

REGULATION OF ENVIRONMENTAL INHIBITORS UNDER THE AGRICULTURAL COMPOUNDS AND VETERINARY MEDICINES (ACVM) ACT AND INCLUSION IN THE GREENHOUSE GAS INVENTORY

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Abstract

This paper discusses the regulation of inhibitors under the Agricultural Compounds and Veterinary Medicines (ACVM) Act (1997), and their accounting in the greenhouse gas inventory. Inhibitors are compounds used to mitigate adverse impacts on the environment, such as nutrient leaching into nearby water bodies, or greenhouse gas emissions. While some of these compounds have been used for years in New Zealand and overseas, the level of regulatory oversight has been light, including in New Zealand. In 2021 the Government decided that the lack of regulatory oversight for environmental inhibitors needed addressing. Therefore, regulation under the ACVM Act (1997) was agreed upon to manage risks to food safety, trade, and animal/plant health. On 18 July 2022, an Order in Council under the ACVM Act declared 46 substances to be agricultural compounds when used as inhibitors. An amendment to the ACVM Act is underway that proposes to amend the definition of an agricultural compound to include environmental inhibitors.

Regardless of the registration status of environmental inhibitors under the ACVM Act, the effect of mitigation technologies per se used on farms will need to be reflected in New Zealand's national emissions estimates via the national Greenhouse Gas Inventory. To maintain the accuracy of these estimates it is important there is strong evidence of the efficacy of any mitigation technology as well as verifiable data on the use of that technology on farms. Accurate accounting of the effect of these technologies on emissions will help ensure the agriculture sector can get credit for the development and deployment of these technologies both domestically and internationally.

Regulatory Oversight of Environment Inhibitors under the ACVM Act

Environmental inhibitors (hereafter, 'inhibitors') are products used in agricultural production to modify either a biological or chemical process to manage or reduce either: 1) the release of greenhouse gases or 2) nutrient leaching.

In 2021, the New Zealand Government decided that inhibitor products require greater regulatory oversight. Given the potential risks posed by the use of inhibitors align with other

products already managed by ACVM, the ACVM Act was deemed the appropriate mechanism to manage risks associated with their use. Through the registration of agricultural compounds, ACVM manages risks to 1) public health; 2) agricultural security; 3) animal welfare; and 4) international trade. Given that a large component of New Zealand's economy relies on the export of agricultural products, it is crucial to ensure that trade is protected. New Zealand has previously used dicyandiamide (DCD) a nitrification inhibitor that reduces the loss of nitrogen from soil. After grazing by milking cows, DCD was detectable in milk which created a trade risk as there were no residue limits set in any country or CODEX. Subsequent to New Zealand withdrawing the use of DCD, trade was disrupted due to some trading partners requiring additional testing and assurances. By requiring registration through ACVM the risks associated with residues can be assessed and managed. Maximum residue levels (MRLs) can be established if required such that MRLs meet the regulatory requirements of trading partners.

There are two mechanisms by which inhibitors are being brought under the ACVM Act: a temporary measure and a permanent measure. The temporary measure is an [Order in Council](#) (OIC), that declares products with an inhibitor claim *and* includes one of 46 substances on the OIC to be an agricultural compound and thus require registration under the ACVM Act. In this case, the requirement for inhibitor registration under the ACVM Act is dependent on the proposed label claim, and its ingredients. The permanent measure is a proposed amendment to the ACVM Act itself, to broaden the definition of 'agricultural compound' to include all products that make a claim to either: 1) mitigate adverse impacts on the environment; or 2) mitigate emissions that contribute to climate change. In the permanent solution, it is solely the label claim that triggers ACVM registration requirements, independent of the ingredients included in the product. The amendment to the ACVM Act is proposed through the Regulatory Systems (Primary Industries) Bill (RSPiB), which was introduced into the house in June 2023, but has not yet undergone first reading.

From an Agricultural Compounds and Veterinary Medicines (ACVM) perspective, inhibitors are subdivided into two categories: agricultural chemicals are applied on or around plants; veterinary medicines are applied on or around animals. An example of an agricultural chemical is a urease inhibitor applied as a coating around urea fertilizer granules, to slow the conversion of urea into ammonium, reducing ammonia volatilisation; an example of a methane inhibitor is a product given with cattle feed to disrupt methanogenesis in the rumen to prevent the release of methane gas into the atmosphere.

Information requirements for inhibitors are closely aligned to information requirements for other agricultural chemicals or veterinary medicines. Depending on the use pattern of the inhibitor, data packages for chemistry and manufacturing, residues, and target animal/plant safety are required. An additional efficacy data package will be required to ensure truth in labelling. Hyperlinks to efficacy guidance documents for both methane inhibitors and urease/nitrification inhibitors can be found at the bottom of this paper. Note that risks to the environment and human health are managed through the Environmental Protection Authority

under the Hazardous Substances and Novel Organisms Act (HSNO), which is administered by the Environmental Protection Authority (EPA). It is recommended that prospective applicants speak to the EPA early on to ensure that requirements are met. An email contact for guidance under HSNO can also be found at the bottom of this document.

Inclusion of Inhibitors into the Greenhouse Gas Inventory - Key Issues and Considerations

Background

The Agriculture GHG Inventory forms a part of New Zealand's emissions reporting to the United Nations Framework Convention on Climate Change (UNFCCC). Emissions are estimated using a national-level model. National inventories are subject to regular review by international sector experts.

The compilation of national inventories are underpinned by the principles of continuous improvement and increased accuracy of reporting, and so the inventory is updated regularly to incorporate new research. As inhibitors are developed and used on-farm, the effect of these technologies on emissions will need to be reflected in our national emissions estimates. However, any changes to the inventory methodology must be sufficiently robust and defensible to maintain international credibility.

Inventory change process

MPI usually follows the steps outlined below for making changes to the Agricultural GHG Inventory methodology. This ensures that all changes are well-documented and provide sufficient evidence that they are based on robust science, and that their inclusion will lead to more accurate reporting of emissions. Evidence of their use in international inventories (if applicable) may also be helpful for justifying changes to the inventory methodology.

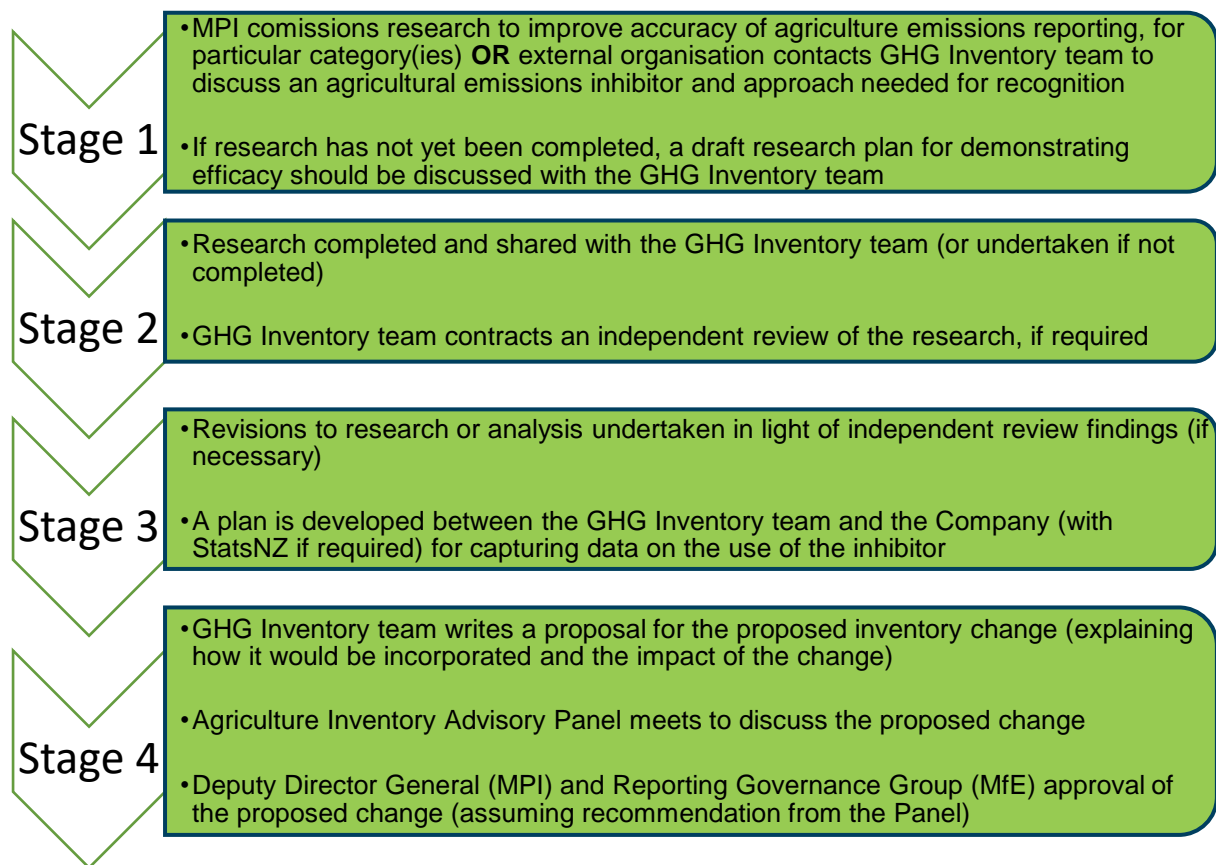


Figure 1. Process used to incorporate an improvement to emissions calculations, including mitigation technologies in the agriculture inventory Research

All proposed inventory changes (including changes to account for the effect of an inhibitor) must be based on a solid scientific foundation. Where an inhibitor has been registered under the ACVM Act, MPI will consider the extent to which data from the registration process meets the requirements of the Agricultural GHG Inventory. The criteria listed below are consistent with both information needs for the inventory and ACVM Act efficacy requirements:

- Research must demonstrate that it is **relevant for New Zealand-specific conditions**. Preferably this would include in-country research, however overseas research may be applicable if evidence is supplied to that effect;
- The **hypothesis being tested, and methodologies used must be sufficiently transparent**, so that it can be readily understood and is repeatable. Results from the research would ideally be published in a peer-reviewed scientific journal;
- Measurement technologies used in the research should be well tested and follow, where available, international good practice guidelines. Measurements and analyses should be carried out by those with sufficient competence, and by those with accreditation as appropriate;
- The inhibitor effect must be able to be modelled at a national-level, therefore the impact needs to be consistent across New Zealand or the average effect of the inhibitor must be quantifiable;
- **There should be a sufficient number of trials, experiments or replicates** to adequately demonstrate the effectiveness of a particular inhibitor, with a consistent response over the range of circumstances under which it will be used. The difference between treated and untreated conditions **should be statistically significant**;

- It would be useful if research took into account whether **new inhibitors affected the efficacy, or were affected by** any other current inhibitors; and
- All raw data collected to prove the effect of the inhibitor is to be made available to allow validation of the research.

Ongoing Data Requirements

If an inhibitor is going to be included in the Agriculture inventory, MPI will require regular, reliable data on the use of these inhibitors, and will need confidence it can acquire this data in the future. The data must be provided with enough detail to allow it to be adopted within the inventory methodologies. For transparency, the data may need to be able to be verified or audited.

See also:

MPI. 2023. Guidance for Incorporating Inhibitors into the Agricultural Greenhouse Gas Inventory. <https://www.mpi.govt.nz/dmsdocument/58045-Criteria-for-Incorporating-Mitigations-into-the-Agricultural-GHG-Inventory>

MPI. 2023. Greenhouse gas reporting. <https://www.mpi.govt.nz/science/open-data-and-forecasting/greenhouse-gas-reporting/>

ACVM guidance on how to register an inhibitor:
<https://www.mpi.govt.nz/agriculture/agricultural-compounds-vet-medicines/acvm-registration-for-inhibitor-applicants/>

Efficacy Guidance Document for methane inhibitors: [Efficacy of methane inhibitor products \(mpi.govt.nz\)](#)

Efficacy Guidance Document for urease/nitrification inhibitors: [Efficacy and Plant Safety of Urease/nitrification Inhibitor Products \(mpi.govt.nz\)](#)

For guidance on authorisation under the Hazardous Substances and Novel Organisms Act, email inhibitors@epa.govt.nz

For more information on the inclusion of inhibitors in the GHG inventory, email ghginventory@mpi.govt.nz