French Ministry of Ecology, Sustainable Development and Planning
Directorate General for Pollution and Risk Prevention
Sub-Directorate for Products and Waste
Office for Chemical Substances and Preparations

GUIDE FOR MANAGERS RESPONSIBLE FOR PLACING BIOCIDAL PRODUCTS ON THE MARKET

Guidelines for the labelling of biocidal products placed on the market in France

Version of 28 August 2007

FOREWORD

The guidelines proposed in this document are intended to provide guidance to professionals in the biocides sector regarding compliance with the French regulations on the labelling of biocidal products placed on the market in France.

The guidelines are indicative. The principles and practices set out in this document can in some cases be replaced with other approaches, provided that these are suitably justified all while remaining consistent with the regulatory texts regarding the labelling of biocidal products placed on the market in France.

This guide was written in collaboration with:

- The Directorate General for Competition, Consumer Affairs and Fraud Control,
- The Directorate General for Labour,
- Technical centres and Federations of professionals, including:
    - the Technological Institute of Forestry, Cellulose and Wood Construction (FCBA),
    - the French Federation for Retail and Trade (FCD),
    - the French Federation of Paint, Inks, Colours, Glues and Adhesives Industries (FIPEC),
    - the French national union of industries for the preservation of wood and wood products (SPB),
    - the French Chemical Trade Association (UFCC).

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1. INTRODUCTION

Biocidal products are often described as non-agricultural pesticides and are found in a wide range of products including household disinfectants, insecticides, wood and water treatment products, and antifouling paints. Intended to destroy, deter or render harmless harmful organisms, biocides are by definition active substances liable to have harmful effects on humans, animals or the environment.

The **European Union Directive 98/8/EC**[1] concerning the placing of biocidal products on the market primarily aims to ensure a high level of protection for humans, animals and the environment by limiting marketing only to effective biocidal products having acceptable risks and by encouraging the marketing of active substances posing the least possible risk to humans and the environment. Its measures aim in particular to prevent long-term effects: CMR (Carcinogenic, Mutagenic, Reprotoxic) effects, and effects of PBT (Persistent, Bioaccumulative and Toxic) substances.
It was transposed into French law partly by the Order of 11 April 2001, set out in **Articles L.522-1 to L.522-18 of the French Environmental Code**, and then by **Decree no. 2004-187 of 26 February 2004**[2] concerning the placing of biocidal products on the market.
There are three ministerial orders implementing the Decree of 26 February 2004, including the **Ministerial Order of 19 May 2004**[3] on the control of the placing on the market of active biocidal substances and marketing authorisation for biocidal products.
The aim of the classification, packaging and labelling regulations is to ensure the protection of people who may be exposed to products, and the protection of the environment. Labels provide users with some first essential and concise information regarding the hazards of products and precautions to be taken during their use.

In France, all biocidal products are subject to the labelling provisions of the **Ministerial Order of 19 May 2004**, described in the rest of this document. Depending on the nature of the substance or mixture,

[1] http://www.ecologie.gouv.fr/IMG/pdf/dir98-8_biocides.pdf
[2] http://www.ecologie.gouv.fr/IMG/pdf/decret_2004-187_biocides.pdf
[3] http://www.ecologie.gouv.fr/IMG/pdf/biocides_20040519_controle.pdf

other regulatory provisions also apply, the most significant of which are briefly summarised in this introduction.

Case of articles: the packaging of articles shall be labelled, and not the articles themselves (example of wipes impregnated in disinfectant solutions set out in Section 2.2.1).

Labelling of hazardous substances and mixtures:

The provisions concerning the labelling of biocidal products shall be applied without prejudice to the other regulations in force, in particular those on the labelling of hazardous substances and mixtures[4]. Any packaging of a hazardous substance or mixture shall thus include a label or a marking, when information is directly marked on the packaging, complying with several regulatory criteria. Statements appearing on packaging shall be written in French and labels shall have a minimum size depending on the packaging volume. Each label shall include information in clear and indelible characters relating to:

- Identification of the marketing manager;
- Identification of the hazardous substance or substances where applicable;
- The name of the preparation;
- The hazards of the hazardous substances or mixture (in particular hazard symbols, risk phrases and safety advice).

All of these provisions are laid out in **Circular DRT no. 13 of 24 May 2006**[5] on the packaging and labelling of hazardous substances and mixtures and on the safety data sheet.

Labelling of detergents:

Certain product-type (PT) 2, 3 and 4[6] biocidal products fall under the provisions on the labelling of detergents of **Regulations (EC) No 648/2004 of 31 March**

[4] in particular:
- Articles L. 231-6 and R. 231-51 of the French Labour Code;
- Articles L. 1342-3, L. 5131-1, L.5132-2 to L. 5132-3, R. 1342-1 to R.1342-12 and R. 5132-46 to R. 5132-56 of the French Public Health Code;
- Ministerial Order of 20 April 1994 as amended;
- Ministerial Order of 9 November 2004 as amended.

[5] http://www.travail.gouv.fr/publications/picts/bo/30062006/TRE_20060006_0110_0006.pdf

[6] the list of the 23 biocidal Product-Types (PTs) described in Annex V of the Biocides Directive 98/8/EC is set out in the annexes of this document.

2004[7] **and (EC) No 907/2006 of 20 June 2006**[8] of the European Parliament and of the Council. In this case the labelling shall include:

- information on the identity of the marketing manager;
- identification of the substance or mixture;
- directions for use of the product;
- special precautions for use, where applicable;
- the concentration of certain components specific to detergents, set out in Annex VII of Regulation (EC) No 648/2004 updated by Regulation (EC) No 907/2006.

Labelling of products releasing VOCs:

Decree no. 2006-623 of 29 May 2006[9] on the limitation of emissions of Volatile Organic Compounds (VOCs) due to the use of organic solvents in certain varnishes and paints and in vehicle refinishing products also requires that companies responsible for the marketing of biocidal paints and varnishes (for example, certain PT 7, 8, 9, 10 and 21 biocidal products) include the sub-category of product and the VOC limit value as defined in Annex II of Directive 2004/42/EC which gave rise to the decree. Moreover, the maximum level of VOCs in the product under normal conditions of use shall be specified.

Labelling of aerosol dispensers:

Furthermore, biocidal products in the form of aerosol dispensers are covered by **Decree no. 97-106 of 3 February 1997**[10] on the prevention of risks resulting from the use of aerosol dispensers. These dispensers shall be provided with a label including information about the person responsible for first placing the product on the market in the European Union. Moreover, specific statements shall be included as well as additional precautions for use that inform consumers of the specific hazards of the product. If aerosol dispensers contain flammable components, they shall be fitted with a label including appropriate safety symbols, corresponding risk phrases and safety advice. Lastly, the words "**For professional users only**" shall be placed on the label in the case of aerosol dispensers for professional use intended for entertainment or decorative purposes.

[7] http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_104/l_10420040408fr00010035.pdf
[8] http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_168/l_16820060621fr00050010.pdf
[9] http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=DEVP0640026D
[10] http://www.legifrance.gouv.fr/texteconsolide/ADHVY.htm

There are other regulations on the labelling of substances and mixtures, in particular concerning the transport and management of hazardous waste.

Case of biocidal products subject to pre-existing MAs[11]:
Certain biocidal products such as disinfectants for agricultural use, rodenticides and water treatment products are currently subject to marketing authorisations that can be issued by two different authorities: the Ministry of Health and the Ministry of Agriculture. Furthermore, there are certain disinfectants that were authorised by AFSSAPS as medicinal products for human use in the past but that, since the adoption of Directive 98/8/EC, have met the definition of biocidal products and not medicinal products. A table on the website of the French Ministry of Ecology, Sustainable Development and Planning[12] lists biocidal products regulated by an authorisation regime in France during the transition period:

- For biocidal products containing substances that are part of the review programme, the stated authorities will continue to issue marketing authorisations until the European decision to list the active substance they contain has been made (listing in Annexes I, IA, IB of Directive 98/8/EC of 16 February 1998) and an MA application fulfilling the requirements of this same directive has been submitted for this product.
- Biocidal products containing substances that are not part of the review programme (not mentioned in Annex II or listed in Annex VII of Regulation (EU) 2032/2003[13]) can no longer be marketed (effective as of 1 September 2006) and their use has been prohibited since 1 September 2007[14].

Since the statements to be placed on products with a pre-existing MA are more or less the same as those required under the Ministerial Order of 19 May 2004 for biocidal products, it is considered that the guidelines described below need not be applied for products with a pre-existing MA pending the issuing of a biocide MA. The labelling rules applicable to biocidal products with

[11] in the rest of the document, all MAs mentioned are 'biocide' MAs
[12] http://www.ecologie.gouv.fr/IMG/xls/periode_transitoire_tableau.xls
[13] http://www.ecologie.gouv.fr/IMG/pdf/reglbioc3-2032-2003.pdf
[14] http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=DEVP0430135A, and http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=DEVP0754227A amended by http://www.legifrance.gouv.fr/WAspad/UnTexteDeJorf?numjo=DEVP0758760A

pre-existing MAs continue to apply to these products pending the issuing of biocide MAs. However, their labelling statements may be supplemented or enhanced in light of the contents of this guide.

2. GUIDELINES FOR THE LABELLING OF BIOCIDAL PRODUCTS PLACED ON THE MARKET IN FRANCE

2.1. General points

2.1.1. Information regarding the Ministerial Order of 19 May 2004[15]

Generally speaking, all of the statements appearing in Article 10 of the Ministerial Order of 19 May 2004 (Annex 3.2) are required.

Only the following indications:
- ***b (authorisation number),***
- ***d (authorised uses of the biocidal product), and***
- ***e (directions for use and dose rate for each authorised use, expressed in metric units)***

in Article 10 of the Ministerial Order of 19 May 2004 are not required for biocidal products pending their authorisation by the Ministry of Ecology (MEDAD).

The sentence "*The statements required in points 'a to f', 'h', 'j' and 'k to n' shall be shown as they appear in the marketing authorisation*", in the Ministerial Order of 19 May 2004, does not release companies responsible for placing products on the market from including these particulars on labels before this marketing authorisation (MA) is issued. These particulars shall be shown word for word as they will appear in the MA once it has been issued and should already appear on labels (with the exception of those in points 'b', 'd' and 'e').

2.1.2. Product transfers

The provisions of Article 10 of the Ministerial Order of 19 May 2004 also apply in the event that a biocidal product is transferred to another container. The container to which the product is transferred shall therefore be

[15] http://www.ecologie.gouv.fr/IMG/pdf/biocides_20040519_controle.pdf

labelled with adaptations made if necessary in relation to the original product, e.g. in relation to the volume it contains.

2.1.3. Principle of non-redundancy

The various regulations that apply to products can require the labelling of similar statements. For the sake of clarity, there is no requirement to list identical statements several times on the same label.

When the statements required by various regulatory texts are similar but not identical, the professional shall assess the relevance of showing the various statements:

Example 1: case of a product classified as a hazardous mixture with labelling of safety advice: "Avoid release into the environment. Refer to the Safety Data Sheet". Here it is not necessary to state "*Do not empty into drains or waterways*" in the section on product disposal and the cleaning of equipment.

Example 2: case of a product classified as a hazardous mixture with labelling of the safety phrase "*wear suitable gloves*". In addition, in the precautionary measures to be taken during use, the type of gloves to be worn should be specified (e.g. "wear CE-marked nitrile gloves), which clarifies the S-phrase[16].

2.1.4. Lack of space on labels

Lack of space on a label cannot in any circumstances justify the non-inclusion of certain information.

The company responsible for the placing on the market of the biocidal product has total freedom to change the packaging of its product, in order to ensure that the required statements are legible and indelible.

This information shall be written in French.

2.1.5. Examples of good practices

These examples apply to products not accompanied by a leaflet. When the product is accompanied by a leaflet, the sentence "**Read attached instructions before use**" must be added to the label. Most indications (c, e, f, h, i, j, k, l and n) can then be mentioned in the leaflet.

[16] reminder: R- and S-phrases cannot be modified.

Example of a biocidal product classified as a hazardous mixture and intended for professional use:

Product intended for exclusive use by professionals

Trade name:
Marketing manager*:
MA number:
Biocidal active substance and CAS no.: Concentration
Type of preparation:
Product use:
Batch no.:
Expiry date:

} Often refers to a specific area of the packaging where these data are ink-jet printed

Directions for use:
(including the dose, time period for action to appear and duration of action)

Precautionary measures:

Labelling in accordance with the regulations on hazardous substances and mixtures (classification in particular)

Also, add:

Adverse side effects
Directions for first aid
Specific risks to the environment

Disposal of the product and packaging:

Equipment cleaning: *for example, rinse the brush with water*

Comments:

The names of the sections should not appear on the 'real' label (only the content of the sections should be shown).

* Information about the marketing manager may appear elsewhere, for example in the “labelling of hazardous mixtures” section.

Example of a biocidal product not classified as a hazardous mixture and intended for the general public:

Trade name:
Details of the packer or importer
MA number:
Biocidal active substance and CAS no.: Concentration
Type of preparation:
Product use:
Batch no.:
Expiry date:

} Often refers to a specific area of the packaging where these data are ink-jet printed

Directions for use:
(including the dose, time period for action to appear and duration of action)

Precautionary measures:

Adverse side effects: Directions for first aid

Harmful environmental effects

Disposal of the product and packaging:

Equipment cleaning:
for example, rinse the brush with water

2.1.6. Provisions relating to the advertising of biocidal products

Advertising[17]: the making of a representation in any form in connection with a trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations.
Examples of advertising: television advertising, radio advertising, promotional catalogues, product brochures, etc.

Article 21 of Decree no. 2004-187[18] of 26 February 2004 transposing Directive 98/8/EC stipulates that:

"Every advertisement for a biocidal product shall be accompanied by the following warnings: '**Use biocides safely. Always read the label and product information before use**'. These warnings shall be clearly distinguishable in relation to the whole advertisement. Advertisers may replace, in the warnings in the previous paragraph, the word 'biocides' with an accurate description of the product-type being advertised. Under no circumstances may the advertising of a biocidal product mention '**low-risk biocidal product**', '**harmless**', or any similar indications. Advertisements shall not refer to biocidal products in a manner which is misleading in respect to the risks from the product to humans or the environment".

Although a label can be deemed an advertisement, it is considered that this warning does not need to appear on the labels of biocidal products already including all product-related information.

[17] Extracted from Directive 2006/114/EC.
[18] http://www.ecologie.gouv.fr/IMG/pdf/decret_2004-187_biocides.pdf

2.2. Guidelines

Shall appear on the label

2.2.1. 'a' indication: *identity of every biocidal active substance contained in the product and its concentration in metric units.*

2.2.1.1. Identity of the active substance

The identity of the biocidal active substance(s) contained in the product must appear on the label of the biocidal product. The indication shall allow the substances to be unequivocally identified.

- As a priority: indication of the names defined in Annex 2 of Regulation (EC) No 2032/2003, with the possible addition of CAS numbers.

  Labelling of: dichlofluanide (CAS no. 1085-98-9)

- If a substance's name is too long to be included on the label, and a generic name is provided in Annex 2 of Regulation 2032/2003, the substance can be referred to by its generic name, with the systematic addition of the CAS number.
  Example: (1,3,4,5,6,7-Hexahydro-1,3-dioxo-2H-isoindol-2-yl)methyl(1R-trans)-2,2-dimethyl-3-(2-methylprop-1-enyl) cyclopropane carboxylate is also commonly called d-trans-tetramethrin (CAS no. 1166-46-7).

  Labelling of: d-trans-tetramethrin (CAS no. 1166-46-7)

- If no generic name is provided, it is then recommended to use the name of the class of the substance, with the systematic addition of the substance's CAS number(s).

  Labelling of: Mixture of quaternary ammonium compounds (CAS no. 7173-51-5 and CAS no. 68956-79-6)

- If there is no CAS number, the name is long and there is no generic name, then the identity of the biocidal substance as defined in Annex 2 of Regulation (EC) No 2032/2003 must be mentioned. This situation applies to fewer than five substances out of approximately 350 listed active substances.

Labelling of: Mixture of 5-Hydroxymethoxymethyl-1-aza-3,7-dioxabicyclo(3.3.0)octane (16.0%), 5-Hydroxymethyl-1-aza-3,7-dioxabicyclo(3.3.0)octane (EINECS 229-547-6; 28.8%) and 5-Hydroxypoly(methyleneoxy) methyl-1-aza-3,7-dioxabicyclo (3.3.0) octane (5.2%) in water (50%)

Note: When the name of the active substance is not explicit, it can be useful to add the name of the class of the active substance, as in the case of disinfectants for professional use. This enables users to make informed choices of products based on their spectrum of activity.

Labelling of: miristalkonium chloride (CAS no. 139-08-2), quaternary ammonium compound

2.2.1.2. Concentration of the biocidal substance

The concentration of the biocidal active substance shall, as a priority, be given in metric system units[19]. The use of percentages is also accepted, provided that the percentage unit is specified.

Example of a labelling statement for a percentage by weight:

Glutaraldehyde: 2% (m/m)

or for a percentage by volume:

Glutaraldehyde: 2% (v/v)

Whenever possible, percentages by weight (which in particular help define the classification of the mixture) should be preferred over percentages by volume.

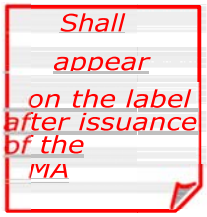
Case of articles treated by a solution which themselves are biocidal products (such as disinfectant wipes): the concentration of active substance to be indicated is that of the solution used to treat the article, and not that of the complete product.

Example of a labelling statement for a treated wipe:

Glutaraldehyde in the impregnating solution: 2% (m/m)

[19] the base units of the metric system that can be used to measure concentrations are the **metre** and **kilogramme**. The units arising from the base units are **gram-derived units (mg, etc.)**. For volumes: one **litre (L or l)** is defined as being equivalent to 1 **dm^3**.

2.2.2. 'b' indication: *authorisation number.*



The MA number will be available once the authorisation has been issued. Applications shall be submitted to the French Ministry of Ecology, Sustainable Development and Planning when all of the biocidal substances contained in the biocidal product have been included in Annex I, IA or IB of Directive 98/8/EC.

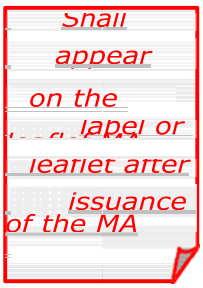
Marketing managers have two years to prepare these applications, which corresponds to the time between the vote on the decision to list the substance and its actual listing.

2.2.3. 'c' indication: *type of preparation.*

The type of preparation can be chosen from the list given in Annex 3 of this document. This list is based on the GIFAP codes[20], currently used for plant protection products, and on catalogues of uses for biocidal products previously approved or pending approval (product-types 8, 14, 18, 19) available on the website of the ECB[21].

2.2.4. 'd' indication: *authorised uses of the biocidal product.*

A catalogue of uses will be available when MA applications are submitted. Then, for each biocidal product, uses will be authorised by the MEDAD and will appear in marketing authorisations as granted by the MEDAD. **During the transition period, it is nonetheless highly recommended to clearly indicate the uses for which the product is being placed on the market.**



2.2.5. 'e' indication: *directions for use and dose rate for each authorised use, expressed in metric units.*

This indication will be mandatory on the label or product leaflet only after the MA has been obtained. **That said, it is recommended to include the directions**

[20] Catalogue of pesticide formulation types and international coding system (CropLife International Technical Monograph no. 5, March 2002)
[21] http://ecb.jrc.it/biocides/

for use and dose rate before the MA is obtained, in order to facilitate use of the product.

The dose rate corresponds to the necessary dose for effective biocidal action. It shall be expressed in metric system units. If marketing managers use 'practical' units for the sake of clarity for users, the general public in particular, they should add the corresponding metric system units.

Examples:

Labelling of: one cap (X g)

or

Labelling of: one pipette (X mL)

Labelling of: one block (X g)

Case of an aerosol:

Labelling of: X spray(s) of Y second(s)

Case of a sprayer:

Labelling of: one spray (X mL)

Shall appear on the label or the leaflet

2.2.6. 'f' indication: *likely adverse side effects, including indirect effects, and directions for first aid.*

Adverse side effects to be listed do not cover only adverse effects for humans (e.g. allergy, irritation) but also all adverse effects for the materials on which the biocidal product is applied.

Example:

This product causes staining when applied on plastic

Nothing needs to be indicated if the marketing manager for the biocidal product has no knowledge of adverse side effects. Otherwise, when adverse side effects have been established, this notice shall include warnings arising from all known data, either on the label or on the leaflet accompanying the biocidal product. In this case, precautionary measures

cannot replace indications of adverse side effects.
Furthermore, a reference to the safety data sheet (SDS) in no circumstances releases the marketing manager from mentioning all information concerning adverse side effects on the label or leaflet.

As for directions for first aid, there should be a statement to contact the poison control centre.
Example:

If swallowed, do not induce vomiting. Seek medical advice immediately and show this container or label. Contact the nearest poison control centre.

Shall appear on the label

2.2.7. 'g' indication: *if the product is accompanied by a leaflet, the sentence "Read attached instructions before use".*

A leaflet is not mandatory but can be a useful way to inform users.
When the biocidal product is accompanied by a leaflet, the sentence "**Read attached instructions before use**" must be included on the label. No variations can be used to replace this sentence. Moreover, this information shall be immediately visible on the product. The sentence shall thus have a large enough font size so that users may see it at first glance.

Shall appear on the label or the leaflet

2.2.8. 'h' indication: *directions for the safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging.*

For packaging, a management mode should be mentioned in accordance with the regulations and in particular with Decree no. 94-609 of 13 July 1994 if the product is not intended for households.
This management mode depends on the packaging material. However, some biocidal products contain hazardous substances. In this case, the packaging waste that contained them is likely to be considered hazardous waste under Decree no. 2002-540 of 18 April 2002 and the producer shall indicate a management mode ensuring that the hazardous substances will not

contaminate other items. In particular, recycling may be prohibited in this situation.

For every product, the case of empty packaging and that of packaging still containing biocidal product shall be dealt with.

The case of refillable containers is not addressed in the following examples and requires a specific statement.

Obviously, professionals should adapt statements to their products: for example, it is not necessary to rinse a cardboard container that contained a solid product not classified as a hazardous mixture.

2.2.8.1. Biocidal product intended for the general public

- Empty containers that contained biocidal products classified as hazardous and intended for the general public:

Dispose of the empty container in accordance with the local regulations for the disposal of this waste, for example by taking it to a waste collection centre.

- Empty containers that contained biocidal products not classified as hazardous and intended for the general public:

*Dispose of the empty, **rinsed** container in accordance with the local regulations for the disposal of this waste, for example, through the selective collection of household packaging waste if the container meets the sorting requirements.*

- Container containing unused biocidal product, whether hazardous or not, intended for the general public:

Dispose of unused products in accordance with the local regulations for the disposal of this waste, for example by taking them to a waste collection centre.
In this case, the container cannot be recycled.
Do not empty into drains or waterways.

2.2.8.2. Biocidal product intended for professionals

- Empty containers and those still containing biocidal product classified as hazardous and intended for professionals:

The container should be disposed of as hazardous waste under the full responsibility of the holder of this waste.
Do not empty into drains or waterways.

- Empty containers and those still containing biocidal product not classified as hazardous and intended for professionals:

The container can be disposed of as non-hazardous waste under the full responsibility of the holder of this waste. *Do not empty into drains or waterways.*

- Specific case of selective collection sectors: specify the specific collection methods.

2.2.9. 'i' indication: *formulation batch number or designation and expiry date under normal storage conditions.*

Formulation batch numbers or designations must be mentioned. For the repackaging or resale of a biocidal product, the new marketing manager must provide a batch number.

The product expiry date corresponds to the storage time for the biocidal product before opening. It is also suggested to mention a use-by date for the biocidal product after opening, but this date cannot replace the expiry date.

The expiry date is determined based on the real-time and/or accelerated stability testing of intermediate and finished products. These tests can be relatively long and complicated to implement. Companies responsible for placing products on the market that have not yet launched studies are therefore advised to contact their trade unions or associations in order to identify the methodologies used in their business sector.
These data shall in particular be provided in the future MA application (see Annex IIB(3), point 3.7 of the aforementioned Ministerial Order of 19 May 2004).
Some professionals use standard expiry dates, based on general knowledge of product behaviour, specifying a time period from the date indicated by the batch number on the label.

Shall appear on the label or the leaflet

2.2.10. 'j' indication: *time period needed for the biocidal effect to appear and its duration of action, interval to be observed between applications of the biocidal product or between application and the next use of the treated product, material or surface, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas.*

Companies responsible for placing products on the market are advised to specify under this indication whether the biocidal effect is preventive or curative. This information, as well as all of the information required by the 'j' indication, can be included with the directions for use on the label ('e' indication).

2.2.10.1. Time needed for the biocidal effect to appear

The time needed for the biocidal effect, or the contact time, shall be specified irrespective of the biocidal product in question. This period may be mentioned as an interval whose high and low values correspond to reasonably foreseeable conditions of use.
Case of a biocidal product with immediate or near-immediate action: this information also must appear on the label. Example of a statement that can be used:

Immediate action

Case of products with lethal action on vertebrates (product-types 14, 15, 17 and 23[3]) or invertebrates (product-types 16, 18): the time needed for the biocidal effect corresponds to the time required for the product to take effect after ingestion, inhalation or contact, depending on the mode of action. Example of a statement that can be used:

Acts within [X minutes, etc.] of [ingestion, contact, etc.] of/with the product

[3] the list of the 23 biocidal Product-Types (PTs) described in Annex V of the Ministerial Order of 19 May 2004 is set out in the annexes of this document.

2.2.10.2. Duration of action of the biocidal effect and interval to be observed between applications

If the biocidal product is for preventive use only or for curative and preventive use simultaneously, the duration of action of the biocidal effect and the interval to be observed between applications shall be specified. The duration of action can then be mentioned as an interval whose high and low values correspond to reasonably foreseeable conditions of use.

If the effect is only curative, it is sufficient to mention the interval to be observed between applications of the biocidal product or between application and the next use of the treated material.

It is also important to note that in no circumstances can information on the frequency of application replace information on the duration of the biocidal effect after application of the product.
Example: "Re-apply the product no more than 3 times per day" does not let users know how long the effect lasts.

For products with lethal action on vertebrates (product-types 14, 15, 17 and 23), the duration of action does not need to be indicated but information regarding the interval to be observed between product applications shall be mentioned.
Example:

Labelling of: Reapply each time traces of rodents are observed

Shall appear on the label or the leaflet

2.2.11. 'k' indication: *particulars regarding the cleaning of equipment*

Reference shall be made to the equipment used to apply the biocidal product: brush, etc. If application of the biocidal product does not require any specific equipment, this information should not be mentioned on the label.

However, information on the cleaning of equipment shall be included whenever the biocidal product requires use of specific equipment or a specific solvent (including water). It is then necessary to specify the type of material, equipment or solvent used for cleaning as well as specific cleaning

conditions, including related precautionary measures. This is valid for all categories of users.

Example:

Labelling of: clean equipment with water

Or

Labelling of: clean tools with solvent 'a', using gloves and a mask

Shall appear on the label or the leaflet

2.2.12. 'l' indication: *particulars regarding precautionary measures to be taken during use, storage and transport*

These particulars shall be mentioned only if special precautionary measures need to be taken during use, storage and transport. They do not include statements related to the transport of hazardous materials, which appear elsewhere when necessary.

Example:

Labelling of: wear CE-marked nitrile or equivalent gloves.

Or/and:

Labelling of: store in a ventilated area

Or/and:

Labelling of: do not shake

Shall appear on the label

2.2.13. 'm' indication: *categories of users to which the biocidal product is restricted.*

This measure applies only to biocidal products for professional use only: unless stated otherwise, it can be considered that products are intended for professionals and the general public.

Moreover, this information shall be immediately visible on the product. The sentence shall thus have a large enough font size so that users may see it at first glance. Statements such as those given below are acceptable:

Example:

Labelling of: Intended for exclusive use by professionals

Or:

Labelling of: Professional use only

Or:

Labelling of: Reserved for professional users

Shall appear on the label or the leaflet

2.2.14. 'n' indication: *information on any specific risk to the environment, particularly regarding the protection of non-target organisms and avoidance of contamination of water.*

The marketing manager shall label the biocidal product in accordance with the regulatory texts on hazardous substances and mixtures as regards the classification of environmental risks.
However, this is not always adequate. It is therefore important to mention any specific risk to the environment, in particular risks to organisms not targeted by the product, the challenge being to expose only target species or at least no protected species.

Examples of statements that can be mentioned, which should be determined on a case-by-case basis depending on the product, the category of user, recommendations for use (and therefore the possibility of migration in various ecosystems), formulations, etc.

- for a wood treatment product classified as R57, toxic to bees, the statement

Do not treat hives

- for an avicide biocidal product containing chloralose or a rodenticide biocidal product containing bromadiolone, labelling of the following statement, to be supplemented with the name(s) of the corresponding target species

Products should be carefully positioned in order to minimise risk of consumption by other animals or by children. If possible, make sure the product cannot be moved elsewhere. *Remove all products after treatment.* *Keep out of the reach of children.* *Use only for [an authorised target species].*

- for a biocidal product liable to interrupt the decomposition of organic matter (e.g. abamectin):

Contains [to be completed]: may disrupt soil life and function

- for wood treatment products for timber structures and roofing:

In order to protect Chiroptera (bats) and swifts, avoid treating timber structures in the spring and summer

Or

Never treat timber structures if you discover bats or swifts. If in any doubt, apply treatment from the beginning of autumn to the end of winter (October to March)

Or

Since all species of bats and swifts are protected, make sure they are not exposed to this product

3. ANNEXES

3.1. Biocidal product-types, listed in Annex V of the Ministerial Order of 19 May 2004 (taken from Annex V of Directive 98/8/EC)

PT	***Product types***
1	Human hygiene products
2	Products for the disinfection of air, surfaces, materials, equipment and furniture not in contact with foodstuffs
3	Products used for veterinary hygiene including products used in areas in which animals are housed, kept or transported
4	Food and feed area disinfectants
5	Drinking water disinfectants
6	Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs
7	Film preservatives
8	Wood preservatives
9	Fibre, leather, rubber and polymerised materials preservatives
10	Masonry preservatives
11	Preservatives for liquid-cooling and processing systems
12	Slimicides
13	Metalworking-fluid preservatives
14	Rodenticides
15	Avicides
16	Molluscicides
17	Piscicides
18	Insecticides, acaricides and products to control other arthropods
19	Repellents and attractants
20	Preservatives for food or feedstocks
21	Antifouling products
22	Embalming and taxidermist fluids
23	Control of other vertebrates

3.2. Article 10 of the Ministerial Order of 19 May 2004

Pursuant to Article 20 of the aforementioned Decree of 26 February 2004, the label of a biocidal product shall show clearly and indelibly the following information written in French:

a) The identity of every biocidal active substance contained in the product and its concentration in metric units;
b) The authorisation number;
c) The type of preparation;
d) The authorised uses of the biocidal product;
e) The directions for use and dose rate for each authorised use, expressed in metric units;
f) Likely adverse side effects, including indirect effects, and directions for first aid;
g) If the product is accompanied by a leaflet, the sentence "**Read attached instructions before use**";
h) Directions for the safe disposal of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging;
i) The formulation batch number or designation and expiry date under normal storage conditions;
j) The time period needed for the biocidal effect to appear and its duration of action, the interval to be observed between applications of the biocidal product or between application and the next use of the treated product, material or surface, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas;
k) Particulars regarding the cleaning of equipment;
l) Particulars regarding precautionary measures to be taken during use, storage and transport;

and, where relevant:

m) Categories of users to which the biocidal product is restricted;
n) Information on any specific risk to the environment, particularly regarding the protection of non-target organisms and avoidance of contamination of water.

In the case of microbiological biocidal products, these provisions apply without prejudice to the specific regulatory provisions on the labelling of these products.

The information required in points *a, b, d* and, where relevant, *g* and *m,* must appear on the product's label. The information required in points *c, e, f, h, i, j, k, l* and *n* can appear on another part of the packaging or be included in a leaflet that accompanies and is an integral part of the packaging.

Without prejudice to the application of the transitional provisions set out in Articles 29 and 30 of the Decree of 26 February 2004, the information mentioned in points *b, d* and *e* is not required for biocidal products containing one or more biocidal active substances appearing on the EU list of active substances on the market as of 14 May 2000, pending the authorisation decision provided for in Section II of Title II of Book V of the French Environmental Code.

The statements required in points *a* to *f, h, j,* and *k* to *n* shall be shown as they appear in the marketing authorisation.
The provisions of this article also apply in the event that a biocidal product is transferred to another container.

Products likely to be mistaken for foodstuffs, beverages or animal feed shall be packaged in such a way as to prevent the risk of such a mistake being made. If they are available to non-professionals, these products shall contain constituents to discourage their consumption. The marketing manager shall provide the Ministry of the Environment with samples, models or packaging, and labels or leaflets.

Moreover, marketing authorisations for biocidal products already authorised in another Member State may be subject to the amendment of the particulars set out in points *e, f, h,* and *j o*f this article.

The table below summarises the conditions for the labelling of the information to be shown on biocidal products.

Information required by the Ministerial Order of 19 May 2004	**Label /Label or leaflet**	**Required since 2004/on issuance of the MA**	**Appears as in the MA/'free' text**
a) **The identity of every biocidal active substance** contained in the product and its **concentration** in metric units	Label	since 2004	as in the MA
b) **Authorisation number**	Label	on issuance of the MA	as in the MA
c) The **type of preparation**	Label or leaflet	since 2004	as in the MA
d) The **authorised uses** of the biocidal product	Label	on issuance of the MA	as in the MA
e) **Directions for use** and **dose rate** for each authorised use, expressed in metric units	Label or leaflet	on issuance of the MA	as in the MA
f) **Likely adverse side effects**, including indirect effects, and **directions for first aid**	Label or leaflet	since 2004	as in the MA
g) If the product is accompanied by a leaflet, the sentence "**Read attached instructions before use**"	Label	since 2004	Required sentence
h) **Directions for the safe disposal** of the biocidal product and its packaging, including, where relevant, any prohibition on the reuse of packaging	Label or leaflet	since 2004	as in the MA
i) The formulation **batch number** or designation and **expiry date** under normal storage conditions	Label or leaflet	since 2004	'free' text
j) The **time period** needed for the **biocidal effect** to appear, its **duration of action**, the **interval** to be observed **between applications** of the biocidal product **or between application and the next use** of the treated product, material or surface, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning **decontamination means and measures** and duration of necessary ventilation of treated areas	Label or leaflet	since 2004	as in the MA
k) Particulars regarding the **cleaning of equipment**	Label or leaflet	since 2004	as in the MA
l) Particulars regarding **precautionary measures** to be taken during use, storage and transport	Label or leaflet	since 2004	as in the MA
m) **Categories of users** to which the biocidal product is restricted	Label	since 2004	as in the MA
n) Information on any **specific risk to the environment**, particularly regarding the protection of non-target organisms and avoidance of contamination of water	Label or leaflet	since 2004	as in the MA

3.3. Types of preparations

– Pending finalisation by the MEDAD; the list will be available in September 2007 –

3.4. Regulatory references and guidance texts

These lists are not exhaustive:

References related specifically to biocidal products:

- **Directive 98/8/EC**[22] of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market;
- **Commission Regulation (EC) No 2032/2003** of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, and its amendments;
- **The French Environmental Code, Articles L.522-1 *et seq*;**
- **Decree no. 2004-187** of 26 February 2004[23] concerning the placing of biocidal products on the market;
- **The Ministerial Order of 19 May 2004**[24] on the control of the placing on the market of active biocidal substances and marketing authorisation for biocidal products.

References related to hazardous substances and preparations:

- **Council Directive 76/769/EEC** of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations;
- **The Ministerial Order of 9 November 2004 as amended by the Ministerial Order of 7 February 2007** defining classification criteria and labelling and packaging conditions for hazardous preparations, transposing **Directive 1999/45/EC** of the European Parliament and of the Council concerning the approximation of the laws,

[22] http://www.ecologie.gouv.fr/IMG/pdf/dir98-8_biocides.pdf
[23] http://www.ecologie.gouv.fr/IMG/pdf/decret_2004-187_biocides.pdf
[24] http://www.ecologie.gouv.fr/IMG/pdf/biocides_20040519_controle.pdf

regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations;
- **The Ministerial Order of 20 April 1994** on the declaration, classification, packaging and labelling of substances, as amended;
- Articles L. 231-6 and R. 231-51 of the **French Labour Code**;
- Articles L. 1342-3, L. 5131-1, L. 5132-2 to L. 5132-3, R. 1342-1 to R.1342-12 and R. 5132-46 to R. 5132-56 of the **French Public Health Code**;
- Article L. 521-9 of the **French Environmental Code**;
- **DRT Circular no. 13 of 24 May 2006** on the packaging and labelling of hazardous substances and mixtures and on the safety data sheet (SDS);
- **INRS brochures** on the classification, packaging and labelling of hazardous chemical substances and preparations[25]: ED 982 "Regulatory texts and comments"; and ED 983 "Guide to classification and labelling, test methods".

3.5. Some links

MEDAD website:
http://www.ecologie.gouv.fr/rubrique.php3?id_rubrique=760
INRS website: Close-up on the labelling of hazardous substances and preparations:
http://www.inrs.fr/htm/classification_etiquetage_fiche_donnees_securite.html
European Commission website:
http://ec.europa.eu/environment/biocides/
ECB website: http://ecb.jrc.it/biocides/

3.6. Glossary

AFSSAPS: French Health Products Safety Agency

'Biocides' MA: marketing authorisation granted by the MEDAD based on an application meeting the requirements of the Ministerial Order of 19 May 2004, established by Directive 98/8/EC, in opposition to 'pre-existing' MAs

[25] http://www.inrs.fr/htm/frame_constr.html?frame=%2Finrs-pub%2Finrs01.nsf%2FIntranetObject-accesParIntranetID%2FOM%3ARubrique%3AD4793FCD377BBF5AC1256C70002C0525%2F%24FILE%2FVisu.html

ECB: European Chemicals Bureau

Expiry date: date until which the product before opening retains its properties 'under normal storage conditions'

GIFAP: International Group of National Associations of Manufacturers of Agrochemical Products

INRS: National Research and Safety Institute

MA: Marketing Authorisation

MEDAD: French Ministry of Ecology, Sustainable Development and Planning

Placing on the market (L.522-1 of the French Environmental Code): The following shall be deemed to be placing on the market:

1º Any supply, whether in return for payment or free of charge, of an active substance or biocidal product;

2º Importation of an active substance or biocidal product from a non-EU Member State with the exception of a substance in transit;

3º Storage of an active substance or biocidal product if this storage is not followed by consignment from the customs territory of the Community or disposal.

'Pre-existing' MAs: granted by regimes existing in France before the adoption of the Biocides Directive, remaining in force until the end of the transition period defined in Article L.522-18 of the French Environmental Code. These are authorisations granted by the Ministry of Agriculture or Health for certain biocidal products

SDS: Safety Data Sheet

Use-by date: date until which the product after opening retains its properties 'under normal storage conditions'