

From: "5.1.2.e"
Sent: Thu, 4 Sep 2025 15:35:27 +0200
To: 5.1.2.e | LingeAgroconsultancy" <5.1.2.e@lingeagroconsultancy.nl>
Subject: RE: cat 4 studies efficacy - Scab 80 WG art 43

Dear 5.1.2.e

I have discussed your request earlier today. I regret to have to inform you that as cMS, Ctgb is not in the position to discuss the approach for the Core dossier with the applicant. Ctgb has the role of cMS for this dossier and will comment on the Core assessment when it is ready and in principal follow the zRMS in their final conclusion about the Core fulfilling the Uniform Principles or not.

Sharda should discuss what data are needed and whether these data qualify as category 4 data with the zRMS. So Ctgb is not open for an informal meeting on this subject.

With kind regards

5.1.2.e

5.1.2.e

Project manager

Ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden

Board for the Authorisation of Plant Protection Products and Biocides

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Van: 5.1.2.e | LingeAgroconsultancy <5.1.2.e@lingeagroconsultancy.nl>

Verzonden: woensdag 3 september 2025 14:59

Aan: 5.1.2.e <5.1.2.e@ctgb.nl>

Onderwerp: RE: cat 4 studies efficacy - Scab 80 WG art 43

Hi 5.1.2.e

Correct, I received your out of office reply. Thanks for coming back on this, we have been patiently waiting for you. Please let me know if you think contact via phone with you or team manager would be necessary/easier. We would like to propose some solution and help each other.

I am looking forward to your answer after internal discussion.

Best regards,

5.1.2.e



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5.1.2.e

From: 5.1.2.e <5.1.2.e@ctgb.nl>
Sent: Wednesday, September 3, 2025 11:43 AM
To: 5.1.2.e <5.1.2.e@lingeagroconsultancy.nl>
Subject: RE: cat 4 studies efficacy - Scab 80 WG art 43

Dear 5.1.2.e

Sorry for my late reply, but your email arrived just when I started my holidays in the end of July.
I will have to check you request with my team management.
Will come back to you as soon as I can.

With kind regards

5.1.2.e

Van: 5.1.2.e | LingeAgroconsultancy <5.1.2.e@lingeagroconsultancy.nl>
Verzonden: dinsdag 29 juli 2025 15:23
Aan: 5.1.2.e <5.1.2.e@ctgb.nl>
Onderwerp: RE: cat 4 studies efficacy - Scab 80 WG art 43

5.1.2.e

Thank you for your email and update below.

We understand the difficulty and uniqueness of the situation. Next to further discussing the situation with the Czech authorities, we would also like to hear the Ctgb's point of view in this matter. Is it possible to set up an online meeting in which we can informally discuss this and discuss potential options which we believe could help the situation? In this meeting Sharda's consultant 5.1.2.e and my colleague 5.1.2.e and me would join. All three of us are consultants working together to find the best solution that is acceptable for both authorities while trying to prevent that the applicant loses their authorization.

Looking forward to your reply.

Best regards,

5.1.2.e



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5.1.2.e

From: 5.1.2.e <5.1.2.e@ctgb.nl>
Sent: Friday, July 4, 2025 1:21 PM
To: 5.1.2.e | LingeAgroconsultancy <5.1.2.e@lingeagroconsultancy.nl>
Subject: cat 4 studies efficacy - Scab 80 WG art 43

Dear 5.1.2.e

We have received feed-back from our Czech colleagues why they consider the efficacy studies for Scab 80 WG as proposed by the applicant are not essential for the product renewal dossier. Ctgb understands their reasons and as CMS cannot take the lead in this dossier. However, Ctgb as CMS considers an evaluation of efficacy in a 61% reduction of the dose per hectare as an essential part of the art 43 Core renewal assessment, which cannot be filled in on a national level.

With kind regards

5.1.2.e

5.1.2.e

Project manager

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Van: 5.1.2.e
Verzonden: dinsdag 17 juni 2025 10:40
Aan: '5.1.2.e' | LingeAgroconsultancy <5.1.2.e@lingeagroconsultancy.nl>
Onderwerp: RE: concept decision for Scab 80 WG NLWG

Dear 5.1.2.e

We contacted our Czech colleagues in order to explain them that Ctgb considers new efficacy data essential for the application and why. We also invited them to discuss the matter with us if they are willing.

Otherwise there might be severe complications. If efficacy of the reduced dose rate is not addressed, there are likely to be many comments and NL as CMS cannot evaluate efficacy at a national level if the zRMS does not. So it may be good if the applicant also presses to the Czech authorities to reconsider.

With kind regards

5.1.2.e

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Project manager

Ctgb

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Van: 5.1.2.e <5.1.2.e@lingeagroconsultancy.nl>

Verzonden: dinsdag 17 juni 2025 09:58

Aan: 5.1.2.e <5.1.2.e@ctgb.nl>

Onderwerp: RE: concept decision for Scab 80 WG NLWG

Dear 5.1.2.e

Thank you for your answer.

Enclosed is the letter that has been submitted to CZ authority by the applicant. We believe this is document they are referring to. I hope this helps you. Let me know in case any other questions.

Best regards,

5.1.2.e

Best regards,

5.1.2.e



5.1.2.e (MSc)

5.1.2.e



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From: 5.1.2.e <5.1.2.e@ctgb.nl>
Sent: Monday, June 16, 2025 12:14 PM
To: 5.1.2.e | LingeAgroconsultancy <5.1.2.e@lingeagroconsultancy.nl>
Subject: RE: concept decision for Scab 80 WG NLWG

Dear 5.1.2.e

We are struggling a little bit with the situation for Scab 80 WG, but we are tending towards contacting our Czech colleagues.

However, may I ask you a question. What are the Czech authorities referring to with what they describe as "guidance document of the Dutch Authority Ctgb".

With kind regards

5.1.2.e

Van: 5.1.2.e | LingeAgroconsultancy <5.1.2.e@lingeagroconsultancy.nl>
Verzonden: woensdag 26 maart 2025 21:25
Aan: 5.1.2.e <5.1.2.e@ctgb.nl>
Onderwerp: RE: concept decision for Scab 80 WG NLWG

Dear 5.1.2.e

As an authorisation holder of a product based on the active substance captan, Sharda Cropchem Ltd, was contacted in October 2024 to adapt GAP and WG for the authorisation of Scab 80 WG to match the new conditions and restrictions for use based on the EU renewal of captan.

On a national level, the Ctgb has interpreted the EU implementation as a required 61% reduction of application rate and 20% reduction of loss of active to the ground. The Ctgb has mentioned that for the Art 43, data will be needed to support that the same level of efficacy can be expected.

For this purpose, Sharda Cropchem Ltd is commissioning efficacy trials and has requested the zRMS for the product renewal Czech Republic for an extension of the deadline for dossier submission based on category 4 studies. UKZUZ has denied the request for category 4 data for efficacy (translated from Czech):

Based on the final opinion of the biological efficacy evaluator, we inform you that the study proposed by the applicant "Trials on orchards for application of captan formulation comparing precision and accuracy achieves via conventional application equipment versus other application equipment and practice reducing exposure" cannot be granted Cat. 4 data status. Regulation (EU) No 2024/2186 sets out the requirements for the use of application equipment in orchards while maintaining the application rate of PPP. The study proposed by you is not necessary for the evaluation of the product for the purpose of renewing its authorisation. At the same time, we would like to point out that the guidance document of the Dutch authority Ctgb submitted by the applicant does not mention the issue of Cat. 4 data.

Even though Cat 4 data has been granted for other aspects extending the deadline for submission to January 2026, it is considered that this is too limited time to generate a supportive data set for efficacy. Setting up specific efficacy trials to test high tech application equipment, requires more planning than standard efficacy trials. This combined with the fact that a successful infection of *Venturia inaequalis* in apple orchards is highly dependent on weather conditions and may simply not occur to a sufficient level in one season, it is considered that at least two seasons (2025 and 2026) are required at a minimum to generate the data. This argument has not been able to sway the zRMS.

Considering that this is an unusual situation in which each member state interprets the EU implantations on a national level, while one zRMS should evaluate, it is unclear to the applicant how to deal with the situation. Is it possible to submit the additional efficacy data to the Netherlands as a cMS for a national evaluation after the zRMS deadline has expired? Or can

Sharda request your help to explain to the Czech authorities that a further extension of the product renewal submission deadline would be required to generate the data required for the Netherlands?

Thank you in advance for your support.

Best regards,

5.1.2.e



5.1.2.e (MSc)

Registration specialist

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From: 5.1.2.e <5.1.2.e@ctgb.nl>

Sent: Monday, January 13, 2025 1:46 PM

To: 5.1.2.e | LingeAgroconsultancy <5.1.2.e@lingeagroconsultancy.nl>

Subject: concept decision for Scab 80 WG NLWG

Dear 5.1.2.e

In a few moments I will send you the concept decision for the NLWG of Scab 80 WG via File Sender.

The concept is not yet approved by the Board, so no rights can be derived from the concept. I hope, the Board will agree on the concept decision by Thursday this week. The main issues were already presented to and discussed by the Board in their meeting in December. The Board also agreed to use the digital process for formalizing these decisions, which should take place in the coming days.

May Linge or Sharda have remarks on significant mistakes in the concept decision or part A, please let me know before Thursday 16 January midnight. No new information can be submitted in reaction to this email.

What happens next:

Presuming the Board agrees, next week the decision will be administratively processed, formalized and published on the Ctgb website.

The decision will be announced in the Ctgb press release after the Board meeting of 22 January.

The decision will be published in the Staatscourant on 29 January.

With kind regards

5.1.2.e

5.1.2.e

Project manager

Ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden

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