Organisation for Economic Co-operation and Development

ENV/JM/MONO(2020)29/REV1

Unclassified English - Or. English

15 June 2023

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Cancels & replaces the same document of 2 June 2023

Guidance on principles for claim development of treated articles

Series on Biocides
No. 15

JT03522067

This document, as well as any data and map included herein, are without prejudice to the status of or sovereignty over any territory, to the delimitation of international frontiers and boundaries and to the name of any territory, city or area.

OECD Environment, Health and Safety Publications

Series on Biocides no. 15

GUIDANCE ON PRINCIPLES FOR CLAIM DEVELOPMENT OF TREATED ARTICLES

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2023

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 38 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in twelve different series: **Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides; Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; Safety of Manufactured Nanomaterials;** and **Adverse Outcome Pathways**. More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (www.oecd.org/chemicalsafety/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organisations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

This publication is available electronically, at no charge.

Also published in the Series on Biocides link

For this and many other Environment,
Health and Safety publications, consult the OECD's
World Wide Web site www.oecd.org/chemicalsafety/

or contact:

OECD Environment Directorate,
Environment, Health and Safety Division
2, rue André-Pascal
75775 Paris cedex 16
France
Fax: (33-1) 44 30 61 80
E-mail: ehscont@oecd.org

© OECD 2023
Applications for permission to reproduce or translate all or part of this material should be made to: Head of Publications Service, RIGHTS@oecd.org, OECD, 2 rue André-Pascal, 75775 Paris Cedex 16, France OECD Environment, Health and Safety Publications

Foreword

The work described in this updated guidance has been performed under auspices of the Working Group on Biocides (WGB) and started in 2016 with the formation of the Expert Group on Claims Development for Treated Articles (EG CDTA).

The efficacy and functionality of a biocides treated article as well as the way the treated article and its benefits for the user are presented (the claim) have a public health impact. The WGB identified a public health concern, in particular because of a possible false sense of security given by the claim, or because of an incorrect interpretation of the claim by the end-users. Since such articles are governed by different product regulations in OECD member countries, a need for harmonised guidance on how to substantiate, assess and approve said claims, was identified.

The EG CDTA therefore investigated claims development and regulatory benchmark tests across OECD countries and developed this guidance to describe principles for claims development for treated articles, and to recommend principles for substantiating and testing such claims.

The original guidance focused on articles treated with disinfectants only and was published in November 2020, while the updated guidance now also provides information for articles treated with insecticides

This Guidance Document was approved by the Working Group on Biocides in September 2022. The Chemicals and Biotechnology Committee agreed to its declassification on 15 February 2023.

This document is published under the responsibility of the Chemicals and Biotechnology Committee.

This report has been produced with the financial assistance of the European Union. The views expressed herein can in no way be taken to reflect the official opinion of the European Union.

Table of Contents

1 Glossary

In this document the following terminology is used. Please consider that in the various OECD regions different standards and legal definitions of these terms might apply[1].

Article:	An object more defined by its shape, surface or design than by its chemical composition.
Article treated for Material Protection:	Article treated with a biocide/pesticide to protect its material from biodeterioration. Such articles usually do not require authorization/registration, but the biocide it is treated with may.
Treated Article with a Health Claim:	Articles that claim to have beneficial properties for the user due to the treatment with biocides/pesticides. Such articles are usually treated with a disinfectant or an insecticide. Articles with a health claim may – depending on the legislation in the area – be seen as a biocide/pesticide itself and require authorization/registration.
Benefit:	The benefit, or functionality, is the intended, promoted, or inferred, helpful result of properly using the treated article. Benefits co-occur with risks.
Biocide/pesticide:	Any substance, or mixture of substances, or article which has the purpose to kill or control organisms which are damaging for material, humans or animals. Note: substances which are controlling organisms damaging for plants are not included, they are plant protections agents.
Disinfectant	A disinfectant is a product that reduces the number of micro-organisms (fungal spores, yeasts, viruses, algae, bacteria and/or bacterial endospores) in or on an inanimate matrix-achieved by the irreversible action of a product, to a level judged to be appropriate for a defined purpose (EN 14885)
Insecticide/insect repellent:	Biocide/Pesticide used to control insects or other arthropods by lethal/repellent effects.
Foreseeable misuse / non-proper use:	The use of a treated article not in line with the instructions for use or without the consideration of some or all common and specific technical, operational and personal protective measures. This excludes (deliberate) abuse, but includes reasonably foreseeable non-proper use. Non-professional users do not necessarily have the knowledge and skills to handle treated articles in compliance with the prescribed instructions and/or control measures. This is also true for part of the professional users.

[1] OECD (2015) Results from the survey questionnaire on performance standards and related authorized label claims for microbicides used in OECD countries' (ENV/JM/BCID(2015)5).

	For example: a false interpretation may lead to the use of the article after the intended service life or beyond the range of intended applications. Or a false sense of safety may increase the risk of careless behaviour with respect to normal hygiene or taking prevention.

2 Introduction

Articles that claim to have beneficial properties due to the treatment with disinfecting, insecticidal, or insect repellent substances are marketed towards professional and non-professional users. Both the promised efficacy and functionality of the article, as well as the way the article is presented, form the claim. Such claims may have a health impact and – when used by many – even a public health impact.

A public health concern was identified by the OECD Working Group on Biocides: a false sense of security can be implied by the claim, leading to neglect in everyday hygienic routines, or in prevention practices against insects. Alternatively, the claim can be interpreted incorrectly by the users, and thus can lead to improper use of the treated article.

Since such treated articles are governed by different regulations in OECD member countries, a need for harmonized guidance on how to substantiate, assess and approve these claims, was identified. The objective of this document is to give guidance on how claims for treated articles that may have an impact on human health can be formulated, interpreted and tested within the framework of the different legislations across OECD countries.

The guidance was not developed for claims relating to material protection, which aims to protect the materials used in the article or the properties of the article in service. In this context, the target organisms have detrimental or other undesirable effects (e.g. biodegradation, discolouration, odour formation) on the material or article. Such effects are sometimes called internal effects and the biocides used are called preservatives. This guidance focuses on effects that are aimed to protect the user of the article against nuisance- or health threatening organisms.

Different perspectives will be described:

- Consumer perception

  What do consumers expect, and how do they translate the claim into the use of the treated article? What is intended by the provider/manufacturer of the article?
- The legal framework

  How does the legal framework affect the claim development and the assessment strategy? What is needed to come to a decision on approval of a claim?
- Testing: The scientific proof

  How can scenarios for efficacy / functionality assessment be identified, how to select testing strategies for the relevant scenarios, and how to assess the results of the testing? What performance can be expected?

These three perspectives are interconnected: Consumers are to be convinced to buy an article based on its claims; at the same time, claims are heavily influenced by a regulatory framework. To deliver scientific proof, the description of the specific context of use should be defined and tested. Regulations require objective criteria to ensure safe use. These perspectives will be further elaborated in Chapter 3.

Chapter 4 proposes principles for claim development for articles treated with disinfectants, insecticides or insect repellents. These principles help in standardizing and clarifying claims, to avoid misinterpretations and a false sense of security, and to foster proper use of such articles.

3 Elements relevant for a claim: three perspectives

3.1 Consumer perception

A supplier places an article treated with a disinfecting, insecticidal or insect repellent substance on the market and makes a health claim about the properties of this article or about the impact of using it. What is intended by the supplier/manufacturer? To help the consumer make a buying decision by promising a certain effect or performance. Articles treated with antimicrobials, insecticides or insect repellents, that make express or implied claims to provide health advantages or to protect against nuisance are the principal focus of this document.

The consumer wants the article to perform as expected. What triggers the consumer's expectations? Not only written claims or pictograms convey information, as is shown by a large body of research on consumer perception. The physical presentation of an article, its design[2], its packaging[3], brand[4], as well as information on composition or method of use affect consumers' perceptions and interpretations of functionality[5]. This information can be given in advertisements, on packaging or labels, on a webpage, etc.

Research suggests that consumers are quite open to a wide range of claims when 'health' as a benefit is implied[6]. However, studies about consumer appreciation of claims show that (written) claims may be difficult to understand by the consumer. Their level of understanding depends on factors such as their expertise, their fears, or their concern for the environment, and can thus lead to misinterpretation of a claim[7]. Therefore, it is challenging to define the 'average consumer', to identify the range of consumer interpretations and to try to quantify the accuracy of consumers' understanding of the claim[8].

To understand how the presentation of the health benefit of an article, or its functionality, is perceived and interpreted by a potential consumer, the first step is to determine what should be required to make this perception as realistic as possible. As an example, the European nutrition law[9] requires that an 'average consumer' can understand the beneficial effects as expressed in the claim. Hence not only should the supplier of a product demonstrate that it does what is claimed – they should also demonstrate that the average consumer can understand these claims. However, current biocides/pesticides legislation does not

2 Kumar M, Noble CH (2016) Beyond form and function: Why do consumers value product design? J Business Research 69(2) 613-620

3 Steenis ND, Van Herpen E, Van der Lans IA, Ligthart TN, Van Trijp HCM (2017) Consumer response to packaging design: The role of packaging materials and graphics in sustainability perceptions and product evaluations. J Cleaner Production 162 286-298

4 Hernandez JMC, Han X, Kardes FR (2014) Effects of the perceived diagnosticity of presented attribute and brand name information on sensitivity to missing information. J Business Research 67(5) 874-881

5 Rosa JA, Qualls WJ, Ruth JA (2014) Consumer creativity: Effects of gender and variation in the richness of vision and touch inputs. J Business Research 67(3) 386-393

6 Van Trijp HCM, Van der Lans IA (2007) Consumer perceptions of nutrition and health claims. Appetite 48(3) 305-324

7 Grunert KG, Scholderer J, Rogeaux M (2011) Determinants of consumer understanding of health claims. Appetite 56(2) 269-277

8 Leathwood P, Richardson D, Sträter P, Todd P, Van Trijp H (2007) Consumer understanding of nutrition and health claims: Sources of evidence. Br J Nutrition 98(3) 474-484

9 Art 5.2 of Regulation 1924/2006 https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A02006R1924-20121129

take consumer perception into account in the same way, although it usually distinguishes between professional and non-professional users, assuming that non-professional users have less understanding and knowledge.

If a non-professional user of a treated article does not understand what the claim means, they can develop a false sense of security, which in turn could lead to reducing their every-day hygienic or preventive practices. For example, the user of a hard surface disinfectant expects that it will kill microorganisms on the surface that is treated with it. However, the user of an antibacterial dishwashing sponge has more difficulty in understanding what it is intended to do. Does it mean that surfaces wiped with it are disinfected? Is it killing bacteria while the user washes the dishes, or does it mean that bacteria will not grow on the sponge when it is left moist beside the sink? For how long will it continue to function?"[10] What should the user of a sleeping-bag with an anti-insect label expect? That it protects the user from insects that would usually bite through the material of the sleeping bag? That it even protects the user's face and that additional insect repellent applied on the skin is not necessary? For how many washes will the treatment last?

From the perspective of consumer protection[11], the claim is part of a safety issue. The assessment of the risk and benefit of an article on consumers' health should consider all observed or reasonably foreseeable use scenarios, including reasonable misuse of the product. The inclusion of reasonably foreseeable misuse scenarios in the assessment can yield critical insights into the consumers' ability to use the article safely.

In conclusion, it is pivotal to analyze how claims are understood by consumers, and how that will impact the use of the treated article. This in turn will determine how to label the article, what level of efficacy is required and how to prove it.

3.2 The legal framework

Whether treated articles may be placed on the market without a regulatory act, or whether they require pre-market approval is dependent on the claim and the function of the treated article and is regulated differently in different OECD regions. Regulations distinguish between goods or commodities in general, and special products like biocides/pesticides, cosmetics, detergents, medical devices, pharmaceuticals, and plant protection products. The applicable legal framework will affect how claims are formulated (for example to avoid falling under a stricter legislation) and this in turn will affect how consumers perceive claims.

What determines how a treated article is regulated? In general, both the claim and the apparent function (what it is used for) are considered to determine under which legislation(s) the article is regulated. The borderlines between legislations are beyond the scope of this guidance. In this guidance, the focus will only be on biocides/pesticides regulations:

In the EU, biocide treated articles (e.g. treated with antimicrobials, insecticides or insect repellents) are regulated by the Biocidal Products Regulation 528/2012[12], (but other regulations can apply as well, e.g. consumer legislation). The treated article is considered to be a biocidal product when it has a primary biocidal function; in this case, it requires product authorization at the national or Union level. If the biocidal

[10] OECD (2018) Guidance document on use and development of tier-2 laboratory based tests used to substantiate claims for efficacy of biocide treated articles. Series on testing and assessment no. 287. Series on biocides No. 13. https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2018)20&doclanguage=en

11 Working Party on Consumer Product Safety. Product Risk Assessment Practices Of Regulatory Agencies. Summary of discussions at Workshops and Meetings of the OECD Working Party on Consumer Product Safety. DSTI/CP/CPS(2014)6/FINAL. January 19 2016. OECD Paris.

[12] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012R0528-20140425&from=EN

function is considered secondary, then it is not considered to be a biocidal product but rather a treated article; it can only be placed on the market provided that the active substance is approved at the EU level for the relevant product type and use. Furthermore, the regulation requires that a claim – in terms of efficacy – must be substantiated. Treated articles shall carry a label that includes the claims made, provided they are substantiated, and the active substance with which it is treated as well as relevant instructions for use, including any precautions to be taken.

In Canada[13], treated articles are defined as pest control products under the Pest Control Products Act. If a pesticide has been incorporated into or applied to an article in order for the article to act as a delivery mechanism for the pesticide, the pesticide (for example, insecticide) and the treated article (for example, clothing) must each be registered as a pest control product under the Pest Control Products Act. If a pesticide has been incorporated into or applied to an article in order to provide a benefit to the product itself (in other words, preservation) the pesticide must be registered under the Pest Control Products Act for that specific use. In this case, the treated article will not typically require registration. These requirements apply to treated articles whether label claims are being made or not. Claims on articles treated with an antimicrobial preservative are limited to the effect of the antimicrobial preservative used on the article itself.

The United States considers any substance intended to control or mitigate any pest, including microorganisms, as a pesticide requiring registration. The EPA has issued a regulation that exempts certain treated articles from the registration requirement. Article 40 CFR 152.25 (a) of the Code of Federal Regulations[14] exempts from registration an article or substance treated with, or containing, a pesticide to protect the article or substance itself (for example, paint treated with a pesticide to protect the paint coating, or wood products treated to protect the wood against insects or fungus infestation) *provided the pesticide is registered for such use*. Such treated articles are considered pesticides, but exempt from all provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Articles treated with pesticides that do not meet the requirements of this exemption are pesticides that must be registered. The registration requirement will apply to any article making claims beyond protection of the article itself, including particularly implied or explicit public health claims. Any such claims will cause the article to be considered a pesticide subject to all requirements of FIFRA. Such an article may not be legally sold or distributed unless it is registered with the EPA.

Generally, regulations dealing with biocides/pesticides may prescribe:

- Whether or not every individual active substance, product or article is assessed and authorized, or whether this assessment is done on a more general level
- Whether claims are subject to authorization
- Whether or not risk – benefit assessments are performed
- What information to consumers is to be provided, the manner in which claims can be formulated, and whether obligatory warnings should be given.

An important part of the legislative framework is to assess whether claims made are substantiated. For this purpose, testing strategies and technical specifications that address efficacy are needed.

- Usually, efficacy data to support the claims made are required.
- It is established within the regulatory framework which claims can be permitted or restricted, if mandatory warning sentences should be added to the label, and whether a certain article would be permitted at all. A complicating factor in the process of authorization can be that the manufacturer of the active ingredient, the

[13] https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/fact-sheets-other-resources/treated-articles.html
[14] https://www.govinfo.gov/content/pkg/CFR-2011-title40-vol24/pdf/CFR-2011-title40-vol24-sec152-25.pdf

manufacturer of a treated masterbatch (e.g. treated plastic pellets for molding), the manufacturer of the article and the person responsible for placing a treated article on the market, will not necessarily be the same.

- If the label of a treated article contains relevant instructions for use, including any precautions to be taken to protect humans, animals and the environment, these instructions and precautions may impact the way the article and its claims are perceived. Likewise, this may be the case for authorized products like pesticides / biocides that will be accompanied with instructions for use, registration numbers on the packaging, and rules for advertising.
- Supporting information, policies, or regulations (like Hygiene Codes or Integrated Pest Management) to foster prudent use may be in place[15]. This will impact how claims and functionality are perceived by both professional and non-professional users.

3.2.1 What is a biocidal claim?

Articles treated with a biocide/pesticide usually fall under biocides/pesticides legislation. The type of claim made regarding the biocidal properties of the article can be crucial for the obligations that follow. All biocides/pesticides regulations define what a pesticide or biocide is. It can be a substance, mixture, or article:

- "with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on…"
- Which "prevents, destroys, repels, or mitigates …,"
- "directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling …"

…organisms that are damaging or unwanted on materials, animals or humans.

The use of such or similar terminology is a clue that a biocidal/pesticidal claim is made. In addition, use of terminology alluding to the (health) impact of using the article ("hygienic, safe, reduces transmission, avoid contamination, prevents or reduces insect bites, prevents malaria") is also a clue that a claim is being made. Please note that several of these example claims would not be allowed in some of the OECD jurisdictions (e.g. "prevents malaria, reduces transmission"). Also mentioning of the presence of an active substance (for example *Contains silver; Contains natural Chrysanthemum extract*) could be a claim regarding the biocidal properties. Even the use of images and pictograms be a claim. These examples are not exhaustive.

Please note that even claims for material protection can trigger regulatory obligations, the least being the obligation to use an approved/registered active substance.

3.2.2 Evaluation of the claim in a regulatory process

Different requirements associated with claims are made by different legislations. In some cases, it is only required that the provider of an article can show on request that a claim is substantiated. In other cases, a claim becomes part of an authorization and is approved. The assessment may include consideration of the benefits of the intended use and the risk of a possible or foreseeable misuse.

For example, a false interpretation or a false sense of security may increase the risk of careless behaviour (with respect to cleaning or taking preventive measures), and its likelihood as well as the severity of the hazards involved may have to be weighed against the benefits of using the product.

[15] https://archive.epa.gov/pesticides/regulating/con-labels/web/html/consumer-labeling.html

As a result of this assessment, a claim might be accepted, modified or not permitted. In other cases, mandatory labelling might be required (for example: "*This product alone does not protect users or others against disease-causing bacteria. Always clean this product." " This product does not prevent Malaria, it only reduces the risk for mosquito bites for up to 10 washes.")*

Furthermore, requirements differ depending on what level of assessment is made:

- If the treated article is assessed on a case-by-case basis, the assessment is often made before the articles may be placed on the market. Future label changes or changes to the article itself may then trigger renewal of authorizations.
- If a pre-market assessment is not required, the active substance or the biocidal product might be assessed for potential use in treated articles; in this case, a representative array of articles and claims should be brought forward and assessed, in order to evaluate the intended or anticipated uses, and decide on possible warnings or use restrictions. The evaluation will truncate the range of claims that subsequently can be made on treated articles that contain the active substance or biocidal product in question.

3.3 Testing: The scientific proof

It is often difficult to prove a claim when it is unclear what the claim means. Therefore, the more precisely the claim, and the problem, which is supposed to be solved by the treatment, are described, the easier it is to set up a regime of proof. Once it is established what the claim is, adequate test methods need to be chosen that can quantify efficacy and demonstrate functionality. For this purpose, use scenarios need to be described, covering all relevant use conditions. These use conditions should then be reflected in the testing. Multiple scenarios may need to be considered for different jurisdictions, product variants, use environments, and users (e.g. professional-, non-professional user, bystander, vulnerable user, etc.).[11]

Use scenarios are like abstractions of possible real-life situations. They should describe the situation of concern: What is the problem with the organism that needs to be prevented or remediated? Under which conditions does it occur? A use scenario describes the relevant use and exposure. Details are needed to establish the speed and pathways via which the active substance in the treated article acts, and under which conditions this will occur (e.g. temperature, pH, humidity, soiling, dust, etc.). It further describes the duration of the effect and which use conditions have an impact on it.

Such use scenarios will highlight the kind of testing that will be needed to give the most relevant and robust estimate of efficacy. Use scenarios will also identify situations that would not be appropriate. In doing so, risks due to lack of efficacy might be identified. Together, the claim and use scenarios will define the type of efficacy testing required and the performance standards to be applied.

OECD guidance documents are available for both Tier 1[16] (2014) and Tier 2[17] (2018) efficacy testing of biocide treated articles, for articles with disinfecting claims. There are no OECD guidance documents available related to efficacy testing for insecticide or insect repellent treated articles.

[16] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)18&doclanguage=en
[17] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2018)20&doclanguage=en

4 Principles of claim development

The intention of this guidance is to support manufacturers of treated articles, and regulators, by identifying steps where choices should be made, and by providing ideas on how to formulate clear claims in order to make them understandable for users and regulators. Furthermore, reference is given on how to test such claims and which performance standards to apply.

The following distinct steps can help to make realistic and understandable claims that can easily be proven:

	Step	To be assessed
1	**What to expect?**	Is a claim made at all? What is the problem which is supposed to be solved by the treatment of the article? What is understood by the user (non-professional and professional)? What legal impact does the claim have?
2	**What are the relevant use conditions?**	Which use scenarios and use conditions are relevant for efficacy testing and thus for the functionality of the article?
3	**How to test**	How to select testing strategies for the use scenarios?
4	**Performance criteria**	Which performance criteria follow from the claim made and the relevant scenarios? How to assess the results of the testing, i.e. is the claim substantiated?
5	**Labelling**	How to estimate the health risks associated with use and foreseeable misuse? Which use instructions and warnings are needed?
6	**Accepted uses, functionalities and claims**	Is regulation needed and mandatory? If so, on which level (active substance, biocidal product, treated article)? Which claims can be approved?

The following sections describe these steps in claim development in more detail.

4.1 What to expect?

Claims are in the first instance marketing instruments, with the purpose to make a treated article desirable for a consumer. But a claim also dictates whether an article falls under biocides/pesticides legislation or not (see chapter 2.2). In this case, the claim is the basis on which regulators make their decision.

When a claim for a treated article, or a type of article, is formulated, the next step would be to establish how this claim is understood by the consumer groups that are intended to use the article. This can be done by involving consumer panels, expert judgement, or a combination of both. There are conflicting interests when claims are formulated. Providers want to help the consumer make a buying decision by promising a certain desirable effect or performance. Consumers want the claims to hold true, but often lack the knowledge or the ability to assess this, so a purchase decision is often based on trust in the label or the way the article is presented. Regulators want a claim formulated in a way that can be proven by scientific methods and that does not give rise to false impressions.

Legislation in different OECD regions have found different ways out of this dilemma. In the U.S., health claims are part of the authorisation of a pesticide; only claims that have been applied for and approved are permitted to be used. However, articles with claims about the protection of materials do not need pre-market approval. Thus, certain claims made for material protection (like antimicrobial), can insinuate a health benefit, even though they do not explicitly claim it. In the EU, if the article has a primary biocidal function due to the presence of the active ingredient, it must be authorized as a biocide[18]. Claims are not approved as they are in the US, although certain statements are subject to authorisation of biocidal products (e.g. against which organisms the biocide is aimed) and are laid down in the "summary of product characteristics", SPC).

'What to expect' needs to be described in more detail as is usually done for marketing purposes. A set of questions should be answered to define a claim:

a) What is the problem the biocidal treatment shall solve?

b) What or who shall be protected?

c) Against which organism groups?

d) How quick is the effect?

e) How long does the effect last?

f) What is the magnitude of the effect?

a) It is of particular importance to describe the problem that the treatment is supposed to solve; this is especially true for the treatment of articles. It is clear what a rodenticide is supposed to do, whereas it is much less clear which problem an antimicrobial kitchen surface is supposed to solve. Likewise, it is clear what to expect of an insect repellent applied directly to the skin, and how long its effect will last. It is much less clear how the protection by an insecticide-treated shirt will work and how many washes the treatment will withstand. Not all the answers to these questions might be used as marketing information; nevertheless, they are useful when prepared by the manufacturer of the treated article, to both be able to respond to questions of potential customers, and to build an application for authorisation, if necessary. Furthermore, it can be useful to ask these questions of the provider of the active substance or the masterbatch that is used to treat the article.

b) Likewise, it is important to describe the protection goal. Is the material to be protected from biodeterioration or from bad smell, or is it human beings or animals that are to be protected from a threat?

- If the biocide is intended to add disinfection-like, insecticidal, insect repellent or other health-related properties to a material or an article, these should be demonstrated to function under the conditions in which it will be used, in order to be capable of delivering a meaningful benefit.

c) For microorganisms, the organism groups against which the biocide has an effect are usually bacteria and bacterial endospores, viruses, yeasts and/or fungi. Sometimes, dependent on the purpose of the treatment, it can be meaningful to further sub-divide these groups (e.g. Gram-

[18] https://echa.europa.eu/regulations/biocidal-products-regulation/treated-articles

Positive and Gram-Negative bacteria, enveloped viruses, fungal spores, etc.). In some jurisdictions, indicative species (e.g. *E. coli, P. aeruginosa, S. aureus, A. niger, C. albicans*) as well as specific target organisms are used to describe the effects, whereas in others, single species claims would not be accepted. Generic terms like germs are not defined and should be avoided.

Insecticide or insect repellent treated materials usually mention the organisms against which the treatment is aimed (e.g. mosquitoes, ticks, lice, fleas). Often, efficacy against particularly resistant, or aggressive standard test organisms is used as an indicator to represent protection against a larger group of organisms (e.g. Aedes, Culex and Anopheles genera are used to represent mosquitoes). This ensures comparability among different products/articles, because tests with the same set of standard organisms are required.

d) – f) For the speed of antimicrobial action, terms like “on contact”, “instantly”, “with X minutes / hours” are often used. Similarly, terms such as “protects against” are employed. These terms are part of the claim and should be taken into account in the demonstration of efficacy. For example, for an antimicrobial treated article that is touched with high frequency, a fast rate of action would be needed. Similarly, the scale of an effect needs to be considered: Is the effect sufficient in size to fulfil the claimed function? Especially in health care settings where, for example, 2-5 log reductions within a few minutes are generally expected for liquid disinfectants, antimicrobial materials might have to demonstrate similar reductions, especially if they are expected to reduce disinfection regimes.

Terms such as bactericidal and bacteriostatic etc. are established for antimicrobial action. Bactericidal effects (i.e. a reduction of the number of bacteria) are usually expected to occur in a short space of time, but longer time may be relevant in some circumstances. Claims associated with treated articles often insinuate that such biocidal effects persist for the lifetime of the article, provided normal cleaning etc are applied. This should obviously be substantiated by a relevant simulation / aging regime. Biostatic effects, i.e. that growth is impeded, imply that growth on an article occurs under the intended conditions of use. This and the effect of the treatment at preventing such growth would need to be demonstrated. This applies for a variety of surfaces in a range of (micro-)environments from continuously wet to continuously dry.

For insecticide and insect repellent treated articles, factors like protection time, protection coverage and the effect of laundering the article should be considered. For instance, does a treated shirt only protect the covered parts of the body (by preventing mosquito bites through the material), or does it also repel insects and prevent bites on uncovered skin (e.g. hands and face)? How many washing cycles does the article withstand while still remaining effective?

When answering the questions above, it is recommended to use terms established in the field (e.g. bactericidal, fungistatic, effective against enveloped viruses, controls, kills, repels, protects against, etc.). If such terms do not exist, or are not well defined, the effects should be described in text.

The aim of the first step is to gain a complete understanding of what the claim is and what effect should be expected when using the treated article. This includes defining the risks associated with use or misuse. It could also help in clarifying the legal status of the article, whether or not it is regulated as a biocide / pesticide, or by another legislation.

4.2 What are the relevant use conditions?

The next step is to define the most relevant use scenarios, dependent on the intended effect, even considering possible interpretation by consumers. What use scenarios are likely? What behaviour can be expected? What are the most relevant use conditions that impact the performance of the article? This needs to be described and assessed in order to set up relevant efficacy / performance testing?

4.3 How to test?

It is important to consider realistic conditions of use, to ensure that they are in line with the claim, and to simulate them as closely as possible during testing. For instance, if cross-contamination resulting from touching surfaces is intended to be reduced, then the touch should be simulated somehow during testing. Furthermore, the speed of the effect should be adapted to the frequency of touch in a realistic use situation, depending on where and how the article is used.

Efficacy testing should be conducted using realistic conditions of use. The duration of the test and the impact of use conditions, as well as the ambient environmental conditions in which the article will be exposed, should be taken into account where appropriate. A relevant control should be included, which should show what happens without a treatment. For example, if protection against mosquitoes is claimed by a piece of treated apparel, the protection should be compared to an untreated piece of the same apparel.

The OECD guidance documents for Tier 1 (2014)[19] and Tier 2 (2018)[20] give further instructions on how to perform meaningful tests for antimicrobial treated articles, whereas no guidance exists for efficacy testing of insecticide or insect repellent treated articles. The EU[21] and the US[22] give some guidance on efficacy testing of antimicrobial treated articles.

4.4 Performance criteria

Linked to the selection of tests for a scenario is the decision of what level of performance is needed, given the use scenarios and expectations. Different performance standards may exist in different use areas and under different legislations. It is important to take these standards into account, if relevant for the intended use.

For disinfectants, performance standards have often already been defined. Although these do not necessarily apply to treated articles with hygienic functions, their requirements can be relevant for treated articles, especially when the articles are intended as a complement to a liquid disinfectant or when they intended even to replace it. If performance standards do not exist, testing protocols should be designed based on the claim, i.e. the problem description, the intended use and the desired effect should be taken into account.

For repellents directly applied to the skin, often complete protection time is stated (i.e. the time of protection until the first confirmed landing)[23]. For treated textiles/articles, it is more relevant to establish criteria to assess the duration of the effect. For how many days or months will the article protect the user? Is it acceptable that the active ingredient is effective for only 2 months? How many washes should an article withstand as a minimum? Furthermore, the reach of the protection should be demonstrated; does a bracelet claiming to protect the user from mosquitos or a dog collar claiming to protect against fleas protect the whole body? How should the protected area be defined?

---

[19] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)18&doclanguage=en

[20] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2018)20&doclanguage=en

[21] Guidance on the Biocidal Products Regulation, Volume II Efficacy – Assessment and Evaluation (Parts B + C), specifically chapter 5.4.6, and Appendix 1, Claims matrices (see Table 9, Treated articles)

[22] US guidance can be found at: https://www.epa.gov/pesticide-registration/interim-guidance-expedited-review-products-adding-residual-efficacy-claims

[23] See for instance the Canadian insect repellent guidance: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/value-new-personal-insect-repellent-products-label-amendments.html

4.5 Labelling and advertising

Apart from identifying the proper testing for efficacy, taking into account realistic conditions of use, and scenarios of potential misuse should be considered and minimized through clear communication to users. Potential misuse may be triggered by the claim. If this leads to unacceptable health risks, this may warrant

- changes to the claim, depending on the risk associated with this misuse, or
- the introduction of mandatory warnings.

As a general guidance, OECD (2016)[11] may be used. Some considerations on foreseeable misuse of treated articles with added hygienic functionality include the use of the article after the intended service life or beyond the range of intended applications. Alternatively, the use of the article may lead to poor compliance to normal hygienic practices. Similarly, for insecticide or insect repellent treated articles, potential misuse may include reliance on protection after the service life of the treatment, or failure to perform other precautionary practices (like scrutinizing the body for ticks).

Generally, information on the label or in any advertising material should not be false or misleading about the function or the risk of an article.[24]

4.6 Accepted uses, functionalities and claim

A compilation of all the information gathered can be used to refine or alter the claim, or to formulate clearer instructions for use. Furthermore, it can be used to support an application for an approval or a registration, if necessary. Regulators will use this information in decision-making when granting approvals or registrations, and possibly even in decisions on mandatory labelling or warnings. In some jurisdictions, the entire claim or certain parts of the claim will become part of the approval/registration.

[24] See e.g. Canadian guidelines for the Advertising of Pest Control Products: https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/regulatory-directive/2016/guidelines-advertising-pest-control-products-dir2016-01.html