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Lessons learned in the management of market access of biocides of interest in the wake of the COVID-19 pandemic

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LESSONS LEARNED IN THE MANAGEMENT OF MARKET ACCESS OF BIOCIDES OF INTEREST IN THE WAKE OF THE COVID-19 PANDEMIC

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Foreword

This document describes the outcome of a survey about the lessons learned in the management of market access of biocides of interest in the wake of the COVID-19 pandemic, which was conducted among members of the OECD Working Party on Biocides (WPB).

During the fourth meeting of the WPB in September 2020, the WPB agreed to investigate the management of crises based on experiences with the Covid-19 pandemic. To this purpose a dedicated (post) Covid-19 working group (WG-PC19) was created which subsequently developed and circulated a survey to the WPB participating delegations on their experiences in the management of the Covid-19 crisis. This document, which is based on the answers received from member countries, is structured around the identification of problems encountered during the crisis, lessons they have learned from the crisis, and provides recommendations for possible future emergency situations.

The document was approved by the Working Party on Biocides on 24 September 2021. The Chemicals and Biotechnology Committee agreed to its declassification on 22 November 2021.

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

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Survey report: Lessons learned in the management of market access of biocides of interest in the wake of the COVID-19 pandemic

Introduction

The Covid-19 pandemic has challenged regulators, health professionals, industry and the public in responding quickly, decisively and efficiently to the impact and consequences of this virus. Responses of governments to the pandemic have varied, and have been, more or less, coordinated with responses in other countries, while the virus travelled swiftly across the globe. The possibility of more efficiency in emergency responses through more coordinated action has been a topic of discussion in the OECD Working Party on Biocides (WPB) and the WPB agreed in their fourth meeting that a project investigating the management of crises has very high priority. Such a project should use the lessons learned during the Covid-19 crisis to investigate approaches for possible future emergency situations, and initial discussions in the fourth WPB meeting revolved around the following three questions:

1. What were/are your issues during the Covid-19 situation? (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.)
2. What did you do about it? (Example: procedures for emergency situations, etc.)
3. What could we do better now with what we have learned so far? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

This project will include specific activities such as the creation of a lessons-learned document, developing best practices for crises, investigating approaches for more efficient communication between regulatory authorities during crises, the further development of test methods on the efficacy of disinfectants.

The dedicated (post) Covid-19 working group (WG-PC19) developed a procedure and questionnaire for WPB delegations, governments and their relevant authorities and agencies as well as stakeholders. The content of the questionnaire explores the three above-mentioned questions in more depth and detail, and the survey questionnaire can be found as an annex to this document. The outcome of this survey provided the input for this lessons-learned document, for which we want to highlight that these are lessons learned “so far”.

The WG-PC19 noted that the project should allow for flexibility since countries are still adapting to the Covid-19 crisis and learning how to best respond to the crisis. Thus, the WG-PC19 considers the lessons-learned document and subsequent best practices stemming from that document, as living documents.

The WG-PC19 furthermore identified that in some countries additional authorities and agencies, i.e. other than those currently represented in the WPB, have been involved in the reaction to cope with the Covid-19 crisis. The WG-PC19 therefore agreed that the Heads of Delegation to the WPB should be invited to circulate the survey questionnaire to all the relevant authorities, agencies or organisations that they deem relevant for the Covid-19 crisis response.

Procedure/timelines

The timeline for the first phase of this project, i.e. developing a lessons-learned document is as follows:

- Circulation of survey questionnaire to the WPB, February 1st, 2021.
- Return of answers to the questionnaire by 5 March 2021.
- Compilation of answers, discussion in WG-PC19 during a teleconference on 27 or 29 April and drafting of an initial lessons-learned document by April 2021.
- Circulation of the initial lessons-learned document to the WPB mid-May 2021, with subsequent discussion of this document and the survey outcome in a dedicated session of the WPB on 26 May 2021.

Answers

Twelve countries answered to the survey request, namely Australia (AU), Belgium (BE), Canada (CA), Estonia (EE), Finland (FI), Germany (DE), Lithuania (LT), the Netherlands (NL), Slovak Republic (SK), Sweden (SE), the United Kingdom (UK) and the United States (US), representing three OECD regions (Asia-Pacific, Europe and North America). Australia, Canada and Finland returned separate answers from multiple organisations involved in the Covid-19 response, these answers are reported together as one country answer.

This report contains a compilation of the responses received for each of the questions of the survey, followed by an initial synthesis of lessons learned based on those responses. The individual answers to the survey, as provided by the responding countries, are attached to this report in Annex 2.

As indicated previously, the survey is structured on three sets of questions that focus on problem setting, problem solving and how to react better in future situations based on the lessons learned from this crisis.

The first set of questions, which revolved around the main issues encountered during the Covid-19 situation, showed that there are large similarities in the answers.

Compilation of answers

Question 1.1 What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.

All responding countries indicate that due to the sharp increased demand for biocidal products supply chain issues arose in some form or another, such as:

- shortages of active substances, excipients and biocidal products.
- but also shortages of packing materials for biocidal products and shortages of Personal Protection Equipment (PPE) occurred.

These shortages led to subsequent issues, for instance:

- increased demands for information from the public and manufacturers for authorities. More detailed information about the type of inquiries is included in the compilation of responses to question 3.4.

- an influx of new manufacturers, including opportunistic manufacturers of novel products or techniques often lacking data regarding efficacy.
- an increase of requests for authorisation of products, and often requesting emergency exemptions or derogations, i.e. requiring evaluations in a shorter timeframe.

The lack of regional approaches on how to deal with shortages resulted in an increased focus on national interests, and for instance export bans of core biocidal active substances and products (SK).

Several countries remarked that manufacturers often lack knowledge of regulatory requirements, as also evidenced by the amount of applications made without sufficient supporting data. This seemed to be particularly valid for the so-called opportunistic manufacturers trying to enter the market with novel products that had limited, if any, data to support their use.

Ensuring the efficacy and safety of products when issuing emergency authorisations/derogations/exemptions was of great concern to the majority of the responding countries. Particular issues related to novel products and techniques, for which no methodology exists yet, but also the testing of regular products by new, and inexperienced, companies was mentioned as a concern. Relatedly, the safe and correct use of products or avoiding non-essential use of products proved to be challenging (NL). Relatedly a lack of proper knowledge about proper prevention techniques was mentioned (LT).

Some countries (AU, SE) mentioned that there were cases where more jurisdictional clarity was needed, for instance when surface disinfectants are used in public spaces, where it was unclear under which legislation such products are regulated. In general it could take some time to determine which type of legal action was required and to adapt the national legislation.

Countries (BE, EE, FI, US) mentioned the need for increased communication and the increased Information supply to the public, new manufacturers, and for instance sensitive populations, as challenging.

Finally, practical aspects of applied Covid-19 restrictions hampered for instance site audits, or homeworking which put a strain on the organisation and capacity of work. All of the above resulted in increased pressure on authorities and their resources, which many responding countries mentioned as problematic, with limited resource allocations to meet the increased demands (CA, SK).

Question 1.2 Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?

All countries reported to have agile process available which allowed them to react to the crisis situation. Such processes either existed in national legislation or regional legislation, such as Article 55 of the EU Biocidal Products Regulation 528/2012 (BPR) and generally allowed for a timely response. In general, these emergency processes seem to work satisfactorily. Some countries mentioned that the temporary aspect of the emergency could create issues when the crisis continues for a prolonged time, that there can be geographic boundaries to such measures, i.e. for an area meeting the statutory definition of “emergency condition” (US). Access to expert knowledge and quick access to data remain necessary for such

processes to be effective. Some countries specifically mentioned exemptions from linguistic requirements, packaging requirements, production location, etc. or a more flexible approach with regard to standard timeframes for applicants.

In one case, a country (US) leveraged specific guidance and allowed manufacturers to submit data proving their product is effective against harder-to-kill viruses, than SARS-CoV-2 and once approved to make off-label claims for use against SARS-CoV-2.

One country (CA) mentioned that no emergency registration process exists for drugs but that interim measures, to facilitate importation of hand sanitizers and disinfectants based on foreign approvals, resolved that issue to address temporary shortages and that these interim measures have fixed end dates. A similar temporary measure was mentioned to allow new entrants to the market for the manufacture of hand-sanitizers, e.g. hand sanitizers produced by gin distillers to a specific formula. It appears that the use of a specific formula, e.g. the WHO formula for hand sanitizers, facilitated the use of temporary/transitional measures (EE).

Question 1.3 In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)

Countries reported varying timeframes for registration/authorization, ranging from 1 month to several years depending on data complexity and availability, the nature of the application and the type of legislation, e.g. either national legislation or regional (EU BPR) . Typical time frames under the BPR range from 1,5-3 years for authorisation of a biocidal product.

One country (US) reported a process lasting three months, for the review of novel protocols for instance for surface coatings with long lasting effects. That protocol would subsequently be used to generate data for product registration.

For the evaluation of Covid-19 related medical devices one country responded (AU) to have formalised time frames for decisions on a new device application (20 days), which can include requests for additional audits with varying time frames. However, in general conformity assessments are finalised in less than six months.

Question 1.4 In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?

In general countries responded that the existing agile processes sufficed and referenced to the responses to question 1.2. However, some countries (US) noted the use of supply chain flexibilities, often in relation to certain formulation changes or changes in manufacturing location, expedited registration and memos for worker safety which are of a temporary nature. Other temporary measures mentioned included the non-enforcement of the requirements to have access to a full data set for the active substance (SE), or to have taken a pragmatic and proportionate approach (UK).

One country (EE) mentioned a very practical approach to deal with the difficulties outlined in question 1.1, namely to involve more people in the regulatory process, or to prioritise Covid-19 related requests (AU).

Also of interest are the mentions of a post market review of the quality of face masks (AU), the cooperation with overseas regulators to process certain applications (AU) and the development of guidance (US) for long-lasting products such as paints and coatings.

Question 1.5 Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.

Almost all responses highlighted the importance of improved and clear communication between all actors involved and or to cooperate with international counterparts (AU, CA, FI).

To have a repository of existing novel products and techniques was considered useful (AU, LT, US) though there was also some concern related to novel techniques stating that a time of crisis is possibly not the best time to experiment with novel techniques which might or might not be effective/useful (DE, NL).

Finally, one country (US) recommended to develop a Best Practice Guide for future crisis/pandemic situations and provided some suggestions for content of such a guide, such as sample interim measures or country specific requirements for import and export.

Question 1.6 Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others:

- → **coatings/paints with long lasting residual efficacy used in such places**
- → **the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers**
- → **position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors.**
- → **position on using disinfection tunnels in public settings as a means to disinfectant humans / objects.**

If so, please provide your suggestion and list behaviour/actions that you think are most relevant.

Most responses are cautious highlighting that novel techniques are interesting but in the current context of concern due to a lack of proven efficacy. However some countries express that they see value in developing OECD guidance or as a combined OECD/WHO activity.

Countries are quite clear in relation to spraying individuals, which is not supported by the survey respondents, and in line with WHO recommendations. Most responding countries also doubt the use and efficacy of large scale, non-target, disinfection of open spaces.

Question 1.7 Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of.

Countries often referenced the previously mentioned emergency measures and highlighted the importance of prioritising Covid-related applications, implementing fast-track procedures and allowing flexibility for applicants (AU).

Some countries highlighted the importance of cooperation between authorities and stakeholders/industry to identify supply gaps and find solutions for them (CA, FI, NL) or indicated the increased cooperation and resource sharing between businesses (EE), or the repurposing of industries (UK, SK) as good examples of how to adapt to increased demands in the supply chain. Other countries mentioned that stocks of an essential active substance, i.e. ethanol were increased (LT).

Question 1.8 In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.

Countries answered that there are advantages when there is a better exchange of data between countries/authorities mostly, as well as stakeholders. However, there were different approaches on how this could be done, for instance to have shared access to assessments or shared data guidelines (AU, NL) including the development of internationally agreed efficacy testing to new techniques such as ultraviolet (UV) disinfection (LT).

Some countries adopted a more regional approach and referred to BPR guidance (EE, FI) or CEN test standards (DE), while others advocated the development of harmonised efficacy test methods, such as (US).

One country mentioned the usefulness of standard formulations such as the WHO formula, where the data for such similar formulations could be more easily exchanged. This could also apply to very simple formulations (NL).

Question 1.9 Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.

All countries mentioned the importance of updated websites for national or regional authorities, such as the European Chemicals Agency (ECHA), and to communicate with industry associations to identify information needs. The provided information should preferably extend beyond the requirements for authorisation only but also include information related to packaging, manufacture and transportation. In general, it seems that the regular and larger companies are quite aware of regulatory requirements, however that newcomers and small companies often struggle with this (CA, NL). A single contact (phone/email) for the national helpdesk and a website with information provided in the national language are considered very helpful (SK)

An additional complicating factor is the borderline with other legislations such as for instance the Cosmetics Regulation.

One country also noted that a centralized OECD website, fact sheet and/or social media with links to the various OECD country regulatory resources might be useful (US).

Question 1.10 How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?

Quite some countries mentioned that this question was outside of their expertise. Some countries did notice though that clear and consistent messaging and communication from government to the public is essential to engender trust and minimise confusion (AU, NL), and that it is essential that governments provide clear guidance (FI, NL). It was also mentioned to focus on the multi-layer aspect of infection prevention, i.e. a combination of strategies is necessary and that such approaches should be science based (US).

One country suggested that a focussed communication strategy and/or website from OECD website with links to reputable public health sources such as WHO would be useful (US).

Question 1.11 Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?

Most countries provided nil responses as they considered this question to be out of their expertise. However, some countries noted that it could be useful to establish guiding principles for specific exposure scenarios, i.e. related to specific contamination pathways (US). Other countries noted that basic and easy to read scenario documents for governments and the general public are useful, explaining ways for effective contamination prevention (NL, LT). On the other hand, it was suggested to provide elaborate, containing peer-reviewed scientific research and international guidelines, information packages and make those accessible to all countries (FI).

Question 1.12 Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.

Most countries referred to their answers under question 1.2 that their response had in general been agile through the available provisions in national and/or regional legislations. However, one country did note it plans to change national legislation that prohibits the repackaging of biocidal products at the storage place or place of use. This national legislation proved to be problematic during the Covid-19 crisis for the refilling of disinfection stations and will thus be changed to allow the refilling of hand disinfectants and surface disinfectants (EE).

The presence of a split regulation or rather, if multiple authorities are responsible for different aspects of the biocidal products market can cause confusion (CA).

Some provisions such as a positive list for active substance suppliers, like the article 95 list in the EU BPR, limited the supply of active substances, compromising the availability of disinfectant products (UK); this could be remedied through the inclusion of an emergency mechanism related to article 95 in the BPR (SK).

One country mentioned the large burden of having to consider all submissions equally at the start, while focusing on the most promising submissions would have saved considerate resources (US). It was also mentioned that the possibility to request waivers for registration became very burdensome due to a lack of understanding of the registration process (US).

Finally, once the review of active substances in the EU is finalised and biocidal products authorised this will make sharing data easier, also with other countries or OECD (NL).

Question 1.13 Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?

Most responding countries noted that the Covid-19 crisis highlighted some sort of jurisdictional ambiguity. This was particularly true for known borderline cases with the Cosmetics Regulation, e.g. hand sanitizers, but also medicines, e.g. treated masks (US), or general chemicals. One country noted that while the jurisdictional situation is normally clear, that the Covid-19 pandemic brought new applicants to the table who represented their products in dubious ways, which in turn could cause jurisdictional ambiguities (CA). Furthermore, the distinction should be made of what is confusing for the public and what is confusing for authorities, which require different solutions.

One country noted that there were no jurisdictional ambiguities and that all directly/indirectly involved agencies showed and are showing good will to help each other (LT).

Question 2.1 Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the future please list those as well.

Responding countries largely found that the actions to deal with the disturbance of the supply chain have been successful and some countries provided additional insights and room for further improvement. For instance, one concern is that the prioritised or expedited reviews for Covid-19 related products are not sustainable in itself due to the high volume of submissions and created a backlog in other areas due to the reallocation of resources (US, SK). However, several countries reallocated personnel and found it a successful approach to deal with the emergency (AU, SK) though some mentioned that an increase in number of personnel is necessary (SK).

The previously mentioned article 95 of the BPR list for suppliers created an obstacle in restoring the supply chain for disinfectants, and might be adapted in a future revision in light of more effective crisis management (EE, FI, SE).

One country noted that time and costs were saved because the competent authority initiated the derogation procedure instead of the manufacturers or producers (SE).

Several countries mentioned the continued need for clear communication with all stakeholders (BE, EE).

Finally, for future outbreaks one country recommended that sufficient products are authorised, i.e. with more products on the market, governments have more options to increase the production capacity of necessary products (NL).

Question 2.2 Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.

The concept of blanket registrations applying to different countries caused some concern but many countries see value in further information exchange and the further development of collaborative assessment and review sharing between countries. This also includes the development of harmonised test methods for efficacy.

One country mentioned that a repository of the quantities of active substance and biocidal product on the market could be helpful in understanding what type of shortages could occur and be better prepared for such occasions (NL).

Question 2.3 Do you think that a "pragmatic approach' to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a "pragmatic approach" could constitute in your country.

All countries noted that the proven efficacy of biocidal products is elemental and cannot be compromised or bypassed using a pragmatic approach. Some countries considered that a pragmatic approach could consist of allowing deviations from use scenarios after discussion with and agreement of the regulator (UK). Others allowed applicants to submit expert judgement and/or scientific literature data in the emergency situation, however with the post-authorisation condition to provide efficacy test reports no later than 3-6 months after authorisation (LT).

One country noted their approach to leverage specific guidance and allow manufacturers to submit data proving their product is effective against harder-to-kill viruses, than SARS-CoV-2, and once approved to make off-label claims for use against SARS-CoV-2 (US). It was considered to be a successful pragmatic approach which could be a valuable approach for other countries (US).

Other countries did not agree with a pragmatic approach and advocated a better preparedness for possible future crises by ensuring that sufficient numbers of products have a proven efficacy in their authorization (DE, NL).

Question 2.4 Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.

Most countries agreed that such a compendium would be useful though one country believed this was a task better suited for WHO, but that OECD can provides expertise on the use of disinfection methods and products (NL). Various countries already provided references (FI) which are compiled in Annex 3.

It was furthermore mentioned that a discussion on varying emerging viral pathogens would be useful at OECD (CA).

Question 2.5 Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.

Some countries found that the increased information regarding the use of disinfectants to the public was vital during the COVID-19 crisis. However, they also recognised that some areas could be improved such as guidance for sponsors/applicants, in particular sponsors new to the regulatory framework (AU, US). Information on key specific products, such as disinfectants, rather than general information and improved consumer education on regulation basics including terminology (CA), targeted consumer information on particular products (AU).

Some countries emphasised that an improved and consistent public communication on how to prevent infection, when to use disinfectants and to avoid non-essential use of disinfectants, use conditions of products for public use and the importance of general hygiene in general

(FI, NL). Others emphasised the need for consistent information and active information against misinformation and false messages (LT).

Question 3.1 How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.

Some countries noted that OECD can use a coordinating role in bringing different competent authorities together and organise regular or ad-hoc meetings between these authorities (AU, BE, FI). Such meetings could be used to exchange information about the regulatory status of products in various countries or include such information in a repository (CA).

It was also suggested to use a less formal way of communication for OECD matters than use of Clearspace, i.e. convene meetings using virtual communication platforms to make participation easier and more efficiently exchange data and information (US).

Question 3.2 Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.

Many countries referenced to the WHO information and guidance related to the handrub formulations as appropriate enough guidance (DE), where it was also mentioned that the use of such recipes should be in line with current regulations, e.g. the BPR (EE, FI).

Some highlighted this could be useful in the context of temporary emergency derogations only (CA, NL), while others mentioned that these types of recipes are not compatible with their pesticide regulatory authority and would thus not be useful (US).

One country noted the need for information to be available in national languages (SK)

Question 3.3 How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.

Responding countries highlighted that the emergency authorisations have a temporary character, which should be clearly communicated to producers (CA). In cases of extension of such authorisations the requesting company is requested to provide a standard authorization application within a determined time frame (BE), in other words to return to the normal situation (US, NL). Relatedly it was mentioned that issues might occur with regard to competition for companies with non-emergency, or normal, authorisations (LT).

One country warned for the possibility that products will stay on the market even if the emergency authorization or derogation is not valid anymore (FI).

Other alternate problems that were mentioned included the sheer volume of requests for emergency authorisations which can be remedied by keeping sufficient staff available, that fees apply for authorisation requests, which should be considered since there are associated obligations for the applicant as well as the competent authority (SK) and to keep websites and e-bulletins up to date with regulatory information (UK).

Question 3.4 What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.

Some countries noted that providing general information to the public was not enough and could have been more specific in some instances, e.g. for instance to care facilities, schools, etc. (AU). Monitoring the enquiries provided useful information on the type information that was considered most valuable as well as how such information should be provided, e.g. use plain English (AU) or the national language (SK). Some countries noted the great variety of questions from the general public, which revolved around the availability of a certain product on the market, what type of product is inside disinfection stations, why a certain products smells bad, etc., or focussed on common false believes. These could be dealt with using for instance a Frequently Asked Questions (FAQ) forum on the websites of authorities or by establishing contact points for the public as well as media (EE, FI, LT, SE, US).

One country noted the sometimes very aggressive marketing techniques of companies, which highlights the need to provide clear information from governments, also on how to identify approved products (CA, FI). Possibly social media could be used more extensively to inform the public, as these seem to be more accessible than websites of competent authorities and research institutes (NL).

One country explained the strategies that were applied to deal with the large influx of enquiries. One approach was to reallocate staff to deal with these enquiries in teams that regularly met to coordinate responses and create consensus answers. These teams were assisted with communication teams to offer support in the form of audio-visuals and infographics. Another approach was to develop an agency wide working group to coordinate rapid responses to enquiries and for the agency to participate in or host webinars to help with public interface (US).

Question 3.5 What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.

Some post-crisis evaluations were mentioned related to the performance of facemasks, products and Covid-19 related medical devices (AU) or to keep the newly established structures with their trained personnel in place and test them during yearly fly outbreaks (LT).

Other follow-up actions could include a more routine testing of Covid-19 vaccines, further innovation of new products developed in response to the crisis that may require innovation in methods of their regulatory assessment and further engagement with stakeholders is essential to manage relationships and expectations when exiting a crisis (AU, CA).

Other countries mentioned to make sure that those products with an emergency authorisation only are removed from the market and to return to the normal situation, which possibly requires an increased effort in compliance and enforcement activities (FI, UK, CA).

A further focus on improving communication with the public and to gain a better understanding of the market in order to avoid future shortages as much as possible was also mentioned (BE). This includes further education of the public on the essential and non-essential uses of disinfectants (NL).

One country mentioned a work group tasked with providing recommendations on how the agency response to future pandemic could be improved moving forward. The group has

stakeholder representation from industry, healthcare, Centers for Disease Control (CDC) and state/regional pesticide regulators (US).

Question 3.6 In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.

Not many countries responded but those who did saw value in the OECD organising further ad-hoc or regular meetings to facilitate information exchange (UK) and possibly to generate a repository of all OECD member country approved product/label search engines to help other countries determine the regulatory status and approved claims when inquiries are received for importation of a particular product or registration/authorization of a particular product (CA).

A similar repository with contact details of OECD member regulatory authority for certain product types for instance for devices, would also be valuable (CA), or similarly having all products of interest during a pandemic in one area with an outline of the regulatory authority in each member country (CA). As an example:

Canada

- Disinfectants (Regulated under the Food and Drugs Act by the Natural and Non-Prescription Health Products Directorate)
- Sanitizers (Regulated under the Pest Control Product Act by the Pest Management Regulatory Agency)
- Etc.

Renewed effort into the development and adoption of the "OECD Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides for Use on Hard Non-porous Surfaces". The results will be an internationally harmonized efficacy test method for bacteria, viruses and fungi. Efforts to date by the US have been unsuccessful. The actions around this method should receive renewed attention by OECD member countries (US).

Question 3.7 Do you have any other suggestions?

Countries noted amongst others that agencies should be encouraged to undertake and share the results of formal reviews of their response to the COVID-19 pandemic (AU), and that a complex set of measures that deal with the issue from different angles, e.g. aiming at behavioural changes, communication, availability of disinfectants, is needed for an efficient protection against the Corona virus; the biocides point of view can only be seen as a part thereof (DE).

Synthesis and recommendations

Problem setting: what have been the problems (by order of importance/difficulty to resolve)?

All countries answered that the sharp increased demand for biocidal products/disinfectants impacted their response the most. Not only as a stand-alone issue, where care institutions and the public lacked sufficient quantities of, or access to, disinfectants, but also because of the associated knock-on effect, e.g. increased requests for authorisations and emergency authorisations, the increased influx of new, and inexperienced, manufacturers, increased number of requests for information, the subsequent need for additional resources, etc.

In terms of severity the reported issues can be ordered broadly in the following categories from high to low severity:

1. the lack of disinfectant products available on the market, because the availability of such products was considered to be essential to curb the spreading of the SARS-CoV-2 virus, which has been and remains the main priority of countries.
2. the lack of efficacy and safety data for certain substances and products, as this prevented the proper assessment of efficacy and the possibility for disinfectant products to enter the market and to become increasingly available. The lack of efficacy of products is detrimental in several ways, first and foremost because products lacking efficacy are not doing what they are supposed to do, i.e. help to prevent the spread of the SARS-CoV-2 virus. Second, because such products, were they to enter the market, provide a false sense of security to the public resulting in a further spread of the SARS-CoV-2 virus. Third, the time needed to assess substances and products is obviously far longer when data is missing and such data needs to be generated, resulting in an increased burden on government resources.
3. the sheer number of authorisation and emergency authorisation requests, which was burdensome on government resources.
4. the influx of new manufacturers, including opportunistic manufacturers of novel products or techniques. Such manufacturers often lacked knowledge of regulatory requirements to bring products to the market and/or brought products and techniques to the market that have no proven functionality against the SARS-CoV-2 virus. Alternatively the efficacy of such products and techniques needed to be assessed with insufficient data and/or there was no, validated, methodology available to prove functionality and efficacy.
5. Extra resources needed for an increased and improved communication to care institutions, manufacturers and the public, with particular care for sensitive populations such as the elderly.
6. The need for jurisdictional clarity in some borderline cases, e.g. related to disinfectant use in public spaces, or cosmetic hand cleansing products with hygiene claims.
7. practical issues related to a changing work environment, due to travel restrictions and teleworking which required extra resources.

Problem solving (lessons learned)

Most countries considered that the available options in their national and/or regional legislations worked sufficiently well with several areas as working particularly well. However, the survey also identified areas with room for improvement as indicated below.

What worked well (and should be done again in case of future crises)

i. most emergency actions, using either national or regional legislation, worked relatively well,

ii. the reallocation of personnel to prioritise the handling of Covid-19 related issues,

iii. the use of blanket registrations, i.e. allowing products with a fixed recipe, such as the WHO hand rub formulation,

iv. the increased information to the public regarding the use of disinfectants,

v. provide guidance and allow the pre-qualification of products that are efficacious against harder-to-kill viruses than the SARS-CoV-2 virus, to streamline the authorisation process of these products,

vi. competent authorities initiating the derogation procedure, to save time/resources, for those products that are considered to be more successful,

What worked less well (and should be avoided in case of future crises)

i. multiple authorities responsible for different aspects of the biocidal products market can cause confusion and should be reconsidered,

ii. the backlog of non-Covid-19 related activities due to the reallocation of personnel,

iii. the “positive” list of suppliers, which created an obstacle in restoring the supply chain, since normally only suppliers included in this list are allowed to make substances or products available on the EU market. When these suppliers were not able to deal with increased demand in these times of crisis, finding alternative suppliers created a conflict with Art. 95 of the BPR, this could be improved for future, more effective, crisis management,

iv. there is still room for improvement on how to share information with the public, industry and stakeholders, e.g. less general information,

Based on the lessons learned from the Covid-19 crisis, recommendations for managing future crises

In the survey responses countries mentioned approaches that could be useful for other countries, highlighted what went wrong or right, and indicated what they perceived as important areas for improvement for possible future crises. The resulting recommendations are either originating directly from those responses or based on their context.

Recommendations for regulatory agencies

Organisational aspects

i. expedite efforts to assess active substances and products against viruses in order to increase the pool of available products in times of crisis, i.e. avoid that shortages of necessary products occur, which includes educating all stakeholders to avoid non-essential uses of disinfectants,

ii. create a procedure to identify work areas of high priority in times of crisis and how to reallocate the necessary personnel to them,

iii. evaluate if the existing knowledge about infection prevention is up-to-date in the agencies and amend if necessary,

iv. device an exit strategy and return back to normal post-crisis, e.g. monitor the market for products with an emergency authorisations only,

Communication and exchange of information

i. at the onset of a crisis engage early with all stakeholders, care institutions, industry and the public,

ii. emphasise the common responsibility of everyone,

iii. create single contact points per country to facilitate the exchange of information among countries,

iv. in particular, facilitate the access to efficacy and safety data for other regulatory agencies in times of crisis,

v. encourage to undertake and share the results of formal reviews of countries responses to the COVID-19 pandemic, this could also include the performance review of products, facemasks and devices, or the information provided to public, companies and other stakeholders,

vi. provide science-based but clear and understandable information to manufacturers and the public, make use of all forms of information sharing, including websites, news streams, social media, etc.

vii. create a single contact point for enquiries and have procedures in place to find and provide answers quickly, e.g. dedicated teams, FAQ, “active” listening and responses,

Recommendations for industry

i. increase the cooperation, and facilitate resource sharing between businesses in times of crisis,

ii. facilitate and organise the repurposing of industries to produce necessary products,

iii. increase the sense of responsibility of producers of disinfectants where needed, i.e. in terms of education, knowledge of the product, as well as regulatory requirements,

iv. increase stocks of essential active substances,

v. be critical of opportunistic competitors and free riders, aggressive marketing,

Recommendations for other stakeholders

i. engage early with authorities to indicate specific needs as soon as possible, e.g. care institutions needing disinfectants as well as personal protection equipment (PPE), expertise, personnel, etc.

ii. cooperate to alleviate, e.g. if not yet available create an organisational structure amongst similar institutions to identify resource needs and find solutions,

iii. educate the public, e.g. research institutes provide easy to follow guidance which is to the point, use simple language,

iv. evaluate if the existing knowledge about infection prevention in the institutions is up-to-date and amend if necessary,

v. keep newly established, i.e. during the Covid-19 pandemic, structures and trained specialists in place and test/train them during seasonal flu outbreaks,

Recommendations for OECD (future activities for the WPB)

i. provide a platform for quick communication, possibly use less formal ways for information exchange,

ii. organising further ad-hoc or regular meetings to facilitate information exchange amongst countries,

iii. initiate a discussion on varying emerging viral pathogens,

iv. develop a Best Practice Guide for managing future crisis/pandemic situations

v. renew the effort into the development and adoption of harmonised guidance and test guidelines for products, such as the project for efficacy testing methods for hard surface disinfectants, and possibly for devices such as UV-emitters.

vi. facilitate approaches on how to arrive at shared reviews and/or assessments of products between countries,

vii. generate a repository of all OECD member country approved product/label search engines to help other countries determine regulatory status and approved claims,

viii. generate a repository with contact details of OECD member regulatory authorities for specific biocidal product types,

ix. remain vigilant for the needs of countries in times of crisis.

Annex 1: Questionnaire Covid-19 issues and future management of emergency crises

Name respondent: …… and Email: ……

Country name: …… and Organisation: ……

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific

	behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: – -coatings/paints with long lasting residual efficacy used in such places – -the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers – -position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. – -position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	

1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	
2.3	Do you think that a "pragmatic approach' to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a "pragmatic approach" could constitute in your country
Answer:	
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	
3.7	Do you have any other suggestions?
Answer:	

End of questionnaire

Annex 2: Individual country responses to the questionnaire

Name respondent: Maria Trainer	and Email: maria.trainer@apvma.gov.au
Country name: Australia	and Organisation: APVMA

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic?
Answer:	• Key challenges, in no particular order, include the following: • Supply chain issues created shortages of particular excipients in agchem product formulations. • Supply chain issues meant that certain approved sources of active constituent were unavailable. • Study data to fulfil certain registration requirements were delayed and, in some cases, study protocols needed to be amended to accommodate lockdown rules. • Site audits of veterinary manufacturing sites were affected by social distancing measures and travel restrictions. • Lack of clarity regarding regulatory jurisdiction for certain biocidal products that, depending on the label claims and application methods, may be regulated as agchem products, veterinary products, or therapeutic goods. • Opportunists seeking to enter the market with "novel" products supported by limited (if any) data. • Regulation of application of disinfectants by drone that have not been approved for use in situations such as semi enclosed stadiums and public spaces. Several challenges with stakeholders arose where the current definitions of an Agricultural product clearly determined the proposed active constituents and products when used in the above situation would require registration/approval or the issuance of an Emergency Use Permit. In one case a currently listed hospital grade disinfectant (regulated by the Therapeutic Goods Administration) was considered but still found to require consideration of efficacy as well as applicator and bystander exposure as the use proposed was very different to the use approved by the TGA as a hospital grade surface disinfectant. • Many companies that produce products such as hospital-grade disinfectants are not familiar with the legislative requirements for agvet products since, ordinarily, their products do not fall under the jurisdiction of the AgVet Code. However, certain use scenarios would trigger the requirement for these products to be registered by the APVMA. In Australian use of chemical products including disinfectants for therapeutic use/medical devises and use in residential settings for hard surface disinfection is regulated by the Therapeutic Goods Administration (TGA). It is possible that some very similar formulations are also regulated as either agricultural or veterinary medicines chemical product by the APVMA depending on the use scenario. As the situations are often very different to household and medical facility disinfection of hard surfaces, the APVMA requires that efficacy in the relevant environment is considered. i.e a standard test of pathogens in a lab may not satisfy the efficacy of a product being applied by boom spray/ drone in a stadium seating situation that is large and exposed to external

	elements such as rain and sunshine requiring a different approach to determining efficacy and safety (both operator, bystander and environmental) in these situations.
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	The APVMA published a notice to industry in April 2020 advising them of our willingness to adopt flexible approaches to addressing the evolving challenges of the pandemic. Details are available here: https://apvma.gov.au/node/66451. Limited availability of particular excipients in agchem product formulations meant that some registrants needed to vary their registered formulations in order to use alternate available excipients. The APVMA had to develop fast-track processes to assess these applications. We did not change our data/information requirements, we just prioritised the assessments; applications with 7 month timeframes were completed sometimes in less than 1 month from lodgement. Similarly, some holders experienced issues with the availability of active constituents from approved sources and sought urgent approval of new manufacturing sites. Again, we prioritised these assessments and were able to complete them in an expedited time frame without compromising our data/information requirements. As an Agency we have standard timeframes that applicants are expected to comply with when we request study data. We have been flexible in extending these timeframes to accommodate a range of different delays due to the impact of the pandemic. In some cases, we have permitted applications to go overdue (i.e., past the statutory due date for the application) in order to provide the applicant sufficient time to respond to a data request. The audit interval of veterinary manufacturing site audits was extended by at least six months to accommodate social distancing measures and travel restrictions: https://apvma.gov.au/node/65406. APVMA already has the capacity to issue emergency permits and regularly does so in appropriate cases (e.g. pest incursions).
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	Standard (i.e., statutory) timeframes for APVMA assessments vary from 1 month to upwards of 24 months depending on the nature of the application and the complexity of the data to be reviewed. A full summary of standard timeframes is available here: https://apvma.gov.au/node/1088. With respect to the applications that we fast-tracked due to COVID, standard timeframes would have been 3-7 months. The majority were completed within 4 weeks of submission. An emergency use permit could be issued in as little as two weeks depending on the amount of assessment and risk management required.
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	To the best of my knowledge, the APVMA was able to implement all of the amended processes without need for legislative amendments. Applications for formulation changes (including substitution or deletion of ingredients due to Covid-related supply shortages) have been fast tracked.

	Where advantageous, APVMA has worked together with overseas regulators (e.g. NZ ACVM group) to process applications for formulation changes.
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	Communicate early, often, and honestly. Be consistent and transparent but be willing to adopt a case-by-case approach where needed to address the specific needs of individual holders where applicable. Engage with international regulatory counterparts, particularly when holders are seeking similar changes in products for overseas markets. It would be advantageous to have a repository of novel techniques or biocide products, devices or application methods being considered by competent authorities in order to reduce duplication of assessments and considerations by individual regulators especially jn an emergency situation. This may likely expedite emergency authorisations for such products and proposed uses.
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	Outside of APVMA's immediate jurisdiction. This question is best addressed by colleagues at the TGA. However, we note that this sounds like a good subject for a future OECD guideline.
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	In Australia, an agchem product must contain an approved source of active constituent (this is a condition of registration); however, holders are free to change approved sources without notification. This reduces burden on holders and the regulator under normal times and almost certainly reduced bureaucratic red tape during Covid. The APVMA published a notice to industry in April 2020 advising them of our willingness to adopt flexible approaches to addressing the evolving challenges of the pandemic. Details are available here: https://apvma.gov.au/node/66451. We implemented a fast-track process to expedite variation applications for changes to formulations in order to address supply chain shortages. We did not change our data/information requirements, we just prioritised the assessments; applications with 7 month timeframes were completed sometimes in less than 1 month from lodgement. Similarly, we implemented fast-track processes to expedite approvals of new

	manufacturing sites for active constituents in order to address supply chain issues. These fast-track processes worked well to enhance supply chain resilience. Use of appropriately verified (for safety and efficacy) standardised recipes for disinfectants and sanitisers would enable speeding up registration of new products. APVMA's interchangeable constituent provisions (where a blanket authorisation is made for particular ingredients or types of ingredients to be substituted or otherwise varied in a particular product class) could be used to further improve supply chain resilience. We gave applicants significantly more flexibility in the timeframes to respond to notices for data and/or additional information to support applications. Any Notice issued by the Agency included a COVID-19 disclaimer advising applicants to contact the Agency should they need additional time to respond because of delays due to the impact of the pandemic. In some cases, we have permitted applications to go overdue (i.e., past the statutory due date for the application) in order to provide the applicant sufficient time to respond to a data request. The audit interval of veterinary manufacturing site audits was extended by at least six months to accommodate social distancing measures and travel restrictions: https://apvma.gov.au/node/65406.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	Colleagues from the TGA will likely have important feedback on this question, particularly with respect to how it relates to testing requirements for biocides. From the APVMA's perspective, it would helpful to share testing methodologies and/or data guidelines with equivalent regulators, particularly for urban pests, and to have access to all efficacy and safety assessments conducted by equivalent regulators. Shared access to assessments is unlikely to succeed, but shared data guidelines could be practicable.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	There may be scope for APVMA to create a dedicated webpage for regulatory requirements for biocides/disinfectants/sanitisers, with links to all relevant guidelines.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	Outside of APVMA's immediate jurisdiction. This question is best addressed by colleagues at the TGA.
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	Outside of APVMA's immediate jurisdiction. This question is best addressed by colleagues at the TGA.
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.

Answer:	As noted above, our legislation performed quite well in terms of providing us with the flexibility to deal with the majority of challenges we experienced during the Covid-19 crisis. However, the crisis did highlight the need to more clearly delineate jurisdictional boundaries for different classes of biocidal products.
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	Yes, the crisis has certainly highlighted inter-jurisdictional grey areas where it was unclear whether products were regulated under the AgVet Code or the Therapeutic Goods Act. For example, surface disinfectants for use in public spaces.

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	We implemented a fast-track process to expedite variation applications for changes to formulations in order to address supply chain shortages. We did not change our data/information requirements, we just prioritised the assessments; applications with 7 month timeframes were completed sometimes in less than 1 month from lodgement. Similarly, we implemented fast-track processes to expedite approvals of new manufacturing sites for active constituents in order to address supply chain issues. Feedback from industry has been overwhelmingly positive.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	I believe that the genesis for this question is largely related to the registration of hand sanitisers, and similar products, which are outside APVMA's immediate jurisdiction. This question is best addressed by colleagues at the TGA. That said, OECD work sharing arrangements, as utilised in the plant protection area, could benefit from faster and more harmonious registration. Sharing of data and assessments between competent authorities is always an efficient use of resources and time. A repository of assessments, even if only in summary form, would also be useful in an emergency situation as publication processes from Authorities of new and emergency use assessments is less likely to occur during a global crisis such as Covid 19.
2.3	Do you think that a "pragmatic approach' to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a "pragmatic approach" could constitute in your country
Answer:	Basic consideration of efficacy is required to ensure that there is at least some benefit to the public. If efficacy is not determined for the use situation proposed, there is likely to be a false sense of security and possible laps of more stringent protective measures such as masks, social distancing, or even cancellation of events to keep super spreading events from occurring. If a product is used that is not proven to be efficacious in some situations where protection is required then it is probably more devastating and will cause adverse effects far greater that if the product had not been used at all.

2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	Outside of APVMA's immediate jurisdiction. This question is best addressed by colleagues at the TGA.
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	/

Continues on next page…

Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	The OECD could play a central coordination role between competent authorities to circulate relevant information quickly and efficiently using currently established distribution lists. Sharing of relevant contacts from different expert areas of different regulatory authorities would help facilitate ad hoc discussions. Establishment of regular meetings between appropriate assessment or expert areas of different regulators for discussion of issues relating to product registration
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	Hand sanitisers are outside of APVMA's immediate jurisdiction. This question is best addressed by colleagues at the TGA. More broadly, APVMA has appropriate application items for dealing with products made to standardised recipes, e.g. item 7 or 8. There is also scope for adding such products to the listed registration provisions in the regulations.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	I am not aware of any emergency use authorisations made in Australia specifically in response to Covid. However, hypothetically speaking, it is possible that chronic exposure to chemicals may not have been fully considered during an emergency authorisation and it would be sensible to have the emergency use authorisations fully assessed and moved to registrations as the use is likely to be required for some time yet.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	/
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	/

3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	/
3.7	Do you have any other suggestions?
Answer:	/

End of questionnaire

Name respondent: Whole of TGA…..	and Email: ……..
Country name: Australia	and Organisation: ……..

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	• Ensuring Australia has access to the medical devices necessary for the COVID-19 response, such as COVID tests, ventilators and personal protective equipment. • Managing new sponsors and manufacturers seeking to supply products such as disinfectants and face masks in response to COVID-19. • Managing greatly increased stakeholder engagement (181% increase in enquiries to medical devices information unit July - December 2020). • Balancing the COVID-19 response against reforms and business-as-usual activities. • Conducting manufacturing audits while under travel restrictions. • The COVID-19 pandemic has created many challenges to the ongoing Good Manufacturing Practice (GMP) regulation of medicine and biological manufacturers. Following the suspension of overseas GMP inspections and QMS audits significant consideration was given to the appropriate level and type of regulatory oversight required to maintain an assurance of product quality without requiring wholesale changes to existing processes. • Overseas regulatory partners also faced disruptions to their on-site inspection programs. This created additional challenges for our existing reliance mechanisms requiring similar flexibility in our regulatory oversight. • Disruptions to supply chains and increased demand increased the risk of shortages of some therapeutic goods (such as hand sanitisers and radiopharmaceuticals). As a result, we needed to respond swiftly to urgent GMP inspections, clearances and licensing to facilitate supply. • Shortage of hand sanitisers for both household/personal and health care use due to significant increase in demand. • Supply issues with ingredients and packaging components e.g. appropriate grade of ingredient; shortages of bottles and pump closures.
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	Yes. Able to establish within a short time a temporary measure (the Therapeutic Goods (Excluded Goods – Hand Sanitisers) Determination 2020, the 'Exclusion Determination')] to facilitate the urgent and on-going manufacture and supply of hand sanitisers by new entrants to the market for use in health care facilities, e.g. hand

	sanitiser production by gin distillers to a specific formula, and with other requirements relating to manufacture, labelling and presentation. Limitations: • To be done quickly, the temporary measure was required to be established within the existing therapeutic goods legislation. • Consultation was required with other relevant agencies/government bodies. Took a risk-based, pragmatic approach to changes to existing registered products and registration of new products in relation to data requirements. This was possible under the existing legislation. Liaised closely with affected stakeholders. Under the Therapeutic Goods Act 1989, time-limited exemptions under legislative instruments, were put in place to respond to emergencies. Exemptions were made for: • COVID-19 tests; • Personal protective equipment such as face masks; and • Ventilators. Expedited full regulatory assessment under the formal priority review pathway is available, however was not undertaken by sponsors for any COVID-19 related medical devices, tests or disinfectants. The above considerations in 1.1 needed to be agile yet sustainable as the length of time that international travel restrictions will remain in place has been difficult to predict. • Providing emergency GMP licensing of manufacturers or clearances for sponsors is not specifically covered in our legislation, but there is some flexibility in the methods that can be used to fulfil some process requirements. As a result, under existing legislation TGA was able to: o Introduce remote inspection processes. o Change documentation requirements for GMP clearance applications submitted through the CV pathway (clearance is a non-statutory mechanism). • Amending regulations is a more straightforward process than amending legislation. To support the timely supply of radiopharmaceuticals and radiopharmaceutical active ingredients (RAI), an amendment to the Therapeutic Goods Regulations (1990) Schedule 7, Part 3-3 was made to exempt certain radiopharmaceuticals and RAI to enable specified persons, within public and private hospitals and public institutions without a manufacturing licence, to manufacture radiopharmaceuticals or RAI for the treatment of a patient in another State or Territory. • Further, Therapeutic Goods Administration (TGA)'s current risk based processes allowed for the prioritisation of GMP assessments of therapeutic goods related to COVID-19 management. • Where recall actions involved products used for the treatment of COVID-19 patients, additional risk-benefit considerations have been taken into account to balance the risk posed by the product defect relative to the risk of the product not being available for treatment at all and/or a shortage situation being created.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	The standard evaluation timeframe for TGA regulated hand sanitisers ranges from 55 working days to 170 working days, this is dependent on the application level and data requirements for the specific application. TGA is required to make a decision on a new device application within 20 working days. This decision is to either include the device in the Australian Register of Therapeutic Goods (ARTG), not include the device in the ARTG or select the application for audit to request further information.

	A Level 1 audit may include clarification of the device classification, a conformity assessment procedure, and/or a review of packaging and labelling to ensure it meets requirements, with a timeframe of 30 working days. A Level 2 audit requires the information for a Level 1 audit plus one or more of the following: clinical evidence, risk management report(s), efficacy and performance data, and/or audit reports from Notified Bodies, with a timeframe of 60 working days. In the Therapeutic Goods Administration Annual performance statistics report: July 2019 - June 2020 the median processing time for Level 1 application audits was 26 TGA days and the median processing time for Level 2 application audits was 98 TGA days. TGA is required to complete conformity assessment applications within 255 working days. In the Therapeutic Goods Administration Annual performance statistics report: July 2019 - June 2020 the median processing time for conformity assessment of new devices was 158 days and the median processing time for variations was 144 days. Disinfectants for use on surfaces (other than medical devices) are considered other therapeutic goods (OTGs), and there are no timeframes for approval or review of these products. Applicants for disinfectants are required to supply information to support the efficacy claims, and those with claims against COVID-19 are prioritised.
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	Refer answer to 1.2. Prioritised and expedited applications for medical devices, COVID-19 tests and disinfectants, under normal processes. Is undertaking a post-market review of face masks to validate the quality of these products. Implemented changed arrangements for domestic audits, including delaying on-site audits where appropriate, completing desktop assessment of the comparable regulator evidence and undertaking remote audits. An expedited process for GMP inspection and licensing was developed during the peak of the pandemic to address the issue of the shortage in sanitisers requiring manufacture in a GMP licensed facility. An excluded goods order was developed for hand sanitisers where under certain criteria a GMP licence was not required for the manufacture of hand sensitizers (see: www.legislation.gov.au/Details/F2020L00340/Download).
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	Coordination and communication are essential to an effective crisis response. Some newly designed processes (e.g. for GMP inspections) will continue to be employed (albeit to a lesser extent) even as current conditions ease. These now in-built improvements in operational flexibility will automatically improve TGA's response to future incidents. Interim measures used during the current pandemic will be recorded into Business Continuity Process documents to assist in managing future pandemics or other disruptive events. TGA has not yet conducted a formal review of our response to the COVID-19 pandemic.

1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	Nil response.
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	TGA undertook a broad range of activity to support the ongoing supply of quality medicines, blood and human tissue products from Australian and overseas manufacturers, including: • prioritisation of applications for manufacture; • addressing supply issues (e.g. by enabling the treatment of cancer in public and private hospitals nationally); • adapting our approach to the conduct of inspections of manufacturers to help ensure their continued operation; • providing information to government on the manufacture of therapeutic goods such as hand sanitisers; and, • contributing to work intended to address medicine shortage issues.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	TGA refers to and accepts testing conducted in accordance with various standards for hand sanitisers, such as EU and FDA guidelines. Working with testing houses/facilities will ensure consistency in the testing regime and the interpretation of international standards, which parallels regulatory expectations. This could address doubts about product efficacy. An example of such working groups is the newly initiated National Measurement Institute working group to inform on face mask testing. To collaborate with industry on the COVID-19 response, TGA and industry used the Regulatory and Technical Consultative Forum (RegTech) for medical devices to discuss issues and coordinate activities. Individual meetings with industry stakeholders were also undertaken.

1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	• TGA website. • Seminars. TGA made readily available and up-to-date information on face masks, personal protective equipment, ventilators, test kits, disinfectants and other medical devices important to the COVID-19 response, with over 30 webpages published on TGA's COVID-19 hub in 2020. Consolidating this information in one hub made it easier for our industry stakeholders to find this information, with additional information for products with stakeholders new to the regulatory framework. Since the declaration of Covid-19 as a pandemic, the various government and industry bodies have frequently updated the information on their respective websites to provide guidance to manufacturers, suppliers and consumers in relation to hand sanitisers.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	Consistency in messaging is crucial to engendering trust and minimising confusion.
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	Nil response.
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	Refer answer to question 1.2. Emergency exemption capability in the legislation facilitated rapid supply of critical products such as COVID-19 tests. Existing legislation enabled TGA to: • Introduce remote inspection processes. • Change documentation requirements for GMP clearance applications submitted through the CV pathway.
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	TGA worked with the Australian Competition and Consumer Commission to address overlap in products that could be identified as either consumer goods or medical devices, such as face masks. Coordination with state and territory governments limited federal-state jurisdictional ambiguities. Legislation was already clear about jurisdictional responsibilities for the regulation of hand sanitisers. Some clarification was required following the introduction of the temporary measure (the 'Exclusion Determination').

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	Refer to question 1.2. These actions have been successful as the supply of hand sanitisers has increased to meet the demand. All measures put in place were successful such as: • Time limited exemptions. • Additional resources to assist manufacturers, sponsors, industry and consumers. • Engagement with States, Territories, peak bodies, international regulators. • Updating guidance materials on the website to assist industry, consumers, manufacturers and sponsors. • Engagement with forums such as International Medical Devices Regulators Forum (IMDRF), RegTech, MTAA. Early interaction with industry through forums such as RegTech has been successful in managing supply chain issues. For example, some medical devices reforms were deferred to better accommodate the industry response to COVID-19. TGA Laboratories has developed capabilities to test surgical masks and respirators, to assess compliance with the requirements of key performance criteria, protecting the quality of approved products. Additional resources were made available to assist in the expedite applications and provide assistance to new sponsors. Where only labelling deficiencies are identified, TGA is working with sponsors to resolve the issues without unnecessarily removing products from the market, where practical, to maintain the supply of important products. TGA actions, including the initial suspension of inspections, the commencement of remote inspections and changes to documentation processes did not introduce any safety or quality risks. The outcomes of these revised arrangements are being actively monitored.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	Further information exchange or collaborative assessment by regulators could help bring products to market faster, in particular as part of the priority review process.

	Forums such as the World Health Organisation (WHO) and International Medical Device Regulators Forum (IMDRF) could further standardise regulation across comparable markets, leading to efficiencies and sooner supply of products across jurisdictions. Information sharing about approaches other international agencies are adopting will always be beneficial to help inform local approaches.
2.3	Do you think that a "pragmatic approach' to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a "pragmatic approach" could constitute in your country
Answer:	Australia has been able to continue full regulatory assessments due to application of mechanisms such as quarantine and social distancing to manage the crisis. A 'pragmatic approach' to efficacy testing of hand sanitisers would be dependent on numerous factors such as the intended use of the product and the formulation. The specific formulations detailed in the 'Exclusion Determination' was based on those recommended by the WHO for Handrub formulations. Provided such products meet the requirements specified in the Exclusion Determination, including formulation, and certain manufacturing, advertising, labelling and presentation criteria, they are not regulated by TGA and do not have to undergo efficacy testing.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	Nil response.
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	Increased information to the public on medical devices and their uses was vital during the COVID-19 crisis. Areas that require improved information include: • Guidance for sponsors, in particular sponsors new to the regulatory framework. • Information on key specific products, such as disinfectants, rather than general information. • Consumer education on regulation basics, and targeted consumer information on particular products. This can be achieved by enhancing TGA's own web information, as well as through greater partnership with other organisations to disseminate materials.

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	Nil response.
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	May be useful, however, TGA already referenced the WHO recommended formulations when developing the Exclusion Determination.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	Emergency exemptions are short term as specified in the Act, so planning for their cessation began when they when they were implemented. In the case of COVID-19 tests, the exemption was replaced with a narrower exemption. Good communication and liaison with impacted sponsors helped manage time-limited exemptions. For example, ventilators supplied under the exemption could not be supplied after the end of the exemption, so TGA liaised with sponsors to mitigate issues such as unsupplied inventory. Responsibility for enforcement or follow-up of issues could be an issue in the longer term.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	Aged care facilities, schools, shopping centres, states and territories, and other stakeholders needed expert advice on effective products to establish or revisit their own response plans. To respond to this TGA published dedicated lists to enable people to see what was approved, or what had been cancelled. TGA gained an understanding that our guidance in some cases needs to be product specific rather than general. In times of crisis the public demanded specific information to address their concerns. Adequate resourcing is essential to providing a timely response to questions from the public. Publishing plain English information helped the public find answers to their own questions. Enquires to TGA informed the kind of information that needed to be published on the website.

	TGA have utilised their processes for responses and included public notices on TGA website with changes to processes. In relation to the Exclusion Determination, appropriate communication with affected stakeholders will be required if and when it is rescinded.
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	While, TGA has not yet conducted a formal review of their response to the COVID-19 pandemic, post-market activities are an immediate priority: • A post-market review to validate the performance of face masks has been underway since May 2020. The review includes desktop reviews of manufacturer information and product testing. • Products that are already supplied to the market and are identified as not performing as intended will be subject to a "Product Defect Alert" to warn users of issues, or to expedited recall. • Cancellations of devices that do not meet regulatory requirements will continue to be published on TGA website. Lists of approved products will be amended as necessary. • Other follow-up actions include: • It is expected that laboratory testing of any COVID-19 vaccines will be ongoing, and eventually become part of TGA's routine batch release program. • New products developed in response to the crisis may require innovation in methods of regulatory assessment. • Engagement with stakeholders is essential to manage relationships and expectations when exiting a crisis.
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	Nil response.
3.7	Do you have any other suggestions?
Answer:	Agencies should be encouraged to undertake and share the results of formal reviews of their response to the COVID-19 pandemic.

End of questionnaire

Name respondent: Belgium….. and Email: ……..
Country name: Belgium ….. and Organisation: ……..

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance
Answer:	• Grant temporary authorization for disinfectant(PT1 & PT2) in a really short time (3-5 days) • Address shortages of alcohol • Ensure efficacy of the PT1 & 2 product • Efficient communication
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	Art.55(1) of the BPR 528/2012 Art.21 of the Belgian Royal Decree of 4 April 2019 regarding the marketing and use of biocides The use of those agile processes was used to grant temporary authorizations of PT1 and PT2 products to face the risk of shortage.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	Under Belgian national legislation is around 3-6 months Under the European BPR 528/2012 it is around 2-3 years.
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	The temporary authorization were used in Belgium
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc.

	Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	In Belgium the use of temporary authorizations (under BPR and national legislations) worked. We noticed that a clear communication was essential with the stakeholders (ASOs, industries,..). To do so we updated regularly the information on our website. In case of pandemic, as we faced, the novel techniques/devices are difficult to handle since we the efficacy as to be proven in a really short time
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	All the new techniques/devices/products can be envisages as long as the efficacy is proven and there is no risk for health and environment. Based on our experience in biocide, we could not authorized none of them since efficacy against Covid-19 was not proven, as well as safety for the human health and the environment.
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	It is important to have a good identification of all the actors/sectors and to match the supply and demand.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	To raise awareness in the industry about the European biocide legislation and its requirements, especially on the efficacy aspects.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	/

1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	/
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	/
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	The temporary authorizations (Art.55(1) of the BPR 528/2012 & Art.21 of the Belgian Royal Decree of 4 April 2019) as well as the publication on our website of all authorized biocidal products
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	The borderline products, specifically on the cosmetic legislation (ex: hand sanitizers)

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	Belgium has a long history of authorizing biocidal products at national and European level. This experience facilitated our fast reaction in delivering temporary authorizations of PT1 and PT2 products. A strong and clear communication on our website or directly to the ASOs helped to deal with the crisis.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	Define clear efficacy requirement on products towards specifics virus, such what was done by WHO regarding the hand disinfectant with a minimum of 70% alcohol.
2.3	Do you think that a “pragmatic approach’ to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a “pragmatic approach” could constitute in your country
Answer:	It could be a good approach as long as the efficacy can clearly been demonstrated otherwise it would be counter productive and will have a negative impact on mitigating the crisis.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	/
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.

Answer:	/

Continues on next page…

Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	Create a network on the biocidal field (countries, european/international agencies on biocide, European Commission,..) to facilitate the communication and define guidelines to try to reach an harmonization.
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	The WHO Handrub Formulations facilitated the authorization in time of crises, therefore we see a need of such guidance. The most critical aspect on having such pre-established standards/recipes is to ensure the efficacy of the product to mitigate the risk of contamination.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	In Belgium we have prolonged the emergency authorizations in accordance with the European and national legislations on biocides under the condition that the company introduces a standard authorization application within a determined delay.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	/
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	Better identification of the Belgian market on biocide (supply and demand) to improve the reaction time The importance of fast and clear communication to the professional and the general public
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.

Answer:	/
3.7	Do you have any other suggestions?
Answer:	/

End of questionnaire

Name respondent: Lisa Duncan	and Email: lisa.duncan@canada.ca
Country name: Canada	and Organisation: Health Canada's Pest Management Regulatory Agency

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	1. Determining proper regulatory pathway in a timely manner for products of interest during the pandemic 2. Developing regulatory guidance for novel technologies 3. Developing expedited processes to approve rapid shifts in supply chains of key biocide ingredients 4. Facing increased demands for expedited reviews of applications for registration 5. Limited resource allocations to meet the increased demands outlined above
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	Emergency Registrations Under Section 18 of the Pest Control Product Regulation (PCPR), emergency registrations may be granted when both of the following criteria are met: 1. An unexpected and unmanageable pest outbreak or pest situation occurs that can cause significant health, environmental or economic problems; and 2. Registered pesticides and cultural control methods or practices are insufficient to address the pest outbreak. Public Health recommendations are limited to the use of registered disinfectants, in addition to other best practices such as social distancing, frequent hand washing and the use of face coverings. It is unlikely that emergency registrations for products subject to the *Pest Control Products Act* (i.e., hard surface sanitizers, long lasting coatings, UV sanitizing devices, etc), that have lower thresholds of efficacy than disinfectants, would be seen as valuable alternatives in a pandemic situation. Also, it is important to note that the standard regulatory framework does allow for workload prioritization based on the need, however this can result in missed deadlines for other product types with potential financial implication for the organization.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)

Answer:	As per the Pest Management Regulatory Agency's Management of Submissions Policy, the timelines to process these requests are as follows: • 80 days for classification decision or requests for regulatory guidance (pre-submission consultations) • 16-22 months, depending on the nature of the active ingredient (conventional or non-conventional chemical), for products containing a new active ingredient(s) or major new use of registered pest control products (defined as the addition of a new use-site category to the use pattern for a specific registered active ingredient). • 12-14 months, depending on the nature of the active ingredient (conventional or non-conventional chemical), for new pest control products containing registered active ingredients or amendment to existing pest control products (for example, product chemistry, labelling).
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	Agile processes: • have been implemented for the use of alternate sources of formulants (e.g., ethanol) and quaternary ammonium compounds (quats) technical grade active ingredients (TGAIs) to formulate pest control products during the COVID-19 pandemic. Both interim measures are intended to address temporary shortages and will be valid until December 21, 2021, or until the supply issues triggered by the current pandemic are resolved. • will be considered for applicable covid-19 related applications for registration, on a case by case basis, once it has been confirmed that a complete high quality application has been received and if resources allow.
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	Although media outlets have been widely sharing pictures of novel application methods and products, it remains unclear whether these are approved in OECD member countries. There would be value in discussing OECD member country positions on these products and applications methods, whether streamlined approval processes have been considered or if a more formal position has been communicating, similar to the position the WHO (link below) communicated at the onset of the pandemic. https://www.who.int/publications/i/item/cleaning-and-disinfection-of-environmental-surfaces-inthe-context-of-covid-19
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors.

	→ position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	Although there has been interest in coatings and paints with long lasting residual efficacy, to date, Health Canada<s PMRA has not received an application for registration for such product types. The use of electrostatic sprayers or foggers are being publicized as a novel means to sanitize large areas and frequently used surfaces. All acceptable methods of application for a hard surface sanitizer must be reviewed by Health Canada's Pest Management Regulatory Agency (PMRA) before it receives authorization to appear on product labels. The application of hard surface sanitizers via electrostatic spraying represents a new method of application, and introduces safety, efficacy and quality considerations for hard surface sanitizers. A hard surface sanitizer must demonstrate efficacy for each method of application and the directions for the use must include any limitations or procedures to reduce any risks associated with that use. With regards to the use of drone technology for broader or aerial application of sanitizers to large public spaces or outdoor environments, it has been Health Canada's PMRA position that, in the absence of any recommendations from public health officials related to the sanitization of large areas, there is expected to be limited value of such use. Additionally, given the volumes of product required for such applications and the shortages faces in product availability, it does not seem reasonable to consider this application in the absence of such recommendations. With regards to the use of disinfection/sanitization tunnels, it has been Health Canada's PMRA position to date to align with the World Health Organization published Interim Guidance that states that spraying individuals with disinfectants (such as in a tunnel, cabinet, or chamber) **is not recommended under any circumstances**. https://www.who.int/publications/i/item/cleaning-and-disinfection-of-environmental-surfaces-inthe-context-of-covid-19
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	As there are few suppliers of industrial chemicals in Canada, a lack of overseas transport for commodity chemicals caused manufacturing issues in many sectors (including pesticides), Stakeholders such as Industry associations alert government of supply chain issues and offer alternate sources for government consideration. In turn, government consults with others (including government branches/departments) to ensure consolidation of efforts and provides flexibility in authorizing the use of alternate sources.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	There have been increased concerns relating to the safety and efficacy of a wide array of novel products and application methods that have flooded the marketplace since the beginning of the pandemic. To date, Health Canada has received limited information to support safety and efficacy for products of interest such as UV devices, long lasting coatings, etc.

	As OECD member countries gain experience in reviewing supporting information for these types of products, it would be beneficial to share with other member countries in hopes of developing standardized.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	In Canada, regulatory requirements may be impacted on the regulatory authority responsible for regulating the product in question. During the pandemic, it has become increasingly apparent that manufacturers, distributors, importers use the terms sterilize, disinfect, sanitize, decontaminate, clean interchangeably. However, these terms are meaningful to Health Canada and these are considered as part of the classification decision determining the appropriate regulatory authority for a product and will dictate the regulatory requirements (i.e., threshold of efficacy required to be substantiated to maintain the claim). Increased industry awareness is required to educate on the meaning of these terms and ultimately guide industry to determine regulatory requirements more easily. Additionally, the crisis brought new players to the market who are not even aware of the basic requirements and the need to get approval before placing products on the market. There needs to be better communication with smaller business that are not captured by the usual industry association.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	This is a public health consideration, outside of PMRA's area of expertise
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	This is a public health consideration, outside of PMRA's area of expertise
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	As per Section 3(1)d) of the Pest Control Product Regulations (PCPR), the PMRA does not have the authority to regulate products that are used to destroy or inactivate viruses, bacteria or other microorganisms in order to treat, mitigate or prevent disease in humans or animals, except in respect of its use in a swimming pool or spa. Those are regulated under a different legislation (Food and Drugs Act).
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	Products of interest during the pandemic are largely regulated under one of three Acts in Canada, the Food and Drugs Act (i.e., disinfectants, hand sanitizers, medical devices), the Pest Control Products Act (i.e., sanitizers, long lasting coatings, devices, silver treated articles) and/or the Canadian Consumer Product Safety Act (i.e., hand soaps, cleaners). Largely regulatory oversight is clear for many products types. However, the pandemic has brought many new stakeholders to the table, many of which do not fully understand any of the three regulatory frameworks. Stakeholders are pushing the boundaries and representing their products in a way that has led to jurisdictional ambiguities. For example, a UV device that is represented for use in hospital settings, operating rooms, but has associated claims of kills 99.9% of bacteria and viruses on surfaces can be one of two regulatory jurisdictions. If the device is meant for use in hospital operating rooms, the threshold of efficacy required is much greater. Therefore, it would be subject to the Food and Drugs Act, but would fail efficacy requirements. If that same device

	were used on commercial or domestic surfaces, such as hand rails, door knows, etc. it would be subject to the Pest Control Products Act. Therefore, challenges in our ability to respond were mostly associated to inquiries where the products were represented with questionable uses, wording and claims.

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	Yes, the implementation of facilitated use of alternate sources of formulants (e.g., ethanol) and quaternary ammonium compounds (quats) technical grade active ingredients (TGAIs) to formulate pest control products during the COVID-19 pandemic has been successful.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	Country have independent regulatory frameworks and therefore it would be difficult to consider blanket registrations for products complying with pre-established standards but acceptance of existing reviews could be promising. That said, there is value in reviewing approaches and methods required by member countries to substantiate the efficacy of novel products or application methods in hopes of streamlining requirements as best as possible. This could be facilitated if countries could freely and quickly exchange their reviews.
2.3	Do you think that a “pragmatic approach’ to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a “pragmatic approach” could constitute in your country
Answer:	It is the PMRA’s view that efficacy testing is currently focused on the reality of the situation; relevant strains are required as part of testing, including the use of relevant samples (i.e., hard vs soft surfaces) and use of internationally accepted test methods. Thresholds of efficacy must be substantiated. Especially in a pandemic situation, the risk associated with failed efficacy is of particular concern.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	It would be valuable for OECD member countries to share available guidance that is referred to in support of the review of safety and/or efficacy of products of interest in a pandemic (i.e., coatings and paints with long lasting efficacy, air sanitizers, UV light emitting devices used as a means to sanitize surfaces, etc.).

2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	The terms disinfection, sanitization, sterilization, decontamination are often used interchangeably, yet for regulators these terms may affect regulatory authority as well as required performance standards. Greater public awareness may be required to help explain the difference between the terms used in addition to communicating that there are many products in the marketplace that have not substantiated the effectiveness of their products. Therefore, their use should not replace routine disinfection procedures, regular hand washing, face coverings or social distancing.

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	In Canada, we have received several inquiries from importers who wish to consider registration of a foreign product or its importation. It has been challenging to confirm the products regulatory status in a member country and whether or not the product claims have been approved. It would be helpful to have access to the list of approved product via a repository/database In Canada for product regulated under the Pest Control Products Act (PCPA), all registered products and approved uses can be accessed using our Pesticide Product Information Database https://pesticide-registry.canada.ca/en/index.html
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	While such recipe may be useful in time of crisis, they can create problems during "normal" time. We generally discourage the public from making their own products due to the risk involved (it can even be considered illegal).
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	In Canada, the PMRA may grant an emergency authorisation for a period of up to one year. There may be consideration for a subsequent emergency authorisation. The problem generally encountered is that certain stakeholders become reliant on the process and never seek a normal registrant. It is important to communicate that emergency registration are not a long term solution.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	In general, the public are seeking confirmation that the products available in the marketplace have been reviewed for their safety and efficacy. For future situations, broader communication on how to identify approved products would be helpful. For example, consumers can recognize products authorized under the Pest Control Products Act (PCPA) (i.e, sanitizers, UV devices, coatings with long lasting efficacy) with the presence of a Pest Control Product (PCP) number on the packaging (e.g., REGISTRATION NO. ##### PEST CONTROL PRODUCTS ACT or REG. NO. ##### P.C.P. Act). Canadians are encouraged to consult the Department's Pesticide Product Information Database for products approved under the PCPA prior to purchasing these products.

3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	Increased compliance and enforcement action to ensure that products which have been imported through interim measures for a specified period of time have been removed from the marketplace. Increased awareness of applicable regulatory authorities for products of interest during a pandemic and greater engagement with stakeholders on the regulatory requirements for applicable products to be approved for sale or use in Canada
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	Preparing a repository of all OECD member country approved product/label search engines to help other countries determine the regulatory status and approved claims when inquiries are received for importation of a particular product or registration/authorization of a particular product. It has also been challenging to determine OECD member regulatory authority for certain product types such as devices: -ozone generating devices for use in sanitizing air and surfaces, UV light emitting devices for use in sanitizing air and surfaces, etc. There would be value in having all products of interest during a pandemic in one area with an outline of the regulatory authority in each member country As an example: **Canada** Disinfectants (Regulated under the Food and Drugs Act by the Natural and Non-Prescription Health Products Directorate) Sanitizers (Regulated under the Pest Control Product Act by the Pest Management Regulatory Agency) Etc.
3.7	Do you have any other suggestions?
Answer:	NIL

End of questionnaire

Name respondent: Shannon C. Wright and Email: shannon.c.wright@canada.ca

Country name: Canada and Organisation:Health Canada's Natural and Non-Prescription Health Products Directorate (NNHPD)

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	1. Determining proper regulatory pathway in a timely manner for products of interest during the pandemic 2. Developing regulatory guidance for novel technologies 3. Developing expedited processes to approve rapid shifts in supply chains of key biocide ingredients 4. Facing increased demands for expedited reviews of applications for registration 5. Limited resource allocations to meet the increased demands outlined above
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	There is no emergency registration process for drugs, as per the Food and Drugs Act and Regulations. Various interim measures were put into place to allow exceptional importation of hand sanitizers and disinfectant drugs, based on foreign approvals. These interim measures are being transitioned into formal Interim Orders (IOs) connected to the Food and Drug Regulations. These interim measures are intended to address temporary shortages and are anticipated to be valid until end of 2021, or until the supply issues triggered by the current pandemic are resolved. Health Canada maintains a list of Hard-surface disinfectants and hand sanitizers accepted under COVID-19 interim measure, with eligibility criteria for inclusion in the list specified. Also, it is important to note that the standard regulatory framework does allow for workload prioritization based on the need, however this can result in missed deadlines for other product types with potential financial implication for the organization. Since mid-March 2020, Health Canada's NNHPD has been expedited the review of any disinfectant drug application that has a direct or indirect efficacy claim against SARS-CoV-2.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)

Answer:

Health Canada's Management of Drug Submission and Applications, indicates the normal performance standards for disinfectant drug applications (Appendix 3), and the COVID-specific Health Canada guideline Applying for a Drug Identification Number (DIN) for a disinfectant drug during the COVID-19 pandemic specifies the expedited COVID targets:

Submission Type	Normal Performance Standard	Expedited COVID Review Targets
DIN-D Full Review with Data (new DIN)	255	150
DIN-D Full Review with Data (amendment)	255	90
DIN-D Labelling Only	135	90
DIN-D Labelling Standard (Monograph)	60	45
DIN-D Administrative	45	40
Post-Authorization Division 1 Change (PDC)	30	30
New Drug Submission (NDS-D)	345	Varies depending on complexity of review

1.4

In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?

Answer:

Over the course of the COVID-19 pandemic, Health Canada's NNHPD has permitted flexibilities for applicable COVID-19 related disinfectant drug applications, on a case by case basis, once it has been confirmed that a complete high quality application has been received and as resources allow. These flexibilities are specified in the COVID-specific Health Canada guideline Applying for a Drug Identification Number (DIN) for a disinfectant drug during the COVID-19 pandemic.

Various interim measures were put into place to allow exceptional importation of hand sanitizers and disinfectant drugs, based on foreign approvals. These interim measures are being transitioned into formal Interim Orders (IOs) connected to the Food and Drug Regulations. These interim measures are intended to address temporary shortages and are anticipated to be valid until end of 2021, or until the supply issues triggered by the current pandemic are resolved. Health Canada maintains a list of Hard-surface disinfectants and hand sanitizers accepted under COVID-19 interim measure, with eligibility criteria for inclusion in the list specified.

1.5

Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc.

Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)?

Please list your suggestions.

Answer:

Although media outlets have been widely sharing pictures of novel application methods and products, it remains unclear whether these are approved in OECD member countries. There would be value in discussing OECD member country positions on these products and applications methods, whether streamlined approval processes have been considered or if a more formal position has been communicating, similar to the position the WHO (link below) communicated at the onset of the pandemic.

https://www.who.int/publications/i/item/cleaning-and-disinfection-of-environmental-surfaces-inthe-context-of-covid-19

1.6

Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others:

	→ coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	Although there has been interest in products with long lasting residual virucidal efficacy claims, to date, Health Canada's NNHPD has not received an application for registration for such product types. The use of electrostatic sprayers or foggers are being publicized as a novel means to disinfect large areas and frequently used surfaces. All acceptable methods of application for a disinfectant drug must be reviewed by Health Canada's NNHPD before it receives authorization to appear on product labels. The application of disinfectant drugs via electrostatic spraying represents a new method of application, and introduces safety, efficacy and quality considerations for disinfectant drugs. A disinfectant drug must demonstrate efficacy for each method of application and the directions for the use must include any limitations or procedures to reduce any risks associated with that use. With regards to the use of drone technology for broader or aerial application of disinfectant drugs to large public spaces or outdoor environments, it has been Health Canada's NNHPD position that, in the absence of any recommendations from public health officials related to the sanitization of large areas, there is expected to be limited value of such use. Additionally, given the volumes of product required for such applications and the shortages faces in product availability, it does not seem reasonable to consider this application in the absence of such recommendations. With regards to the use of disinfection/sanitization tunnels, it has been Health Canada's NNHPD position to date to align with the World Health Organization published Interim Guidance that states that spraying individuals with disinfectants (such as in a tunnel, cabinet, or chamber) **is not recommended under any circumstances**. https://www.who.int/publications/i/item/cleaning-and-disinfection-of-environmental-surfaces-inthe-context-of-covid-19
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	There are few suppliers of industrial chemicals in Canada, and a lack of overseas transport for commodity chemicals caused manufacturing issues in many sectors (including disinfectant drugs). Stakeholders such as Industry associations alert government of supply chain issues and offer alternate sources for government consideration. In turn, government consults with others (including government branches/departments) to ensure consolidation of efforts and provides flexibility in authorizing the use of alternate sources.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	There have been increased concerns relating to the safety and efficacy of a wide array of novel products and application methods that have flooded the marketplace since the

	beginning of the pandemic. To date, Health Canada has received limited information to support safety and efficacy for products of interest such as probiotic and bacteriophase-based disinfectant, on-site disinfectant generating devices, UV disinfecting devices, long lasting virucidal products, etc. As OECD member countries gain experience in reviewing supporting information for these types of products, it would be beneficial to share with other member countries in hopes of developing standardized.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	In Canada, regulatory requirements may be impacted on the regulatory authority responsible for regulating the product in question. During the pandemic, it has become increasingly apparent that manufacturers, distributors, importers use the terms sterilize, disinfect, sanitize, decontaminate, clean interchangeably. However, these terms are meaningful to Health Canada and these are considered as part of the classification decision determining the appropriate regulatory authority for a product and will dictate the regulatory requirements (i.e., threshold of efficacy required to be substantiated to maintain the claim). Increased industry awareness is required to educate on the meaning of these terms and ultimately guide industry to determine regulatory requirements more easily. Additionally, the crisis brought new players to the market who are not even aware of the basic requirements and the need to get approval before placing products on the market. There needs to be better communication with smaller business that are not captured by the usual industry association.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	This is a public health consideration, outside of Health Canada's NNHPD's area of expertise
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	This is a public health consideration, outside of Health Canada's NNHPD's area of expertise
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	The Food and Drugs Act and Regulations are applicable for disinfectants regulated as drugs, and they are intended for traditional drug products, and not necessarily biocidal products. As a result, many proposed types of products like those with long lasting residual virucidal efficacy claims or for disinfectant uses in air and water do not fall within their regulatory scope. The split regulation of some biocidal products by PMRA vs. other by NNHPD causes significant confusion for industry, with calls for regulatory modernization increasing substantially over the course of the COVID-19 pandemic. As a result of this regulatory split, Health Canada deals with significant regulatory shopping from industry, seeking the easiest, quickest, cheapest, and least robust regulatory pathway.
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	Products of interest during the pandemic are largely regulated under one of three Acts in Canada, the Food and Drugs Act (i.e., disinfectants, hand sanitizers, medical devices), the Pest Control Products Act (i.e., sanitizers, long lasting coatings, devices,

	silver treated articles) and/or the Canadian Consumer Product Safety Act (i.e., hand soaps, cleaners). Largely regulatory oversight is clear for many products types. However, the pandemic has brought many new stakeholders to the table, many of which do not fully understand any of the three regulatory frameworks. Stakeholders are pushing the boundaries and representing their products in a way that has led to jurisdictional ambiguities. For example, a UV device that is represented for use in hospital settings, operating rooms, but has associated claims of kills 99.9% of bacteria and viruses on surfaces can be one of two regulatory jurisdictions. If the device is meant for use in hospital operating rooms, the threshold of efficacy required is much greater. Therefore, it would be subject to the Food and Drugs Act, but would fail efficacy requirements. If that same device were used on commercial or domestic surfaces, such as hand rails, door knows, etc. it would be subject to the Pest Control Products Act. Therefore, challenges in our ability to respond were mostly associated to inquiries where the products were represented with questionable uses, wording and claims.

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	Yes, the implementation of facilitated use of alternate sources of formulants (e.g., ethanol) and quaternary ammonium compounds (quats) active ingredients) to formulate disinfectant drugs during the COVID-19 pandemic has been successful.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	Countries have independent regulatory frameworks and therefore it would be difficult to consider blanket registrations for products complying with pre-established standards but acceptance of existing reviews could be promising. That said, there is value in reviewing approaches and methods required by member countries to substantiate the efficacy of novel products or application methods in hopes of streamlining requirements as best as possible. This could be facilitated if countries could freely and quickly exchange their reviews.
2.3	Do you think that a “pragmatic approach’ to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a “pragmatic approach” could constitute in your country
Answer:	It is the NNHPD’s view that efficacy testing is currently focused on the reality of the situation; relevant strains are required as part of testing, including the use of relevant samples (i.e., hard vs soft surfaces) and use of internationally accepted test methods. Thresholds of efficacy must be substantiated. Especially in a pandemic situation, the risk associated with failed efficacy is of particular concern.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	It would be valuable for OECD member countries to share available guidance that is referred to in support of the review of safety and/or efficacy of products of interest in a pandemic (i.e., products with long lasting residual virucidal efficacy claims, air disinfectants/sanitizers, UV light emitting devices used as a means to disinfect/sanitize surfaces, etc.). Additionally, a discussion on varying emerging viral pathogens approaches between OECD member countries would be beneficial. Health Canada’s

	NNHPD has had an emerging viral pathogens approach published in the disinfectant drugs guidance documents since 2014, with the January 2020 update to the guidance document noting the following: 5.0 Claims against Emerging Viral Pathogens When the Public Health Agency of Canada (PHAC) has issued a public notice that an emerging viral pathogen poses a significant risk to Canadians or has been declared by the World Health Organization (WHO) as a public health emergency of international concern, manufacturers can immediately provide communications containing qualifying language like "expected to be effective" and "likely to be effective" to the public regarding the expected efficacy of certain market authorized disinfectant drugs against the emerging pathogen: this includes communications through their web sites, toll free consumer information services, and similar media. Disinfectants that have received market authorization for either of the following claims will be permitted to make indirect efficacy claims against emerging viral pathogens: • "Broad-spectrum virucide", supported by an efficacy claim against any of: o Adenovirus type 5 (ATCC VR-5) o Bovine Parvovirus (ATCC VR-767) o Canine Parvovirus (ATCC VR-2017) o Poliovirus type 1 (ATCC VR-1562) OR • For emerging viral pathogens for which the taxonomic genus of the virus has been identified, efficacy data against other viruses within that genus may be considered acceptable (e.g., any Influenza A virus for a claim against Influenza A H1N1). Manufacturers may add claims against emerging viral pathogens to their market authorized product labels, provided that their products qualify for the claims, through the post-authorization Division 1 change (PDC) process, which requires a notification to be sent to Health Canada within 30 days of adding the claim, as permitted through section C.01.014.4 of the *Food and Drug Regulations*. This emerging viral pathogens approach forms the backbone of our COVID-19 response, with a broadening of the surrogate viruses permitted in support of indirect COVID-19 claims, as noted in the Health Canada webpage Hard-surface disinfectants and hand sanitizers (COVI-19) – Information for manufacturers.
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	The terms disinfection, sanitization, sterilization, decontamination are often used interchangeably, yet for regulators these terms may affect regulatory authority as well as required performance standards. Greater public awareness may be required to help explain the difference between the terms used in addition to communicating that there are many products in the marketplace that have not substantiated the effectiveness of their products. Therefore, their use should not replace routine disinfection procedures, regular hand washing, face coverings or social distancing.

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	In Canada, we have received several inquiries from importers who wish to consider registration of a foreign product or its importation. It has been challenging to confirm the products regulatory status in a member country and whether or not the product claims have been approved. It would be helpful to have access to the list of approved product via a repository/database. In Canada for products regulated under the *Food and Drugs Act* (FDA), all registered products can be accessed using our Drug Product Database https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html Health Canada's NNHPD has found great utility in the US EPA's PPLS repository for approved antimicrobial pesticide labels, as it has been a key verification tool for proposed products seeking to use our interim measures for exceptional import. Health Canada does not currently post approved labels for disinfectant drugs to the Drug Product Database, however there is a proposal to start to do so, as it would likely be helpful for a broad range of stakeholders to be able to quickly access this information – including our own compliance and enforcement groups within Health Canada.
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	While such recipes may be useful in times of crisis, they can create problems during "normal" time. We generally discourage the public from making their own products due to the risk involved (it can even be considered illegal).
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	In Canada, the NDED has put in place a temporary interim measure for exceptional import. These interim measures are intended to address temporary shortages and are anticipated to be valid until end of 2021, or until the supply issues triggered by the current pandemic are resolved. The problem generally encountered is that certain stakeholders become reliant on the process and never seek a normal registrant. It is important to communicate that emergency registration are not a long term solution.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.

Answer:	In general, the public are seeking confirmation that the products available in the marketplace have been reviewed for their safety and efficacy. For future situations, broader communication on how to identify approved products would be helpful. For example, consumers can recognize products authorized under the *Food and Drugs Act* (FDA) (i.e, disinfectant drugs) with the presence of a Drug Identification Number (DIN) number on the packaging. Canadians are encouraged to consult the Department's Drug Product Database for products approved under the FDA prior to purchasing these products.
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	Increased compliance and enforcement action to ensure that products which have been imported through interim measures for a specified period of time have been removed from the marketplace. Increased awareness of applicable regulatory authorities for products of interest during a pandemic and greater engagement with stakeholders on the regulatory requirements for applicable products to be approved for sale or use in Canada
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	Preparing a repository of all OECD member country approved product/label search engines to help other countries determine the regulatory status and approved claims when inquiries are received for importation of a particular product or registration/authorization of a particular product. It has also been challenging to determine OECD member regulatory authority for certain biocidal product types, and the added nuance of disinfectants being regulated as drugs in Canada has added to that challenge. There would be value in having all products of interest during a pandemic in one area with an outline of the regulatory authority in each member country. As an example: **Canada** Disinfectants (Regulated under the Food and Drugs Act by the Natural and Non-Prescription Health Products Directorate) Sanitizers (Regulated under the Pest Control Product Act by the Pest Management Regulatory Agency) Etc.
3.7	Do you have any other suggestions?
Answer:	NIL

End of questionnaire

Name respondent: Martha Sikorski……	and Email: chemg@baua.bund.de……..
Country name: Germany ……..	and Organisation: BAuA……..

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	Due to the Covid-19 pandemic, an increased demand for surface and hands disinfectants was observed which could not be met sufficiently by the resources available so far in the beginning with the applicable regulations (BPR). Therefore, German authorities (BAuA - CA for biocides) had to react quickly on this shortage by issuing an emergency authorisation for additional disinfectants taking into account questions on the efficacy and safety of these products.
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	In regards to biocides the German Chemicals Act in conjunction with the German Infection Protection Act and the German Animal Health Law allows for emergency authorisations when human or animal health are endangered and the respective crisis cannot be averted with authorised products or products marketable under transitional rules. In April 2020 an emergency authorisation was issued for surface and hand disinfectants. Since October 2020 the emergency authorisation only applies for hand disinfectants.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	In cases, where the rules laid down in article 55 (1) of the BPR are not applicable the timelines of the usual authorisation procedures of the BPR (~2-3 years) are applicable. Products marketable under transitional rules only need to be registered online (effective immediately after successful registration).
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	not applicable

1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	A danger to public health caused by the Covid-19 disease requires a quick reaction which is facilitated by the possibility of national measures of derogation to the BPR. The Federal Office for Chemicals (BfC - Bundesstelle für Chemikalien) being a division of the BAuA is running the REACH-CLP-Biozid Helpdesk. The helpdesk provides support for and enables communication with manufacturers, importers and users of chemical substances including disinfectants regarding the registration, evaluation, authorisation and approval as well as the classification and labelling of chemical substances and biocides. This platform was also a successful tool for the communication regarding the emergency authorisations. Additionally in order to support manufacturers of hand and surface disinfectants, the BfC is publishing a catalogue of questions and answers on a rolling basis. An exchange of information between international stakeholders on available and suitable disinfectant products might also take place on the OECD website "Emergency responses for the supply of disinfectants against Covid-19" after the measures had been taken. Novel application techniques have first to be evaluated regarding their safety and efficacy before they are recommended. Validated methods to test novel non-biocidal methods are not available to our knowledge and have first to be developed.
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	/
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	/
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc.

	Please list your suggestions in order of importance and most likely to succeed.
Answer:	Any doubts about the efficacy of disinfectants are best resolved if there is proof of efficacy according to relevant harmonised test standards. For most types of uses that are necessary in the context of epidemics (i.e. hand disinfection, surface disinfection) there are relevant test standards published by CEN upon which one can rely.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	BfC is publishing all important information on the registration / emergency authorisation of disinfectants on the BAuA and REACH-CLP-Biozid Helpdesk Website. Following the BfC on Twitter enables the industry to be up to date with all published information. Please consider also our answer to question 1.5 on the REACH-CLP-Biozid Helpdesk and the possibility of placing relevant information on available and suitable disinfectant on the OECD website “Emergency responses for the supply of disinfectants against Covid-19”.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	/
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	/
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	The possibility of a national emergency authorisation facilitated the ability to respond regarding the increased demand for disinfectants.
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	/

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	Regarding the increased demand of disinfectants at the beginning of the pandemic the emergency authorisation was successful. No further action required.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	Please refer to our answer on questions 1.5 and 1.9
2.3	Do you think that a “pragmatic approach’ to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a “pragmatic approach” could constitute in your country
Answer:	In our view, no matter whether there is a time of crisis or not, it must be ensured that disinfectants are efficacious. This means that there should be proof that the respective product passes the relevant efficacy testing standards and the requirements should not be lowered in times of crisis. For emergency situation requiring a quick reaction publicly available formulations of proven efficacy (like the WHO-recommended Handrub Formulations) can be used by an increased demand for disinfectants.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	/
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	/

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	The emergency authorisation is a national procedure. The disinfectants covered by the derogation according to Art 55 (1) of the BPR may only be produced or imported by the addressees of the derogation that are located in Germany. Companies that are located outside of Germany are not allowed to market the mentioned biocidal products in Germany under the emergency measures. They have first to establish a connection to appropriate addressees located in Germany who are then allowed to import the product. However, there is still the possibility of communication via the REACH-CLP-Biozid Helpdesk. Additionally, all important information on the registration / emergency authorisation of disinfectants is published on the BAuA and REACH-CLP-Biozid Helpdesk Website. We also provide the relevant information as far as possible in English. However, considering the urgency of the situation the English translations are not always available as fast as necessary. E.g. the catalogue of questions and answers on the emergency authorisation are still available in German only. This can still be improved.
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	In our view it is best to use products that have already been assessed for their safety and efficacy, i.e. authorised in the context of the biocidal products regulation. For the rare emergency situations where the established products are no longer able to satisfy sudden spikes in demand, we believe that the already available public descriptions of simple formulations (like the WHO handrub formulations) are a sufficient basis for emergency measures. Thus, we do not see a need for further guidance on this issue.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	/
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.

Answer:	Making available on the market of disinfectant formulations not covered by the BPR and the possibility of an emergency authorisation of disinfectants with different active substances cover most of the questions we receive. Regarding the way we deal with these questions please refer to our answers to questions 1.5, 1.9 and 3.1. This is the way we will continue in the future.
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	/
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	/
3.7	Do you have any other suggestions?
Answer:	For an efficient protection against the Corona virus a complex set of measures (of different specializations) is needed; the biocides point of view can only be seen as a part thereof.

End of questionnaire

Name respondent: Aive Telling	and Email: aive.telling@sm.ee
Country name: Estonia	and Organisation: Ministry of Social Affairs

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	The main difficulty for Estonia was the availability of disinfectants. Due to the Covid-19 demand for disinfectants rose significantly and the availability of disinfectants became scarce. Because of the closure of European borders, the import of active substance became difficult (e.g. isopropanol) for disinfectant producers. This reduced availability of active substances and therefore disinfectants for general public. Main objective was to restore supply of disinfectants. For the biocide competent authority (Health Board), the workload rose several times. In Estonia all biocides need to be registered or authorised before placing to the market in Health Board Due to the demand of disinfectants from general public the amounts of applications and illegal disinfectants in the market raised several times. The difficulty was that there were many newcomers among registrants, therefore the workload of helpdesk to clarify the requirements raised also several times. Re-organising the working procedures and capability of the computer systems due to working from home offices promptly.
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	For disinfectants depending on the composition of active substances Regulation (EU) No 528/2012 of the European Parliament and of the Council (BPR) and/or national transitional legislation applies. There are no existing agile processes available in national legislation to respond to such emergencies in Estonia because Regulation (EU) No 528/2012 article 55 stipulates derogations from the biocidal product requirements. In order to secure the supply of disinfection products a temporary exemption from the Regulation (EU) No 528/2012 article 95 for the making available on the market and use of the disinfectants containing ethanol was granted in Estonia. Manufacturers of biocidal products with the WHO formulation II had to apply for a temporary registration via transitional measure from Health Board instead of standard procedure. For aviation industry exemption according to Regulation (EU) No 528/2012 article 55 for the use of Biobor JF was given.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)

Answer:	The standard timelines for authorisation are according to the Regulation (EU) No 528/2012. According to the Art 89 of the Regulation (EU) No 528/2012 the transitional measures are stipulated in national Biocidal Products Act for active substances still under BPR review program. The standard timeline for the registration on national requirements is up to 1 month.
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	Health Board speeded up the registration process by involving more people to the process.
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	List of harmonised approaches and instructions bearing in mind also the regulatory measurements already available in the EU.
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	Most quickest and affordable measures are the disinfection stations, but all such stations should be labelled as required in Art 69 of the Regulation (EU) No 528/2012 to make the public aware of the content/disinfectant used in of such a station.
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of.
Answer:	During the Covid-19 crisis many Estonian disinfectant producers started to work together and outsourcing their active substances for bottling to other companies and share resources. Health Board speeded up the registration process by involving more people to the process. We also temporarily didn't follow the Art 95 requirement of the Regulation (EU) No 528/2012 for ethanol allowing to use the ethanol as active substance from food processing industry.

1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	We advise to check the guidance's which European Chemicals Agency has prepared and published on their website. https://echa.europa.eu/et/-/speeding-up-the-supply-of-disinfectants https://echa.europa.eu/et/covid-19
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	European Chemicals Agency and also Health Board updated the news and guidance's in order to speed up the process. https://echa.europa.eu/et/-/speeding-up-the-supply-of-disinfectants https://echa.europa.eu/et/covid-19
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	We do not have suggestions.
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	We do not have suggestions.
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	According to the national Biocidal Products Act it is prohibited to repackage the biocidal product at the place of storage and making available. During the Covid-19 crises it was necessary to refill the disinfectant stations, therefore the national law will be changed to allow draw off/refilling the hand disinfectants (PT1) and surface disinfectants (PT2) in disinfectant stations or in smaller units.
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	Yes, we experienced. As disinfection stations in public areas are new, so there has been several problems on this issue. The disinfection stations are at the moment out of the scope of the Biocidal Products Act. It includes refilling and labelling and also it wasn't clear who should make the state supervision.

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	In order to increase supply of disinfectants Regulation (EU) No 528/2012 art. 95 exemption was made that increased the number of suppliers of ethanol and relieved the market situation but on the other hand caused additional problems (e.q. quality of ethanol). On national level Health Board speeded up the registration process by involving more people to the process, simplified and made the registration process clearer and approved digitally signed registration applications. Daily interaction with biocide industry and other government agencies were essential to understand and remove bottlenecks to provide disinfectants to the market.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	We find that the climate, cultural and economy factors are different, so there can't be any "blanket requirement", but it should take into account different regions.
2.3	Do you think that a "pragmatic approach' to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a "pragmatic approach" could constitute in your country
Answer:	On the transitional period, when active substance is still under BPR review program, the minimum requirements to justify the efficacy are the scientific literature search results or performed efficacy tests. In case of special statement (e.g. kills bacteria) claimed the test report is required to support that statement.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	Nice idea, but we do have no suggestions for guidances.
2.5	Are there areas where increased or improved information to the public is necessary?

	If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	We think that it is necessary to provide the scientifically supported information to refute the false information and myths. Authorities should use their websites, media, social media etc.

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	We find that European Chemicals Agency has on their webpage well communicated the options to speed up the making available of the disinfectants to the market.
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	We do support this idea however one should bear in mind that in EU there is a list of approved active substances and notified active substances – so not all active substances are accepted.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	Emergency authorisations do create alternate problems and they should be evaluated and dealt with according to cost benefit ratio and more state supervision is needed. Main issues are quality of the disinfectants. In Estonia it was temporarily accepted to use ethanol in disinfectants from alternative sources other than Art 95 list of Regulation (EU) No 528/2012. But it appeared that this measure caused a problem in quality and in efficacy of the active substance and hence of the disinfectant. Although these registrations were valid temporarily, it still caused problems on the market as the registration holders did not followed the requirements on the registration certificate.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	With all questions has been dealt case-by-case and following questions have raised/Following questions have raised and has been dealt on a case-by-case basis: • What is in the disinfectant stations? No information of the content. (Estonia has now paid attention that all disinfectant stations need to be labelled/marked with information of the content.) • Why my disinfectant has a bad smell? • Why my disinfectant has no smell? • Why my disinfectant is sticky? • Why my disinfectant is like water?

3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	We have no suggestions.
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	We have no suggestions.
3.7	Do you have any other suggestions?
Answer:	We have no suggestions.

End of questionnaire

Name respondent: Sari Penttinen	and Email: sari.penttinen@tukes.fi
Country name: Finland	and Organisation: Finnish Safety and Chemicals Agency (Tukes)

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	Availability of disinfectants and packaging materials. The demand increased so fast that it was not possible to produce or import sufficient amounts of disinfectants on the market. Especially the lack of consumer products concerned the public and Tukes was very busy when answering the inquiries and giving advice. New manufactures and importers appeared. They had limited knowledge of relevant regulatory requirements (i.e. BPR, CLP). Therefore, they also needed a lot of advice. There was not enough information available on applicability and efficacy of different active substances/biocidal products against Covid-19.
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	As an EU Member State Finland applied the article 55(1) of Biocidal Products Regulation (BPR). This provision allows national authorities to give time-limited derogations from the standard product authorisation requirements in situations where there is a threat to public health. Since the active substance ethanol is still under evaluation (thus not approved at the EU level yet) and according to the national legislation disinfectants do not need authorization in Finland, only a Chemical Notification was needed to place ethanol-based disinfectants to the market.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	Timetables mentioned in the BPR.
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	Please see our answer to question 1.2.

1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	In Europe the Commission and ECHA facilitate the communication between Member States and it is very useful. However, the role of European Centre for Disease Prevention and Control (ECDC) and WHO (both also giving instructions etc.) could be stronger for example in efficacy issues. Currently authorities don't have wide knowledge on efficacy of biocides, because evaluation and authorization of disinfectants have not been finished in Europe. Therefore, general information from WHO/ECDC about efficient disinfectants and efficient concentrations of active substances would have been appreciated in Member States.
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	Novel application techniques would be welcome. However, they must be designed to be safe for general public – otherwise we create a new potential panic reaction in the media (we do not want another debate type "vaccines cause autism"). We have doubts on whether disinfection of public space by fogging or spraying of chemicals is useful or effective. In addition, we are worried about safety of using disinfection tunnels for humans in public space.
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	Finland has a National Emergency Supply Organization, which is based on the co-operation between the administration and business community and it is coordinated by the National Emergency Supply Agency. One of Agency's objective is to ensure availability of critical raw materials and products under different crises. In Finland an attempt has been made to improve the availability of domestic packaging materials and to reduce the dependence from foreign ones.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.

Answer:	From a perspective of European competent biocide authority, this questions concerns mainly products intended to be placed on the market according to article 55 derogation of the BPR. In these cases, it is in the interests of the applicant to gather efficacy information. Often the problem is uncertainties connected with the data provided. Formulation, test conditions, test organisms etc. differ from the applied product leaving too many uncertainties. Depending on the active substance, the other product applications according to BPR may contain very relevant information but it is proprietary. The most useful solution from the authority point of would be if this information could be utilized in some general and possibly coordinated manner. This data is already accessible to authorities and in a familiar format. For active substances not included in BPR product dossiers the problem is much more difficult to solve because the problem is typically not the lack of data per se but lack of data that can be considered to describe efficacy of the assessed product in the intended use. This information may not exist at all or only in the possession of direct competitors of the applicant. Data protection issue could be avoided if the data base on efficacy would be open to institutional users only.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	Close cooperation with industrial associations in order to identify relevant information needs. To gather all available information into a package, where not only the requirements for disinfectant authorizations is available but also other relevant regulatory requirements, i.e. regarding transportation, storage, manufacturing sites etc.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	/
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	/
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	/
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	In the beginning of Covid-19 crisis it was important and useful to discuss with other authorities about each other's jurisdiction in order to be aware who is responsible for certain subjects.

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	EU authorisation system of biocides created a bottleneck when the situation got acute in Finland. The amount of ethanol provided by the suppliers included in the review programme of active substance was not sufficient. Finland among the other EU member states reacted by permitting additional sources of supply of ethanol. Therefore, in the beginning of Covid-19 crisis it was necessary in Finland to allow using ethanol not only from the suppliers in the BPR article 95 list but also from other suppliers who produced ethanol in the EU region. This was done to ensure the availability of disinfectants. Only a few derogations according to BPR 55(1) was notified in Finland, since we had concerns about the efficacy of most products. Tukes participated in an ad-hoc working group with industry and National Emergency Supply Agency. This cooperation was important to get relevant information on availability on disinfectants and suitable packaging materials. In the EU, reaction/advise from ECHA/COM could have been quicker to make harmonised and simultaneous reaction from member states possible.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	Please see our answer to question 1.5.
2.3	Do you think that a “pragmatic approach’ to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a “pragmatic approach” could constitute in your country
Answer:	From our perspective, a separate “pragmatic approach” guidance would not be very useful. The BPR efficacy guidance consists of tiered approach meaning that efficacy of a product needs to be shown with different, lower and higher tier tests, depending on the product type, use and target organisms. The lower tier tests can be considered to represent the “pragmatic approach”. If an applicant intends to place a product on the market according to article 55 derogation of the BPR and cannot perform all the normally required tests, they are likely to concentrate on the lower tier tests. We will then evaluate the need for disinfectants in relation to the tests provided.

2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	/
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	Information regarding the use of hand sanitisers and other disinfectants should be consistent even if released by different authorities. For example, it is important to remind the public that it is not necessary to use hand sanitisers or disinfectants at home, if you or your family are not ill. To maintain good hand hygiene usually washing hands with soap and warm water is enough. However, if you cannot wash your hands e.g. on the train or grocery, hand sanitisers can be used.

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	In general, we find the cooperation with other EU Member States useful. It would be very advantageous if the information about the BRP article 95 list would spread outside Europe. Maybe OECD can help with that.
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	We found the information on pre-established recipes useful, but the products should be authorized according to the BPR.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	It is possible that products will stay on the market even if the emergency authorization or derogation is not valid anymore
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	Usually people are asking same questions and have common false beliefs. Therefore, a frequently asked questions (FAQ) forum on a web-site or social media could be applicable. We are often asked if a certain biocidal product is on the Finnish market. To search for information on chemicals on the Finnish market KemiDigi register can be used.
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	It is important that products having an emergency authorization or derogation would not be on the market after the authorization or derogation is not valid anymore.
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	/

3.7	Do you have any other suggestions?
Answer:	/

End of questionnaire

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Country name: Finland	and Organisation: Finnish Institute for Health and Welfare

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations / registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places

	→ the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	We have given the following guidance for controlling the airborne and surface born infection (coronavirus). If you get symptoms, go get tested for coronavirus and otherwise stay at home. Keep a distance of more than 2 meters to other people. Maintain good hand hygiene and follow the coughing etiquette. Wear a mask when you cannot keep a safe distance from others. Increase the ventilation rate. If this cannot be done mechanically, please open windows. Cleaning in workplaces to prevent coronavirus infection We have been developing cleaning guidelines together with Finnish Institute of Occupational Health. General cleaning in all type of premises Start cleaning from cleaner areas and proceed towards dirtier areas. All surfaces that are frequently touched (e.g. door handles, armrests, table tops, light switches, water taps) need to be cleaned thoroughly and frequently.

In public premises where people touch the surfaces, the cleaning should be done daily at least. If possible even more often e.g. between 2-4 hours especially during the epidemic.

The public premises of workplaces must be cleaned using different equipment than the premises used by employees.

Use a mildly alkaline all-purpose detergent for cleaning. The cleaning of sanitary facilities can be enhanced by using a disinfectant.

Wear gloves to protect the hands when cleaning surfaces. Use tight-fitting disposable gloves, for example, as all-purpose gloves, or chemical resistant gloves. Learn more about the instructions on how to remove gloves (in Finnish). https://www.ttl.fi/wp-content/uploads/2016/11/Malliratkaisu_Kertakayttokasineiden_riisuminen.pdf.

In particular, bins of bio- and mixed waste are coated with easily removable, leakproof bags in waste bins. Monitor waste bins and do not let them get more than three-quarters full. Waste bins are emptied daily, especially in public premises. The collected bin bags must be closed tightly.

Carefully clean the equipment used in cleaning at the end of the cleaning process. Wash reusable cleaning cloths at a temperature of at least 90°C or disinfectant. Clean your keys, the handles of the cleaning cart and the floor cleaning equipment and the contact surfaces of the cleaner containers with the disinfecting multi-purpose cleaner.

After cleaning, the permanent gloves must be carefully washed and dried. Disposable gloves are placed in mixed waste. Wash your hands up to your elbows with water and soap when the gloves are taken off.

Work clothes are changed to your own clothes before leaving the workplace. The work clothes must be washed at the workplace or your employer must acquire appropriate laundry services.

In the instructions there is chapter for cleaning the toilets, special cleaning for areas previously occupied by persons infected by persons infected with Covid-19 and in addition, how should cleaning workers protect themselves from viral infections. The guidelines are available from: https://www.ttl.fi/en/cleaning-guidelines-for-the-prevention-of-covid-19-infections%e2%80%af/.

Ozonisation

Ozonisation should not be used to control the coronavirus, as no scientific evidence is available on the effectiveness of this method against the virus. At worst, the use of an ozoniser may put your life at risk. Ozone itself causes acute health harms: chest pain, coughing, breathing difficulties and throat irritation. Ozone may also exacerbate asthma symptoms and weaken immunity. The chronic effects of ozone include triggering of asthma, hardening of arteries and shorter life expectancy. Prolonged exposure to ozone at high concentrations also increases mortality associated with respiratory diseases in older people. Additionally, ozonisation creates secondary impurities, which are harmful to health and can remain in indoor air for months or even longer.

There is no research evidence of the efficacy of ozonisation, even when performed in an ozone cabinet, against the coronavirus. This is why we do not recommend the use of an ozone cabinet to destroy the coronavirus.

In an ozone cabinet, ozonisation takes place in an enclosed space from which no leaks to the surrounding facilities should occur. Exposure to ozone and ozonisation by-products is thus unlikely. It is possible, however, that by-products of the ozonisation process spread into the indoor air from the cabinet when the door is opened. The adsorption of the by-products in the objects to be ozonised is also possible. In theory, exposure to ozone by-products is thus possible.

Photocatalytic coatings

The active ingredient in photocatalytic coatings is typically titanium dioxide, which is capable of oxidizing organic matter in the air. However, when used in the coating, there is no reliable evidence of the effectiveness of titanium dioxide against pollutant concentrations in room air.

The powder form of titanium dioxide is classified as carcinogenic category 2, ie it is suspected of causing cancer by inhalation (H351) (EU 2020/217). However, the classification only applies to titanium dioxide powder containing at least 1% of particles

with an aerodynamic diameter not exceeding 10 µm. When titanium dioxide is included in liquid or solid mixtures, titanium dioxide does not cause the mixture to be classified as carcinogenic. However, such mixtures may need to be labeled in accordance with Part 2 of Annex II to CLP with an additional labeling phrase. Liquid mixtures containing at least 1% of the abovementioned titanium dioxide particles must be labeled with the additional phrase EUH211 - 'Warning! Hazardous respirable droplets may be formed when sprayed. Do not breathe spray or mist.'

To minimize the risk to health, it should be demonstrated that the use of photocatalytic paints (coatings) indoors is safe, for example with measurement results showing that the amount of secondary products such as formaldehyde and acetaldehyde does not rise above harmful levels indoors. Measurements should take into account the effect of ventilation, dustiness of the premises, etc. on the formation of secondary products. If necessary, the manufacturer / importer should provide guidance on safe use.

Other biocides

Cleaning of premises and surfaces with disinfectants should not be used as a means of controlling the coronavirus in homes or premises where there is a regular stay (unless it is the living space of a coronavirus patient). Repeated handling of cleaning and disinfecting agents may cause for example skin and respiratory tract irritation. Disinfection tunnels and spraying of biocides in premises that are occupied should not be used, since it may pose a health hazard. Disinfectant should always be used on a clean surface. It must be acknowledged that biocide usage can produce different reaction products, some of which may be harmful and which may trigger a further reaction and produce more irritating and corrosive by-products. They may also be adsorbed into building and interior decoration materials or remain in indoor air for long periods of time. Using of biocides should always be considered on a case-by-case basis, and it should be carried out by a professional with appropriate precautions and in unoccupied premises. It is the responsibility of the operator to ensure that biocides are used safely, secondary products do not rise above harmful levels indoors and that the products are fit for purpose.

Air purifiers

An air purifier may be suited for reducing viruses in indoor air, as long as suitable cleaning techniques are used, and the equipment is maintained and positioned in the room to be cleaned appropriately.

The following section describes the advantages and disadvantages of different techniques. Studies indicate that mechanical filtration (HEPA and ULPA filters) and adsorption (including an activated carbon filter) remove particulate impurities, which also include viruses. These techniques do not generate harmful secondary impurities.

UV radiation is commonly used to destroy viruses in laboratories, the food industry and operating theatres. However, the secondary impurities created while using this technique should be taken into account, including ozone, which has been found to have adverse health effects. Photocatalytic oxidation and plasma disinfection are also used to destroy viruses, but these techniques, too, produce secondary impurities, including formaldehyde, acetaldehyde, nitrogen oxides and ozone. Electronic filtration is suited for removing particulate impurities, such as viruses, but harmful particles with an electronic charge, ultra-fine particles and ozone may be produced during their use. It should be noted that in the case of combined techniques, i.e. using mechanical filtration and adsorption in addition to one of the techniques listed above, the device may remove contaminants generated as by-products.

Ionizers, or air ionizers, are not suitable for virus control, as they are based on releasing ions into the air. Ions bind in particles, in this case the virus, and as the result the viruses become charged. The charged viruses may attach to such surfaces as walls, floors, and furniture.

Extreme care should be taken when placing the air purifier in a room. It must be ensured that there is no bypass in the air purifier, but that all the air passing through it is filtered. You should also ensure that the air flow direction in the device is correctly adjusted: not ‘from dirty to clean’, causing such impurities as viruses to spread around the room. Any areas which the air purifier cannot reach should also be taken into account, providing a sufficient number of devices and positioning them correctly. Care should be taken to maintain and clean the equipment (including replacing the filters frequently enough).

	Ventilation Good indoor air quality supports health and well-being. Well-functioning ventilation is also important in removing any contaminants including viruses in the indoor air. There are several ways you can improve your ventilation performance. For example, in a home and other living space, ventilation must be uninterrupted. If there are no occasional users in such a space, the power can be reduced, but ventilation should not be shut off completely. In a space that is not used continuously, ventilation should be started in the building two hours before the space is used and closed two hours after the end of use. This is also good to keep in mind when using the space in the evenings or on weekends (This is the instruction in Finland, since the ventilation is typically on adequate level). Ventilation supply air must be outdoor air and must always be dimensioned according to the occupancy of the room. Air should travel from clean rooms to dirty rooms. Return air should be avoided to prevent the possible airborne transmission of viruses from one space to another. Minimum ventilation levels must be observed in accordance with regulations. For example the ASHRAE recommendation in "normal situations" is 7-10 l / s / person, where ECDC refers to COVID ventilation guidelines. According to the guidelines of WHO, in hospital wards and individual hospital rooms where COVID-19 patients are treated, the ventilation factor should be at least 12 1 / h (new building) or at least 6 1 / h (old building) and in a vacuumed isolation room at least 12 1 / h. When performing treatment procedures that generate aerosols, the air flow should be 160 l / s / person in rooms with gravity ventilation. Similarly, in rooms with mechanical ventilation, the ventilation factor should be 6 to 12 ventilations per hour, preferably 12 ventilations per hour in new buildings. The recommended pressure difference ≥2.5 Pa to ensure that air flows from the corridor to the patient room. If the technical air characteristics of the ventilation unit cannot be adjusted in accordance with the regulations, the supply air can be adjusted to the maximum output. Always make sure that the adjustments you make do not impair the ventilation. If the ventilation cannot be adjusted efficiently enough, the room can be ventilated for a short time, preferably in a cross-section, weather permitting. Ensure that the ventilation systems are working properly: replace the air filters at normal replacement intervals and clean the ventilation ducts regularly. Climate, cultural or economy depending factors Climate has a major impact on building design, including ventilation. In cold climates, window ventilation is challenging. In this case, it is easier to recommend more efficient mechanical ventilation. In the Nordic countries, mechanical ventilation is the most common type of ventilation, especially in new buildings. This differs from the ventilation system in many areas of the world where gravity ventilation is the most common method. On the other hand, the investment in the usage and efficiency of mechanical supply and exhaust ventilation is expensive. Also, different air filtration technologies can be a great investment. The prevalence, marketing and control of the use of biocides can vary greatly around the world. Therefore, changing attitudes to follow common guidelines can be challenging. In Finland, biocides are generally very rarely used especially in households. According to our HITEA study, Finnish schools did not use disinfectants at all in classroom cleaning, while in Spain they were clearly more commonly used. In the Netherlands the usage was minor. At the same time the microbial exposure was lowest in Finland.
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	It is important to compile an information package on the guidance provided by Member States' expert representatives, based on current peer-reviewed scientific research and

	international guidelines. This information package requires the approval of a representative from each Member State. This information package should be easily accessible to all.
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	
2.3	Do you think that a "pragmatic approach' to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a "pragmatic approach" could constitute in your country
Answer:	
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	American Biological Safety Association. SARS-CoV-2/COVID-19 Toolbox. Available from: https://absa.org/covid19toolbox/ American Society of Heating Refrigerating and Air-Conditioning Engineers (ASHRAE). Position Document on Filtration and Air Cleaning [updated 29 January 2015]. Available from: https://www.ashrae.org/file%20library/about/position%20documents/filtration-and-air-cleaning-pd.pdf

	ECDC. Heating, ventilation and air-conditioning systems in the context of COVID-19: first update. Saatavilla osoitteesta: https://www.ecdc.europa.eu/sites/default/files/documents/Heating-ventilation-air-conditioning-systems-in-the-context-of-COVID-19-first-update.pdf Finnish Institute of Occupational Health. Cleaning quidelines for the prevention of Covid-19 infections. Available from: https://www.ttl.fi/en/cleaning-guidelines-for-the-prevention-of-covid-19-infections%e2%80%af/ Government of Canada. Biosafety and Biosecurity. Available from: https://www.canada.ca/en/services/health/biosafety-biosecurity.html REHVA. 2020. How to operate HVAC and other building service systems to prevent the spread of the coronavirus (SARS-CoV-2) disease (COVID-19) in workplaces. REHVA COVID-19 guidance document, August 3, 2020. Available from: https://www.rehva.eu/fileadmin/user_upload/REHVA_COVID-19_guidance_document_V3_03082020.pdf WHO. 2020. Severe Acute Respiratory Infections Treatment Centre Practical manual to set up and manage a SARI treatment centre and a SARI screening facility in health care facilities. Available from: https://apps.who.int/iris/bitstream/handle/10665/331603/WHO-2019-nCoV-SARI_treatment_center-2020.1-eng.pdf?sequence=1&isAllowed=y
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	Public communication is needed to raise awareness how to prevent droplet spreading as well as air- and surface-mediated spread of the coronavirus. On the other hand, there is a need for education of the possible harmful effects of biocides and various air purification techniques (chemical) on health and various materials. This can be done through national communication campaigns e.g. through press releases, webpages, social media, through a child-care clinic, home care or social system. Interpretation to immigrants, hearing-impaired and visually impaired persons is very important. In Finland, the social media and infographics have reached the public widely. Also roadside advertisement and info boards in public transportation, shopping centers etc. have found to be very effective way to reach the public. In our webpages we have also provided freely printable material packages about social distancing, hand and coughing hygiene, wearing mask etc. This could be very useful way to inform people also about biocides. Different parties can print and offer these materials freely to their customers.

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	Communication between national and international actors involved in the registration of biocidal products can be improved by establishing a close network at national level (representatives of experts from different institutions), which regularly discusses emerging cases, provides national guidance and disseminates information internationally. Regular contact with the international network, for example through a regular network working group meeting, is very important.
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	We have received many contacts from the media, employers and citizens regarding the use of ozonization and other biocides to prevent the spread of the coronavirus. Questions have also been raised regarding individual products. In addition, we have been contacted about the use of various air purification methods in buses and schools, for example. At the same time, companies marketing biocides and air purifiers are approaching quite aggressively in marketing purposes. We have compiled answers to the most common questions on our website, which is addressed to authorities and citizens. We have also created an internal database in which all contacts and

	instructions are registered. We have appointed experts from various fields as contact persons to answer to the contacts from public and media.
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	
3.7	Do you have any other suggestions?
Answer:	

End of questionnaire

Name respondent: Mark Montforts and Email: mark.montforts@rivm.nl

Country name: Netherlands on behalf of the Dutch Ministries, the Board for the Authorisation of plant protection products and biocides, and the National Institute of public health and the environment.

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	1. Availability of effective disinfectants a To ensure that the disinfection products on the market were effective against Covid-19 and sufficient product was available for the high demand. Shortages lead to many requests for advice on which alternatives to choose, how to adapt procedures and how to prioritize allocation (e.g. health care first). This also involved dealing with shortages in raw-materials like denaturalised alcohol and packaging materials. b This included both the challenge to provide timely emergency derogations for disinfection products trusted to be effective, as well as the enforcement of products not fulfilling the requirements of these emergency derogations nor being authorised products against (enveloped) viruses. Dealing with many new producers without any previous knowledge or experience with the BPR, REACH and/or CLP regulations was a challenge. In many cases answers were not readily available or required multi-party cooperation. 2. Ensuring safe and effective products were used correctly a Preventing non-essential use in situations where cleaning or washing of hands was deemed sufficient to prevent Covid-19 infections. b Ensuring correct use, e.g. when dispensers are used and the instructions on the packaging cannot be accessed by the individual users. c Differentiating in professional and non-professional users in cases where disinfectants are used in places where both professional and non-professional users visit, like shops, sport clubs and schools. d With respect to worker safety (professional use): To ensure that the legal information to the users of the allowed disinfection products enables both employers and workers to take necessary measures in accordance with Working conditions Act and provisions. For instance correct classification and labelling should be clear (to warn them and this also triggers certain legal obligations under the Working Conditions Act and provisions). Workers under 18 yrs are not allowed to come into contact with carcinogenic, mutagenic and reprotoxic substances. Also keeping record of the personal exposure to disinfection products is obligatory for carcinogenic and mutagenic substances.
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations?

	Under what circumstances or for what product types have you applied agile processes?
Answer:	Yes, there are processes available like emergency derogations to allow products on the market that are not yet authorised (in the Netherlands all biocides need authorisation under National Law or the BPR before being marketed). The NL government issued emergency derogations for PT1 and PT2 disinfectants for use against the Corona virus. That means allowing already authorised products without virus claim to be used against the Corona virus and allowing non-authorised disinfectants to enter the market for use against the Corona virus. From March 2020 till March 2021, several emergency derogations were given for hand disinfection and surface disinfection for formulations known to work against Covid-19 (for hand disinfection this included the WHO formulations). A separate derogation was provided for authorized disinfection products to lift some restrictions in the authorizations, including 1) in packaging other than that specified in the authorization; 2) produced at locations other than specified in the authorization; 3) provided with a label, other than in the Dutch language, in English; 4) supplied in ready-to-use dilutions instead of concentrated formulations. For the shortages of denaturalized ethanol the Dutch tax authorities granted permissions to temporarily use consumption alcohol without the obligation to pay excise duties. Also emergency derogations were given for fuel additives for aircraft fuels, to prevent growth of micro-organisms in fuel tanks of aircrafts that are not in use because of the pandemic. In order to manage flow of new products to the market an electronic notification form was made available. The inspectorate saw over one hundred notifications for new products. Most were eligible under the generic derogation, several concerned unauthorised products. Issues with composition, labelling, and allocation (the generic derogation was for professional use only) had to be solved quickly. Limitations: • Derogations are temporary emergency measures. For long term solution, ample regular authorizations are needed to enable sufficient disinfection products for (enveloped) viruses. Many authorized products did not have an (enveloped) virus claim in their authorization. Therefore we communicated that from March 2021 only derogations were given to disinfection products for which an application to the Dutch Board for the Authorization of Plant protection products and biocides was submitted. These derogations are still limited to formulations known to be effective against viruses = same formulations as in the previous derogations. • The process for emergency registrations requires input from experts. Advice on effectivity of substances and applications takes time and calls for quick access to data.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	Normal procedures for authorisation of biocidal products take 1-3 years. Once under the BPR all active substances have been assessed and thus the BPR is fully in effect, the mutual recognition of products could speed up the process, provided that products with appropriate efficacy claims are on the market.
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	Above (1.2) we mentioned some ad hoc measures that were possible under the current legislation.
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc.

	Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	In the Netherlands, the government issued generic derogations for disinfectants, , whose efficacy and safety could be carried out with a shortened and accelerated assessment and could be produced in large quantities within a short period. For preservatives for aircraft fuel ECHA made a risk assessment for substantiating a derogation, which could be used by all member states. Such a centralised assessment is efficient and helps harmonisation. How to deal with innovations / innovative techniques during a crisis needs attention. During a crisis there is little time to get acquainted with new techniques or (disinfection) methods that might be useful, but could be ineffective in hindsight. Testing innovations comes with risk (of losing valuable time) in times where you would rather be safe than sorry. Procedures should include all actors, and these actors should be informed in advance, about what contribution is expected in what time frame.
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	From the Public Health point of view, cleaning is an equal part of breaking the chain and should be added to all instructions and policies. It is the first step, after which to determine if an additional step of disinfection is required. Our suggestion is to clarify that non-targeted disinfection like disinfection of open spaces, roads, outdoor street furniture, people at entrances, etc. does not contribute to stopping the spread of viruses like the Corona virus. It may even provide a false sense of security and elicit careless behaviour. Targeted disinfection with the aim to break the chain of infection is a much more effective and efficient way of disinfection with less negative impact on human health, the environment and the development of resistance.
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	Early stage contact with the association of manufacturers and with the umbrella organisation of user groups (e.g. healthcare) to align expectations is needed. In the Netherlands, the Ministry of Health signed a letter of intent with certain members of the Dutch association for detergents, maintenance products and disinfectants to prioritise the supply to health care settings. Above (1.2) we mentioned some ad hoc measures to enable timely supply, that were possible under the current legislation.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved

	information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	Efficacy is the first issue to deal with when it comes to disinfectants. So, for every product used it must be clear that it is efficacious against the organism that needs to be controlled. During an emergency it might be beneficial to have a central point where all efficacy data of products now currently stored in closed databases can be viewed by a central body / authority. For simple disinfectants based on active substances like ethanol, sodium hypochlorite and hydrogen peroxide, general data on efficacy as available in general literature can be used for assessing efficacy in case of an emergency derogation. However, during emergencies a lot of scientific publications on efficacy become available. Also the review of these publications on harmonised criteria could be beneficial and coordination who makes these evaluations.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	The Netherlands has a full authorization requirement before disinfection products can be placed on the market, both under the Biocidal Product Regulation (BPR) and under transitional legislation (products based on active substances not yet approved by the European commission but still under review). We have the experience that industry is aware of the requirements of the BPR, but is not always aware of the transitional law. This is not limited to COVID but also a general observation. In time, when all active substances have been reviewed and when approved under the Biocidal Products Regulation, this should be solved. The COVID situation however brought many new parties to the table, who had no experience with the BPR. For that reason, an electronic notification form was launched. We also noticed that the borderline with the Cosmetics regulation, for example hygienic hand rubs targeting consumers, also created a challenge.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	Communication to the public is important. Many stakeholders, organizations and branches create recommendations independently. Manufacturers and commercial parties can advocate the use of products in circumstances that deviate from the desired application. Clear guidance should be provided by governmental organizations. Hand hygiene should be presented in such communications being the first and often sufficient step. General knowledge about for instance 'targeted disinfection' should be available for Competent Authorities and governmental organisations that provide advice. For instance, in the form of a scenario document for emergency issues concerning outbreaks of contagious micro-organisms in society. What to do and what not to do?
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	Developing basic and easy to read scenario documents for governments and for the general public, explaining ways to effectively prevent contamination. There is an overlap with what WHO does.
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.

Answer:	The database of efficacy data on individual products authorised proved to be very useful to provide emergency authorization based on generic formulations besides the WHO formulations. We think that once all active substances are reviewed and products are authorized under the European biocidal product regulation, it will be easier to access all data available in Member states and thus can more easily be shared with other countries or OECD.
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	For the anticipation on future outbreaks, it is necessary that sufficient products are authorized and proven to be effective against a broad spectrum of microorganisms. Now there was a limited number of products with a proven (enveloped) virus efficacy. This will allow both government and industry to have more products already on the market that can increase their production capacity during outbreaks with proven efficacy.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	It might be beneficial to have a system where authorisation holders and firms that bring disinfectants to the market are obliged to annually report the quantities of active substances and/or disinfectants that they bring to the market. These figures help to find out not only which products are available in the market, but also how much of those products is available. Regarding a level playing field one can only go so far, as already authorised products have paved the way for 'easier access' to the market. We do not accept blanket registrations due to level playing field among producing companies
2.3	Do you think that a "pragmatic approach' to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a "pragmatic approach" could constitute in your country
Answer:	No, there cannot be any compromise when it comes to proving efficacy of disinfectants. The only suggestion is that for simple formulations, efficacy data from general literature can be used. As described above, we should already anticipate on future outbreaks, and ensure that a sufficient number of products already has a proven efficacy in their regular authorization.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.

Answer:	This sounds like a task for WHO. Although we can envisage that OECD provides expertise on the use of disinfection methods and products.
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	Yes. Improved information must be provided to the public (and other parties like retail) that should lead to an increased awareness and better understanding of the function, necessity and risks of (lack of) proper hygiene and disinfection. It should be made clear when disinfection is needed and when proper hygiene (with water and soap) suffices. When disinfection is required, the public should become more aware of the importance to follow the instructions of use – especially regarding contact time. Perhaps it should be part of education? Besides ensuring correct and sufficient content of the given information, more attention there should be given to ensuring that this information is also received and understood by the target audience.

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	/
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations for use in blanket authorisations in times of crisis? (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf). Please provide suggestions for what would need to be included in such a guidance.
Answer:	Yes, regarding the temporary emergency derogations this would be useful (we would not give blanket authorisations for products)..
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	In the Netherlands, the prolongation of emergency derogations is connected to measures to return to the normal situation of authorised products only, by requiring that only products for which an official application for authorisation is submitted were eligible (being based on the same formulations previously derogated).
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	It would probably be best to make use of (social) media to actively inform the public, rather than trust that they will look for advice e.g. on the RIVM website. It is not easy to reach the public, while at the same time other parties (e.g. retail) also communicate with their customers about their customer-oriented measures for a safe 1.5m society.
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	A rethink on effective ways of using disinfectants in large scale pandemics. Prevent ongoing regular use of disinfection products when disinfection has no additional benefit to cleaning or washing hands to prevent resistance against the active substances. And instruct users of correct use of disinfectants.
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis?

	Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	/
3.7	Do you have any other suggestions?
Answer:	/

End of questionnaire

Name respondent: Johan Helgesson	Email: johan.helgesson@kemi.se
Country name: Sweden	Organisation: The Swedish Chemicals Agency

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	Find out which legal actions that are applicable and make the necessary adoption of national legislation. Decision making under tight time pressure. Keep an updated status on the general needs of disinfectants in all sectors in the society.
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	In the BPR, time limited derogations from the requirements in the legislations may be granted due to emergency situations. In SE derogations according to the BPR have been granted for disinfectants in PT 1, 2, 3 and 4. A temporary exemption from the linguistic requirements was applied for products used by professionals, so that the SDS and product label did not have to be labelled in Swedish. This made relabelling of the packaging unnecessary given that the information was provided electronically to the user. As there was a shortage of labels/inks and packaging materials, this measure facilitated the use of imported products being labelled in foreign languages.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	1,5-3 years for a biocidal product with the condition that the active substance is approved in the relevant product type.
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	A temporary position not the enforce the requirement of article 95 to accept manufacturing and selling of disinfectants without the suppliers being on the Article 95 list was applied, as there is no legal possibility to grand derogations from the article 95 requirement in the BPR.

1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	/
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	/
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	/
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	/
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	/
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	/
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?

Answer:	/
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	/
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	Nationally, we had issues in determining which official body that have the main responsibility for assessing the overall national situation regarding disinfectants, and to provide updated information on the demand and on the risk for shortage in different sectors in the society. There have however not been any issues related to the regulatory responsibility to decide on derogations from the requirements in the BPR.

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	The position not to enforce article 95 made it possible for alternative manufacturers, such as distilleries and biofuel industries, to produce large volumes of disinfectants. The requirement in article 95 should otherwise have significantly reduced the available amount of active substance. Thus, in a future revision of the BPR, we consider it should be possible to also waive the requirements of article 95 due to a crisis. The exemptions granted in accordance with article 55 of the BPR were initiated by the competent authority, so no need for the manufacturers or producers of disinfectants to submit product specific applications. We found this approach to be both time and cost efficient. The exemptions granted were substance specific and not product specific, which made it possible for manufacturers to utilize the exemptions for all their products provided that the general requirements specified in the decision were met.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	/
2.3	Do you think that a “pragmatic approach’ to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a “pragmatic approach” could constitute in your country
Answer:	Yes, in some situations it would be necessary to apply a pragmatic approach. This could perhaps be based on best available knowledge on what type of disinfectant that normally is used for a certain group of microorganisms, i.e. enveloped and non-enveloped viruses. Such information (incl. information on minimum use concentration etc.) could be complied by the health authorities and be made publicly available.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.

Answer:	Such a compendium could be useful, but we do not have any relevant guidance to provide at the moment.
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	/

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	/
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	It is important to establish a minimum concentration for products to be effective against pathogens. However, the recipes should not be too specific and only focus on the active substance, as this otherwise might hinder products that are effective to be used and limit the total availability of disinfectants in a crisis situation.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	Companies with products that have been authorised might encounter a competitive disadvantage as the competitive products are not put on the market under the same terms.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	Compile and update Q&A and make such information publicly available as soon as the situation emerge.
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	/
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	/
3.7	Do you have any other suggestions?

Answer:	/

End of questionnaire

Name respondent: CHMELIKOVA Jana	and Email: jana.chmelikova@mhsr.sk……..
Country name: Slovakia (SK)	and Organisation: Ministry of Economy of the Slovak Republic

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	Insufficient biocidal active substances production capacities of those subjects listed in Art. 95 Biocidal Products Regulation (BPR) list of suppliers resulting in bans on export of core biocidal active substances and biocidal products in several EU countries and in focus on national interests. A lack of EU-wide BPR mechanism for coping EU-wide pandemic situation. Increase of the amount of national helpdesk inquiries, applications for biocidal product registrations and permits under art. 55(1) BPR during extremely short time period. A lack of understanding of biocidal products regulation and questioning significance of efficacy proofs at registrations stage by new subjects entering the biocidal products market.
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	Ethanol and several other biocidal active substances are still under review in EU and thus transitional measures at national level still apply for biocidal products comprising those actives. Processes under national transitional measures proved to be agile to respond such emergency. Also mechanism of emergency permits under Art. 55(1) BPR proved to be agile process to respond to such emergencies. Insufficient biocidal active substances production capacities of those subjects listed in Art. 95 BPR list of suppliers and bans on export of core biocidal active substances and biocidal products in several EU countries represented limitations relating to said national transitional measures and emergency permits. During certain period of time active substances were supplied outside sources listed in Art. 95 BPR list of suppliers. Furthermore, existing processes are as agile as an authorization/registration body is equipped with sufficient amount of personnel and experts. Product types 1 to 5 were prioritised over other products types and products types 1, 2 and 4 prevailed in the agile processes.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	Standard timelines for registration under transitional measures and permits udder Art. 55(1) BPR vary depending on completeness and complexity of documentation

	supporting the application and efficacy claims claimed on draft labels between 15 to 30 work days. In exceptionally cases - low quality documentation and/or complex cases timelines for registration the timelines depend on responsiveness of the applicant. During the worst phase of increased amounts of registrations and permits our timelines were 2-5 work days, which was possible only by involvement of the almost every member of our work team in transitional measures and permits udder Art. 55(1) BPR, by streaming administrative procedures and by temporary termination of other tasks.
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	No suggestion.
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	No suggestion.
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	No suggestion.
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	By immediate amendment of national rules national producers of ethanol – distillers - were allowed to supply ethanol for biocidal products production purposes. National producers of ethanol decides to apply for Art. 95 BPR listing.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.

Answer:	No suggestion.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	Clear and concise web page in national language increases awareness about where to find regulatory requirements for bringing products on the market. A single phone and single email contact for national helpdesk published at the web page proved as very helpful for industry.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	No suggestion.
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	No suggestion.
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	Transitional measures and Art. 55(1) BPR permits facilitated our ability to respond to the Covid-19 crisis.
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	The registration/permit holders were not able to meet Art. 95 BPR requirements for a certain period of time and thus Art 95 BPR was violated. Emergency mechanism in relation to Art. 95 BPR should be introduced in BPR.

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	We believe that actions - fast-track registrations and permits, temporary termination of "non-urgent" tasks and participating all available staff at emergency registrations and permits and helpdesk related thereto - to deal with the disturbance of the supply chain have been successful. Strengthening of the amount of personnel is needed.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	No suggestion.
2.3	Do you think that a "pragmatic approach' to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a "pragmatic approach" could constitute in your country
Answer:	A "pragmatic approach' to efficacy testing should be allowed in times of crisis. Registrations and permits based on WHO/OECD guidances on the use of pre-established recipes.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	No suggestion.
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	No suggestion.

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	No suggestion.
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	Yes, in our opinion such a guidance on the use of pre-established standards/recipes would be very helpful. However it should be available in national languages. Biocidal products where specified efficacy claims were tested and reliably proved should be included.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	There are annual fees (annuity) under transitional measures and thus holders are forced reconsider the transitional registration annually. Permits under Art. 55(1) BPR may be granted only for maximum 180 days. If not extended or re-granted they expire.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	As a registration and authorisation body we mainly dealt with questions of the industry and prospective applicants. Information in national languages would be very helpful towards the public.
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	No suggestion.
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	No suggestion.

3.7	Do you have any other suggestions?
Answer:	No other suggestion.

End of questionnaire

Name respondent: Richard :Lomax	and Email: ……Richard.lomax@hse.gov.uk
Country name: United Kingdom	and Organisation: Health and Safety Executive

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	1. Ensuring enough manufacturing sources of disinfectant active substances are available 2. Ensuring enough effective disinfectant products are available (where the active substance has been approved). Some of the efficacy testing has been poor due to being carried out by new, inexperienced companies; this has caused delays. There have been some issues with certain test guidelines (EN1500) that require volunteers, and have therefore need to be adapted during the pandemic. 3. Keeping manufacturers and suppliers of disinfectants informed of regulatory requirements and developments.
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	1.The UK has a formal process for issuing temporary derogations from the regulatory requirement for biocidal products to be authorised, in situations where a danger to public health cannot be controlled 2.The UK also has a formal process for issuing temporary derogations from the regulatory requirement for an active substance to have been approved, in situations where a danger to public health cannot be controlled
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	1.Processing application for new manufacturing source of an active substance (i.e. “Article 95” listing): a few months 2.Demonstration that a new manufacturing source of an active substance is technically equivalent: a few months 3.Processing application for approval of a new active substance: typically 21 months 4.Processing application for a new product based on a previously approved active substance: typically 12 months
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges

	outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	3.The UK has no formal process to derogate from the regulatory requirements for manufacturing sources of active substances to be included on a positive list ("Article 95"), and has taken a pragmatic and proportionate approach on regulating the supply of active substances.
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	HSE has received questions from stakeholders and media organisations about the use of novel techniques and application methods, but considers that regulatory decisions should be based on evidence or a robust justification.
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects. If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	HSE does not recommend spraying individuals with disinfectants (such as in a tunnel, cabinet, or chamber) under any circumstances. We consider that this practice could be harmful to health and would not reduce an infected person's ability to spread the virus through droplets or contact. Even if someone who is infected with COVID-19 goes through a disinfection tunnel or chamber, our view is that as soon as they start speaking, coughing or sneezing they can still spread the virus. HSE has also received questions from stakeholders and media organisations about the use of such application methods to disinfect indoor and outdoor public spaces. However in general evidence to demonstrate that they prevent transmission of COVID-19 and are safe has not been available.
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	Manufacturers of other products (e.g. alcoholic drinks) have repurposed to supply active substances for the manufacture of biocidal hand sanitisers.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use

	of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	HSE considers that for efficacy testing, in general previously agreed standards should still be met. Therefore, if manufacturers perform these it should eliminate doubt. However, we think that the strategy used by the WHO to share formulations was useful. Since a lot the hand sanitisers were similar in formulation perhaps a similar approach where data could be shared more easily for similar products could be adopted.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.
Answer:	We think this is relatively well known for the UK but, again, a lot of the applicants were very inexperienced.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	We look forward to these questions being resolved.
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	We look forward to these questions being resolved.
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	Requirement in biocides legislation for active substance suppliers to be included on a positive list ("Article 95 list") limited the supply of active substances for manufacture of disinfectant products in the early stages of the pandemic. Similarly regulatory requirements from customs and excise legislation initially limited the manufacture of alcohol-based hand gels from denatured alcohol and duty-free spirits.
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	Biocide legislation shares boundaries with other types of product (medicines, cosmetics, general chemicals). A significant number of manufacturers have requested clarification of the regulatory status of individual products and queried different regulatory requirements and . In addition many products within the scope of biocides legislation were not yet subject to authorisation due to transitional arrangements – this had both advantages (easier to get products to market) and disadvantages (less regulatory oversight)

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	HSE considers that the measures taken to increase availability of hand sanitisers were successful, in that we have not (since the early stages of the pandemic) had any reports of shortages.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	/
2.3	Do you think that a “pragmatic approach’ to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a “pragmatic approach” could constitute in your country
Answer:	The UK has tried to use a pragmatic approach to efficacy testing, and has been open to discussing deviations with applicants throughout, although most have opted to stick to the testing EN testing listed in guidance.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	/
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	/

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	Ad hoc meetings
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	Information from the WHO on hand rub formulations based on ethanol and propan-2-ol has been very useful in identifying hand sanitiser products which are effective against the virus causing COVID. For active substances which are more chemically complex than simple alcohols, information on the maximum content of impurities would be beneficial.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	The sheer volume of enquiries from prospective applicants that the UK biocides helpdesk had to deal with has been challenging. We consider that the lessons learned are to ensure that sufficient staff are available to deal with a huge and sustained surge in enquiries, and to keep websites and e-bulletins up to date with regulatory changes.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	/
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	Identification of criteria for withdrawing emergency use derogations and returning to previous regulatory regime.
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	Organising ad hoc meetings of regulators and relevant stakeholders

3.7	Do you have any other suggestions?
Answer:	/

End of questionnaire

Name respondent: …Kristen Willis	and Email: willis.kristen@epa.gov
Country name: …… United States	and Organisation: Environmental Protection Agency……

Question 1: What were/are your issues during the Covid-19 situation (Examples: availability of disinfectants, emergency procedures or fast-track registrations, concerns about efficacy of products, etc.) and what did you do about it (Example: procedures for emergency situations, etc.)?

nr.	Question
1.1	What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? Please list those difficulties in order of importance.
Answer:	1. Approval of disinfectant products effective against SARS-CoV-2 and review under expedited time frames. 2. Novel product types for which standards and efficacy testing methods do not exist (e.g., air treatments, long lasting coatings) and emergency exemption requests for these products. 3. Communication on safe and effective use of disinfectants and challenges for sensitive populations (e.g., children, individuals with asthma) and the volume of inquiries from stakeholders. 4. Enforcement and compliance activities related to the sale and distribution of fraudulent products or products making false and misleading claims and extending flexibilities for compliance under certain circumstances in particular for agricultural workers (e.g., access to fit tests for respirators). Both civil and criminal enforcement activities were undertaken during the pandemic. 5. Availability of disinfectant end use products and active ingredients. Supply chain disruptions were particularly challenging for quarternary ammonium-containing disinfectants as well as isopropyl alcohol-based food contact sanitizers. 6. Coordinating response with state, regional and federal partners. 7. Availability of PPE, laboratory supplies and materials, as well as equipment for SARS CoV2 laboratory studies (BSL-3).
1.2	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)? If so, kindly indicate any limitations relating to emergency authorizations/registrations? Under what circumstances or for what product types have you applied agile processes?
Answer:	Yes. Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizes EPA to allow Emergency Exemptions (also called “Section 18s”) for unregistered uses of pesticides to address emergency conditions. Under such an exemption, EPA allows limited use of the pesticide (including antimicrobial products) in defined geographic areas for a finite period of time once EPA confirms that the situation meets that statutory definition of "emergency condition." The regulations governing Section 18 of FIFRA (found at Title 40 of the Code of Federal Regulations, part 166 (40 CFR 166)). Under Section 18, EPA conducts assessments of potential risks to human health and the environment to confirm the pesticide use meets the required safety standards and specific to the public health exemptions for COVID-19, included review of efficacy data. Emergency exemptions are time limited and are typically approved for

	up to 1-year. Section 18 exemptions can only be requested by state or federal agencies and can not be requested by industry or company representatives. EPA approved several emergency authorizations in response to the pandemic. The first approved in August 2020 and amended in January 2021, was for a coating that provided long-lasting antiviral efficacy on hard nonporous surfaces. The second approval in January 2021 was for a product used to treat air in indoor occupied spaces where social distancing was not possible. EPA is considering several other applications from other states in the US. In addition, while not considered legislation, EPA was able to leverage specific guidance for emerging viral pathogens (EVPs) that was finalized in 2016. Under this guidance, EPA allows manufacturers to provide the agency with data, even in advance of an outbreak, to show their products are effective against harder-to-kill viruses. Once approved, these companies can make non-labeling marketing claims (e.g. websites, social media) for use against the novel virus, in this case SARS-CoV-2. EPA activated the emerging viral pathogens policy for SARS-CoV-2 in January 2020 and companies were able to immediately make these off label claims. EPA began expediting the addition of new EVP claims in March 2020. These reviews typically were completed in under 30-days and did not require the review of new efficacy data. Beginning in May 2020, EPA began expediting reviews that required review of new data (e.g., new products and new claims). In order to qualify for expedited review, products had to be eligible for inclusion on EPA's List N; a list of disinfectant products effective against SARS-CoV-2 first published in March 2020. In order to qualify for a List N, products have to meet one or more of the following requirements: (1) Demonstrated efficacy against the coronavirus SARS-CoV-2 (COVID-19), (2) Demonstrated efficacy against a pathogen that is harder to kill than SARS-CoV-2 (COVID-19), (3) Demonstrated efficacy against a different human coronavirus similar to SARS-CoV-2 (COVID-19) List N currently has over 535 products. Currently, EPA is co-chairing a stakeholder workgroup to provide a retrospective analysis of the strengths and weaknesses of the first use of the emerging viral pathogens guidance and provide recommendations for improvements to address the current ongoing and future public health emergencies.
1.3	In the absence of agile processes, what are the standard timelines for registration/authorization? (e.g., disinfectants, sanitizers, coatings with long lasting effects, etc.)
Answer:	The standard statutory review time frames for registration actions that require the review of new data range from 4-months for amendments to existing registered products (e.g., add a claim for a harder to kill virus) to several years for products with new active ingredients. Product registration for new products with existing active ingredients is 7 + months. Applications that included new uses for which EPA has not done risk assessments will extend the time frame for registrations beyond the 7-months. EPA also has a process to review novel protocols such as for surface coatings with long lasting effects. The review time for the protocol is 3-months. The company would then use that protocol to generate data to be used for product registration.
1.4	In the absence of agile processes, what interim measures/interim orders or changes in legislation or policy have been considered to respond to the difficulties/challenges outlined in question 1.1 (e.g., flexible substitution of a formulant, fast track registrations)?
Answer:	1. Supply chain flexibilities: To address supply chain issues, throughout spring 2020, EPA created flexibilities for manufacturers by temporarily allowing registrants to notify EPA of certain formulation and manufacturing facility changes and immediately release the product for sale without waiting for EPA approval. These flexibilities communicated through 3 amendments to Pesticide Registration Notice 98-10 extended to certain active and inert ingredients and allowed companies to be able to switch suppliers without waiting for EPA approval. EPA will continue to assess the need for these flexibilities and a provide a minimum 7-day notice prior to termination. 2. Expedited registration: In March 2020, EPA began expediting review of new emerging viral pathogens claims that did not require new data review. In May 2020, EPA began expediting review of new products and amendments to existing product labels that

	require the review of new efficacy data. In July 2020, EPA began to expedite applications to add directions for use with electrostatic sprayers to products intended to kill SARS-CoV-2. EPA aimed to expedite review time frames 1-2 months faster than statutory time frames. 3. Memos affecting worker protection: In Spring/Summer 2020, EPA issues three memos that impact worker protection in the agricultural pesticide sector. These three memos include: • Statement Regarding Respiratory Protection Shortages and Reduced Availability of Respirator Fit Testing Related to Pesticide Uses Covered by the Agricultural Worker Protection Standard during the COVID-19 Public Health Emergency • Guidance on Satisfying the Annual Pesticide Safety Training Requirement under the Agricultural Worker Protection Standard during the COVID-19 Emergency • Guidance Regarding the Certification of Pesticide Applicators during the COVID-19 Public Health Emergency Similar to the supply chain flexibilities, these measures are intended to be temporary and will sunset at some point in future. 1. Guidance for novel long-lasting products- EPA published new guidance and interim test methods for long-lasting coatings/paints in October 2020 and announced expedited review for these product types. EPA received public comments on the initiative in January 2021; EPA is currently reviewing the comments and plans to adjust the guidance as deemed appropriate. It is anticipated the final guidance and methods will be finalized by September 2021.
1.5	Can we formulate suggestions to streamline the response process for future cases? These suggestions can include improved communication between authorities and stakeholders, standardised wording for interim measures/interim orders, etc. Should such suggestions include novel techniques or biocide products, devices or application methods (e.g., fogging, electrostatic spraying)? Please list your suggestions.
Answer:	It would be useful to have a repository of methods/guidance as well as a list of data requirements for novel product types, devices and/or application methods along with appropriate contact information for different member countries. In that way, when one country faces an issue they have a base of information and experts that they can rely on. It may also be useful to develop a "best practices" guide for future pandemic/emergency situations to include different areas that biocide regulatory agencies/member countries should consider. This could include sample interim measures though it is important to acknowledge that different regulatory frameworks have some unique considerations. This best practice guide could include a guide for country specific regulatory requirements for imports/exports to be shared with OECD member countries. It is important to establish that just because a product is registered in one country, that same registration may not be applicable in another country.
1.6	Can we formulate suggestions of what would constitute a space open to the public, and if a specific behaviour or action is warranted to manage different types of spaces open to the public, i.e. by disinfection, behavioural action, prohibition, others? Situations that can be considered include amongst others: → coatings/paints with long lasting residual efficacy used in such places → the requests to add a new method of application (i.e. fogging, electrostatic sprayer) to currently authorized or new disinfectants or sanitizers → position of the use of drones to apply biocides in large spaces whether indoor (i.e., stadiums after a concert) or outdoors. → position on using disinfection tunnels in public settings as a means to disinfectant humans / objects.

	If so, please provide your suggestion and list behaviour/actions that you think are most relevant.
Answer:	This type of document/guideline could be useful in particular if there is a possibility for co-branding with WHO or another recognized global public health authority. Of particular interest would be use of disinfection tunnels, DIY disinfectants, UV and other devices and wide area disinfection of public spaces (e.g., sidewalks, streets) which were prevalent during the pandemic though widely believed to be unnecessary at best and potentially hazardous at worst. Equally important is the need to emphasize non-biocidal infection prevention strategies (e.g. social distancing and mask wearing).
1.7	Can we envisage ways to make supply chains more adaptable to sharply increased demands such as seen with the Covid-19 crisis? Please list the actions that have been taken in your country by the various stakeholders and that you are aware of
Answer:	As stated in response to Question 1.4, the US response to supply chain issues included: Supply chain flexibilities: To address supply chain issues, throughout spring 2020, EPA created flexibilities for manufacturers by temporarily allowing registrants to notify EPA of certain formulation and manufacturing facility changes and immediately release the product for sale without waiting for EPA approval. These flexibilities communicated through 3 amendments to Pesticide Registration Notice 98-10 extended to certain active and inert ingredients and allowed companies to be able to switch suppliers without waiting for EPA approval. EPA will continue to assess the need for these flexibilities and a provide a minimum 7-day notice prior to termination. Finally, conditional approvals (up to 6-months) were granted for non-EPA registered sources of ingredients. Public health agencies in the US (e.g. the Centers for Disease Control) had recommendations for dilution of household bleach and isopropyl alcohol when other approved disinfectants were not available.
1.8	In case of doubt about the efficacy of products, can we envisage ways for a better exchange of information between countries and industry (academia?) to tackle such doubt? This could include questions on how to deal with proprietary data, improved information exchange from industry to countries and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	1. Harmonized efficacy test methods- In the US, we frequently encountered situations where a company had generated data using an EU/other efficacy test method and wanted to register the product in the US. Given the differences between the regulatory disinfectant methods we were generally not able to accept that data. A harmonized set of efficacy test methods would allow for data to be accepted by all OECD countries and could potentially allow for expedited review time frames if there were review sharing agreements in place. 2. EPA has been working to harmonize a quantitative efficacy test method currently under consideration as well by the OECD Working Group on Biocides. The method has been shown to accommodate bacteria, viruses and fungi and could serve as a common platform for data collection on the efficacy of disinfectants for new emerging pathogens. EPA has determined through laboratory studies that the method is suitable for evaluating disinfectants against human coronavirus on hard,non-porous surfaces as well as porous materials. This activity should receive renewed attention by OECD member countries.
1.9	Can we envisage ways to increase industry awareness about where to find regulatory requirements for bringing products on the market? Please list your suggestions.

Answer:	A centralized OECD website and/or fact sheet and/or social media with links to the various OECD country regulatory resources might be useful.
1.10	How can we make clear what the effective and safe ways are for breaking the chain of infection in case of airborne and/or surface-borne infection? Are there climate, cultural or economy depending factors?
Answer:	1. Focus on the science- Determining how to break the chain of infection, whether via air or through surfaces, is a basic science question and depends in large part on the type of pathogen and the way it spreads. For emerging pathogens, as was the case with COVID, it's important to acknowledge that strategies may change as the science evolves. 2. Emphasis on a multilayered approach to infection prevention- To break the chain of infection, a combination of strategies is essential (e.g., mask wearing, social distancing, air circulation and surface transmission). There is no one strategy that is 100% effective. There are certainly a number of dependent factors that influence outcome including those mentioned here (climate, cultural and economy) that may need to be considered depending on the member country and type of pandemic (e.g., virus transmitted via surface vs air). For example, at the beginning of the pandemic, the route of exposure for infection and the role of environmental surfaces in transmission was unclear, and as a result, there was intense interest from the public for surface disinfectants. As the science and our understanding has shifted to indicate that surfaces don't play a significant role in transmission, there has been a reluctance to shift behavior. From a cultural perspective, people want to feel like they are "doing something" to protect themselves from the virus. In contrast, other strategies such as mask wearing have been highly politicized. 3. Communication strategy- A focused communication strategy and/or website from the OECD that provides links to information from reputable public health sources (e.g., WHO) could be beneficial to the public and stakeholders.
1.11	Based on information gathered in topic 1.10, how can we establish a system of basic rules for that, which can be applied in case of a new outbreak of (yet unknown) microorganisms?
Answer:	Guiding principles could be established for agents that are thought to be transmitted via air vs surfaces. One important note is that with any new pathogen, as was the case with SARS-CoV-2, the mechanism of transmission (e.g., droplet spread vs aerosol) may be unknown. It may also be practical to establish guiding principles for when little is known about how a pathogen may be transmitted.
1.12	Are there elements of your legislation that impeded, or facilitated, your ability to respond to the Covid-19 crisis? Please provide details.
Answer:	1. EPA's 2016 Emerging Viral Pathogens policy facilitated response to the COVID-19 crisis in the US. By late January, EPA had activated the policy and companies with pre-qualified products could advertise the availability of effective products immediately. By March 3rd, EPA had a list of nearly 100 effective products. This policy was developed in response to the West African Ebola outbreak in 2014. At the start of that outbreak there were no available products that were specifically labeled as effective against the Ebola virus. The policy utilizes the microbial hierarchy of susceptibility to viruses to chemical disinfectants in order to pre-qualify products as effective against emerging or remerging viruses. 2. Throughout the pandemic, EPA was frequently approached by company representatives requesting waivers for registration of their products. In some cases, these requests for waivers were based on the fact that their products were registered in other countries. Other times, the requests were motivated by a lack of understanding of the registration process in the US or misunderstanding the allowances that had been made for alcohol-based hand sanitizing products. In either case, EPA statutes do now allow us to grant waivers for registration of pesticides, which include antimicrobial

	products. This caused significant frustration for companies with products and was also a large resource burden on the agency. 3. A mechanism to triage novel products based on the pathogen, the evolving science around transmission, and the benefit ot the technology to reducing exposure to the pathogen would be useful. The influx of requests for products that may provide little to no benefit have resulted in a significant investment in resources that have could have been directed toward more beneficial and/or efficacious products. EPA must consider all submissions equally at the initial point of submission. Resources should be directed to the "tools" with the most promise. EPA's Section 18 Emergency Exemption authority is in part designed to deal with these types of submissions. However, this was still a challenging mechanism to utilize for the pandemic. For example, while US federal agencies are eligible to apply for emergency exemptions, all federal agencies were inundated with the COVID response. Several states applied for and were granted exemptions; however, those exemptions were only approved for those handful of states rather than on a nationwide basis. Further, given the novel uses (e.g., residual coatings, treatment of air for mass transit), it was challenging to provide a thorough scientific review under a short time frame.
1.13	Did you experience jurisdictional ambiguities that impacted your ability to respond? For example, did you experience any issues in determining which agency had regulatory oversight for certain products?
Answer:	In the US, we did experience some issues determining jurisdiction between US EPA and US Food & Drug Administration (FDA). Some biocidal products are jointly regulated by EPA & FDA. One particular area of jurisdictional authority uncertainty was over treatment of masks including surgical masks as well as cloth face coverings for use by the general public. Under FDA, these could be considered medical devices as masks are intended to protect users from COVID-19. Under EPA authority, historically things like treated clothing (e.g., permethrin treated items) have been considered EPA jurisdiction. This required some coordination to address the uncertainty regarding appropriate jurisdiction for potential registrants. Another issue that was confusing for the public, though not for EPA and FDA, was the jurisdiction over hand sanitizing products. FDA has jurisdiction over hand sanitizers while EPA over products for use on surfaces. This distinction was difficult for the public to understand. Many products intended to be used as hand sanitizing wipes were imported and labeled as for use on surfaces which was confusing to end-users. Further, when FDA (as well as many other countries), announced flexibilities for alcohol based hand sanitizers following a specific recipe, this caused a great deal of confusion for potential registrants who thought that a similar approach could be followed for disinfectants (see 1.12 above on requests for waivers).

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Question 2: How effective were the actions taken to confront the Covid-19 crisis? Were they the right ones?

nr.	Question
2.1	Have your actions to deal with the disturbance of the supply chain, e.g. fast-track authorisations, retraining personnel, early interaction with industry, (possible other measures?) been sufficiently successful? Are additional actions required in the future and would these be? Please list your actions and provide information why that action was sufficiently successful or not. If additional actions are required in the please list those as well.
Answer:	In general, the flexibilities implemented for supply chain issues have been successful and well received. There is interest from industry stakeholders in extending the sunset period to come into compliance once the temporary amendments are terminated. This is something that will have to be considered by EPA. On the expedited review for products, this has also been successful, however not sustainable. Even at present, the ability to keep up with the expedited actions has significantly diminished given the high volume of submissions. It has also caused significant strain and backlogs in other parts of EPA's pesticide program as resources had to be reallocated to address with the increased workload.
2.2	Can we envisage ways for a better exchange of information between countries and industry (and academia) to cope better with a surge in registration requests? This could include questions on how to deal with, blanket registrations for products complying with pre-established standards/recipes, regulatory requirements for registrations, claims for virucidal activity against Covid, proprietary data, improved information exchange from industry to authorities and between countries, possible use of harmonised or compatible data systems, the shared development of testing methods or strategies, etc. Please list your suggestions in order of importance and most likely to succeed.
Answer:	See 1.8 above. Harmonized efficacy test methods with potential for review sharing.
2.3	Do you think that a "pragmatic approach' to efficacy testing should be allowed in times of crisis and, if yes, can we describe in a guidance what it means or what it should at least constitute? Please list your suggestions for what a "pragmatic approach" could constitute in your country
Answer:	The successful use of EPA's Emerging Viral Pathogen Policy to allow registrants to pre-qualify their products seems like a pragmatic model that could be useful in other countries. We also understand that Canada has a similar approach. EPA currently has a workgroup panel to advise on ways we could improve this policy moving for future situations. This could include expansion of the policy to include other types of microorganisms beyond viruses and consideration for expanded labeling and marketing statements to increase public understanding. Bridging data (e.g., data to support multiple formulation types) when available is also useful. In addition, consideration should be given to evaluating existing efficacy test methods to determine whether methods can be modified to address new efficacy claims. EPA was successful in modifying two existing test methods to accommodate claims for residual coatings and porous materials. Finally, in the US there are only a handful (< 5) of labs that routinely conduct GLP (Good Laboratory Practice) efficacy studies to support registration. With the small number of labs, they were quickly inundated with testing requests and at capacity. EPA allowed for submission of non-GLP study reports provided that any deviations from GLP were

	noted. This is an example of a pragmatic approach that could be considered in the future.
2.4	Can we create a compendium of available guidance on how to deal with emerging pathogens? If you think this to be relevant, please provide any relevant guidance you are aware of on how to deal with emerging pathogens.
Answer:	EPA's Emerging Viral Pathogen Guidance: https://www.epa.gov/pesticide-registration/emerging-viral-pathogen-guidance-antimicrobial-pesticides
2.5	Are there areas where increased or improved information to the public is necessary? If so, please list in what areas increased or improved information to the public is necessary. Please also list suggestions on how you would do this.
Answer:	See 1.9 above to help potential registrants better understand the different regulatory authorities across member countries. There is also certainly an opportunity to help the public better understand antimicrobial products and how to use these safely and effectively. This is a very challenging issue given the differences across member countries.

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Question 3: With what we have learned so far, what could we do differently or additionally now? (Examples: can we do so in a more harmonised/concerted effort? Can the OECD help with such an effort?)

nr.	Question
3.1	How do we envisage that the communication between the national and international actors involved in the registration of biocides can be increased or improved? Please list your suggestions.
Answer:	With the increasing sophistication of virtual communication platforms, one consideration could be better use of these platforms. While the OECD clear space is certainly a useful and important site, a less formal method of communication could be considered as well (e.g., Microsoft teams channel) so participants could engage in sharing information in an easier way.
3.2	Is there a need to create guidance on the use of pre-established standards/recipes, such as the WHO-recommended Handrub Formulations (https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf), for use in blanket authorisations in times of crisis? Please provide suggestions for what would need to be included in such a guidance.
Answer:	For the US EPA, these types of recipes are not compatible with our pesticide regulatory authority and would not be useful.
3.3	How do jurisdictions deal with the prolonged use of emergency authorisation, e.g. is it possible that emergency authorisations create alternate problems and how should these be dealt with? Please list any issues that you have encountered or think you might encounter when the use of emergency authorisations is prolonged.
Answer:	In the US, emergency authorizations have very specific criteria and are by definition time limited (see 1.2 above for a more through description of these authorizations). They are also intended to bridge the gap to a full (non-emergency) registration.
3.4	What have we learned from the Covid-19 crisis about how to best deal with questions from the public? Please provide insight in the type of questions that you received from the public and how you would address these in a future situation.
Answer:	Early on in the pandemic, EPA developed and posted lists of frequently asked questions (FAQs) for disinfectants, air and water. These FAQs are continuously updated as new questions arise that warrant development of an FAQ. EPA received questions that cover every possible topic related to COVID. To highlight a few, these queries included disinfectant use, registration, overuse of products and impacts on sensitive populations, wide are disinfection (e.g., drone, fogging) and safe and effective use in schools. EPA had several strategies to deal with the huge influx of questions. One strategy was reallocation of staff to be able to answer the increased volume coming in through email boxes specific to pesticide questions. The teams answering these questions coordinated on responses and had consensus answers to the cover some of the more common inquiries. In addition to answering questions, the communications team worked on outward facing resources such as infographics and videos to help with public understanding of disinfectant use. Another strategy is an agency wide working group that rapidly responds to inquiries. This group meets regularly and is committed to providing responses within a few days to inquiries. EPA also participated in and/or hosted many webinars that were targeted to specific groups to help with public interface and give opportunities for questions.

	In a future situation, a similar approach would likely be used however there is a desire to be proactive in getting some resources available to the public to help them better understand antimicrobial products and how products can be used safely and effectively. Over the course of the pandemic, EPA has participated in hundreds of pre-submission meetings with companies interested in registering their products. The vast majority were new companies that needed assistance in navigating the complexities of the pesticide registration process. This was very resource intensive and is something that would be worthwhile to devote resources to improving in the future.
3.5	What type of follow-up actions will be necessary when exiting a crisis? Please list any follow-up actions you foresee and describe their importance.
Answer:	There are a number of temporary allowances and flexibilities (see 1.4) as well as expedited reviews that will eventually need to sunset and/or communicated that these activities will no longer be in place. EPA will also need to determine when the emerging viral pathogen guidance for the SARS-CoV-2 pandemic is complete (guidance states 24-months after the end of the pandemic) at which time off label claims can no longer be made. As also mentioned previously, EPA is co-chairing a work group tasked with providing recommendations to EPA on how the agency response to future pandemic could be improved moving forward. The group has stakeholder representation from industry, healthcare, Centers for Disease Control (CDC) and state/regional pesticide regulators.
3.6	In relation to the dedicated OECD meeting in April 2020, do you believe there are other/additional ways that the OECD can help countries in times of crisis? Please provide suggestions on how you think that the OECD can help countries in times of crisis.
Answer:	The Agency has been actively engaged with the OECD Working Group on Biocides to move forward with the adoption of the "OECD Guidance Document on Quantitative Methods for Evaluating the Activity of Microbicides for Use on Hard Non-porous Surfaces".as a guideline document. The results will be an internationally harmonized efficacy test method for bacteria, viruses and fungi. Efforts to date by the US have been unsuccessful. The actions around this method should receive renewed attention by OECD member countries. Refer to this link: http://www.oecd.org/chemicalsafety/testing/evaluating-the-activity-of-microbicides-used-on-hard-non-porous-surfaces.htm.
3.7	Do you have any other suggestions?
Answer:	/

End of questionnaire

Annex 3: Compilation of guidance references provided in Question 2.4

Country	Guidance on how to deal with emerging pathogens
Finland	American Biological Safety Association. SARS-CoV-2/COVID-19 Toolbox. Available from: https://absa.org/covid19toolbox/ American Society of Heating Refrigerating and Air-Conditioning Engineers (ASHRAE). Position Document on Filtration and Air Cleaning [updated 29 January 2015]. Available from: https://www.ashrae.org/file%20library/about/position%20documents/filtration-and-air-cleaning-pd.pdf ECDC. Heating, ventilation and air-conditioning systems in the context of COVID-19: first update. Saatavilla osoitteesta: https://www.ecdc.europa.eu/sites/default/files/documents/Heating-ventilation-air-conditioning-systems-in-the-context-of-COVID-19-first-update.pdf Finnish Institute of Occupational Health. Cleaning quidelines for the prevention of Covid-19 infections. Available from: https://www.ttl.fi/en/cleaning-guidelines-for-the-prevention-of-covid-19-infections%e2%80%af/ Government of Canada. Biosafety and Biosecurity. Available from: https://www.canada.ca/en/services/health/biosafety-biosecurity.html REHVA. 2020. How to operate HVAC and other building service systems to prevent the spread of the coronavirus (SARS-CoV-2) disease (COVID-19) in workplaces. REHVA COVID-19 guidance document, August 3, 2020. Available from: https://www.rehva.eu/fileadmin/user_upload/REHVA_COVID-19_guidance_document_V3_03082020.pdf WHO. 2020. Severe Acute Respiratory Infections Treatment Centre Practical manual to set up and manage a SARI treatment centre and a SARI screening facility in health care facilities. Available from: https://apps.who.int/iris/bitstream/handle/10665/331603/WHO-2019-nCoV-SARI_treatment_center-2020.1-eng.pdf?sequence=1&isAllowed=y
Canada	Health Canada's NNHPD has had an emerging viral pathogens approach published in the disinfectant drugs guidance documents since 2014, with the January 2020 update to the guidance document noting the following: 5.0 Claims against Emerging Viral Pathogens When the Public Health Agency of Canada (PHAC) has issued a public notice that an emerging viral pathogen poses a significant risk to Canadians or has been declared by the World Health Organization (WHO) as a public health emergency of international concern, manufacturers can immediately provide communications containing qualifying language like "expected to be effective" and "likely to be effective" to the public regarding the expected efficacy of certain market authorized disinfectant drugs against the emerging pathogen: this includes communications through their web sites, toll free consumer information services, and similar media. Disinfectants that have received market authorization for either of the following claims will be permitted to make indirect efficacy claims against emerging viral pathogens: • "Broad-spectrum virucide", supported by an efficacy claim against any of: o Adenovirus type 5 (ATCC VR-5) o Bovine Parvovirus (ATCC VR-767) o Canine Parvovirus (ATCC VR-2017) o Poliovirus type 1 (ATCC VR-1562) OR • For emerging viral pathogens for which the taxonomic genus of the virus has been identified, efficacy data against other viruses within that genus may be considered acceptable (e.g., any Influenza A virus for a claim against Influenza A H1N1). Manufacturers may add claims against emerging viral pathogens to their market authorized product

	labels, provided that their products qualify for the claims, through the post-authorization Division 1 change (PDC) process, which requires a notification to be sent to Health Canada within 30 days of adding the claim, as permitted through section C.01.014.4 of the Food and Drug Regulations. This emerging viral pathogens approach forms the backbone of our COVID-19 response, with a broadening of the surrogate viruses permitted in support of indirect COVID-19 claims, as noted in the Health Canada webpage Hard-surface disinfectants and hand sanitizers (COVI-19) – Information for manufacturers (https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/information-manufacturers.html#Disinfectant).
United States	EPA's Emerging Viral Pathogen Guidance: https://www.epa.gov/pesticide-registration/emerging-viral-pathogen-guidance-antimicrobial-pesticides