 and 4 shall cease when the following conditions are fulfilled: (a) the chemical has become a chemical subject to the PIC procedure; (b) the importing country being a Party to the Convention has provided the Secretariat with a response in accordance with Article 10(2) of the Convention indicating whether or not it consents to import of the chemical; (c) the Commission has been informed of that response by the Secretariat and has forwarded that information to Member States. The first subparagraph shall not apply where the importing country being Party to the Convention explicitly requires continued export notification by exporting Parties, for example through its import decision or otherwise. The obligations set out in paragraphs 2, 3 and 4 shall also cease when the following conditions are fulfilled: (a) the designated national authority of the importing Party or the

	appropriate authority of the importing other country has waived the requirement to be notified before the export of the chemical; (b) the Commission has received the information from the Secretariat or from the designated national authority of the importing Party or the appropriate authority of the importing other country and has forwarded it to Member States and made it available on the Internet. 7. The Commission, the relevant designated national authorities of the Member States and the exporters shall provide importing Parties and other countries with available additional information concerning the exported chemicals, when requested. 8. Member States may establish systems obliging exporters to pay an administrative fee for each export notification given and for each request for explicit consent made, corresponding to the costs to them of carrying out the procedures set out in paragraphs 2, 3 and 4 of this Article and in Article 13(3), (6) and (7).
8.1-2	*Export notifications received from Parties and other countries* 1. Export notifications received by the Commission from the designated national authorities of Parties or the appropriate authorities of other countries concerning the export to the Community of a chemical the manufacture, use, handling, consumption, transport or sale of which is subject to prohibition or severe restriction under that Party's or other country's legislation shall be made available by electronic means through the database maintained by the Commission. The Commission shall acknowledge receipt of the first export notification received for each chemical from each Party or other country. The designated national authority of the Member State receiving that import shall receive a copy of any notification received together with all available information. Other Member States shall be entitled to receive copies on request. 2. Should the designated national authorities of the Member States receive any export notifications either directly or indirectly from the designated national authorities of Parties or the appropriate authorities of other countries, they shall immediately forward those notifications to the Commission together with all available information.
9.1-3	*Information on export and import of chemicals* 1. Each exporter of: — substances listed in Annex I, — preparations containing such substances in a concentration that could trigger labelling obligations under Directive 1999/45/EC irrespective of the presence of any other substances, or — articles containing substances listed in Parts 2 or 3 of Annex I in unreacted form or preparations containing such substances in a concentration that could trigger labelling obligations under Directive 1999/45/EC irrespective of the presence of any other substances, shall, during the first quarter of each year, inform the designated national authority of its Member State regarding the quantity of the chemical, as a substance and as contained in preparations or in articles, shipped to each Party or other country during the preceding year. That information shall be given together with a list of the names and addresses of each importer to which shipment took place during the same period. That information shall list separately exports pursuant to Article

	13(7). Each importer within the Community shall provide the same information for the quantities imported into the Community. 2. Upon request from the Commission or the designated national authority of its Member State, the exporter or importer shall provide any additional information relating to chemicals that is necessary to implement this Regulation. 3. Each Member State shall provide the Commission each year with aggregated information in accordance with Annex III. The Commission shall summarise that information at Community level and shall make the non-confidential information publicly available on its database via the Internet.
10.6-8	*Notification of banned or severely restricted chemicals under the Convention* /……../ 6. Upon request from any Party or from the Secretariat, the Commission shall provide additional information concerning the chemical or the final regulatory action, as far as practicable. The Member States shall, upon request, assist the Commission as necessary in compiling that information. 7. The Commission shall forward immediately to the Member States information that it receives from the Secretariat regarding chemicals notified as banned or severely restricted by other Parties. Where appropriate the Commission shall evaluate, in close cooperation with the Member States, the need to propose measures at Community level in order to prevent any unacceptable risks to human health or the environment within the Community. 8. Where a Member State takes national final regulatory action in accordance with the relevant Community legislation to ban or severely restrict a chemical, it shall provide the Commission with relevant information. The Commission shall make that information available to the Member States. Within four weeks of that information having been made available Member States may send comments on a possible PIC notification, including, in particular, relevant information about their national regulatory position in respect of the chemical to the Commission and to the Member State which submitted the national final regulatory action. After consideration of the comments the submitting Member State shall inform the Commission whether the latter shall: — notify the Secretariat, pursuant to this Article, or — provide the information to the Secretariat, pursuant to Article 11.
12.1-2; 5-6	*Obligations in relation to imports of chemicals* 1. The Commission shall immediately forward to the Member States any decision guidance documents which it receives from the Secretariat. /……../ 2. In the case of a chemical banned or severely restricted by one or more Member States, the Commission shall, at the written request of the Member States concerned, take the information into account in its import decision. /……/ 5. Each designated national authority within the Community shall make the import decisions under paragraph 1 available to those concerned within its competence, in accordance with its legislative or administrative measures. 6. Where appropriate, the Commission shall evaluate, in close cooperation

	with the Member States, the need to propose measures at Community level in order to prevent any unacceptable risks to human health or the environment within the Community, taking into account the information given in the decision guidance document.
13.1;2; 5-8	*Obligations in relation to exports of chemicals other than export notification requirements* 1. The Commission shall immediately forward to the Member States and European industry associations information which it receives, whether in the form of circulars or otherwise, from the Secretariat regarding chemicals subject to the PIC procedure and the decisions of importing Parties regarding import conditions applicable to those chemicals. It shall also immediately forward to the Member States information concerning any cases of failure to transmit a response in accordance with Article 10(2) of the Convention. The Commission shall keep all information regarding import decisions, which shall each be assigned an import decision reference identification number, available in its database, which shall be publicly available on the Internet, and provide anyone with that information upon request. /……./ 3. Each Member State shall communicate the responses forwarded by the Commission under paragraph 1 to those concerned within its jurisdiction. /……./. 5. The Commission and the Member States shall advise and assist importing Parties, upon request and as appropriate, to obtain further information to help them to make a response to the Secretariat concerning import of a given chemical. 6. Substances listed in Parts 2 or 3 of Annex I or preparations containing such substances in a concentration that could trigger labelling obligations under Directive 1999/45/EC irrespective of the presence of any other substances shall not be exported unless either of the following conditions is fulfilled: (a) explicit consent to import has been sought and received by the exporter through his designated national authority in consultation with the Commission and the designated national authority of the importing Party or an appropriate authority in an importing other country; (b) in the case of chemicals listed in Part 3 of Annex I, the latest circular issued by the Secretariat pursuant to paragraph 1 indicates that the importing Party has given consent to import. In the case of chemicals listed in Part 2 of Annex I that are to be exported to OECD countries, the designated national authority of the exporter may, in consultation with the Commission and on a case-by-case basis, decide that no explicit consent is required if the chemical, at the time of importation into the OECD country concerned, is licensed, registered or authorised in that OECD country. Where explicit consent has been sought pursuant to point (a), if the Commission or the designated national authority of the exporter has not received a response to its request within 30 days, the Commission shall send a reminder. Where appropriate, if there is still no response within a further 30 days, the Commission may send further reminders as necessary. 7. In the case of chemicals listed in Parts 2 or 3 of Annex I, the designated national authority of the exporter may, in consultation with the Commission and on a case-by-case basis, decide that the export may proceed if, after all reasonable efforts, no response to a request for explicit consent pursuant to

	paragraph 6(a) has been received within 60 days and there is evidence from official sources in the importing Party or other country that the chemical has been licensed, registered or authorised. When deciding on the export of chemicals listed in Part 3 of Annex I, the designated national authority in consultation with the Commission shall consider the possible impact on human health or the environment of the use of the chemical in the importing Party or other country. 8. The validity of each explicit consent obtained pursuant to paragraph 6(a) or waiver granted pursuant to paragraph 7 shall be subject to periodic review by the Commission in consultation with the Member States concerned as follows: (a) for each explicit consent obtained pursuant to paragraph 6(a) a new explicit consent shall be required by the end of the third calendar year after the consent was given, unless the terms of that consent require otherwise; (b) unless a response to a request has been received in the meantime, each waiver granted pursuant to paragraph 7 shall be for a maximum period of 12 months, upon expiry of which explicit consent shall be required. In the cases referred to in point (a) of this paragraph, exports may, however, continue after the end of the relevant period, pending a response to a new request for explicit consent, for an additional period of 12 months. All new requests shall be channelled through the Commission.
15.1-4	*Information on transit movements* 1. Parties to the Convention requiring information concerning transit movements of chemicals subject to the PIC procedure, together with the information requested by each Party to the Convention through the Secretariat, shall be as listed in Annex VI. 2. When a chemical listed in Part 3 of Annex I is transported through the territory of a Party to the Convention listed in Annex VI, the exporter shall, as far as practicable, provide the designated national authority of the Member State in which he is established with the information required by the Party to the Convention in accordance with Annex VI no later than 30 days before the first transit movement takes place and no later than eight days before each subsequent transit movement. 3. The designated national authority of the Member State shall forward to the Commission the information received from the exporter under paragraph 2 together with any additional information available. 4. The Commission shall forward the information received under paragraph 3 to the designated national authorities of Parties to the Convention which requested that information, together with any additional information available, no later than 15 days before the first transit movement and prior to any subsequent transit movement.
17.1	*Obligations of the authorities of the Member States and exporters for controlling imports and exports* Each Member State shall designate authorities such as customs authorities that shall have the responsibility of controlling the import and export of chemicals listed in Annex I, unless it has already done so before the entry into force of this Regulation. The Commission and the Member States shall act in a targeted and coordinated way in monitoring exporters' compliance with this Regulation. Each Member State shall, in its regular reports on the operation of procedures

	pursuant to Article 21(1), include details of the activities of its authorities in that regard.
18	*Penalties* Member States shall determine the penalties applicable to infringements of the provisions of this Regulation and take all measures necessary to ensure correct implementation of these provisions. The penalties shall be effective, proportionate and dissuasive. If they have not already done so before the entry into force of this Regulation, Member States shall notify the Commission of those measures by 1 August 2009. They shall also notify it of any further modifications as soon as possible after their adoption. Member States shall make all information regarding penalties available upon request.
19.1-3	*Exchange of information* 1. The Commission and the Member States shall, as appropriate, facilitate the provision of scientific, technical, economic and legal information concerning chemicals subject to this Regulation, including toxicological, eco-toxicological and safety information. The Commission, with the support of the Member States as necessary, shall, as appropriate, ensure: (a) the provision of publicly available information concerning regulatory actions relevant to the objectives of the Convention; and (b) the provision of information for Parties and other countries directly or through the Secretariat concerning those actions which substantially restrict one or more uses of a chemical. 2. The Commission and the Member States shall protect any confidential information received from a Party or other country as mutually agreed. 3. As regards the transmission of information under this Regulation, and without prejudice to Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information (1), the following information at least shall not be regarded as confidential: (a) the information specified in Annex II and Annex IV; (b) the information contained in safety data sheets referred to in Article 16(3); (c) the expiry date of a chemical; (d) the production date of a chemical; (e) information concerning precautionary measures, including hazard classification, the nature of the risk and the relevant safety advice; (f) the summary results of toxicological and ecotoxicological tests; (g) information concerning handling packaging after chemicals have been removed. A compilation of the information transmitted shall be prepared regularly by the Commission on the basis of the contributions by Member States.
20	*Technical assistance* The Commission and the designated national authorities of the Member States shall, taking into account in particular the needs of developing countries and countries with economies in transition, cooperate in promoting technical assistance, including training, for the development of the infrastructure, the capacity and the expertise necessary to manage chemicals properly throughout their lifecycles. In particular, and with a view to enabling those countries to implement the Convention, technical assistance shall be promoted by means of the provision

	of technical information concerning chemicals, the promotion of the exchange of experts, support for the establishment or maintenance of designated national authorities and the provision of technical expertise for the identification of hazardous pesticide formulations and for the preparation of notifications to the Secretariat. The Commission and the Member States shall actively participate in the Information Network on Capacity Building set up by the Intergovernmental Forum on Chemical Safety, by providing information concerning the projects they are supporting or financing to improve the management of chemicals in developing countries and countries with economies in transition. The Commission and the Member States shall also consider giving support to non-governmental organisations.
21.1-3	*Monitoring and reporting* 1. Member States shall regularly forward to the Commission information concerning the operation of the procedures provided for in this Regulation, including customs controls, infringements, penalties and remedial action. 2. The Commission shall regularly compile a report on the performance of the functions provided for in this Regulation for which it is responsible and shall incorporate it in a synthesis report integrating the information provided by the Member States under paragraph 1. A summary of that report, which shall be published on the Internet, shall be forwarded to the European Parliament and to the Council. 3. As regards the information supplied pursuant to paragraphs 1 and 2, the Member States and the Commission shall comply with relevant obligations to protect the confidentiality of data and ownership.