



PRESS RELEASE – for immediate release

October 11, 2011

Government proposals on data protection are a huge disappointment to the makers and sellers of agrichemicals and veterinary medicines.

The proposals – included in a Ministry of Agriculture and Forestry discussion document - recommend no change in much of the current regime and float the possibility of small change in only one aspect of data protection.

“Continued lack of data protection reduces the availability of technology for farmers and growers, but that’s not all,” said Graeme Peters, chief executive of Agcarm, the industry association for crop protection and animal health manufacturers and distributors.

“Lack of data protection results in labels carrying incorrect or out-of-date information; the continued sale of older and more hazardous substances which the government would like to deregister; and more products being used off label, meaning they are used in situations for which they have not been tested and approved by regulators.”

The absence of data protection is a particular headache for growers of minor crops and farmers of minor species. They find it difficult if not impossible to obtain products registered for their particular needs, and are then unfairly criticised for breaching residue limits on their produce.

“This criticism is cruel and unfair as the government’s data protection regime sets these growers up to fail,” Mr Peters said.

Data protection is common overseas and is particularly important in New Zealand because it is a small market.

Agcarm has seen numerous examples of off-patent products which will not be registered for sale in New Zealand because suppliers cannot make a dollar out of registering them. Equally, companies are reluctant to invest in researching New Zealand solutions to New Zealand pest and disease control problems.

“New Zealand is the only developed country in the world which does not give businesses a decent go at generating a return on the high cost of registering many products, in particular new uses and improved versions of existing products,” Mr Peters said.

The government appears to be of the single-minded view that even a modest amount of data protection will stifle generic competition. This is untrue.

Greater data protection is not retrospective and will therefore have no impact on any product which is already registered.

Many generics companies support data protection because they are keen to develop and improve existing products, for which they are required to submit their own data. They also support data protection because they cannot copy a product or new use which isn't registered because of a lack of data protection.

"There is widespread industry support for data protection, which was clearly evident from the 11 submissions in an earlier round of public consultation. Indeed, it's difficult to find anyone opposed to data protection apart from the government, which seems to be basing its decisions on flawed information, incorrect modelling, and a lack of real knowledge about a complicated topic.

"The MAF discussion paper is actually an attempt to close down discussion, which is disappointing. Agcarm will be lodging yet another submission supporting data protection, and encouraging others to air their views. We hope that the government will start to listen, Mr Peters said."

What is data protection?

Before any agrichemical or veterinary medicine is used in New Zealand, approval must be granted by two regulators: the Ministry of Agriculture and Forestry and the Environmental Protection Authority.

The approval process requires applicants to supply supporting information or data on a range of product features including chemistry, manufacture, toxicology, efficacy, and likelihood of residues remaining after use.

This package of data supplied in support of an application represents a significant investment – costing hundreds of thousands of dollars to assemble.

In most cases, this data is not protected from competitors. Consequently, they can produce identical products and obtain regulatory approval by the relevant regulator cross referencing the data provided by the original applicant without having to incur the cost of producing the data.

Why should it be protected?

Greater protection would give a greater incentive to bring new technologies into New Zealand. These technologies are safer and more effective forms of chemical or biological compounds, or new ways for existing products to be used. To remain competitive, New Zealand agriculture needs to access the latest innovations in crop science and crop protection. In summary, data protection is an incentive for suppliers and manufacturers to invest in new solutions for growers and farmers.

The MAF discussion document is available here:

<http://www.foodsafety.govt.nz/elibrary/industry/consultation-data-protection/>

Graeme Peters
027 66 77 400
04 499 4225

ends