



July 20, 2018

European Chemicals Agency (ECHA)
P.O. Box 400
00121 Helsinki
Finland

[REDACTED]
Bayer CropScience LP
890 Embarcadero Drive
West Sacramento, CA 95605
United States

**Subject: Terpenoid Blend QRD 460 - CLH classification process -
Comments related to alpha-terpinene, p-cymene, and d-limonene.**

Tel.: [REDACTED]
Mobile: [REDACTED]
[REDACTED]

Dear Sir and/or Madam:

Applicant:
Bayer AG
Alfred-Nobel Str 50
40789 Monheim am Rhein
Germany

The active substance Terpenoid Blend QRD 460 was approved subject to the conditions laid down in Annex I of the Commission Implementing Regulation (EU) No 2015/1192 of 20 July 2015 approving the active substance in accordance with Regulation (EC) No 1107/2009. Please note that the subject conditions have been met.

In May 2017 I received a notification from Bureau REACH NL indicating that the active substance was being evaluated for classification as part of the CLP process, I was informed that because Terpenoid Blend QRD 460 was a blend of three terpenes, and therefore a mixture, it could not be classified as a single substance and that separate classification dossiers on the three terpenes had been produced. I replied and received the following response contained herein.

Response from Bureau REACH, NL to Bayer's comment that the classification should have been conducted on the blended active substance:

"According to title V of CLP, harmonised classification is only possible for substances. As terpenoid blend does not fulfil the definition of a substance as defined in article 2 but rather the definition of a mixture defined in the same article, a harmonised classification of terpenoid blend is not possible. This has been discussed with ECHA before starting with the CLH dossier(s). ECHA has discussed this with COM. The COM agreed with the interpretation that no CLH dossier should be submitted for terpenoid blend since it is considered as a mixture and instead separate dossiers for the three active substances should be submitted. In addition, specific justification demonstrating the need for action at EU level is not required, since the substances can be considered as active substances."

While we have read the above response to Bayer's request that this active substance be assessed as a single substance rather than as three separate components, and acknowledge the process that was indeed used, there remains a substantial disconnect between the way the terpenoid blend was reviewed and approved under (EC) 1107/2009 as a single active substance and the manner in which it was reviewed here. And while we agree that the three terpenes - in combination - are the active



constituents, they are not considered or registered as individual pesticide active ingredients. (Note: d-limonene has some registrations, mainly in pet pest control, not crop protection.)

Perhaps this was considered by the Agency as a minor point when comparing the overall classification process and goal of a harmonized approach to the registration approval status of one particular active ingredient, but it is an important consideration for Bayer. The effort required to successfully obtain approval for the single substance concept was significant for not only Bayer, but also for the RMS (ctgb) tasked with evaluating the dossier. The classification approach used here diminishes those efforts, but even more so because the extensive safety data studies (utilizing animals) generated to support the registration dossier of terpenoid blend QRD 460 were not considered. This is likely due to the classification process employed, however, there are clear provisions in the CLP classification criteria (EC 1272/2008) for such a situation.

Section 3.7.3.2.1 (Classification of mixtures when data are available for complete mixture), the CLP classification criteria states:

“Classification of mixtures will be based on the available test data for the individual ingredients of the mixture using concentration limits for the ingredients of the mixture. ***On a case-by-case basis, test data on mixtures may be used for classification*** when demonstrating effects that have not been established from the evaluation based on the individual components.”

It seems reasonable to conclude that some of the GLP studies conducted with the terpenoid blend active could have supported the classification process, and been used as supplementary information in cases where no data were available for the individual components. Bayer’s preference would be to classify terpenoid blend QRD 460 as a single active substance corresponding to its EU approval status, but short of that we believe at the very least the data provided for registration should be consulted and utilized for the classification process.

In case anything is unclear, or additional information is required, please do not hesitate to contact me. Please note that this correspondence does not contain confidential information.

Sincerely,



Global Regulatory Manager
Biologics