

Practical Guide

Fast-Tracking Disinfectants during the COVID-19 Pandemic

Practical Guide on Fast-Tracking the Supply of Disinfectants during the COVID-19 Pandemic under the EU Biocides Rules

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Version 1.2 – 29 May 2020

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<p>WHY?</p>	<p>EXCEPTIONAL PROCEDURES FOR EXCEPTIONAL CIRCUMSTANCES</p> <p>The use of hand sanitisers and surface disinfection (“disinfectants”) helps combat the COVID-19 pandemic. Companies and authorities need to know how to fast-track the availability of disinfectants in order to support the public at large, public health systems, and key workers. This requires extraordinary measures derogating from the usually lengthy pre-market authorisation procedures, which apply to disinfectants under the EU Biocidal Products Regulation (BPR) and related national rules.</p> <p>This guide sets out the main procedures for fast-tracking the availability of disinfectants in order to address the current danger to public health. <i>Appendix 1</i> sets out a table of measures, which have been adopted in various European countries. The applicable rules are determined by national law and/or the BPR.</p>
<p>WHO?</p>	<p>WHO IS CONCERNED BY THESE PROCESSES?</p> <p>The making available (i.e. any supply) of disinfectants is regulated at national and EU level. The rules relating to supply are therefore relevant to manufacturers, importers, distributors, retailers and other suppliers of regulated disinfectants, as well as actors in the supply of substances contained therein.</p> <p>Non-EU companies will want to coordinate with their EU importers to ensure product compliance and availability, even if the non-EU actors have no direct regulatory obligations placed upon them. They may also need to review their contractual obligations with EU importers/suppliers to ensure they are doing all that is necessary to ensure compliance and availability in light of the COVID-19 outbreak.</p>
<p>WHAT?</p>	<p>WHICH BIOCIDAL PRODUCTS ARE CONCERNED?</p> <p>This Practical Guide addresses the fast-tracking of biocidal products falling under the BPR product-types 1 (Human hygiene) and 2 (Disinfectants and algacides not intended for direct application to humans or animals).¹</p> <p>The active substances approved or under review for PT1 and PT2 at EU level are listed in <i>Appendix 2</i>.</p>

¹ Annex V to the BPR.

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<p>WHEN?</p>	<p>TIMELINES RELATED TO FAST-TRACKING</p> <p>Fast-tracking is underway all across Europe, with many countries having adopted derogation measures to deal with the supply of disinfectants in the context of the COVID-19 outbreak. Where specific applications need to be made by companies, these can be done at any time (subject to any national rules, conditions and limitations – see <i>Appendix 1</i>). There are daily changes/additions to the rules being developed.</p> <p>Different durations apply for the fast-tracking of market access for disinfectants, depending on when and for how long countries issue derogations and on the route followed (see “How?” section below). This means that in each national territory the start and stop dates for fast-tracking may differ (see Start date and Expiry date in <i>Appendix 1</i>).</p>
<p>HOW?</p>	<p>TWO MAIN ROUTES TO FAST-TRACKING SUPPLY</p> <p>Fast-tracking is available under two main routes:</p> <ul style="list-style-type: none"> • Article 55(1) of the BPR, or • national rules. <p>Thus far four scenarios have been distinguished:</p> <p>(i) Where <u>all</u> the active substances in a biocidal product have already been approved at the EU level (<i>Appendix 2</i> lists approved active substances for PT1 and PT2²), national competent authorities <i>may</i> permit the making available on the market and use of the biocidal product in <i>their</i> territory without following the standard BPR authorisation procedure for the product (as set out in Article 17 and 19 of the BPR and the provisions to which those Articles refer). The legal framework for fast-tracking in this scenario is Article 55(1) of the BPR. National derogations from the normal product authorisation procedure can be granted for a period <i>not exceeding</i> 180 days. There are examples of countries granting shorter periods. What happens at the end of the 180-day period and how Article 55(1) operates as a whole is explained further below.</p> <p>(ii) Where all the active substances in a biocidal product are “new” substances, i.e. substances that are not approved and not included in the Review Programme, according to ECHA³, the same route of Article 55(1) of the BPR also applies.</p>

² See also [ECHA’s list of approved substances](#).

³ See ECHA’s [“Q&As: advice for companies on making disinfectants available on the EU/EEA market”](#), Version 3.0, 18 May 2020.

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	<p>(iii) Where <u>not</u> all the active substances in a biocidal product have already been approved at the EU level but (some) are still under review, national rules on disinfectants apply. These are the “transitional” regimes, which apply as long as active substances are being reviewed under the EU review programme for active substances. The Article 55(1) BPR derogation procedure does <u>not</u> apply in these circumstances.⁴ A relatively small number of active substances are approved under the BPR⁵, which may create supply challenges - especially in times of particular danger to public health.</p> <p>(iv) Where one or more active substances in a product are non-approved, i.e. subject to a Commission non-approval Decision, Member States have not applied Article 55(1).</p>
	<p>ARTICLE 55(1) DEROGATIONS EXPLAINED: 180 + 550 DAYS</p> <p>National derogations from the normal authorisation procedure may be granted for a period <i>not exceeding</i> 180 days. These are at the sole discretion of each Member State. They are not decided upon by the European Commission or ECHA.⁶ Article 55(1) does not allow for EU-wide derogations to be granted to disinfectants. Although ECHA and the Commission play no role in the initial granting of derogations, national derogations are notified to other authorities and the Commission. The current state of notifications is included in the table in <i>Appendix 1</i>. The notifications may encourage national authorities of other countries to take similar approaches, through knowledge sharing, but do not formally compel them to do so.</p> <p>An extension may be granted, for a period <i>not exceeding</i> 550 days. This is granted by the Commission. Conditions may be attached to these extensions. The Commission can only act where it receives a reasoned request from the national competent authority who originally granted the derogation. This means that if you benefit from a derogation you may have to raise the need for an extension directly with competent national authorities. Extensions are adopted by a procedure involving the Standing Committee on Biocidal Products, an EU committee of Member State experts in which all Member</p>

⁴ In practice, some countries' derogations appear to cover both approved and substances still being reviewed even though they refer to Article 55(1) of the BPR.

⁵ The Review Programme is a Commission work programme for reviewing all existing biocidal active substances. The programme was set up under the Biocidal Products Directive and continues under the BPR. Only 30% of active substances in Product Types (PT) 1 and 2 have been through the review Programme. See “Progress of the review programme of existing active substances under Article 89 of the BPR”, CA-Feb20-Doc.5.1 for 87th CA Meeting.

⁶ ECHA stated on 3 April that it will not develop a centralised submission system for applications covering individual countries.

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	<p>States participate and vote.⁷ The extensions are EU level decisions but, in principle, only apply to the national territory of the national competent authority requesting it.</p> <p>The derogation will expire either at the end of the period of up to 180 days granted in the derogation if no extension is granted, or at the end of the extension period of up to 550 days granted by the Commission.</p>
<p>MISC</p>	<p>WHICH STANDARD RULES STILL APPLY?</p> <p><u>General</u></p> <p>Fast-track rules do not exclude that EU and national rules governing the supply of disinfectants cease to apply. Key rules, aside from those on biocides, which remain applicable include the following rules concerning:</p> <ul style="list-style-type: none"> • misleading and comparative advertising between businesses⁸, • unfair business-to-consumer commercial practices in the internal market.⁹ <p>This means, for example, that claims may not be made about the efficacy of products which are unsubstantiated.</p> <p><u>Article 95 BPR</u></p> <p>ECHA’s clearly stated view¹⁰ is that the Article 95 list of suppliers still applies to products which are fast-tracked. This means that, according to ECHA, a biocidal product still may not be made available unless either the substance supplier or the product supplier is included in the list, <i>i.e.</i> an entity within the same supply chain needs to be on the list (but not all entities in the supply chain). Keep in mind that if one operator in your supply chain is not on the Article 95 list and you wish to be included a letter of access to a full dossier or a full hardcopy dossier will need to be submitted to ECHA. As soon as an entity within the same supply chain is on the list, other entities do not need to have a letter of access (to the active substance dossier) in order to make the product available.</p> <p>Some Member States appear to take the view that Article 95 does not apply and/or have indicated that they will not be enforcing it in view of the extraordinary challenge COVID-19 is posing. However, approaches to this</p>

⁷ The “comitology” committees, and in particular, the “Examination Procedure” under Article 5 of Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers.

⁸ Under EU Directive 2006/114 concerning misleading and comparative advertising.

⁹ Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market (‘Unfair Commercial Practices Directive’).

¹⁰ ECHA’s [“Q&As: advice for companies on making disinfectants available on the EU/EEA market”](#), 18 May 2020 – [version 3.0](#).

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	<p>issue are not consistent between Member States. In so far as a position has been expressed publicly, this is noted in <i>Appendix 1</i>.</p> <p>ECHA has also indicated that they would speed up the evaluation of new requests for inclusion on the Article 95 list.¹¹ ECHA will start the evaluation before the fees are paid but will only issue a final decision after the fees have been paid.</p> <p><u>Fees</u></p> <p>The following still applies:</p> <ul style="list-style-type: none">• <u>fees charged by ECHA for applicants to the Article 95 list;</u>• <u>fees charged by ECHA for decisions on technical equivalence</u>¹² in relation to new sources of approved active substances for biocidal products already authorised under the BPR; and• <u>fees charged by national authorities</u>, for example, where transitional regimes require an individual application and decision for fast-tracking. <p><u>Technical Equivalence</u></p> <p>For already authorised disinfectants, the requirement for the authorisation holder to establish technical equivalence, in order to switch to another source of active substance, still applies. ECHA has put in place an accelerated technical equivalence procedure for two active substances: propan-1-ol and propan-2-ol.¹³ ECHA has also issued recommendations on the compositional requirements for these two active substances,¹⁴ and for the active substances active chlorine released from sodium hypochlorite, hydrogen peroxide and peracetic acid.¹⁵</p>
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¹¹ ECHA's "[Q&As: advice for companies on making disinfectants available on the EU/EEA market](#)", version 3.0, 18 May 2020, question 4.

¹² 'Technical equivalence' means similarity, as regards the chemical composition and hazard profile, of a substance produced either from a source different to the reference source, or from the reference source but following a change to the manufacturing process and/or manufacturing location, compared to the substance of the reference source in respect of which the initial risk assessment was carried out, as established in Article 54 BPR.

¹³ "Propan-1-ol and propan-2-ol: Procedure and requirements for accelerated technical equivalence applications for these active substances under Article 54 of the BPR", 30 March 2020, available at <https://www.echa.europa.eu/covid-19>.

¹⁴ "Recommended requirements for the active substances Propan-1-ol and Propan-2-ol, for the purpose of derogations under Article 55(1) of the BPR", 23 March 2020, available at <https://www.echa.europa.eu/covid-19>.

¹⁵ "Recommended requirements for the active substances active chlorine released from sodium hypochlorite, hydrogen peroxide and peracetic acid", 7 April 2020, available at <https://www.echa.europa.eu/covid-19>.

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	<p>Whilst some countries still require some level of chemical similarity¹⁶ or equivalence test for active substances, others refer to the recommendations by ECHA.</p>
	<p>WHICH STANDARD RULES DO <u>NOT</u> APPLY?</p> <p>Fast-tracking also means that some rules related to standard pre-market authorisation procedures also cease to apply to the supply of disinfectants, under Article 55 BPR. Key rules which are <u>not</u> applicable for biocidal products where <u>all</u> the active substances in a biocidal product have already been approved at the EU level, include:</p> <ul style="list-style-type: none"> • the requirement to have a decision from ECHA on technical equivalence for the authorisation of an emergency biocidal product;¹⁷ • the requirement to have a dossier or a letter of access for each active substance in the biocidal product;¹⁸ and • labelling and packaging requirements in accordance with Articles 22(1) and 69 of the BPR¹⁹, which refer to the EU CLP Regulation (EC) No 1272/2008. <p>For products where <u>not</u> all the active substances in a biocidal product have already been approved at the EU level, national rules (if any) apply and the extent to which they disapply standard procedures must be checked on a case-by-case basis – see <i>Appendix 1</i>.</p>

<p>WHERE TO START?</p>	<p>WHAT SHOULD COMPANIES CHECK IN ORDER TO GET STARTED?</p> <p>Determine whether all the active substances in the disinfectant are already approved at EU level. <i>Appendix 2</i> to this guide lists the active substances approved for PT1 and PT2. If all active substances are already approved, Article 55(1) of the BPR is applicable (see section “How?”) above, otherwise national rules apply.</p>
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¹⁶ A chemical similarity check is an assessment similar to the technical equivalence assessment, performed in circumstances where a decision on the approval of the active substance has not yet been adopted and, therefore, the official reference source of the active substance is not yet established. It would typically look at only the substance identity and chemical composition of an active substance originating from one source with the aim of establishing its similarity regarding the chemical composition of the same substance originating from a different source.

¹⁷ Article 19(1)(c) of the BPR, from which Article 55(1) expressly derogates.

¹⁸ Article 20(1)(a)(iii) of the BPR. Article 19, from which Article 55(1) expressly derogates, cross-refers to Article 20 of the BPR.

¹⁹ Since these are referred to in Article 17(5) of the BPR, from which Article 55(1) expressly derogates.

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	<p>Determine whether the biocidal product falls under the scope of national derogations already adopted. <i>Appendix 1</i> provides an overview of derogation measures adopted. The derogation measures may be product specific (requiring an individual application and decision) or grant a blanket permission to a category of products meeting specified criteria without the need for an individual pre-market submission. If you identify a disinfectant as necessary for public health but there is not yet a national derogation measure which covers it, you should raise this directly with competent <i>national</i> authorities (see ECHA list of Biocides authorities).</p> <p>Verify Article 95 list status. Biocidal products may in principle only be placed on the market if either the substance supplier or the product supplier is included in the Article 95 list.²⁰ Some countries have declared that they would not enforce compliance with this obligation for the COVID-19 derogation measures (see column “Approach to Article 95” in <i>Appendix 1</i>). The Article 95 list is available at: https://echa.europa.eu/regulations/biocidal-products-regulation/approved-suppliers.</p>
<p>WHEN TO STOP?</p>	<p>WHEN WILL DEROGATIONS EXPIRE?</p> <p>Derogations are not granted for unlimited periods of time. The date of expiry of derogations for fast-tracking supply of disinfectants depends on the type of derogation:</p> <ul style="list-style-type: none"> • Derogations granted under national legislation will expire on a specific date indicated in the derogation or at the end of the duration indicated in the derogation – see <i>Appendix 1</i> for an overview of granted derogations and their duration. • Derogations granted under Article 55(1) of the BPR will expire either: <ul style="list-style-type: none"> ○ At the end of the period granted in the Article 55(1) derogation, which cannot exceed 180 days; or ○ If an extension is requested and granted by the Commission, at the end of the period granted in the Commission extension decision, which cannot exceed 550 days. <p>HOW CAN COMPANIES ANTICIPATE THE EXPIRY OF DEROGATIONS?</p> <p>Article 55(1) of the BPR does not provide for a grace period when derogations end. The supply of disinfectants covered by the derogation is thus subject to an abrupt stop when derogations expire. To anticipate this, companies can:</p> <ul style="list-style-type: none"> • Monitor the validity of derogations alongside supply and the evolution of the COVID-19 pandemic, to identify anticipated further supply demands for disinfectants;

²⁰ Article 95(2) of the BPR.

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	<ul style="list-style-type: none">• Reach out to national competent authorities to seek assurances that a reasoned request for an extension of the duration of the derogation will be submitted to the Commission, if needed;• Reach out to national competent authorities to request the granting of new derogations, where appropriate (such new derogations could have a different scope from the initial derogations and focus, for instance, on making available existing stocks of the disinfectant). <p>Some Member States appear to take the view that Article 95 does not apply and/or have indicated that they will not be enforcing it in view of the extraordinary challenge COVID-19 is posing.</p> <p>However, by the end of the derogation period, in order to meet obligations under the BPR for the continued making available of disinfectants on the market you must take the necessary actions to ensure that one operator in the supply chain is included on the Article 95 list. Keep in mind that if one operator in your supply chain is not on the Article 95 list and you wish to be included, a letter of access to a full dossier or a full hardcopy dossier will need to be submitted to ECHA.</p>
RESOURCES	WHERE CAN COMPANIES FIND ADDITIONAL INFORMATION? <p>The Appendices to this Practical Guide provide the following information:</p> <ul style="list-style-type: none">• <i>Appendix 1</i> provides an overview of derogation measures adopted by countries to date in order to deal with the COVID-19 pandemic (subject to regular updates); and• <i>Appendix 2</i> lists the active substances that are approved or undergoing review for PT1 and PT2. <p>Additional information and updates may be found on ECHA’s dedicated webpage on COVID-19, available at: https://www.echa.europa.eu/covid-19. The information made available includes:</p> <ul style="list-style-type: none">• A list of contact points in the national competent authorities;• Q&As for companies seeking to make available on the EU market disinfectants for the purpose of managing the COVID-19 pandemic;• Accelerated technical equivalence and compositional requirements for active substances• Information on emergency export requests under the Prior Informed Consent (“PIC”) Regulation.

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ABOUT US:

 <p>A.I.S.E. represents the European manufacturers of cleaning, hygiene and disinfectant products. Its membership totals 29 national associations, covering about 900 companies ranging from small and medium sized enterprises to large multinationals. Biocidal products manufactured by A.I.S.E. members include a vast range of disinfectants for household and institutional use, as well as insect control products.</p>	 <p>CEHTRA is a consulting company created almost 20 years ago, offering high quality scientific and innovative solutions, and ensuring regulatory compliance of chemicals to international obligations: from portfolio strategy to the notification of chemicals, from human exposure to site audits. CEHTRA provides high quality regulatory services, to companies committed to the safety of their products according to a large variety of regulatory legislations (i.e. Biocides, REACH, Plant Protection, Cosmetics, Medical Devices, Pharmaceuticals, etc.)</p>
 <p>EBPF is an industry platform, with more than 80 members, where all industry stakeholders involved in the biocides sector – be they active substance manufacturers, formulators, relevant trade associations or national federations– can exchange views and give an input in the ongoing debates. Its members place a wide range of disinfectants, preservatives, insecticides and rodenticides on the market for the benefit of EU citizens.</p>	 <p>European Association of Chemical Distribution (Fecc). Fecc is the voice of the Chemical Distribution Industry in Europe, with an active membership of companies and national associations. Fecc represents around 1,600 companies of which many are small and medium sized companies (SMEs). Fecc and its members contribute to innovation and sustainability besides adding value in the supply chain, by sourcing, developing, marketing, and distributing a wide range of specialty chemicals and ingredients to over one million downstream users ranging from automotive, electronics, paint, construction to pharmaceutical, cosmetics, food and nutrition industries, each with their own specialised needs.</p>
 <p>Fieldfisher is a law firm that advises and represents clients on matters arising out of a variety of EU product legislation, including chemicals (REACH), pesticides, biocides, cosmetics, medical devices, general product safety and codesign requirements, and more broadly EU market access legislation. It has strong litigation experience in challenging EU decisions before the European Courts, as well as ECHA decisions before the Board of Appeal of ECHA. In addition, the EU team is actively involved in advocacy and lobbying efforts on behalf of clients with EU and national authorities.</p>	 <p>Steptoe is an international law firm. Our chemicals and environment team provides strategic advice on chemicals regulation, with a particular focus on biocides, food contact materials, REACH and plant protection products. We have an especially active litigation practice in the EU, including before the ECHA Board of Appeal, European and national courts. Most recently the team has been assisting with urgent market access for disinfectants, the extension of regulatory deadlines, supply chain issues for active substances and biocidal products, and support with contractual issues arising from the COVID-19 crisis.</p>

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Appendix 1 and 2

- **Appendix 1** provides an overview of national measures (either under the Article 55 of BPR and/or national laws) that have been adopted in various European countries
- **Appendix 2** lists all the active substances approved or under review for PT1 and PT2 at EU level. Further checks by companies with regards to the efficacy against encapsulated viruses, such as corona viruses should however be conducted.

These 2 documents are provided as independent documents.