



**Australian Government**  

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**Australian Pesticides and  
Veterinary Medicines Authority**



**Draft amending instrument to the Agricultural and Veterinary  
Chemicals Code (Agricultural Active Constituents)  
Standards 2022**

Submissions received

April 2023

18<sup>th</sup> October 2022

Director Chemistry and Manufacture  
Australian Pesticides and Veterinary Medicines Authority  
GPO Box 3262  
Sydney NSW 2001

Dear Director of Chemistry and Manufacture,

**Draft amending instrument to the Agricultural and Veterinary Chemicals Code (Agricultural Active Constituents) Standards 2022.**

Nufarm welcomes the amendments to the Agricultural Active Constituents Standards to include updated guidance on the analysis of polychlorinated dibenzodioxins and dibenzofurans in technical active constituents. The proposed changes to include a quarterly quality control program will ensure the availability of low dioxin products in Australia.

Nufarm is supportive of all the changes proposed but has some concerns regarding the practicalities involved in the frequency of the proposed quality control program with respect to 'campaign' manufacturing, the exclusion of 2,4-D esters and the phase in period.

***Formation of polychlorinated dibenzodioxins and dibenzofurans during esterification of 2,4-D***

It is noted in the proposal that in order to meet the standard, in certain circumstances a scientific argument may be used in conjunction with analytical results to demonstrate that the level of PCDD's and PCDF's are acceptable in the technical active constituent. The example used was the compliance of the 2,4-D used to manufacture a 2,4-D ester. Nufarm has observed that small increases of PCDD's and PCDF's may be formed during the esterification of 2,4-D. Therefore, to ensure that the level of PCDD and PCDF's in products supplied in Australia is compliant and safe, Nufarm proposes that such esters are not exempt from the proposed quality control program.

***Phase-in period for new guidance***

As noted in the proposal, the analytical methods used for the determination of the low levels of PCDD's and PCDF's in technical material require specialised equipment and skilled personnel. There are very few laboratories who provide such service, and such analysis is considerably expensive. The proposed increased testing regime will require an increase in testing capacity and skilled personnel.

The proposed amendments do not include a phase in period. Nufarm would like to propose a phase in date of July 2023 to allow for the capacity building and generation of data.

***Reporting of PCDD and PCDF in 2,4-D***

The proposal lacks clarity regarding the reporting of the results of this quality control program. Will there be a requirement to regularly report the results of this program to the APVMA, or is the data only to be provided in the event of a request from the APVMA?

Will the guidance require the inclusion of the levels of each of the 17 congeners on the certificate of analysis as a range over the previous two years, or will a report of total combined PCDD and PCDF's as a range over two years suffice?

***Requirement to meet quality control program for campaign batches of technical material***

On occasion Nufarm manufactures certain technical material on a campaign, that is the material is not regularly manufactured throughout the year. In such cases a quality control program involving the testing of batches at least every three months is impractical.

Nufarm proposes that such campaign technical active constituents are exempted from the proposed amendment and replaced with a requirement for testing that campaign batch only.

Yours sincerely,

