



## DECISION

6 April 2016

Substance	MODIFIED REASSESSMENT OF CALLISTO
Application code	APP202063
Application type	To modify an existing approval for a hazardous substance under Section 63A of the Hazardous Substances and New Organisms Act 1996 ("the Act")
Application sub-type	Modified reassessment – externally generated
Applicant	Syngenta Crop Protection Limited (the Applicant)
Purpose of the application	To extend the use of the registered product Callisto to turf, the product is to be marketed under the name Tenacity Turf Herbicide
Approvals to be amended	HSR002475 – Callisto
Date application received	13 April 2015
Submission period	28 April 2015 – 10 June 2015
Submissions received	Moreen Taylor Te Rūnanga o Ngāi Tahu (Ngāi Tahu) Bay of Plenty Regional Council
Consideration date	1 March 2016
Considered by	A subcommittee of the Hazardous Substances and New Organisms (HSNO) Committee of the Environmental Protection Authority (referred to as 'the Committee'), which comprised: <ul style="list-style-type: none"><li>• Deborah Read (Chair)</li><li>• Louise Malone</li><li>• Nick Roskrug</li></ul>
Decision	<b>Approved with controls</b>
Approval code	<b>HSR002475 - Callisto used as TENACITY Turf Herbicide</b>
Hazard classifications	<b>6.4A, 6.9A (O), 9.1A, 9.2A</b>

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## 1 Background

- 1.1. Callisto was approved in April 2006 for use as a herbicide for the selective control of a wide range of broadleaf weeds in grain and silage maize. It contains 480 g/L mesotrione as the active ingredient. The application for reassessment of Callisto is for use on turf, which would require an increase in the maximum application rate and the frequency of applications compared with currently approved uses and would therefore significantly exceed the current permitted application rate. This new use would be marketed as Tenacity Turf Herbicide, but to remain consistent throughout this document, this substance is referred to as 'Callisto'. The Environmental Protection Authority (the EPA) considered in July 2013 that reassessment of the Approval of the substance is justified on the grounds of a significant change of use [Section 62(2) (c) of the HSNO Act].
- 1.2. The application for a reassessment of Callisto was made by Syngenta Crop Protection Limited (the Applicant). They provided pre-lodgement summary information which was circulated by the EPA to Te Herenga.

## 2 Application process

### Background to the application

- 2.1 The Applicant has applied for a modified reassessment of Callisto to allow an increase in the maximum application rate and frequency of applications. This will allow it to be used on turf.

Specifically, the Applicant wishes to remove this modification to the E2 control:

*'The following application rate is set for Callisto: 450 mL product (290 g mesotrione)/ha in maize, once a year.'*

And replace it with a modification which increases the application rate to 600 mL product (389 g mesotrione<sup>1</sup> )/ha, twice per year and to allow it to be used on turf, as Tenacity Turf Herbicide.

### Formal receipt and notification

- 2.2 Grounds for a modified reassessment were granted by a decision making committee of the EPA on 5 July 2013.
- 2.3 The application for a modified reassessment was lodged pursuant to section 63A of the Act and was formally received on 13 April 2015.
- 2.4 The Minister for the Environment was advised of the application on 28 April 2015.

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<sup>1</sup> The technical grade mesotrione used in Callisto is 74% pure. The concentration of technical grade mesotrione in Callisto is 649 g/L thus the concentration of pure mesotrione in Callisto would be 480 g/L. The initial Callisto control gave the amount of active ingredient (mesotrione) based on the technical grade mesotrione (450 mL Callisto containing 290 g technical grade mesotrione which is equal to 216 g pure mesotrione). The updated controls reflect the historical control (600 mL Callisto containing 389 g technical grade mesotrione which is equal to 288 g pure mesotrione).

- 2.5 The Ministry for the Environment (MfE), WorkSafe New Zealand, the Ministry of Health (MoH), the Department of Conservation (DOC) and the Agricultural Compounds and Veterinary Medicines group of the Ministry for Primary Industries (ACVM-MPI) were identified as having a specific interest in the application. They were notified of the application and the submission period. No comments were received.
- 2.6 The application was publicly notified in accordance with section 53 of the Act and open for submissions from 28 April 2015 until 10 June 2015.
- 2.7 The timeframe of the application was waived under section 59 of the Act to obtain further information from the Applicant.
- 2.8 This application was considered by the Committee on 1 March 2016.

## Submissions

- 2.9 Three submissions were received, from:
- Moreen Taylor,
  - Bay of Plenty Regional Council and
  - Te Rūnanga o Ngāi Tahu (Ngāi Tahu).

Moreen Taylor and Te Rūnanga o Ngāi Tahu opposed the proposed change of controls and the Bay of Plenty Regional Council neither supported nor opposed the proposed change. Ngāi Tahu indicated that they would like to be heard in support of their submission but subsequently withdrew their request to be heard.

## EPA Staff Evaluation and Review Report

- 2.10 In order to assist the Committee in its decision making process, the Evaluation and Review (E&R) Report was prepared, which is the EPA Staff's review of the application and supporting information, including submissions and the original application and associated documents. This included reviewing confidential material submitted by the Applicant for this application. The E&R Report was publicly released on 15 February 2016.

## 3 Consideration

- 3.1 As there were no submitters wishing to present in support of their submissions the Committee held a consideration via teleconference. The Chair of the Committee was Dr Deborah Read. The other members of the Committee were Dr Louise Malone and Dr Nick Roskruge.
- 3.2 The Committee considered that it had received sufficient information to proceed with its consideration of the application. The EPA Staff were also in attendance at the teleconference held on 1 March 2016.

## The requirements of section 63A

- 3.3 According to section 63A(1)(b), a modified reassessment may be carried out where the EPA considers that the reassessment will involve only a specific aspect of the approval and the proposed amendment is not a minor or technical amendment to which section 67A applies.
- 3.4 According to section 63A(6), the Committee may approve or decline an application for reassessment under this section, as it considers appropriate, after taking into account:
- (a) all the effects associated with the reassessment; and
  - (b) the best international practices and standards for the safe management of hazardous substances.
- 3.5 The modified reassessment application lodged by the Applicant was for a significant change in the use pattern of the substance Callisto. Under the Act, the Committee could only consider and decide upon aspects of the approval relating to the proposed new use pattern.

## Identification of risks, benefits and costs

### Potentially non-negligible risks

- 3.3 The E&R Report determined that the hazard classification of Callisto had not changed from its original assessment and is 6.4A, 6.9A (O), 9.1A, 9.2A. The E&R Report included a review of the proposed modifications to the use of Callisto. As the application, equipment and parameters for use of Callisto on turf have different exposures to the existing uses of Callisto, a quantitative risk assessment of both human health and the environment was performed using the different use pattern.<sup>2</sup>
- 3.4 The Staff assessment identified that the following human health and environmental risks were above the level of concern to (i.e. could be non-negligible unless suitable controls are put in place):
- workers during mixing, loading and application;
  - aquatic plants;
  - non-target and threatened native plants - from spray drift; and,
  - bees and other beneficial insects.
- 3.5 The E&R Report concluded that these risks can be adequately managed using appropriate controls.
- 3.6 The Committee agreed with the risk assessments as carried out by the EPA Staff in the E&R report and agreed that the risks, with the proposed controls in place, will be negligible.

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<sup>2</sup> These assessments are set out in Appendices B and C of the [EPA Staff Evaluation and Review Report](#), which is available at [www.epa.govt.nz/hazardous-substances](http://www.epa.govt.nz/hazardous-substances) [search:APP202063]

### Potential costs and benefits

- 3.7 The Applicant's information stated that the turf management market caters to approximately 45,000 hectares. The Applicant also stated that Callisto:
- has lower toxicity than other products on the market.
  - can be used to control both broadleaf and grass weeds, thereby decreasing the number of herbicides needing to be applied.
  - will result in lower injuries to people participating in sports and recreational activities on turf, as high quality turf provides a surface without irregularities.
  - represents an alternative mode of action that prevents herbicide resistance.

### Relationship of Māori to the environment

- 3.6 The Committee noted that the Staff assessed the potential effects of the proposed change on the relationship of Māori to the environment in accordance with sections 5(b), 6(d) and 8 of the HSNO Act. The Committee acknowledged the Staff Report considered this in detail and the Committee has taken this into account.
- 3.7 Based on the information provided, including the use patterns, and the proposed changes in controls as recommended in Appendix A, the Committee considered the impact of Callisto on the relationship of Māori to the environment will be negligible. With this assessment in mind the Committee considered that the application is consistent with the principles of the Treaty of Waitangi.

### New Zealand International Obligations

- 3.4 On the basis of the Staff's advice, the Committee considered that this modification of the Callisto approval for Tenacity Turf Herbicide would not impact on any of New Zealand's international obligations.

## 4 Controls

- 4.1 The Committee considered the EPA Staff Report's conclusions and the proposed controls in the areas of:
- specifying maximum rates and frequency of applications;
  - requirements for approved handler status;
  - stipulating use of personal protective equipment (PPE);
  - reducing the effects of spray drift by requiring nozzles to spray coarse droplets;
  - applying downwind buffer zones including separation distances to waterways and non-target plants; and,

- requiring certain controls, limitations and restrictions to be displayed on labels.

4.2 The Committee agreed that these controls would manage the potential risks associated with the proposed new use of the product and that, with these controls in place, the risks would be negligible.

## Review of controls for cost-effectiveness

4.3 The Committee considered that the proposed controls are the most cost-effective means of managing the identified risks and costs associated with this application.

## 5 Decision

5.1 The Committee determined that the application meets the criteria for consideration under section 63A. In doing so, the Committee applied the relevant sections of the Act and clauses of the Hazardous Substances and New Organisms (Methodology) Order 1998 (“the Methodology”).

5.2 The Committee considered that, taking into account the controls listed in Appendix A, significant adverse impacts on the social or economic environment are not anticipated.

5.3 The Committee considered that significant negative effects on Māori culture or traditional relationships with ancestral lands, water, site, wāhi tapu, valued flora and fauna or other taonga are not anticipated.

5.4 The Committee considered that benefits may be derived for New Zealand by approving the reassessment.

5.5 The Committee has replaced the previous controls with the new controls, below, for Callisto as Tenacity Turf Herbicide and **approved the application** on reassessment.



**Deborah Read**

**Date: 6 April 2016**

Chair, Decision Making Committee,  
Environmental Protection Authority

HSR002475

## Appendix A: Controls for Callisto as Tenacity Turf

The following are the controls for Callisto (HSR002475) including the revised controls from this reassessment (in bold).

Please refer to the Hazardous Substances Regulations and the modifications listed below for the requirements of each control. The regulations can be found on the New Zealand Legislation website <http://www.legislation.co.nz>.

### Hazardous Substances (Classes 6, 8, and 9 Controls) Regulations 2001

Code	Regulation	Description	Variation
T2	Regs 29, 30	Controlling exposure in places of work through the setting of workplace exposure standards (WESs)	A WES is adopted for the following component of Callisto:  Component G (vapour and mist) = TWA Ceiling 50 ppm (127 mg/m <sup>3</sup> )
T3	Regs 5(1), 6	Requirements for keeping records of use	
T4	Reg 7	Requirements for equipment used to handle substances	
T5	Reg 8	Requirements for protective clothing and equipment	<b>The following sub clause is added after sub clause (1)(b) of regulation 8:</b>  <b>(1)(c) A person handling (mix, load or apply) this substance must ensure minimum requirements for PPE are worn:</b>  <b>(a) Coveralls</b> <b>(b) Shoes</b> <b>(c) Socks</b> <b>(d) Gloves</b> <b>(e) Hood/Visor</b>
T7	Reg 10	Restrictions on the carriage of toxic or corrosive substances on passenger service vehicles	<b>(f)</b> The maximum quantity of this substance that can be carried on a passenger service vehicle is 1.0 L per package
E1	Regs 32 – 45	Limiting exposure to ecotoxic substances through the setting of environmental exposure limits (EELs)	The following EELs are set for mesotrione:  <ul style="list-style-type: none"> <li>EEL<sub>surface deposition</sub> = 0.0037 mg/m<sup>2</sup> for mesotrione in the terrestrial environment.</li> <li>EEL<sub>soil</sub> = 0.0001 mg/kg dw soil.</li> <li>EEL<sub>water</sub> = 0.0008 mg/L.</li> </ul> There is insufficient data to calculate an

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Code	Regulation	Description	Variation
			EEL for sediment.
E2	Regs 46 – 48	Restrictions on the application of substances within application areas	<p><b>A maximum application rate is set for this substance.</b></p> <p><b>The person in charge of the application of this substance, and any person applying the substance, must ensure that the application is carried out in accordance with the following restrictions:</b></p> <ul style="list-style-type: none"> <li>• <b>the substance must not be applied at rates exceeding 600 mL of formulated product/ha per application (equivalent to 387 g mesotrione /ha); and</b></li> <li>• <b>the substance must not be applied to the same area more than two times in any 330-day period; and</b></li> <li>• <b>an interval of at least 14 full days must be observed before the substance is reapplied to the same area.</b></li> </ul>
E5	Regs 5(2), 6	Requirements for keeping records of use	
E6	Reg 7	Requirements for equipment used to handle substances	
E7	Reg 9	Approved handler/security requirements for certain ecotoxic substances	This control is only applicable at the 'use' phase of Callisto's lifecycle.

## Hazardous Substances (Identification) Regulations 2001

Code	Regulation	Description	Variation
I1	Regs 6, 7, 32 – 35, 36(1) – (7)	Identification requirements, duties of persons in charge, accessibility, comprehensibility, clarity and durability	
I3	Reg 9	Priority identifiers for ecotoxic substances	
I9	Reg 18	Secondary identifiers for all hazardous substances	
I11	Reg 20	Secondary identifiers for ecotoxic substances	
I16	Reg 25	Secondary identifiers for toxic substances	
I17	Reg 26	Use of generic names	
I18	Reg 27	Requirements for using concentration ranges	
I19	Regs 29 – 31	Additional information requirements, including situations where substances are in multiple packaging	
I21	Regs 37 – 39, 47 – 50	General documentation requirements	
I23	Reg 41	Specific documentation requirements for ecotoxic substances	
I28	Reg 46	Specific documentation requirements for toxic substances	
I29	Regs 51, 52	Signage requirements	

## Hazardous Substances (Packaging) Regulations 2001

Code	Regulation	Description	Variation
P1	Regs 5, 6, 7(1), 8	General packaging requirements	
P3	Reg 9	Criteria that allow substances to be packaged to a standard not meeting Packing Group I, II or III criteria	
P13	Reg 19	Packaging requirements for toxic substances	
P15	Reg 21	Packaging requirements for ecotoxic substances	

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Code	Regulation	Description	Variation
PG3	Schedule 3	Packaging requirements equivalent to UN Packing Group III	
PS4	Schedule 4	Packaging requirements as specified in Schedule 4	

## Hazardous Substances (Disposal) Regulations 2001

Code	Regulation	Description	Variation
D4	Reg 8	Disposal requirements for toxic and corrosive substances	
D5	Reg 9	Disposal requirements for ecotoxic substances	
D6	Reg 10	Disposal requirements for packages	
D7	Regs 11, 12	Information requirements for manufacturers, importers and suppliers, and persons in charge	
D8	Regs 13, 14	Documentation requirements for manufacturers, importers and suppliers, and persons in charge	

## Hazardous Substances (Emergency Management) Regulations 2001

Code	Regulation	Description	Variation
EM1	Regs 6, 7, 9 – 11	Level 1 information requirements for suppliers and persons in charge	
EM6	Reg 8(e)	Information requirements for toxic substances	
EM7	Reg 8(f)	Information requirements for ecotoxic substances	
EM8	Regs 12 – 16, 18 – 20	Level 2 information requirements for suppliers and persons in charge	
EM11	Regs 25 – 34	Level 3 emergency management requirements: duties of person in charge, emergency response plans	
EM12	Regs 35 – 41	Level 3 emergency management requirements: secondary containment	
EM13	Reg 42	Level 3 emergency management requirements: signage	

## Hazardous Substances and New Organisms (Personnel Qualifications) Regulations 2001

Code	Regulation	Description	Variation
AH 1	Regs 4 – 6	Approved Handler requirements (including test certificate and qualification requirements)	Refer to control E7

## Hazardous Substances (Tank Wagon and Transportable Containers) Regulations 2004

Code	Regulation	Description	Variation
Tank Wagon	Regs 4 to 43 as applicable	Controls relating to tank wagons and transportable containers	

## Additional controls

Code	Section of the Act	Control
Water	77A	This substance must not be applied into or onto water <sup>3</sup>
App method	77A	The application of the substance is limited to ground-based application methods only <sup>4</sup> <b>This substance must be applied with nozzles equipped to provide a coarse spray<sup>5</sup></b>
Buffer Zone	77A	<b>This substance must not be applied within ten metres<sup>6</sup> of a downwind<sup>7</sup> water body<sup>8</sup></b> <b>This substance must not be applied within 15 metres<sup>9</sup> of downwind non-target plants</b>

<sup>3</sup> Where 'water' means water in all its physical forms, whether flowing or not, and whether over or under ground, but does not include water in any form while in a pipe, tank or cistern or water used in the dilution of the substance prior to application.

<sup>4</sup> Ground-based methods of applying pesticides include, but are not limited to, application by ground boom, air blast or knapsack, and do not include aerial application methods

<sup>5</sup> Where a coarse quality of spray is according to the American Society of Agricultural & Biological Engineers (ASABE) droplet size classification scheme.

<sup>6</sup> This distance is the distance between the edge of the application area closest to the water body and the edge of the water in the water body closest to the application area.

<sup>7</sup> Downwind refers to a location in a direction to where the wind blows away from the application area.

<sup>8</sup> A water body includes modified water courses such as reservoirs, irrigation canals, and water-supply races, canals for the supply of water for electricity generation or farm drainage canals, as well as natural water bodies.

<sup>9</sup> This distance is the distance between the edge of the application area closest to the non-target plants and the non-target plants.

Code	Section of the Act	Control
Sch 8	77A	<p>This schedule prescribes the controls for stationary container systems. The requirements of this schedule are detailed in the consolidated version of the Hazardous Substances (Dangerous Goods and Schedule Toxic Substances) Transfer Notice 2004, available from <a href="http://www.epa.govt.nz/Publications/Transfer-Notice-35-2004.pdf">http://www.epa.govt.nz/Publications/Transfer-Notice-35-2004.pdf</a></p> <p>The following clause replaces Clause 1 of Schedule 8 of the Hazardous Substances (Dangerous Goods and Scheduled Toxic Substances) Transfer Notice 2004:</p> <p><i>This Schedule applies to every stationary container system that contains, or is intended to contain the substance.</i></p>
Label	77A	<p><b>The following statements or words to the same effect must be included on the label:</b></p> <ol style="list-style-type: none"> <li>1. <b>A person handling (mixing, loading or applying) this substance must ensure minimum requirements for PPE are worn:</b> <ul style="list-style-type: none"> <li>• Coveralls</li> <li>• Shoes</li> <li>• Socks</li> <li>• Gloves</li> <li>• Hood/Visor</li> </ul> </li> <li>2. <b>This substance must not be applied into or onto water</b></li> <li>3. <b>This substance must be applied with nozzles equipped to provide a coarse spray</b></li> <li>4. <b>The application of the substance is limited to ground-based application methods only</b></li> <li>5. <b>The substance must not be applied at rates exceeding 600 mL of formulated product/ha per application (equivalent to 387 g mesotrione /ha)</b></li> <li>6. <b>The substance must not be applied to the same area more than two times in any 330-day period and an interval of at least 14 full days must be observed before the substance is reapplied to the same area</b></li> <li>7. <b>This substance must not be applied within ten metres of a downwind water body</b></li> <li>8. <b>This substance must not be applied within 15 metres of downwind non-target plants</b></li> </ol>