

'Test Data Protection' for agvet regulatory data – underpinning solutions for the future

Background

In October 1999 Federal Cabinet approved changes to agvet chemical *test data protection* which will simplify and enhance current arrangements under the *Agvet Code Act 1994*, administered by the National Registration Authority.

Federal Cabinet's considerations followed a joint proposal from the National Farmers' Federation and Australia's agvet chemical industry with detailed assessment from the Commonwealth Data Protection Working Party over some 18 months.

In early 2000 proposed changes to legislation will be circulated to the State and Territory Ministers for agreement under the *National Registration Scheme*.

What is 'test data protection'?

Test data are the mandatory regulatory studies required by the NRA to grant and maintain registrations and approvals.

Test Data Protection provides for a defined and limited period during which the NRA must not refer to the test data of one party to grant registration or approvals for another party without the agreement of the data owner, or where specified, unless agreed or arbitrated *terms of access* have been reached.

In essence, test data protection recognises the significant investment necessary to generate and provide test data to meet Australia's agvet regulatory requirements. It encourages maintenance, product development, innovation and access to chemistries by providing for a short period of exclusive data protection, or, third-party access through a scheme of compensated cross-referencing.

Why is 'test data protection' needed?

Australia's agvet regulatory requirements exist to protect human health, the environment, and to support trade objectives. Australia's agvet regulatory requirements are consistent with OECD standards.

Scientific, technical, trade and community standards continue to evolve. These advances are reflected in the quantum and nature of test data required to allow regulatory

approvals for agvet products. Additionally, as with other countries, Australia has a strong reliance on traditional older agvet chemistries. There is need for continuing investment in test data generation and regulatory review to ensure these products meet contemporary standards.

Australia's current test data protection provisions are widely recognised as inadequate to meet future needs. For

instance, if a company currently undertakes to develop an existing agvet product on a new crop or animal species and invests say \$400,000 to generate the mandatory regulatory data, then on the day on which the new registration is granted by the NRA all competitors may lodge applications and gain identical registrations by referencing the original test data at no cost with respect to the test data owner.

This '*free-riding*' is a fundamental disincentive towards providing the necessary environment for adequate investments to meet Australian agricultural and livestock production needs and ensuring primary production remains internationally competitive.

Table 1: Elements of the proposed changes to the agvet data protection legislation

Category	Agricultural chemicals	Veterinary chemicals
Category 1: New active constituent and its associated product(s) not previously registered in Australia	5 years exclusive data protection* + 5 years compensated cross-referencing	5 years exclusive data protection* + 5 years compensated cross-referencing
Category 2: New product, formulation or use of an existing active constituent	5 years exclusive data protection	3 years exclusive data protection - food producing animals only
Category 3: Call-in data (formal review initiated by the NRA)	10 years compensated cross-referencing	10 years compensated cross-referencing

* This period of exclusive data protection was enacted into legislation on 1st April 1999 in response to the World Trade Organisation's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

The effective dates for data protection are to apply from a period related to the date of registration or regulatory decision.

The introduced legislation will be subject to a review at 3 years after commencement. The legislation will have a sunset of 5 years.

What are the reforms agreed by Federal Cabinet?

The elements of the proposed legislative changes are outlined in Table 1.

The major stakeholders have also worked closely with the Commonwealth in the development of the mechanics and detailed procedures for implementation of the legislative amendments.

Further Information

For any additional information, please contact Avcare:

Claude Gauchat, Executive Director, or
Colin Sharpe, Scientific & Regulatory Affairs Director

Phone: (02) 6230 6399 **Fax:** (02) 6230 6355

Email: colins@avcare.org.au

Address: Level 2, 1 Hobart Place
Canberra ACT 2601

Snapshot - agvet chemical industry and operating environment

Agriculture in Australia

- no countries (possibly other than the USA) have the range of geographic, climatic and established agricultural and livestock industries as Australia;
- approximately 80% of Australia's primary produce is exported;
- Australian agriculture faces many challenges including management of health, safety, environment and trade, some unique to Australia;
- Australia's farmers need to maintain international competitiveness through access to appropriate crop production and animal health tools.

Agricultural and Veterinary Chemicals

- the Australian market represents nearly 1.8% of the global agricultural chemical market and 1.4% of the global animal health market;
- approximately 6700 agvet products are registered by the NRA (3686 agricultural and 3176 veterinary in 1998) with a total sales value of disposals approaching \$2015m (agchem - \$1584m, vetchem - \$431m);
- for agricultural chemicals, in 1998, more than 73% of products had recorded sales of less than \$300K and 87.7% less than \$1m (1997). For veterinary chemicals more than 78% had recorded annual sales of less than \$150K and 90.2% less than \$400K. Refer Table 2;
- there is continuing decline in the discovery, development and commercialisation of agvet chemicals placing increasing reliance on existing active constituents to meet the needs of agriculture and livestock production. This is an international trend and is the result of increasing requirements for regulatory data, more stringent and sophisticated screening processes, increasing R&D costs, complicating factors such as issues of residues in traded commodities, and other factors associated with risks for investments;
- for agricultural chemical products more than 1500 are based on active constituents discovered prior to 1960 (some dating back to the turn of the century). More than 2200 are based on active constituents discovered prior to 1970. Contemporary patented chemicals represent less than 10% of current active constituents;
- many of the older chemicals will continue to have a pivotal role in agriculture and livestock production – and have the potential for improvement (new, safer and more convenient formulations), and increase in utility (registrations in new crops, situations). These chemicals will also form the basis for replacement of other chemicals which may be discontinued for regulatory, trade or other reasons;
- most agricultural chemical products are registered for a wide range of applications (crops/situations and uses). Some individual agricultural chemical products are

registered on more than 100 crops to control more than 100 pest species.

Industry research and development

- local investment in R&D, as a % of sales, has been declining since the early 1990s (<3% in 1998);
- the costs of a development program (eg existing chemical in a new crop or species) are independent of the market size – ie the NRA requires the same regulatory data irrespective of whether the sales market size is \$100,000 per annum or \$2 million;

Table 2: Sales categories by value of agvet chemical products (1998)

\$A Sales 1998 <i>(source: NRA)</i>	Agricultural Chemicals			Veterinary Chemicals		
	Number of Products	Cumulative Total (excluding \$0 sales)	Cumulative %	Number of Products	Cumulative Total (excluding \$0 sales)	Cumulative %
\$0	948	<i>excluded</i>	<i>excluded</i>	642	<i>excluded</i>	<i>excluded</i>
>\$0–10,000	514	514	19.7%	655	655	27.5%
10,000–25,000	333	847	32.6%	428	1083	45.5%
25,000–50,000	269	1116	43.0%	297	1380	58.0%
50,000–100,000	354	1470	56.6%	323	1703	71.6%
100,000–200,000	281	1751	67.4%	259	1962	82.4%
200,000–400,000	259	2010	77.3%	185	2147	90.2%
400,000–500,000	80	2090	80.4%	37	2184	91.8%
500,000–1 million	216	2306	88.7%	95	2279	95.8%
1–1.5 million	87	2392	92.0%	48	2327	97.8%
1.5–2 million	51	2444	94.0%	19	2346	98.6%
2–2.5 million	32	2476	95.2%	13	2359	99.1%
2.5–3 million	24	2500	96.2%	7	2366	99.4%
>3 million	99	2599	100%	14	2380	100%
Total products:	3547			3022		

- new uses for an existing product can be as simple as the addition of a new pest to an existing crop, costing in the order of \$80,000. Product development programs at the other end of the spectrum may range into the order of millions of dollars and run over extended periods;
- the cost of generation of mandatory regulatory data to achieve registration of a new development may represent a significant proportion of the total annual sales of an individual product.

The regulatory environment

- Australia's agvet chemical registration requirements are consistent with those of other developed countries, and the EU, USA and Japan in particular;
- the full operating cost of the NRA (\$15.75m in 1997-98) is cost recovered from industry through fees, levies and charges.

Frequently Asked Questions

Most agvet chemicals were protected by an original patent to allow a return on investment. Why is test data protection needed?

- Figure 1 provides a general description of the life-cycle of an agvet chemical products which assists in understanding the stages from discovery to maturity;
- more than 90% of active constituents contained in current registered products are not covered by patents;
- more than 1500 agricultural chemical products are based on active constituents discovered prior to 1960. Some notable examples include:

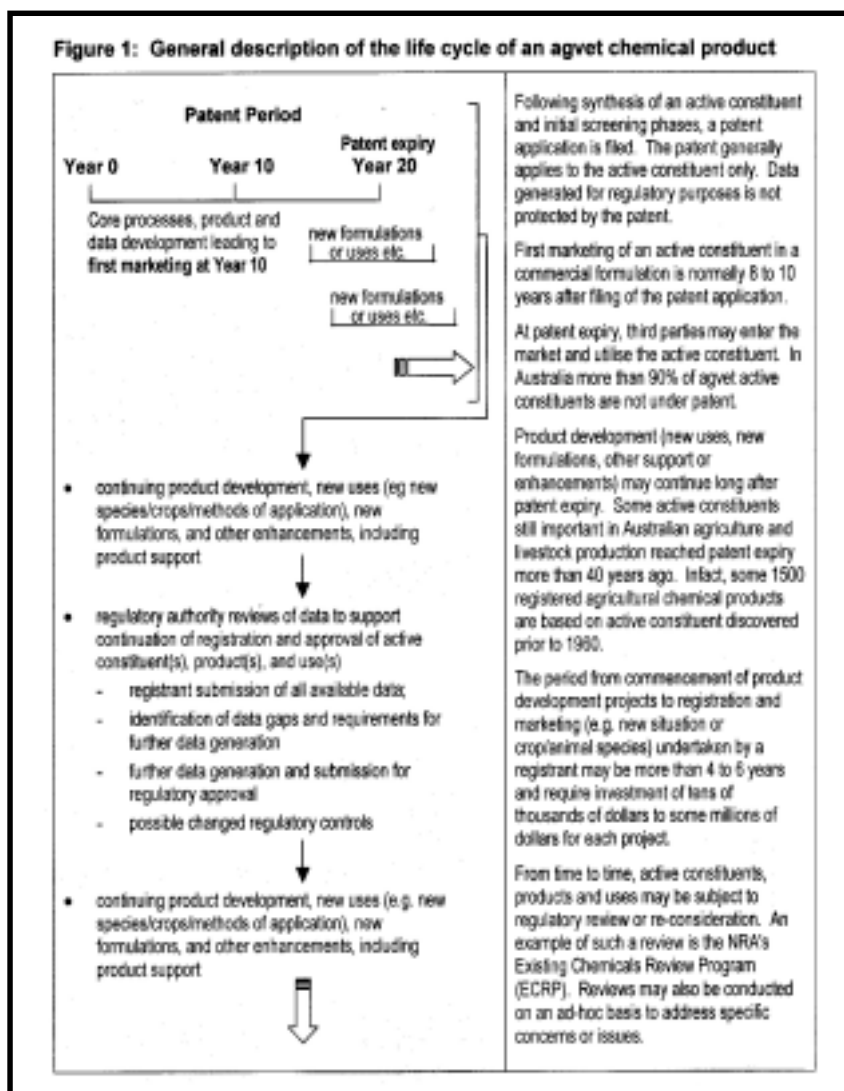
Year	Active Constituent
1897	Dazomet
1900	Copper oxychloride
1910	Sodium chlorate
1930	Pyrethrins
1936	Metalddehyde
1942 - 1950	2,4-D acid/esters/salts, thiram, ziram, zineb, MCPA acid/ester/salts, dichlorophen, parathion, piperonyl butoxide, 2,4-DB, <i>Bacillus thuringiensis</i>
1950 - 1960	Chloroprpham, endothal, dimethoate, diuron, captan, parathion-methyl, maldison, amitrole, mecoprop, mevinphos, diazinon, azinphos-ethyl, azinphos-methyl, diclorvos, dicofol, MSMA, endosulfan, simazine, propazine, dodine, trichlorfon, carbaryl, atrazine, metiram, diquat, paraquat, pebulate, omethoate, chlorthal, dichlobenil, fenthion, propanil, tri-allate, chlormequat, ametryn, dichloran, fenitrothion, trifluralin

- for such active constituents there are multiple product registrants – for example:

diuron:	21 registrants
diazinon:	19 registrants
ametryn:	7 registrants
trifluralin:	12 registrants
2,4-D:	21 registrants
maldison:	22 registrants

- in some cases the 'originator' no longer exists;
- all product registrants have the opportunity to undertake further development work to improve formulations and to expand the utility of chemicals for which patents have expired;
- if any registrant, for instance, decided to develop new formulations and uses for a 2,4-D amine product it is of little relevance that another company once held a patent which expired some 40 years ago;
- the rationale for test data protection is to provide an environment which fosters –

- ongoing enhancement and development of agvet products (including new uses and improved formulations) by providing short defined periods of exclusive test data protection¹; and
- required maintenance of mandatory regulatory data to support continued registration of existing products by providing a compensation mechanism for test data 'called' or required by the NRA to be further generated.



In essence, *patents* and *test data protection* are two very different forms of intellectual property and there is no connection between the purposes they seek to achieve.

Test data protection supports the ongoing development of mandatory regulatory data to maintain and enhance products for the benefit of the Australian market.

¹ Exclusive test data protection means only that the NRA may not refer to the data of one party to support the registration of a third-party without the permission of the data owner. It does not confer any exclusivity on the 'use' or 'development' but only to the data. This is further discussed in context of the practical example over.

Frequently Asked Questions

What is an example of the practical application of test data protection?

An illustrative example of the practical application of test data protection on product formulation changes is provided below.

There would be no impact of test data protection on what are regarded as minor formulation changes. This is because the same regulatory data is required for all applicants, i.e.

- Statement of formulation composition;
- Demonstration that active constituents are approved;
- Demonstration of acceptable non-active constituents;
- Demonstration of product stability and shelf-life;
- Consideration of efficacy, safety etc.

Example 1:

An agricultural product, applied by aircraft, has a high odour level which is causing community concerns. It is determined desirable to remove or reduce the odour. In addition to the above, there would be need to demonstrate that the odour producing agents had been removed or significantly reduced in the formulation. This is logically a regulatory requirement for all registrants to address with respect to individual products. So in this case whilst data submitted may have gained protection, test data protection has no practical application.

Example 2:

Similarly, in the animal health area, the inclusion of a dye marker in a cattle tickicide product would have the same data requirements for all registrants. Again test data protection would have no practical application as each individual application would be reviewed on its own merits.

Example 3:

A more significant formulation change may exist in the following example - A currently registered product is a suspension concentrate formulation containing 250g/L of active constituent. Due to the toxicity profile and relatively low active constituent content, the product has been included in Poisons Schedule 5.

A company utilises an innovative closed-system dispensing delivery system (available in other industries but not utilised in agriculture) that eliminates worker exposure. A formulation is developed specifically for this system - the product is an emulsifiable concentrate formulation that contains 750g/L active constituent. The products profile (changed formulation type and increased active constituent content) fits a Poisons Schedule 6 classification.

In addition to the normal regulatory data the following data requirements also apply:

- Acute toxicity studies on the formulation (acute oral, dermal, ocular, inhalation toxicity);
- Efficacy equivalence data;
- Target crop/animal safety data;

- Residue data to demonstrate existing maximum residue limits (MRLs) are not exceeded;
- Supporting data and information on occupational health and safety relating to the new formulation and the dispensing/delivery system.

Under test data protection, secondary applicants wishing to register an identical product would have the following options:

- (a) reach a commercial arrangement for access to the data with the holder; or
- (b) gain access to equivalent data from other sources; or
- (c) generate own data.

If the market were large there would be high incentive for entry. If the market were small or niche there may be less incentive for other players to respond and they could continue marketing their current product (the 250g/L suspension concentrate) which would have a place in the market for some time (or on-going) as the rate of adoption of the new technology may be slow and the original products may serve a purpose for a segment of the market. The commercial 'risk' lies with the innovating company in outlaying its research and development investment and developing its market share.

Test data protection does not guarantee that investments will be rewarded. Rewards only come if the marketplace sees commercial and social value in the product or development. Test data protection does increase the importance of investments and developments that do have value in the marketplace. This reward for investment, risk taking and creativity is a proven and important catalyst for technological advancement in free market economies. Protected data is also a tradeable commodity. If a small company, or any company for that matter, does not have the ability, desire, or sufficient market presence in a particular market segment to effectively utilise its developments it may choose to reach commercial arrangements with other parties. In this way the enterprise and innovation of the originating company is encouraged and the 'new development' reaches market application.

Will test data protection decrease competition in the market place?

- the 'market' for agvet products is recognised as being the 'fields of use' or treatment requirement. For example, competition needs to be considered in context of, for instance, *control of wild radish in barley* rather than sales of individual products.
- for the control of wild radish in barley there are more than 80 products registered (based on 26 active constituents) from some 12 manufacturers. Such situations represent extremely competitive markets and also provide farmers with a number of 'options' which must be rotated as part of an essential resistance management program;
- other than for a very limited number of existing active constituents/products and potential new uses it has not been commercially feasible for industry to invest in further research and development in the absence of

Frequently Asked Questions

test data protection – recognising that on the day on which the new registration is granted by the NRA all competitors may lodge applications and gain identical registrations by referencing the original test data at no cost with respect to the test data owner.

In the calendar year of 1998, the National Registration Authority received a total of 2027 applications. Applications in the following key NRA classes reflect the low level of activity in developing existing active constituents and products:

- (a) veterinary chemicals:
 - 1 application for the registration of a new combination product;
 - 5 applications for the registration of major changes in formulation; and
 - 3 applications for major extensions of use for food/fibre producing species.
 - (b) agricultural chemicals²:
 - 2 applications for the registration of new combination products;
 - 7 applications for the registration of new products with approved actives in new situations;
 - 4 applications for the registration of major changes in formulation; and
 - 14 applications for major extensions of use.
- test data protection has the potential to increase market competition through the registration of alternate control options available to farmers and livestock producers.

How does test data protection support agricultural objectives?

Test data protection supports agricultural objectives by:

- providing the environment for support of existing products and new improved formulations and uses;
- providing a basis for encouraging product development which may assist with resistance management;
- providing a basis for improved residue management by encouraging the generation of necessary regulatory data;
- assisting farmers to only use registered products for the purposes for which they are registered;
- encouraging active marketplace competition; and
- enhancing the role and reputation of the *National Registration Scheme*.

Test data protection works to provide an environment that encourages any market participant to actively participate in product development to enhance and improve tools offered to farmers and livestock producers.

² Note: the numbers also include non-farm products under the broad NRA definitions of agricultural chemicals

How do the reforms agreed by Federal Cabinet compare with schemes operating in other countries?

The recognition of test data protection (or proprietary rights) is fundamental to agvet regulatory schemes in OECD countries. Schemes operating in North America, Japan and Europe have been in place for more than 20 years.

The need for test data protection increases with increasing mandatory regulatory requirements – if test data is not required to be generated and submitted to the regulatory authority then one registrant may not be disadvantaged against another registrant.

There are differences in international practice with regard to periods of protection and their basis. Some countries grant eternal protection (eg Japan), others grant permutations of periods of exclusive data protection and data compensation. For example, the USA EPA grants 10 years exclusive data protection followed by 5 years data compensation for various categories of test data. 1996 amendments to the US Food Quality Protection Act provide for up to an additional 3 years of exclusive data protection to encourage product development leading to minor-use registrations.

There are also differences in international practice between agricultural chemicals and veterinary chemicals. Australia is an unusual example of where agricultural and veterinary chemicals are evaluated and registered by one regulatory authority, under one legislative framework. Historically, internationally, there has been closer linkage between veterinary chemicals (sometimes referred to as veterinary pharmaceuticals or veterinary drugs) and pharmaceuticals than agricultural chemicals.

The reforms agreed by the Federal Cabinet provide less protection than the protection operating in major countries with equivalent regulatory requirements, in particular the USA, Canada, Japan and Europe.

Does Avcare have any concerns with the reforms agreed by Federal Cabinet?

Avcare supports the package of reforms agreed by the Federal Cabinet in October 1999, however has expressed concerns that the measures, particularly for Category 2 (new product, formulation or use an existing active constituent) may not achieve the intended results for the following reasons:

- (a) the periods of protection are relatively short; and
- (b) the proposed operation under a 3 year review and 5 year sunset for the legislation allow little time for investment decision-making, development project initiation/completion and registration within the sunset period – there is uncertainty for investment decision-making and resource allocation/investment until after the results of the 3 year review are finalised.

Despite these concerns the agvet industry recognises the reforms as an important move in the right direction and supports their adoption into legislation.