EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL
Safety of the food chain
Pesticides and Biocides

NOTE FOR DISCUSSION WITH COMPETENT AUTHORITIES FOR BIOCIDAL PRODUCTS

This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with Member States' Competent Authorities for biocidal products. Please note, however, that Member States are not legally bound to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.

Concepts of placing and making available on the market in the context of Regulation (EU) No 528/2012

1. SCOPE OF THIS NOTE

The purpose of this note is to clarify the concepts of placing and making available on the market in the context of Regulation (EU) No 528/2012 (the BPR) and to address frequently asked questions in relation to these concepts[1].

In so far as they are relevant for the implementation of the BPR, this note draws on the principles laid down in the Blue Guide on the implementation of the EU product rules[2], which purpose is to explain the principles of the New Legislative Framework.

The New Legislative Framework brought together Regulation (EC) No 765/2008[3] and Decision No 768/2008/EC. In particular, Decision No 768/2008/EC[4] provides for elements and definitions that the three institutions (Council, Parliament and Commission) had committed themselves to adhere to and to have recourse to as systematically as possible when drawing up product related legislation. As not every element of the Decision was relevant for the BPR, this approach was partially followed. In particular, the definitions of "placing" and "making available on the market" and a reference to Regulation (EC) No 765/2008 as regards market surveillance[5] were integrated into the BPR.

[1] All guidance applicable to Member States according to this note applies also to EFTA States.
[2] http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf
[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF
[4] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008D0768&from=EN
[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:en:PDF

The Blue Guide provides guidance for the implementation of the provisions and concepts laid down in the New Legislative Framework. In that respect, it is directly relevant for the elements of Decision 768/2008/EC which have been integrated into the BPR. In other aspects of lesser relevance, the Blue Guide can be used with a view to ensuring a more uniform and coherent application of similar principles between biocidal products, treated articles and other products.

However, whenever considering principles from the Blue Guide, it must be borne in mind that the BPR establishes a comprehensive set of rules for the making available on the market of biocidal products, which are subject in particular to authorisation, which is not the case for products covered by the New Legislative Framework.

Finally it is important to note that, with regard to biocidal products, this document is written solely from the perspective of products containing approved active substances and authorised in accordance with the provisions of the BPR.

2. GENERAL PRINCIPLES

2.1 Products within the scope of the BPR

The BPR lays down rules for two categories of products: biocidal products, for which the BPR provides a comprehensive set of rules regarding their making available on the market and use, and treated articles, for which the BPR establishes only limited provisions regarding their placing on the market.

The following Blue Guide principles are of relevance for both biocidal products and treated articles in the context of the BPR.

"The product[6] must comply with the legal requirements that were in place at the time of its placing on the market.

The BPR applies to all forms of supply, including distance selling and selling through electronic means. Hence, regardless of the selling technique products within the scope of the BPR and intended to be made available on the Union market must be in conformity with the BPR.

A product intended to be placed on the Union market, offered in a catalogue or by means of electronic commerce, has to comply with the BPR when within the scope of the BPR and when the catalogue or website directs its offer to the Union market and includes an ordering and shipping system."

Despite the acknowledged difficulty of taking actions against suppliers located outside the EU, where Member States authorities have no jurisdiction, the biocidal product or the treated article on offer remain nonetheless within the scope of the BPR and, as such, should comply with the applicable provisions. Actions can be taken against the non-compliant products and,

[6] Throughout this note, unless otherwise provided, product refers to both biocidal products and treated articles.

if possible, against economic operators other than the supplier located outside the EU, which are making available these products on the EU market (i.e. the importers or distributors).

2.1a. Biocidal products

Under the BPR,

- any substance or mixture,

- in the form it is supplied to the **user** [emphasise added],

- consisting of, containing or generating one or more active substances

- with the intention[7] to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

is considered to be a biocidal product.

In addition, in very specific circumstances, such as for instance ozone generated from ambient air or chlorine from sea water, a substance or mixture, generated from substances or mixtures which do not themselves correspond to the above description of a biocidal product, shall nonetheless be considered as biocidal product in so far as they are used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

Furthermore, under the BPR, the **user** (hereafter referred to as the end-user) of a biocidal product is to be understood as the person who is going to use the biocidal product with a view to exerting a biocidal action against a harmful organism. Such biocidal action would also cover the treatment with or the intentional incorporation of a biocidal product in a substance, mixture or article.

Therefore active substances, mixtures, concentrates and other premixes used for the manufacture of a biocidal product, because they are not supplied to an end-user, shall not be considered as **biocidal products**. Accordingly, they do not need an authorisation to be placed on the market.

Conversely, active substances, mixtures, concentrates and other premixes supplied to an end-user, in a form which requires actions from the end-user before use, such as mixing or

[7] The notion of intention goes beyond the claim made and shall also take account of all the characteristics of the product (e.g. pictures or photos on the label, information on the manufacturer or distributor's website, intended use or user, etc.). Thus, even when no claim is made, when it is clear from the evidence available that a product is going to be used to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, that product could still be regarded as a biocidal product.

dilution, shall be considered as **biocidal products**. Accordingly, they need an authorisation to be placed on the market.

Moreover, it is important to clarify that even if a substance or mixture is supplied without the intention to be used as a biocidal product, when the end-user uses that substance or mixture to generate a substance or mixture to be used with the intention of exerting a biocidal action, this substance or mixture would then meet the second part of the definition of a biocidal product and have to be authorised as such.[8]

Furthermore, pursuant to Article 17(1), biocidal products cannot be used if they have not been authorised. This means in particular that a product supplied without the intention to be used for a biocidal purpose cannot be used for such a purpose unless it has been authorised as a biocidal product.

The only exception is food and feed used as repellent or attractant, for which a derogation is provided in Article 2(5)(a) and to which the Regulation does not apply.

In cases where end-users may wish to exert a biocidal action with a product that was not authorised, which may be the case when the product may be used for other purposes and the manufacturer or importer of the product is not interested to place it on the market for a biocidal purpose, end-users themselves or distributors of the product could apply for authorisation under the BPR so that the product can then be authorised and used as a biocidal product.

Finally, in this case as in similar others in which it appears that obligations of the BPR might be difficult to enforce, authorities should:

- use discretion when deciding what enforcement action may be appropriate,
- use their sensible judgement as regards:
    - the severity and scale of potential or actual harm;
    - the seriousness of any potential breach of the BPR;
    - knowledge of the end-user's past compliance records;
    - the enforcement priorities;
    - the practicality of achieving results;
    - and the wider relevance of the event, including serious public concern;
- and take proportionate action when conducting their activities.[9]

[8] For example, this could be the case of several commodity substances, which can be used for different purposes, in particular as precursors for the in-situ generation of active substances.

[9] Based on HSE Enforcement Policy Statement (http://www.hse.gov.uk/pubns/hse41.pdf)

2.1b. Treated articles

Under the BPR,

- any substance, mixture or article,

- which has been treated with, or intentionally incorporates, one or more biocidal products

is considered to be a treated article.

The only exception is when the treated article has a primary biocidal function. In such case, the treated article shall be considered a biocidal product.

Furthermore, in accordance with the Blue Guide principles 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.

2.2 Making available

- A biocidal product shall not be made available on the market or used unless authorised in accordance with the BPR.
- A biocidal product or treated article is made available on the market when supplied for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge (Article 3(i) of the BPR, see also Blue Guide p.17).
- The concept of "making available" covers the first supply (i.e. the placing on the market) and any subsequent supply.
- The concept of "making available" refers to each individual biocidal product or treated article.

The following Blue Guide principles[10] are of relevance for both biocidal products and treated articles in the context of the BPR.

"Supply includes any offer for distribution or use on the Union market market which could result in actual supply (e.g. an invitation to purchase, advertising campaigns).

The concept of making available refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series.

The making available of a product supposes an offer or an agreement (written or verbal) between two or more legal or natural persons for the transfer of ownership, possession or any other right concerning the product in question after the stage of manufacture has taken place. The transfer does not necessarily require the physical handover of the product.

[10] Throughout this note, principles directly reproduced from the Blue Guide are in italics.

This transfer can be for payment or free of charge, and it can be based on any type of legal instrument. Thus, a transfer of a product is considered to have taken place, for instance, in the circumstances of sale, loan, hire, leasing and gift. Transfer of ownership implies that the product is intended to be placed at the disposal of another legal or natural person.

Supplying a product is only considered as making available on the Union market, when the product is intended for end-use on the Union market.

The supply of products for further distribution, for incorporation into a final product, for further processing or refinement with the aim to export the final product outside the Union market is not considered as making available[11].

Commercial activity[12] *is understood as providing goods in a business related context. Non-profit organisations may be considered as carrying out commercial activities if they operate in such a context. This can only be appreciated on a case-by-case basis taking into account the regularity of the supplies, the characteristics of the product, the intentions of the supplier etc. In principle, occasional supplies by charities or hobbyists should not be considered as taking place in a business related context.*[13]*"*

Finally, once a biocidal product has been authorised by a Member State, the authorisation covers any supply in that Member State. Therefore no further authorisation is required for the subsequent supply of the biocidal product (e.g. from a distributor to a retailer or from a retailer to an end-user) in that Member State. The same applies to a biocidal product authorised by the Commission, except that in that case no further authorisation is required for the subsequent supply of that product on the whole EU market.

[11] This point is particularly relevant in the case of a biocidal product used to treat an article to be exported into a third country, for which according to the BPR, there is no use, but also for which there is no making available on the market.

[12] In the definition of *'making available on the market*', the notion of '*commercial activity*' however refers to the supply, which means that whether the use takes place in the context of a commercial activity or not is not relevant for the purpose of the definition.

[13] In such cases, end-users could be confronted to a situation where no placing on the market is considered to occur and therefore no authorisation is needed whilst, according to the BPR, the product would not be allowed for use since it would not be authorised. Enforcement authorities should be mindful of these specificities when conducting their activities.

2.3 Placing on the market

- A biocidal product or treated article is placed on the market when it is made available for the first time on the Union market (Article 3 (j) BPR, mirroring Article R1(2) of Decision 768/2008)

- Treated articles made available on the market must comply with the BPR at the moment of placing on the market.

- Biocidal products made available on the market must be authorised before they can be placed on the market and must comply with the terms and conditions of their authorisation at the moment of their placing on the market.

When an authorisation holder supplies a biocidal product, or when a manufacturer or an importer supplies a treated article, *to a distributor or an end-user for the first time, the operation is always labelled in legal terms as "placing on the market". Any subsequent operation, for instance, from a distributor to distributor or from a distributor to an end-user is defined as making available.*

Placing a product on the market takes place when making it available for the first time. It even includes *any offer for distribution or use on the Union market which could result in actual supply (e.g. an invitation to purchase, advertising campaigns)*, but not the physical handover of the product.

However, storage of a biocidal product by the authorisation holder or by the manufacturer or importer, on behalf of the authorisation holder, is not regarded as placing on the market in so far as the product has not been offered for distribution or use.

Subsequently, upon placing on the market, a distinction must be made with regard to the notion of storage, between:

- Storage during distribution, which is not covered by the notion of use and corresponds to situations where the product is stored in a warehouse, in a retail shop before reaching the end-user; and

- Storage during use, which is covered by the notion of use and corresponds to situations where the end-user has been transferred the right to dispose of the biocidal product as owner (through purchase or gift) and stores it before, during or after handling, mixing or application.

The following Blue Guide principles would also be of relevance in the context of the BPR.

"*Placing on the market is considered not to take place where a product is:*

- *manufactured for one's own use*[14,15]*;*
- *bought by a consumer in a third country while physically present in that country*[16,17]*;*
- *transferred from the manufacturer in a third country to an authorised representative in the Union whom the manufacturer has engaged to ensure that the product complies with the BPR*[18]*;*
- *introduced from a third country in the EU customs territory and has not been released for free circulation*[19]*. This includes the cases of products in transit, placed in free zones, warehouses or temporary storage;*
- *manufactured in a Member State with a view to exporting it to a third country (this includes components supplied to a manufacturer for incorporation into a final product to be exported into a third country);*[20]
- *transferred for testing or validating pre-production units considered still in the stage of manufacture*[21]*;*
- *displayed or operated under controlled conditions at trade fairs, exhibitions or demonstrations*[22]*; or*

[14] With the exception of biocidal products exclusively incorporated into or used to treat articles for export, it is however important to emphasise that biocidal products cannot be used, including for one's own-use, unless they are authorised, even though there would be in such case no placing or making available on the market.

[15] It is important to note that '*manufacture for one's own use*' does not include '*manufacture for one's own use for the benefit of a third party*'. For example, a product manufactured by a service provider and subsequently applied within customer facilities is in fact supplied to the customer and therefore considered as being placed on the market.

[16] This principle is also applicable to biocidal products, which may be bought by a consumer when physically present in an EU Member State and then travelling to another EU Member State with that product. In such case, no placing on the market takes place in that other Member State.

[17] In such cases, consumers could however be confronted with a situation where no placing on the market is considered to occur and therefore no authorisation is needed, whilst, according to the BPR, the product would not be allowed for use since it would not be authorised. Enforcement authorities should be mindful of these specificities when conducting their activities.

[18] For biocidal products, this principle would also translate into *transfer from the manufacturer in a third country to the authorisation holder*.

[19] According to Article 29 of the Treaty on the Functioning of the European Union, products coming from a third country shall be considered to be in free circulation in a Member State if the import formalities have been complied with and any customs duties or charges having equivalent effect which are payable have been levied in that Member State, and if they have not benefited from a total or partial drawback of such duties or charges.

[20] This point is particularly relevant in the case of a biocidal product used to treat an article to be exported into a third country, for which there is no use according to the BPR, but also no placing on the market.

[21] For biocidal products, it is however important to note that tests or experiments carried out with a biocidal product, are considered as a use of a biocidal product and shall be done in accordance with the provisions of Article 56 of the BPR.

- *in the stocks of the manufacturer (or the authorised representative established in the Union) or the importer, where the product is not yet made available.*[23]

As for 'making available', the concept of placing on the market refers to each individual product, not to a type of product, and whether it was manufactured as an individual unit or in series. "

Consequently, even though a treated article model or type has been supplied before the BPR became applicable, individual units of the same model or type, which are placed on the market after the new requirements have become applicable, must comply with these new requirements.

The placing on the market is the most decisive point in time concerning the application of the BPR.

For treated articles, when made available on the market, they must be in compliance with the BPR at the time of placing on the market. Accordingly, new treated articles manufactured in the Union and all treated articles imported from third countries – whether new or used – must meet the provisions of the BPR when placed on the market i.e. when made available for the first time on the Union market. Compliant treated articles once they have been placed on the market may subsequently be made available along the delivery chain without additional considerations, even in case of revisions to the applicable legislation or the relevant harmonised standards.

However, for biocidal products, individual units of a given biocidal product must comply with the terms and conditions of the authorisation.

In addition, for biocidal products, it is important to note that Article 52 of the BPR provides for specific rules regarding the making available and use of existing stocks of biocidal products, for which the authorisation is cancelled, amended or not renewed.

Additional specific rules are also provided in Articles 89 and 93 concerning products placed on the market in accordance with national rules, when the active substance contained in these products is not approved yet or when, following the approval of the active substance, no application for product authorisation is submitted.

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[22] In such circumstances, no orders can be placed and a visible sign must clearly indicate that the product in question may not be placed on the market or used until it has been made to comply.

[23] For biocidal products, this principle would translate into *in the stocks of the manufacturer (or the authorised representative established in the Union), importer or authorisation holder, where the product is not yet made available.*

2.4 Actors in the supply chain and their obligations

Decision No 768/2008/EC on the EU common framework for the marketing of products provides, in the form of reference provisions, definitions and general obligations for economic operators and a range of conformity assessment procedures from which the legislator can select as appropriate. It defines in particular 'economic operators'[24] which shall mean the manufacturer, the authorised representative, the importer and the distributor of a product, and also provides a set of obligations for each of these economic operators.

Although the BPR does not explicitly refer to these definitions, it mentions manufacturers and importers of active substances and of biocidal products as being entitled to submission or access to a substance dossier (Article 95(1)), and creates obligations for persons responsible for the placing on the market of treated articles (Article 58(2) and (3)) and suppliers of treated articles (Article 58(5)).

2.4.1 Persons responsible for the placing on the market of biocidal products

The most significant difference between Decision No 768/2008/EC and the BPR lies in the fact that for biocidal products it is the authorisation holder who is responsible for the placing on the market of a biocidal product in a particular Member state or in the Union, as the case may be.

The authorisation holder may, or not, be the manufacturer or importer of the biocidal product, as any person established in the EU can be authorisation holder. It may thus be either the manufacturer or importer of the biocidal product, the company supplying the biocidal product, the company manufacturing the devices in which the biocidal products will be used, or the company using the biocidal products.

Where a manufacturer or importer is delivering a biocidal product to the authorisation holder or to distributors, following the instructions of the authorisation holder, the manufacturer or importer is acting on behalf of the authorisation holder, who is the person responsible for placing the product on the market. There is in such cases no placing on the market from the part of the manufacturer or importer.

In absence of an authorisation and therefore of an authorisation holder, there could be three different situations:

- When a biocidal product manufactured in the EU is found on the market of the Member State where it was manufactured, the manufacturer is then responsible for the non-compliant making available on the market;

[24] See Article R1 (7) of Annex I to Decision No 768/2008/EC.
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008D0768&from=EN

- When a biocidal product manufactured outside the EU is found on the market of the Member State where it was imported, the importer is then responsible for the non-compliant making available on the market;

- In any other case, the person having introduced the product on the market in that particular Member State is then responsible for the non-compliant making available on that market.

The BPR establishes that the person responsible for the placing on the market of a biocidal product is the holder of the authorisation.

- The authorisation holder is the person responsible for the placing on the market of a biocidal product, as specified in the authorisation of that product.
- The authorisation holder may or not have manufactured the product himself.
- The authorisation holder must be established within the European Union.
- The authorisation holder is subject to a series of obligations including record-keeping and reporting (see Article 68).[25]
- The authorisation holder is responsible for ensuring that the product placed on the market is properly classified, packaged and labelled (see Article (69).
- The authorisation holder must inform the competent national authorities for biocidal products in case of becoming aware of information that may affect the authorisation of his product (see Article 47(1)).

Regarding the place of establishment, it is important to clarify that the authorisation holder only needs to be established within the EEA or in Switzerland and is not required to have specifically a place of business in the Member State where the product is to be authorised.

2.4.2 Persons responsible for the placing on the market of treated articles

Concerning treated articles, the BPR does not specify which economic operator is the person responsible for the placing on the market of a treated article.

However, according to Annex I of Decision No 768/2008/EC, the person responsible for the placing on the market of an article will be the manufacturer of the treated article, when the treated article is manufactured in the EU, or the importer of the treated article, when the treated article is manufactured in a third country.

For treated articles, *the operation* of placing on the market *is reserved either for a manufacturer or an importer, i.e. the manufacturer and the importer are the only economic operators who place products on the market.*

[25] In addition, manufacturers of biocidal products are subject to quality requirements in accordance with Article 65(2).

Therefore in case a non-conform treated article is found on the market, in particular in the case of non-compliant labelling, the responsibility will be of the manufacturer when the product was manufactured in the Union and of the importer otherwise.

2.4.2.a Manufacturers of treated articles

- The manufacturer is any natural or legal person who manufactures a product[26] or has a product designed or manufactured, and places it on the market under his own name or trademark.
- The manufacturer does not have to be established in the European Union.
- The manufacturer is responsible for the conformity assessment of the product and is subject to a series of obligations including traceability requirements.
- The manufacturer must cooperate with the competent national authorities in charge of market surveillance in case of a product presenting a risk or being non-compliant.

Furthermore, the following principles from the Blue Guide would then be relevant for treated articles in the context of the implementation of the BPR[27].

"The manufacturer is any natural or legal person who is responsible for designing or manufacturing a product and places it on the market under his own name or trademark. The definition contains two cumulative conditions: the person has to manufacture (or have a product manufactured) and to market the product under his own name or trademark. So, if the product is marketed under another person's name or trademark, this person will be considered as the manufacturer.

The responsibilities of the manufacturer apply also to any natural or legal person who assembles, packs, processes or labels ready-made products and places them on the market under his own name or trademark. Further, the responsibility of the manufacturer is placed on any person who changes the intended use of a product in such a way that different essential or other legal requirements will become applicable, or substantially modifies or re-builds a product (thus creating a new product), with a view to placing it on the market.

The manufacturer may design and manufacture the product himself. As an alternative, he may have it designed, manufactured, assembled, packed, processed or labelled with a view to placing it on the market under his own name or trademark, and thus presenting himself as a manufacturer. Where subcontracting takes place, the manufacturer must retain the overall control for the product and ensure that he receives all the information that is necessary to fulfil his responsibilities according to the relevant Union harmonisation act [i.e. the BPR]. *The manufacturer who subcontracts some or all of his activities may in no circumstances discharge himself from his responsibilities, for example to an authorised representative, a distributor, a retailer, a wholesaler, a user or a subcontractor.*

Finally, if an importer or distributor modifies a product or supplies it under his name, then he is to be considered the manufacturer and must undertake all the obligations incumbent on

[26] In this section 2.4.2.a and in the following one 2.4.2.b, product refers to treated article.
[27] These principles would apply equally to manufacturers and importers of an active substance.

the manufacturer. Accordingly, he must ensure that the product complies with the applicable Union harmonisation act [i.e. the BPR]*."*

2.4.2.b Importers of treated articles

- The importer is a natural or legal person established in the Union who places a product from a third country on the EU market.
- His obligations build on the obligation of the manufacturer.

The following Blue Guide principles would also be of relevance in the context of the BPR.

"The importer is the economic operator established in the Union who places a product from a third country on the Union market.

The importer must ensure that the manufacturer has correctly fulfilled his obligations. The importer is not a simple re-seller of products, but has a key role to play in guaranteeing the compliance of imported products."

2.4.3 Distributors of biocidal products or treated articles

- The distributor is a natural or a legal person in the supply chain, other than the authorisation holder, manufacturer or the importer, who makes a product available on the market.
- Distributors are subject to specific obligations and have a key role to play in the context of market surveillance.

Along with authorisation holders for biocidal products, and with manufacturers and importers of treated articles, distributors are the third category of economic operators who are subject to specific obligations. The distributor is a natural or a legal person in the supply chain, other than the authorisation holders for biocidal products and the manufacturer or importer for treated articles, who makes a biocidal product or a treated article available on the market.

The distribution conditions may, in the absence of specific provisions in the BPR, be regulated to some extent on the national level in accordance with Articles 34 and 36 of the Treaty on the Functioning of the European Union (TFEU).

This may prove relevant as the distribution conditions (for example transport or storage) may have an impact on maintaining the compliance with the provisions of the BPR.

In addition, it is important to note that additional national rules may apply to the manufacture, import, distribution or use of biocidal products, in so far as these rules address matters not covered by the BPR. This may in particular be the case of measures geared at ensuring the sustainable use of biocidal products, such as measures concerning the certification of pest control operators or the distribution of certain biocidal products.

Notwithstanding the above, active substance approval decisions may set conditions regarding the making available on the market of the approved substances. Such conditions would then have to be observed by distributors along the supply chain.

The following Blue Guide principles would nevertheless be of relevance in the context of the BPR.

"Retailers, wholesalers and other distributors in the supply chain are not required to have a preferential relationship with the authorisation holder for biocidal products, or the manufacturer or importer for treated articles.

A distributor acquires products for further distribution either from the authorisation holder for biocidal products, or from the manufacturer or importer for treated articles, or from another distributor.

Distributors must act with due care[28] in relation to the applicable requirements. They have to know, for instance, what information is to accompany the product, whether personnel protective equipment have to be supplied with the product (e.g. gloves for antifoulings), what are the language requirements for labelling, user instructions or other accompanying documents, and what is a clear indication of the product being non-compliant.

Distributors have an obligation to demonstrate to the national market surveillance authority that they have acted with due care.

Distributor must not supply products that they know or should have assumed, on the basis of information in their possession and as a professional, not to be in compliance with the legislation. Further, they must cooperate with the competent authority in actions taken to avoid or minimise these risks, inform the manufacturer or the importer as well as the competent national authorities.

Similar obligations bind distributors once a product is made available. If they have reasonable grounds to believe that a product is not in conformity, they have to make sure that corrective measures to bring the product into conformity are taken by the manufacturer or the importer and inform the competent national authorities. Distributors have to contact the importer or manufacturer to clarify any doubt about the conformity of the product."

[28] As indicated in the Blue guide, the concept of due care refers to "*the effort made by an ordinarily prudent or reasonable party to avoid harm to another, taking the circumstances into account. It refers to the level of judgment, care, prudence, determination, and activity that a person would reasonably be expected to do under particular circumstances." (p. 29).*

BIOCIDAL PRODUCTS

Authorisation

1. When is an authorisation required?

Subject to derogations, exemptions, and transitional measures, an authorisation is required before a biocidal product is placed on the market in a particular Member State.

2. To what extent does a biocidal product require authorisation if it is manufactured in Member State A and stored in Member State B pending sales in Member State C?

If the manufacturer of the biocidal product in Member State A is manufacturing the biocidal product solely with the purpose of distributing it in other Member States than Member State A, the manufacturer shall not be required to seek authorisation in Member State A, as the product will not be made available on the market in Member State A.

Storage by/on behalf of the manufacturer in Member State B when the biocidal product is not offered for distribution or use in that Member State does not require authorisation in Member State B as the product is not placed on the market in that Member State.

Authorisation is however required in Member State C before the product is supplied for distribution or use, that is, before it is placed on the market in Member State C.

3. To what extent is an authorisation required when the manufacturer supplies the biocidal product to a distributor who receives the product with the intention of supplying it as it is to the end-user.

When the manufacturer is supplying the biocidal product to a distributor, the product is offered for distribution and use and is therefore placed on the market. An authorisation is thus required.

The authorisation holder may be a separate entity to the manufacturer.

In such cases, where the manufacturer is acting on behalf of the authorisation holder when it physically supplies the product to the distributor, the responsibility for placing the product on the market remains with the authorisation holder.

4. To what extent is an authorisation required when the manufacturer supplies a biocidal mixture to a distributor, in a package that is obviously not intended to be supplied to the end-user (e.g. in a big container). For example, the distributor receives the mixture with the intention to re-package it and then supply it to the end-user.

A product which is not in the final form under which it is supplied to the end-user is not a biocidal product. Its making available on the market is therefore not subject to authorisation.

However, when the distributor subsequently produces the final form of the product and then supplies it to the ***end-user***, a biocidal product would then be placed on the market and its placing on the market must be authorised beforehand[29].

This scenario would typically cover wood preservatives sold in DIY shops at colour mixing desks.

5. When an active substance is generated in situ by the final end-user from a precursor.

Where a precursor is supplied to the ***end-user*** for the in situ generation of an active substance, that precursor is supplied in the form in which it is intended to be used by the ***end-user***. In consequence, the precursor is a biocidal product which needs to be authorised before it is made available on the market.

However, when precursors are not supplied to the ***end-user*** for the in situ generation of an active substance but used by the ***end-user*** for that purpose, the generated active substance is then regarded as a biocidal product and its use subject to authorisation.

6. When an end-user makes a biocidal use of a purchased bulk chemical, on which no biocidal claim is made.

The use of a biocidal product is not allowed unless it is authorised.

Therefore, although the bulk chemical may not be placed on the market by its manufacturer with the intention to have a biocidal effect on harmful organisms, the bulk chemical cannot be used as biocidal product unless it is authorised as a biocidal product.

7. When an end-user generates an active substance in situ for its own use from a precursor supplied with no biocidal claim.

The use of a biocidal product, whether for one's own use or not, is not allowed unless it is authorised.

Therefore, although the precursor may not be placed on the market by its manufacturer with the intention that it can be used to generate an active substance, the substance

[29] The same would apply to (authorised) biocidal products purchased (i.e. by a distributor), and subsequently repackaged - an operation which could result in the product being placed on the market with a different label, pack size or container - before being offered for sale to the end-user.

generated from this precursor is to be used with the intention to have a biocidal effect on harmful organisms.

This active substance is therefore a biocidal product, which must be authorised before use. Alternatively, the precursor could be authorised in place of the substance generated in situ.

Holder of the authorisation

8. Does the manufacturer of a biocidal product need to be the authorisation holder?

The authorisation may be granted to any other natural or legal person other than the manufacturer of the biocidal product. This person is then the authorisation holder and is *responsible* for the placing on the market of the biocidal product.

The authorisation must however be granted before the placing on the market or first use of the biocidal product.

9. Does the importer of a biocidal product need to be the authorisation holder?

The authorisation may be granted to any other natural or legal person than the importer of the biocidal product, provided it is established within the EU. This person is then the authorisation holder and is responsible for the placing on the market of the biocidal product.

The authorisation must however be granted before the placing on the market or first use of the biocidal product.

Import/export

10. Is import into the EU deemed to be placing on the market?

For treated articles as for biocidal products, in accordance with the practice established in the context of the so-called 'New Approach' directives, an imported treated article or biocidal product is deemed to be placed on the market upon release for free circulation by the customs authorities, except when the imported treated article or biocidal product remains within the stocks of the importer and is therefore not made available yet[30].

11. Does manufacturing in the EU for export outside of the EU involve a placing on the market?

For treated articles as for biocidal products, in accordance with the practice established in the context of the so-called 'New Approach' directives, manufacturing in the EU with a view to export the product outside the EU does not involve a placing on the market.

In addition, a biocidal product which is not authorised in the EU may be used for the treatment of articles, in so far as the use of the product is limited exclusively to the

[30] See p. 18 of the "blue guide": http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf . See also question 16 for the case when a treated article is imported and used by the same person.

treatment of articles for export and that the treated articles are not placed on the EU market[31].

12. ***Does import with a view to re-export constitute placing on the market?***

In so far as the product has not been released for free circulation or, when it has, has not left the stocks of the importer and is not yet made available, there is no placing on the market.

There would in particular be no placing on the market where the product has been released for free circulation, but is then re-exported to a third country after temporary storage, and is not made available on the EU market.

13. What if the imported biocidal product is stored, handled, mixed or applied before it is re-exported?

The operations of storage, handling, mixing or application are not considered as use when they are carried out with a view to export the biocidal product outside the Union.

Therefore, in such a case, in so far as the product is not made available in the EU, there is no placing on the market.

14. What about a biocidal product brought by a private individual from outside the EU?

In so far as the individual was physically present in the country where the biocidal product was purchased, bringing back this product for one's own personal use, outside of any commercial activity, would not constitute it being placed on the market.

In such cases, consumers would however be confronted with a situation where no placing on the market is considered to occur and therefore no authorisation is needed, whilst, according to the BPR, the product would not be allowed for use since it would not be authorised. Enforcement authorities should be mindful of these specificities when conducting their activities.

15. What about cross-border provision of services involving the use of a biocidal product for professional use crossing borders (e.g. disinfectants for toilets on cross-border trains or pest-control operations)?

The biocidal product shall have been legally available in the market where it was supplied to the end-user and where the placing on the market occurred, which implies that it shall have been authorised if supplied in the EU.

The use of the product, and in particular its storage, in the context of the provision of a service would be considered as use for which an authorisation would be required in the

[31] Furthermore, in such cases, the active substances contained in such products would still benefit from the provision of Article 15 of the REACH Regulation.

MS where the product is being used, an obligation which in certain cases might be difficult, if not impossible, to be complied with.

Enforcement authorities should be mindful of this difficulty when conducting their activities.

16. What about the sale of biocidal products on means of transport such as airplanes, trains and boats between different MS within the EU and also with third party countries

By analogy with the provisions of the VAT Directive[32], where a biocidal product is sold on board ships, aircraft or trains, the place of supply shall be determined by the place of departure of the means of transport.

The biocidal product shall therefore have been legally available in the market of the place of departure of the means of transport which implies that, if the place of departure was within the EU, it shall have been authorised by the MS with jurisdiction over the place of departure.

However, an authorisation would be required in the MS where the product is being used, an obligation which in practice might be difficult, if not impossible, to be complied with if the product is bought by an end-user.

Enforcement authorities should be mindful of this difficulty when conducting their activities.

TREATED ARTICLES

Placing on the market

17. Are treated articles already placed on the market affected by new labelling requirements?

Unless otherwise specified, the obligation to comply with new labelling requirements applies from the point a treated article is placed on the market. Thus, if stocks of a treated article were already placed on the market at the time of entry into force of new requirements, the treated articles could continue to be distributed through the supply chain without recall.

18. Where exactly does 'placing on the market' of an imported treated article occur?

An imported treated article is placed on the market upon its release for free circulation by the customs authorities, except when the imported treated article remains within the

[32] See Article 37(1) of Council Directive 2006/112/EC of 28 November 2006 on the common system of value added tax - OJ L 347, 11.12.2006, p. 1–118 (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0112&from=EN)

stocks of the importer and is therefore not supplied for distribution or use on the EU market[33].

19. Is a treated article which is brought by a private individual from outside the EU for his own use while physically present in that country 'placed on the market' and therefore subject to the treated articles requirements?

The case of a private individual bringing back a treated article from a third country for one's own personal use while physically present in that country is not considered as placing on the market provided that the treated article is not supplied for distribution or use in the course of a commercial activity.

The treated article is therefore not subject to BPR requirements, which means in particular that it may have been treated with an active substance not approved or under evaluation in the EU and not labelled in accordance with the provisions of Article 58(3).

When however a treated article is purchased via a catalogue or a website where the catalogue or website directs its offer to the Union market and includes an ordering and shipping system, it has to comply with the BPR as the treated article is supplied on the EU market for distribution or use in the course of a commercial activity.

20. Against whom actions can be taken if the treated article is not properly labelled?

Enforcement authorities can take action against the identified manufacturer, when the treated article is manufactured in the EU, the importer, when it is manufactured in a third country or in the absence of an importer in the EU, against any economic operator present in the EU and involved in the making available on the market of the treated article.

Import/export

21. Is a treated article imported by an EU retailer from outside the EU and then held in a warehouse (e.g. prior to being stocked on retail shelves) 'placed on the market'?

In so far as the treated article has not yet been made available and has been kept in the stocks of the importer, whether this person is a retailer or not, the treated article shall not be considered as being placed on the market.

22. Is it possible to use in the EU without authorisation a biocidal product imported from a third country, if the only use to be made of this product is the treatment of articles that will not be placed on the EU market but exported outside the EU?

[33] See p. 18 of the "blue guide": http://ec.europa.eu/enterprise/policies/single-market-goods/files/blue-guide/guidepublic_en.pdf .

Operations, such as storage, handling, mixing or application, carried out with a biocidal product with a view to exporting a treated article outside the Union are not considered as use under the BPR.

The treatment with or the incorporation into a substance, mixture or article of an imported biocidal product would therefore not be considered as a use of a biocidal product in the meaning of the BPR, when the treated article is to be exported outside the EU. Accordingly, there would be no placing on the market of a biocidal product and no need for an authorisation.

If however, the treated article is placed on the EU market, the biocidal product used to treat that article will need to be authorised before it can be placed on the EU market and used.

23. What if instead of being imported from a third country, the biocidal product comes from another EU Member State?

For the purpose of a treated article, it does not make a difference, the biocidal product must be authorised in the Member State where the treatment is taking place unless the treated article is manufactured with a view to be exported outside the EU and not to be placed on the EU market.

Miscellaneous

24. If treated with or incorporating a biocidal product, would objects for display in museum or galleries be regarded as treated articles and be regarded as placed on the market?

Objects for display in museum or galleries which have been treated with or incorporating a biocidal product shall be considered as treated articles.

However, since the product is considered to be on display at exhibitions, it will not be considered to be placed on the market.

25. If treated with or incorporating a biocidal product, would art objects sold in auction houses or other retail companies, most of which will be second-hand, be regarded as treated articles and be regarded as placed on the market

Art objects sold in auction houses or other retail companies which have been treated with or incorporating a biocidal product, unless clearly supplied as antiques or as products to be repaired/reconditioned prior to being used, shall be considered as treated articles[34].

The BPR applies to newly manufactured products but also to used and second-hand products imported from a third country when they enter the Union market for the first time. Therefore,

[34] By analogy with the Blue guide principle that "used and second-hand products supplied to consumers are covered by the GPSD and have to be safe, unless they are supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier has clearly informed the person to whom he supplies the product to that effect" (see footnote 38, Blue guide).

second-hand treated articles which are imported and placed on the EU market for the first time, will need to comply with the provisions of the BPR.

This obligation might in practice be difficult, if not impossible, to be complied with. Enforcement authorities should be mindful of this difficulty when conducting their activities.

ANNEX I

Relevant Legal Provisions of the BPR

Article 3

Definitions

1. For the purposes of this Regulation, the following definitions shall apply:

(a) ‘biocidal product’ means

— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.

(c) ‘active substance’ means a substance or a micro-organism that has an action on or against harmful organisms;

(g) ‘harmful organism’ means an organism, including pathogenic agents, which has an unwanted presence or a detrimental effect on humans, their activities or the products they use or produce, on animals or the environment;

(i) ‘making available on the market’ means any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge;

(j) ‘placing on the market’ means the first making available on the market of a biocidal product or of a treated article;

(k) ‘use’ means all operations carried out with a biocidal product, including storage, handling, mixing and application, except any such operation carried out with a view to exporting the biocidal product or the treated article outside the Union;

(l) ‘treated article’ means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;

(m) ‘national authorisation’ means an administrative act by which the competent authority of a Member State authorises the making available on the market and the use of a biocidal product or a biocidal product family in its territory or in a part thereof;

(n) ‘Union authorisation’ means an administrative act by which the Commission authorises the making available on the market and the use of a biocidal product or a biocidal product family in the territory of the Union or in a part thereof;

(o) ‘authorisation’ means national authorisation, Union authorisation or authorisation in accordance with Article 26;

(p) ‘authorisation holder’ means the person established within the Union who is responsible for the placing on the market of a biocidal product in a particular Member State or in the Union and specified in the authorisation;

Article 17

1. Biocidal products shall not be made available on the market or used unless authorised in accordance with this Regulation.

Article 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 disposal, 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 disposal and use of existing stocks of the biocidal products concerned.

Article 89

3. […] 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.