Survey: the post-Covid 19 crisis and its impacts for future management of emergency crises.

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 crises, 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 emergency crises in general, 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 you can find the survey questionnaire as an annex to this document. The outcome of this survey will provide input for a lessons-learned document, for which we want to highlight that these will be 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 timelines agreed by the WG-PC19 for the first phase of this project, i.e. developing a lessons-learned document are as follows:

- Circulation of survey questionnaire to the WPB, beginning of February 2021.
- Return of answers to the questionnaire by 5 March 2021.
- Compilation of answers, discussion in WG-PC19 and drafting of an initial lessons-learned document by April 2021.

- Circulation of the initial lessons-learned document to the WPB at the beginning of May 2021, with subsequent discussion of this document and the survey outcome in a dedicated session of the WPB by the end of May 2021.

Request

- We kindly invite the WPB to:

1. Circulate the questionnaire to the relevant authorities, agencies or organisations that you know have been involved in reacting to the Coivd-19 crisis with the request to fill out the questionnaire in the Annex below.
2. Fill in the questionnaire in the Annex below.
3. Return all questionnaires, i.e. yours and those from additional authorities and agencies, to the Secretariat **by 5 March 2021**.

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

Name respondent: 5.1.2e 5.1.2e ***and Email:*** 5.1.2e ***@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.

4.

5.

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.)?

6.

7.	8. **Question**
9.	10. What have been the most pressing difficulties/challenges in responding to the Covid-19 pandemic? 1 . **11.** Please list those difficulties in order of importance. 1
12. 13. 14. 15. 16. 17. 18. 19. 20. 21. 22.	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.
	f.	g.	Are existing agile processes available in your legislation to respond to such emergencies (e.g., emergency authorizations/registrations)?
	1.	h.	If so, kindly indicate any limitations relating to emergency authorizations/registrations?
	2	i.	Under what circumstances or for what product types have you applied agile processes?
	j.	k.	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.
		l.	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.
		m.	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.

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•	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.)
•		• 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)?
•		• 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.
•		• 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.
•		• 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
•		• 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.
•		• 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.

•		• 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?
•		• 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?
•		• 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.
•		• 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?
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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.
	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.
	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
	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.

	• 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.
	• 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.
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.
	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.
	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.
	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.

	• 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.
3.7	Do you have any other suggestions?

End of questionnaire