Application form C

This form is used to determine whether the limited assessment procedure can be used for applications for the authorisation of biocidal products or for the amendment or renewal of authorisations of such products under Netherlands transitional law of the Plant Protection Products and Biocidal Products Act (Wgb). The transitional law of the Wgb applies to biocidal products based on active substances that have been included in the European review programme of the Biocidal Products Regulation (BPR), but for which no official decision on approval has yet been taken. If in doubt, information can be obtained from the Ctgb service desk.

After filling in this form if it appears that it is not possible to use the limited assessment procedure, then a regular application must be submitted to the Ctgb (application form B).
The following appendices apply to these two types of applications:

FORM	**Application for limited assessment**	**Regular application**
Basic form: always fill this in!	Application form B	Application form B
Data on the active substance	LoA	Appendix A
Data on the product	LoA	Appendix B
Comparative assessment	Application form C	Not applicable
Proposal legal conditions for use and instructions for use (WGGA)	Appendix D WGGA	Appendix D WGGA
Overview of requested uses and methods (PGB-PUB)	Appendix E PGB-PUB	Appendix E PGB-PUB
Composition of the product	Appendix F Composition	Appendix F Composition
References	Appendix G	Appendix G
Efficacy studies by use, claim justification, resistance	Appendix WKZ	Appendix WKZ
Data on packaging, shelf life, analysis methods	Appendix FCE	Appendix FCE
Data on classification, labelling and packaging (CLP)	Appendix CLP	Appendix CLP
Comparison of product that is being applied for with reference product in terms of composition	Appendix S	Not applicable
Comparison of product that is being applied for with reference product in terms of use	Appendix T	Not applicable
Additional human toxicology risk assessment	Appendix C22	Not applicable
Additional dermal absorption risk assessment	Appendix C23	Not applicable
Additional human toxicology combitox risk assessment	Appendix C24	Not applicable
Additional human toxicology risk assessment based on new insights	Appendix C25	Not applicable
Additional environmental risk assessment	Appendix C32	Not applicable
Additional environmental combitox risk assessment	Appendix C33	Not applicable
Additional environmental risk assessment based on new insights	Appendix C34	Not applicable

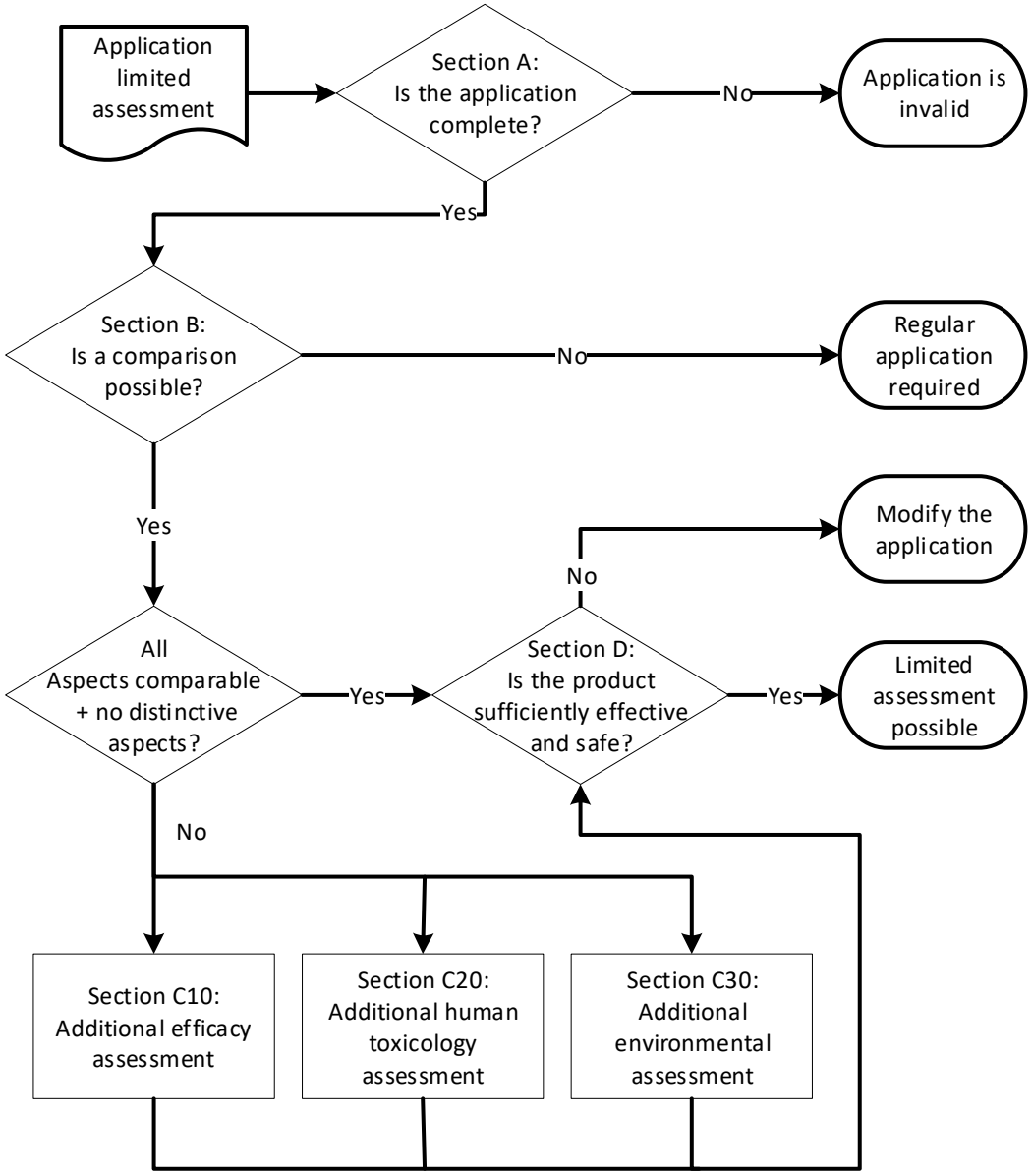
Overview

The attached diagram provides an overview of the process to determine if a limited assessment is possible. The section codes correspond to those in the application form below.
The limited assessment procedure can be used for applications for authorisation, amendment of the authorisation (including extended authorisation) and renewal of the authorisation.

The diagram concerns an application for a new authorisation (TBL-application). For an application for an amended authorisation (including an extended authorisation; WB-application), the same diagram can be used, but the text must be read in such a way that it specifically relates to the amended authorisation.

The diagram can also be used for applications for renewal of the authorisation (TVB application). An application for renewal must not extend the scope of permitted use or include any major changes. A separate application must be submitted for an extended authorisation or major changes.
With an application for renewal, it is possible to apply for a narrower scope of permitted use than has been authorised up to now. It is also possible to request administrative changes as part of the application for renewal of the authorisation.

In the case of an application for renewal (TVB), the previous full assessment of the product for which renewal is requested is used for comparison (reference product is equivalent to the product itself). Therefore, only the following questions need to be answered on this form:
Section A: questions 1 to 7
Section B: questions 11 and 14
Section C: questions 1, (11), 25 and 34
Section D: question 2



Submitting an application

To submit an application using the limited assessment procedure, fill in Application Form B and Application Form C and include the relevant appendices listed in the table above.
Section A of Application Form C can be used to determine if you have a complete dossier that can be used with an application submitted through the limited assessment procedure.

When compiling an electronic file, use folders that are named as indicated on this form. In some cases, all data can be included in the appendices (for example Appendices D, E and F) and you do not need to submit additional documents.
In other cases, for which additional documents are submitted, a folder must be created and named as indicated on the application form.
Extra documents and studies that do not fit in one of the folders as mentioned in this application form, can be saved in a folder 'Reports".
The folders must be named as indicated or the application will not be accepted by the Ctgb.

For payment details, see Application Form B.

Application form C for an assessment of a biocidal product under Netherlands transitional law of the Wgb Product name:

Section	*No.*	*Step*	*Explanation*	*Complete answer?*	*Ctgb*
A		**A COMPLETE DOSSIER MUST BE PROVIDED CONTAINING THE ELEMENTS LISTED BELOW**	**HOW CAN YOU COMPLY WITH THIS OBLIGATION?**		
	1	Composition	Provide the composition of the product. Use Appendix F for this purpose.	○ Missing ○ Complete	
	2	Draft legal conditions for use/instructions (WGGA)	Provide a draft of the Legal Conditions for Use (WG) and for the directions for use (GA) for the product. The text that is entered here will be used by the Ctgb as the basis for the assessment. Use Appendix D WGGA for this purpose.	○ Missing ○ Complete	
	3	Use of biocidal products in practice (PGB-PUB)	The draft WGGA should be supported with corresponding details “Appendix E PGB-PUB”. This must clearly indicate which uses have been applied for and what the details are for each use (dose, frequency, etc.). A separate column must be created in Appendix E PGB-PUB for each unique use.	○ Missing ○ Complete	
	4	Recent SDSs for all formulants and co-formulants	A safety data sheet (SDS), not older than 5 years, must be provided for all ingredients in accordance with: Regulation (EC) No 1907/2006 and must be in Dutch or English. Submit the safety data sheets in a folder named SDS.	○ Missing ○ Complete	

	5	Description of packaging	The packaging in which the product will be placed on the market must be described in Appendix FCE. Create a folder named FCE for additional appendices (if any).	○ Missing ○ Complete	
	6	Substantiated proposal for CLP labelling	Describe the CLP labelling of the product. Submit this in Appendix CLP and include the substantiation for the proposal. In case of an application for renewal (TVB), a new proposal is necessary only if changes are needed compared to the classification already determined by the Ctgb.	○ Missing ○ Complete	
	7	Reference to complete substance dossier(s)	If you are the owner of a complete substance dossier, you can refer to it. If you are not the owner, you must provide a recent Letter of Access (LoA), in which the owner of the substance dossier states that the Ctgb may use that dossier for the assessment of your product. Submit the LoAs on paper and electronically in a folder named LoA.	○ Missing ○ Complete	
	8	Reference to product studies	In the assessment of a reference product (see B1), special protected studies may have been provided. If so, you must have access to those studies based on a recent LoA. Submit the LoAs on paper and electronically in a folder named LoA.	○ Missing ○ Complete	
	9	Demonstrate shelf life	What shelf life do you want to include on the product packaging? Submit the studies in a folder named FCE. The studies should also include measurements of the relevant technical characteristics associated with the formulation type. Submit this information in Appendix FCE.	○ Missing ○ Complete	
	10	Efficacy dossier	Demonstrate that the efficacy of the product is sufficient for all uses stated in the WGGA or the PGB-PUB. For this purpose, submit signed studies for all tests required by the BPR efficacy guidance part B/C. Submit the studies in a folder named WKZ. In addition, submit Appendix WKZ with a summary of all provided efficacy studies, including information on the mechanism of action of the active substance(s) and information on the possibility of developing resistance.	○ Missing ○ Complete	

	11	Analysis methods	Submit the validation of the analysis methods for determining the active substance in the product as used in the shelf life study. Use Appendix FCE for this purpose. Create a folder named FCE for additional appendices (if any).	◯ Missing ◯ Complete	
	12	Dermal absorption data	The dermal absorption data indicates the percentage of the active substance that is absorbed if the product contacts the skin. This percentage is strongly dependent on the composition of the product. In Appendix C23, state this percentage and the evidence on which it is based.	◯ Missing ◯ Complete	
		CONCLUSION COMPLETE DOSSIER	**DETERMINE WHETHER THE APPLICATION CAN BE ACCEPTED**		
	13	Does the dossier meet all requirements? Are questions A1 to A12 all answered with 'complete'? (for TVB applications: only questions A1 to A7)	If yes: continue with Section B. If not: complete the dossier before proceeding with submitting the application.	◯ Yes ◯ No	

Section	No.	Step	Explanation	Yes/No	Ctgb
B		**COMPARISON WITH REFERENCE PRODUCT**	**HOW CAN YOU DETERMINE THAT A VALID COMPARISON WITH REFERENCE PRODUCTS IS POSSIBLE?**		
	1	Which authorised products (maximum of 2) do you want to use as a reference products?	Provide the names and authorisation numbers of reference products that are used for comparison in Appendix S. A reference product must have an original authorisation, contain the same active substance(s) as the product that is being applied for, have comparable uses and a realistic expiry date in the future (not the date 09-09-9999, or a reference to the European process). A reference product itself may not be authorised on the basis of a comparative assessment. For renewal applications, reference can be made to the previous assessment of the applicant's own product.	◯ Yes ◯ No	
	2	Is the composition of your product and the reference product similar?	For all the active substances in your product and the reference product, provide the concentrations in the product. Use Appendix S for this purpose. Are the concentrations of active substances in your product and the reference product similar?	◯ Yes ◯ No	
	3	Are the use concentrations of active substances in your product and the reference product similar?	For your product and those of the reference product, provide the u**se** concentrations of active substances for all uses. Use Appendix S for this purpose. Are the use concentrations of active substances for your product and the reference product similar?	◯ Yes ◯ No	
	4	Are your product and the reference product similar in terms of the scope and magnitude of use (e.g. frequency of use, duration of use, season of use, area to be treated, and other instructions that ensure the efficacy of the biocidal product)?	For your product and the reference product, indicate the frequency of use, the duration of use, the area to be treated, any other relevant aspects and all relevant instructions for use. Use Appendix S for this purpose. Are the scope and magnitude of the use of your product comparable to or smaller than that of the reference product?	◯ Yes ◯ No	

Section	No.	Step	Explanation	Yes/No	Ctgb
	5	Are your product and the reference product similar in terms of use?	Indicate the uses of your product and those of the reference product. It is important here that your product has the same (or fewer) emission routes to the environment and the same (or fewer) exposure routes to humans and animals. Use Appendix T to specify these aspects. Are the emission routes to the environment and the exposure routes to humans the same or less extensive for your product than for the reference product?	○ Yes ○ No	
B10		**SPECIAL SITUATIONS WITH RESPECT TO THE COMPARISON**	**ARE THERE CIRCUMSTANCES THAT REQUIRE ADDITIONAL DATA TO BE SUBMITTED?**		
	11	Is there a chance that the target organism can develop resistance to the active substance(s) in the product?	If yes, specify your answer in Appendix WKZ (see question C11)	○ Yes ○ No	
	12	Does the dermal absorption percentage for the active substance in the product deviate significantly from the value used in the assessment of the reference product?	If yes, specify your answer in Appendix C24 (see question C24)	○ Yes ○ No	
	13	If the product contains more than one active substance, does the combitox assessment differ from that of the reference product?	If yes, specify your answer in Appendix C24 and/or Appendix C33 (see questions C24 and C33)	○ Yes ○ No	
	14	Are there new insights that make it necessary to modify the previous assessment of the reference product?	If yes, specify your answer in Appendix C25 and/or Appendix C34 (see questions C25 and C34). Any new data will be used only for new applications, not for intervention in existing authorisations	○ Yes ○ No	

Section	*No.*	*Step*	*Explanation*	*Yes/No*	*Ctgb*
		CONCLUSION ABOUT COMPARISON WITH REFERENCE PRODUCTS	**DETERMINE HOW TO CONTINUE FILLING THIS FORM**		
	15	Are all steps under B1-B5 completed with a "Yes" and are there no "Yes" answers to questions B11-B14 (for TVB applications: only questions B11 and B14 are relevant; questions B1-B5 are not relevant)?	If yes, continue with Section D (Section C can be skipped).	○ Yes ○ No	
	16	All other situations	Continue with Section C.		

C		**ADDITIONAL RISK ESTIMATION IS REQUIRED**	**IF A 100% COMPARISON IS NOT POSSIBLE (SECTION B), OR IF THERE ARE SPECIAL SITUATIONS (SECTION B10), AN ADDITIONAL RISK ASSESSMENT IS REQUIRED TO DEMONSTRATE THAT THE PRODUCT CAN STILL BE AUTHORISED**		
	1	Is additional data required on the efficacy aspect due risk of resistance?	If yes, specify this in Section C10.	○ Yes ○ No	
	2	Is additional data required on the risk for humans and animals?	If yes, specify this in Section C20.	○ Yes ○ No	
	3	Is additional data required on the environmental aspect?	If yes, specify this in Section C30.	○ Yes ○ No	
	4	Have questions C1 to C3 all been answered with 'No"?	Then go to Section D.		

Section	*No.*	*Step*	*Explanation*	*Yes/No*	*Ctgb*
C10		**ASSESSMENT OF THE EFFICACY ASPECT (INCLUDING INSTRUCTIONS FOR THE WGGA)**	**INDICATE THE ADDITIONAL DATA THAT IS NECESSARY TO CONCLUDE THAT THE EFFICACY OF THE PRODUCT IS SUFFICIENT**		
	11	Is there any indication that the product promotes the development of resistance in target organisms?	In Appendix WKZ state whether your product can promote resistance in target organisms or whether your product contains one of the substances for which the Ctgb has indicated that a resistance sentence is required (see the Ctgb website). State which measures must be prescribed to prevent the development of resistance as much as possible. To submit relevant appendices (f any), create a folder with the name WKZ.	○ Yes ○ No	
C20		**ASSESSMENT OF THE RISK FOR HUMANS AND ANIMALS**	**INDICATE WHAT ADDITIONAL DATA IS NECESSARY TO CONCLUDE THAT THE PRODUCT IS SUFFICIENTLY SAFE FOR HUMANS AND ANIMALS**		
	21	In the comparison with the reference product, your product has a higher concentration, the use concentration is higher, the magnitude of use is greater, no direct comparison is possible for one or more uses, or there are special situations mentioned under B12, B13 and/or B14. Is this statement correct?	If yes, then proceed to question C22. If no, then there is a special situation that is not covered by this form. If necessary, contact the Ctgb service desk.	○ Yes ○ No	
	22	In the comparison with the reference product, your product has a higher concentration, the use concentration is higher, the magnitude of use is greater, or no direct comparison is possible for one or more uses. Is this statement correct?	If yes, create an appendix with the name Appendix C22 and clearly specify why your product can still be authorised for the aspect of risk to humans and animals. For example, the use concentration of your product could be 2x higher than that of the reference product, but the risk assessment of the reference product shows that the risk for the user is so low that a 2x higher use concentration is also safe. Then continue to C23. If no, continue to C23.	○ Yes ○ No	

Section	*No.*	*Step*	*Explanation*	*Yes/No*	*Ctgb*
	23	The dermal absorption percentage of the active substance in the product is higher than the value used in the assessment of the reference product. Is this statement correct?	If yes, in Appendix C23 (create this appendix if necessary) clearly specify why there is no risk to human and animal health with your proposed used and the higher value for dermal absorption. Then go to C24. If no, continue to C24.	○ Yes ○ No	
	24	Your product contains more than one active substance and the risk to humans and animals of the combination of the active substances is not covered by the comparison with the reference product(s). Is this statement correct?	If yes, in Appendix C24 (create this appendix if necessary) clearly specify why the risk to humans and animals due to the combined exposure to all active substances during your proposed use does not pose a risk to human and animal health. Then go to C25. If no, continue to C25.	○ Yes ○ No	
	25	Due to new insights, the previous assessment of the risk to human and animal health of the reference product is no longer valid for your product. An updated risk assessment is therefore required. Is this statement correct?	If yes, in Appendix C25 (create this appendix if necessary) clearly specify these new insights and how it follows that your proposed use does not pose a risk to human or animal health. Then go to C30. If no, continue to C30.	○ Yes ○ No	
C30		**ASSESSMENT OF THE ENVIRONMENTAL RISK ASPECT**	**INDICATE WHAT ADDITIONAL DATA IS NECESSARY TO CONCLUDE THAT THE PRODUCT IS SUFFICIENTLY SAFE FOR THE ENVIRONMENT**		
	31	In the comparison with the reference product, your product has a higher concentration, the use concentration is higher, the magnitude of use is greater, no direct comparison is possible for one or more uses, or there are special situations mentioned under B13 and/or B14. Is this statement correct?	If yes, continue to C32. If no, then there is a special situation that is not covered by this form. If necessary, contact the Ctgb service desk.	○ Yes ○ No	

Section	*No.*	*Step*	*Explanation*	*Yes/No*	*Ctgb*
	32	In the comparison with the reference product, your product has a higher concentration, the use concentration is higher, the magnitude of use is greater, or no direct comparison is possible for one or more uses. Is this statement correct?	If yes, in Appendix C32 (create this appendix if necessary) clearly specify why your product can still be authorised for the aspect of environmental risk. For example, the use concentration of your product could be 2x higher than that of the reference product, but the risk assessment of the reference product shows that the risk to the environment is so low that a use with a 2x higher use concentration is also safe. Then continue to C33. If no, continue to C33.	◯ Yes ◯ No	
	33	Your product contains more than one active substance and the risk to the environment of the combination of the active substances is not covered by the comparison with the reference product(s). Is this statement correct?	If yes, in Appendix C33 (create this appendix if necessary) clearly specify why the risk to the environment from the combined exposure to all active substances in your proposed use does not pose a risk to the environment. Then go to C34. If no, continue to C34.	◯ Yes ◯ No	
	34	Due to new insights, the previous environmental risk assessment of the reference product is not valid for your product. An updated risk assessment is therefore required. Is this statement correct?	If yes, in Appendix C34 (create this appendix if necessary) clearly specify these new insights and how it follows that your proposed use does not pose a risk to the environment. Then go to D. If no, continue to D.	◯ Yes ◯ No	

D		CONCLUSION ON APPLICATION			
	1	Your application is not an application for renewal of the authorisation. Your application is complete in accordance with Section A, your product is 100% comparable in composition and use in accordance with Section B1-B5, or additional data has been provided in accordance with Section C which shows that your product is still sufficiently effective and safe for humans, animals and the environment. Are these statements correct?	If yes, then your conclusion is that authorisation of your product is possible and you can submit your application to the Ctgb. If no, then you cannot conclude that authorisation of your product is possible. You should either revise your application or conclude that there is a special situation which is not covered by this form. If necessary, contact the Ctgb service desk.	○ Yes ○ No ○ N.A.	
	2	You have an application for renewal of the authorisation (TVB). Your application is complete for questions A1-A7 in Section A, questions B11 and B14 have been answered 'No', and/or additional information has been provided with questions C11, C25 and/or C34 which shows that the product is still is sufficiently effective and safe for humans, animals and the environment. Are these statements correct?	If yes, then your conclusion is that authorisation of your product is still possible and you can submit your application to the Ctgb. If no, then you cannot conclude that authorisation of your product is still possible. You should either revise your application or conclude that there is a special situation which is not covered by this form. If necessary, contact the Ctgb service desk.	○ Yes ○ No ○ N.A.	