Efficacy Assessment for PT1 to PT5 Biocidal Products

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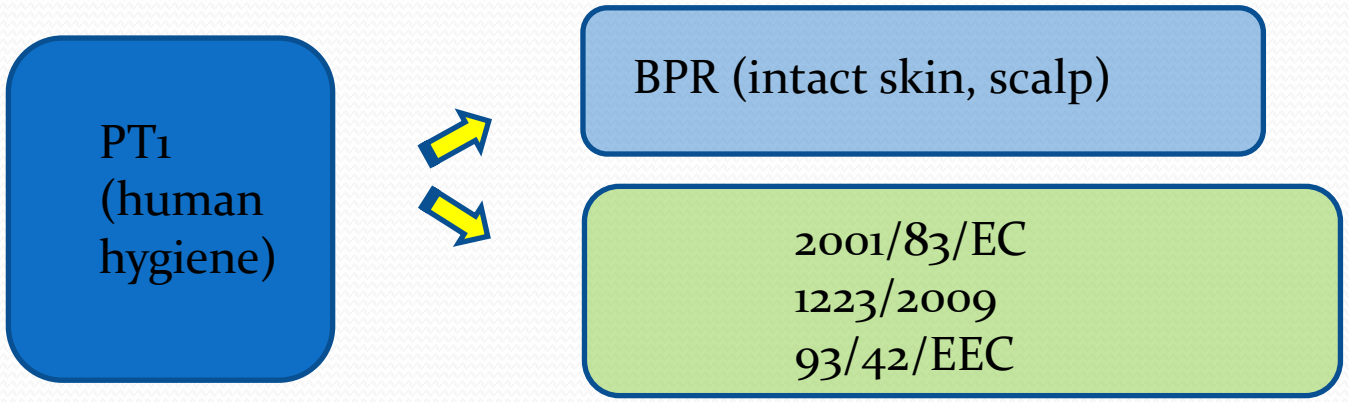
MAIN GROUP 1: disinfectants

No products without a claim for disinfection

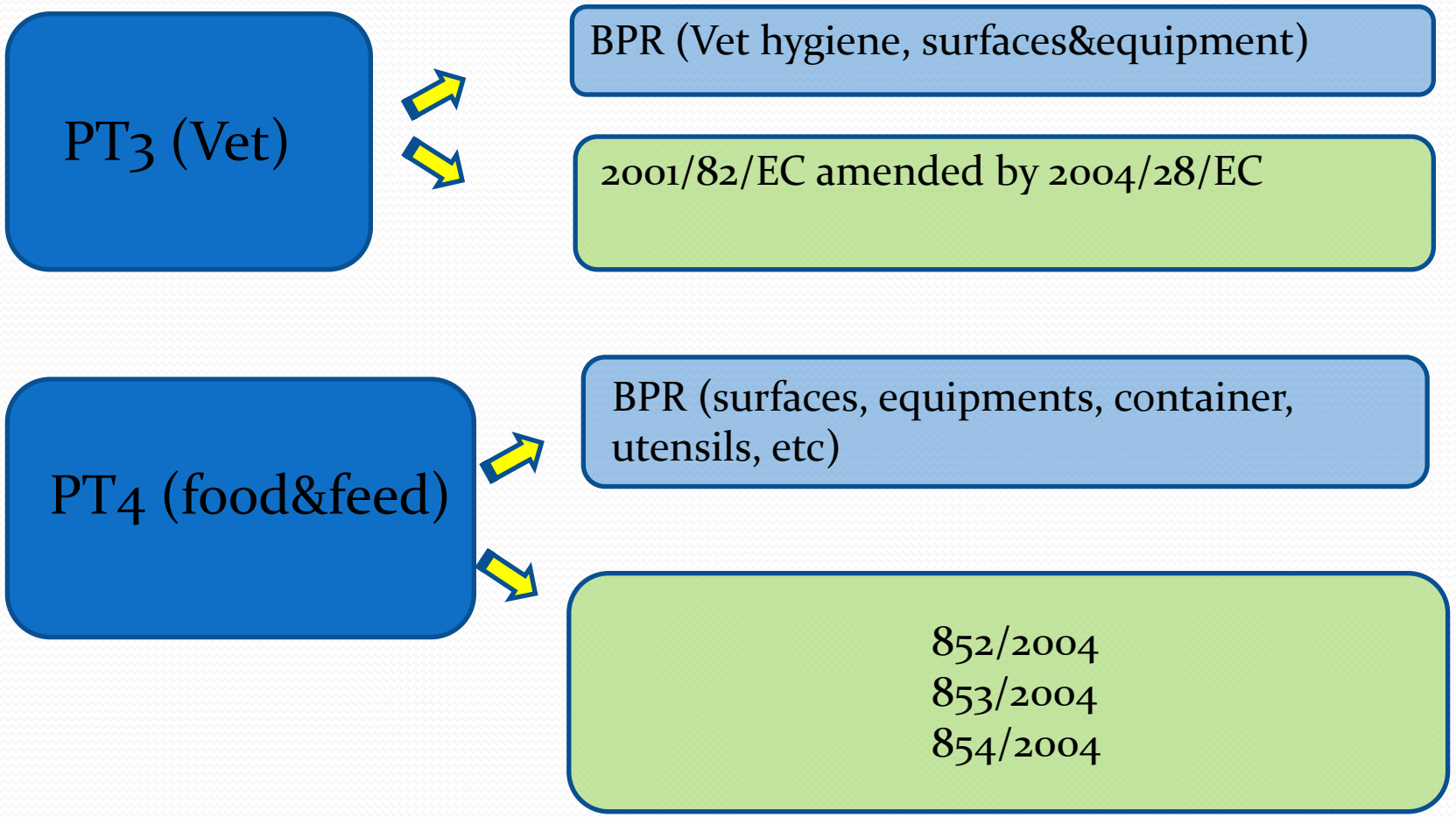
- PT1 (human hygiene)
- PT2 (Disinfectants and algaecides not intended for direct application to humans or animals)
- PT3 (Veterinary hygiene)
- PT4 (Food and feed area)
- PT5 (drinking water)

Check for correct reference directive/regulation

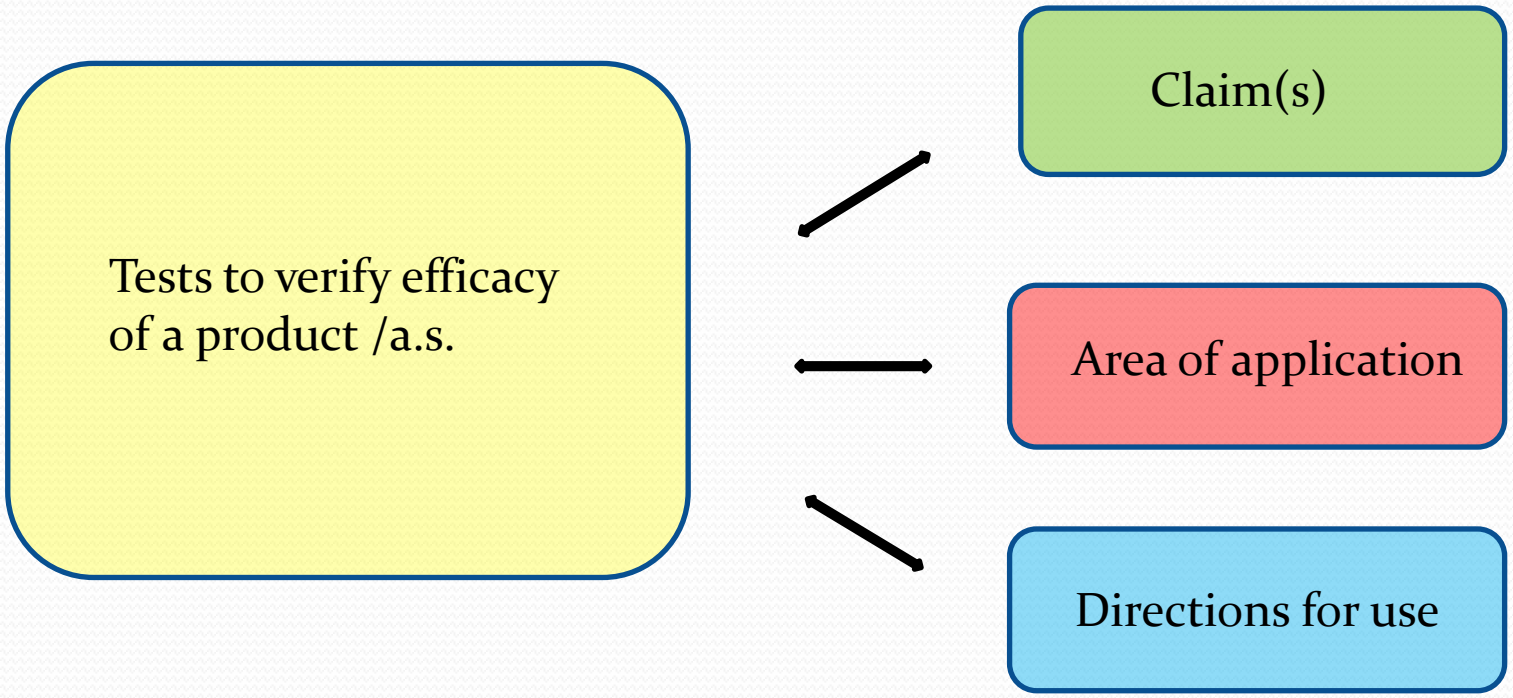


To be noted: products for wound disinfection or pre-operative skin disinfection before surgery and disinfection before injection are under the 2001/83/EC

Check for correct reference directive/regulation



What infos must be provided



Claim

- The purpose (e.g. prevent biodeterioration, disinfect surfaces);
- The function of the product (e.g. bactericide, wood preservative, repellant, etc.);
- The (group of) target organisms to be controlled;
- In-use concentration;
- Use conditions and area of use;
- The effect which will result from using the product on the target organisms (e.g. kill, control, repel, prevent, etc.);
- Any products, organisms or objects to be protected.

Area of application/directions for use

- Use in hospitals, swimming pools, bathrooms, on textiles, etc
- Contact time/method(s) of application
- Resistance:
  - incorporation of appropriate label warnings;
  - application with one or more biocidal active substances to enhance efficacy;
  - alternate use of biocides based on a.s. with different mode of action;
  - periodical switch to a different a.s. to which resistance rarely or never develops.

Tiered approach for efficacy testing

- Phase 1 tests are screening tests not related to in-use conditions
- Phase 2/step 1 tests are quantitative suspension tests to establish that a product has -cidal activity, simulating practical conditions appropriate to its intended use.
- Phase 2/step 2 tests are quantitative laboratory tests, on carriers or living tissues with dried-on micro-organisms, simulating practical conditions to establish that the product has a -cidal activity.
- Phase 3/field tests

Test report

- Introduction
- Materials and Methods (e.g. tested product composition, conditions of the test temperature, humidity,)
- Tested organisms
- Results and raw data
- Conclusion/discussion based on criteria defined in guidance

Tests to evaluate efficacy of a.s/products

EN 14885

Claim matrices on BPR

PT 02 Hard Surfaces										
	Product description type	**Use area**	**Target site**	**Purpose**	**Min spectrum of activity**	**Additional optional activity**	**User Type**	**Application type**	**Appropriate methodology**	**Appropriate performance standard relevant to target site**
	Description of product within a specific PT:	*Intended sector of application:*	*Where the product is typically used:*	*Primary objective of the product and expected result by the user [Several purposes can be combined in one product]*	*Obligatory range of targeted harmful organisms*	*[and / or]*	*As defined by BPD (Professional/ industrial, non-professional)*	*Method how the product is applied **[and / or]***	*Types of test to be used*	
1	Hard surface biocidal product	health care	hospital rooms, bathroom, operation room, laboratories, dental centres, isolation rooms	reduce risk of infection	bactericidal and yeasticidal	fungicidal virucidal sporicidal mycobacteric idal tuberculo-cidal	professional	spraying, wiping, mopping, scrubbing, foaming, flooding	suspension and surface lab tests	EN 14885 (medical area) and when not applicable OECD 187 as appropriate
2	Hard surface biocidal product	industry, (e.g. cosmetic, pharmaceuti cal), institutions, health care facilities	hard surfaces, e.g. floors, walls, work surfaces, kitchen surfaces (excluding food contact surfaces), bathroom seats, toilet bowls (outside), outdoor surfaces	reduce risk of infection, prevention of product contamination and to prevent product spoilage	bactericidal and yeasticidal	fungicidal virucidal sporicidal	professional	spraying, wiping, mopping, scrubbing, foaming, flooding	suspension and surface lab tests	EN 14885 (institutional area, domestic area, industrial area; virucidal: medical area) and when not applicable OECD 187 as appropriate
3	Hard surface biocidal	institutions, health care facilities,	hard surfaces, e.g. kitchen surfaces (excluding food	reduce risk of infection, prevention of	bactericidal and yeasticidal	fungicidal virucidal sporicidal	professional	impregnated wet wipes	suspension tests + surface lab	EN 14885 (relevant area) (EN 16615

PT 02 Hard Surfaces										
	Product description type	Use area	Target site	Purpose	Min spectrum of activity	Additional optional activity	User Type	Application type	Appropriate methodology	Appropriate performance standard relevant to target site
	product	industry	contact surfaces), bathroom, hospital rooms, dentists, isolation rooms	product contamination and to prevent product spoilage		mycobactericidal tuberculo-cidal			tests with mechanical action, information on storage after opening should be given, optional simulated in use testing	surface test with mechanical action)
4	Hard surface biocidal product	institutions, health care facilities, industry	surfaces, e.g. bathroom surfaces and cellars, outdoor surfaces	anti-staining and reduction of fungal spores with allergenic potential	fungicidal	n.a.	professional	spray, wipe	suspension and surface lab tests	EN 14885 (relevant area)
5	Hard surface biocidal product	institutions, health care facilities, industry	indoor or outdoor surfaces	anti-staining, anti-slipping	algaecidal	n.a.	professional	spraying, wiping, scrubbing	suspension and surface lab test (if available) or field trial	to be developed, field trial demonstrating difference before and after treatment
6	Hard surface biocidal product	institutions	surfaces, e.g. kitchen surfaces (excluding food contact surfaces), bathroom surfaces, toilet seats, outdoor surfaces, drains, e.g. bathroom, sink plug	control of malodour caused by micro-organisms	bacterio-static and/ or fungistatic	bactericidal yeasticidal fungicidal sporicidal	professional	spraying, wiping, mopping, scrubbing, foaming, flooding	suspension lab tests and odour panel test	bacteriostatic or fungistatic tests (growth inhibition but not killing; suspension: VAH method 7; surface: ISO DIS

Introduction to EN tests

This (EN14885) European Standard specifies the laboratory methods to be used for testing the activity of products, i.e. chemical disinfectants and antiseptics in order to support claims that they have specific properties appropriate to their intended application. These laboratory methods may also be used for active substances and products under development.

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Chemical disinfectants and antiseptics should always be used responsibly. This should take into account the environmental impact of inappropriate product in-use concentrations (too high or too low) and of unnecessary use.

Tests to evaluate efficacy of a.s.

- Screening tests (EN1040, EN1275, EN14347)

The evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious

- Semi-field or field tests

Tests to evaluate efficacy of products

- Screening tests (EN1040, EN1275, EN14347)

- Lab tests

- Simulation tests

- Semi-field or field tests

With rare exceptions

- a quantitative suspension test (phase 2/step 1)
- a quantitative carrier test (phase 2/step 2);
  - both simulating practical conditions appropriate to its intended use (temperature, soiling, different surfaces, contact time, etc.)
- When necessary, a semi-field or a field test

Phase2/step1 EN tests

- Quantitative suspension tests to verify –cidal activity in simulating in-use conditions

PT2, PT4	PT3	PT1
EN1276 (bactericidal) EN1650 (fungicidal) EN13610 (virucidal vs bacteriophages) EN13704 (sporicidal)* EN12623 (legionella)	EN1656 (bactericidal) EN1657 (fungicidal) EN14204 (mycobactericidal) EN14675 (virucidal)	EN13727 (bactericidal) EN13624 (fungicidal) EN14348 (mycobactericidal) EN14476 (virucidal) prEN17126 (sporicidal)

Phase2/step2 EN tests

- Quantitative tests simulating in use conditions

PT2, PT4	PT3	PT1
EN13697(bactericidal/fungicidal on surface) EN16616 (textile) EN16615 (bactericidal/yeasticidal with mechanical action-wipes)	EN14349 (bactericidal NP surfaces) EN16437 (bactericidal P surfaces) EN16438 (fungicidal NP surfaces)	EN1499 (handwash) EN1500 (handrub) EN12791 (surgical handrub) EN14561(bactericidal-instruments) EN14562 (fungicidal-instruments) EN14563 (mycobactericidal-instruments) EN16615 (bactericidal/yeasticidal with mechanical action-wipes) prEN16777 (virucidal)

Others

- Chemothermal disinfection – EN 16616.
- NF T 72-281 for room disinfection
- Virucidal claim for PT4 products – adapt EN14476 (PT1) with the interfering substance(s) used in PT4-dedicated norms

For high T° applications

- If products (PT 2-4) are tested with high temperatures above 40ºC:
  - *E. faecium* for bactericidal activity
  - MPV for virucidal claim
  - Spores of *B.cereus* or *C.sporogenes* for sporicidal claim

- For mycobacteria, yeasts and fungal spores no relevant test organisms for high temperatures are available. Most yeasts and fungal spores are already irreversibly inactivated by high temperature (>40 ºC) in the control without active substance. However, ascospores of several fungi can become heat resistant and can cause problems in, for instance, the food industry.

- When efficacy against mycobacteria, yeasts and fungal spores is claimed and no temperature resistant strains are available, the standard test organisms should be tested at the maximum temperatures for which the test is validated.

- For specific claims against heat resistant species (e.g. *Talaromyces flavus*) efficacy tests with these organisms should be provided. In these tests a control without biocide should be included which shows survival of the test organisms at the high test temperature.

PT2

- NF T 72-281 for room disinfection
  - Does not disinfect the air!
- Swimming pools/hot tubs/etc
  - a quantitative suspension test (phase 2, step 1);
  - simulated-use tests with pool water or a surface test (phase 2, step 2)
  - and a field test (phase 3) - ”Guidance Document for Demonstrating Efficacy of Pool and Spa Disinfectants in Laboratory and Field testing” (OECD Series n. 170, Oct 2012)
  - alghicidal claim (?)
  - biofilm claim (?) (also

Biofilm claim

- Phase2/step1 suspension test
- Simulated test conditions (static conditions/flow conditions) considering the claim:
  - disruption of biofilm?
  - Inhibition of biofilm formation?
  - Mono or multispecies biofilm?
- Field test

To generate standard biofilm: CEN/ISO15883-5 (annexF) – ASTM E2196 and ASTM2562

PT2

- Textiles
  - phase 2/step 1 suspension tests as described in EN 14885
  - phase 2/step 2 tests involving
    - a full-scale laundry machine test (EN 16616)
    - for products not intended to be used in washing machines, small scale laboratory setting (e.g. for pre-soaking in a bucket) may be considered (e.g. ASTM E4206 or ASTM E2274).

PT4 or PT5?

Disinfection is done in the water system while it is in service and the water itself is also disinfected?

PT5

Water systems are disinfected in closed circuits, after which the system is washed with clean water?

PT4

Data to support efficacy of a product to be utilized in water distribution systems (disinfection of pipework) (PT4)

- Quantitative suspension test phase 2/step1 – food area
- Quantitative suspension test for Legionella (EN13623)
- Field tests (phase 3)
- Claim vs biofilm

PT5

- Disinfection for the drinking water suppliers and their water distribution systems
- Disinfection of raw water for individual supply (1-2 premises)
- Disinfection in collective drinking water systems
- Disinfection of water in reservoirs
- Disinfection of water of undefined quality for small scale use (up to 5 L/person/day)
- Disinfection of water for animals

Drinking water suppliers & their water distribution system

- Quantitative suspension test phase 2/step1 (bactericidal, fungicidal, etc) – food area
  - Modified to reflect in use-conditions (T° range, soiling, time of contact)

- Simulated-use test

- Challenge test x secondary disinfection

Efficacy against bacteria and virus. Other MOs (i.e. protozoa) only if specified in the claim

Raw water for Individual supply

- Quantitative suspension test phase 2/step1 (bactericidal, fungicidal, etc) – food area
  - Modified to reflect in use-conditions (T° range, soiling, time of contact)

- Simulated-use test

Collective drinking water systems (hospitals, hotels, etc)

- Laboratory tests
  - Quantitative suspension phase2/step1 tests
  - Quantitative suspension test for Legionella (EN13623)- Modified to reflect in use-conditions (T° range, soiling, time of contact)*
- Simulated-use test / Field trial
  - Locations/duration of the tests/Typer of water/legionella conc/sampling points

Water in reservoirs (ships, mobile house, dentistry chairs, etc)

- Suspension tests phase2/step1 – food area / challenging efficacy test (Mos/soiling)

Water of undefined quality

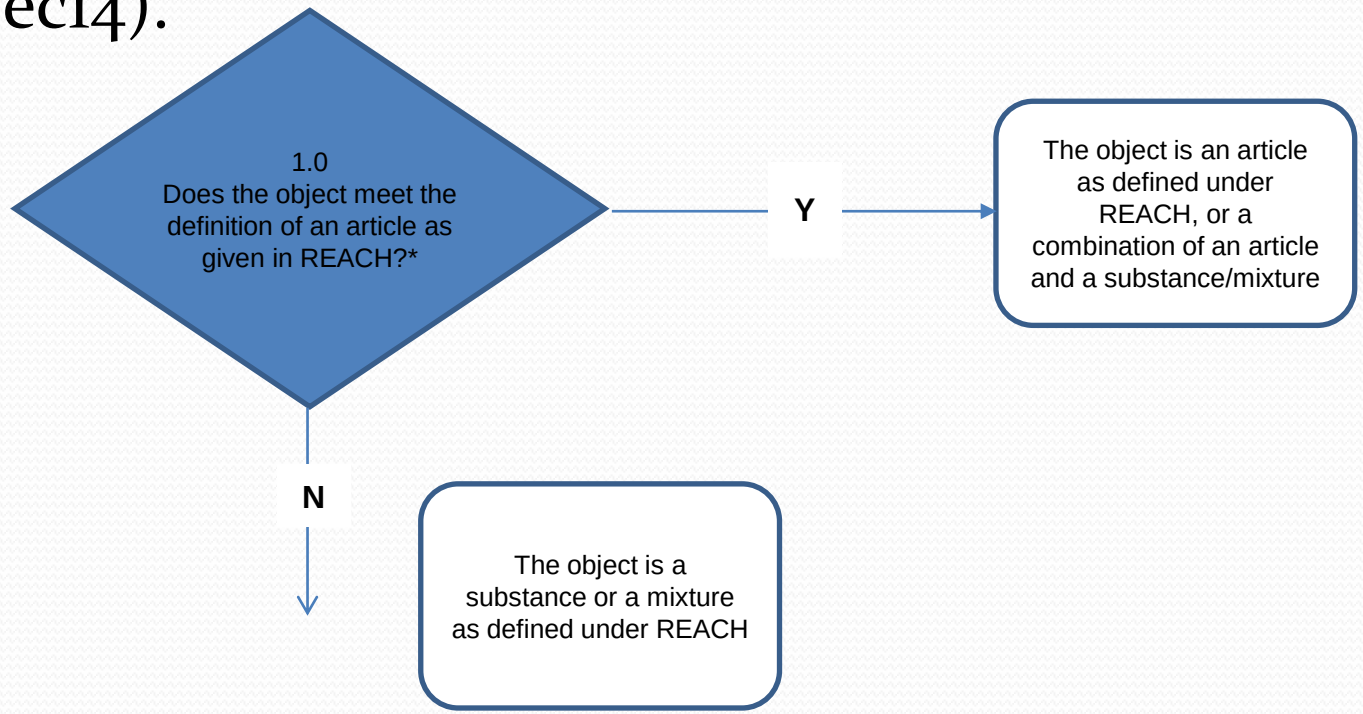
- Suspension tests phase2/step1 – food area (Modified to reflect in use condition)

Water for veterinary use

- Quantitative suspension test phase2/step1 – food area
- Simulated-use test or Field trial
- Biofilm (if applicable)

TREATED ARTICLES

- Any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products (from CA-Sept 13 Doc5.1-rev Dec14).



Active substances notified for PTs 1-5 (Main group 1) are usually used in (liquid) biocidal products as for instance hand disinfection or surface disinfection products. These products are clearly considered biocidal products. But sometimes active substances belonging to PTs 2, 3 or 4 are incorporated into textiles and other solid materials; the protection of the material itself is not intended, but a new property is introduced to an article, intended to protect its user. For such claims, testing is particularly challenging and the specific conditions of use have to be considered when designing the efficacy testing.

The assessment of an active substance is done on the basis of a representative product, and the active substance is approved if at least one biocidal product containing that substance is expected to meet the criteria for authorisation. This implies that, as a general rule, not all possible uses of an active substance are considered at the time of approval.

PT1 (human hygiene disinfectants)	**Any chemical substance, mixture or article containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.**
PT2 (disinfectants) **PT3 (veterinary hygiene products)** **PT4 (food and feed area disinfectants)**	Chemical substances or mixture containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect. The incorporation of biocidal products of this PT in an article generally indicates an intended effect in the final good, and such articles, if not biocidal products by themselves, would qualify as treated articles.
PT5 (drinking water disinfectants)	Any chemical substance, mixture or article containing AS that fall into this PT are likely to be classified as biocidal products due to their use and the nature of the biocidal effect.

- Guidance document on Tier-2 laboratory based tests used to substantiate claims for efficacy of biocide treated articles – deadline for comments dec 2017 (http://www.oecd.org/env/ehs/testing/Tier%20II%20GD%20efficacy%20of%20treated%20articles_website.pdf)

What infos must be provided

Tests to verify efficacy of a product /a.s.

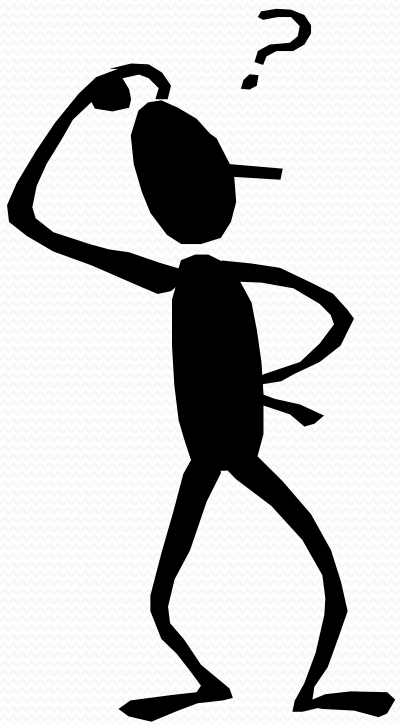
- Claim(s)
- Area of application
- Directions for use

Label

- Intended use
- Site of application
- Spectrum of activity
- Directions for use

Label

- Clear instructions for use
- Avoid
  - general indication such as «fast acting» or directions too difficult to follow (i.e. for a concentrated product «… dilute to 1,5%)
  - names of target Mos
- Specify the contact time



Thanks for your attention