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NATIONAL REGISTRATION AUTHORITY FOR AGRICULTURAL AND VETERINARY CHEMICALS

SUBMISSION TO THE PRODUCTIVITY COMMISSIONS INQUIRY INTO COST RECOVERY

NOVEMBER 2000

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Background to the National Registration Authority (NRA)

The National Registration Authority for Agricultural and Veterinary Chemicals (NRA) is the Australian agency responsible for the assessment and registration of agricultural and veterinary (agvet) chemical products prior to sale, and their regulation up to an including the point of retail sale.

The NRA administers the National Registration Scheme for agvet chemicals in partnership with the State and Territory Governments and with the active involvement of other Commonwealth agencies. Through the National Registration Scheme, the NRA delivers registration, quality assurance and compliance. In particular, the NRA:

- assesses the safety and performance of products;
- determines whether their use is likely to jeopardise trade;
- regulates the supply of agvet chemicals to the Australian market by approving product labels and specifying conditions of use.

The work of the NRA safeguards the health of people, animals and the environment, and international trade.

The NRA's main customers are people and companies who must;

- register products;
- obtain approval of technical grade active constituents (TGACs);
- obtain permits to use chemicals in emergency, research and off-label situations, or obtain manufacturing licences.

The NRA has a large number of stakeholders. They include the agvet chemicals industry, farmers, rural sector organisations, environmental, consumer and community groups, other Commonwealth and State/Territory government agencies that help operate the National Registration Scheme, and international regulatory authorities.

Cost Recovery Arrangements

When the NRA was established in June 1993, it was largely funded by the Commonwealth. In line with government policy targets, full cost recovery was achieved in the 1995-96 financial year. The costs of running the NRA's National Registration Scheme are recovered through fees and levies paid by the agvet chemicals industry.

The NRA recovers most of its costs through collecting:

a) application fees;
b) annual registration renewal fees;
c) levies on disposals of registered products.

Application Fees

The NRA imposes application fees under the Agricultural and Veterinary Chemicals Code (scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*). The Code's Regulations set out these fees, which vary according to the type of application and the assessment required. Current application fees, fee categories and assessment timeframes are at Attachment 1

Registration applications are processed as soon as the necessary data is presented and the appropriate fee is paid. NRA staff help applicants determine the appropriate evaluation category and fee before applications are submitted.

Registration Renewal Fees

Registration renewal fees are also imposed under the Agvet Code, and are set out in the Code's Regulations. Payment of renewal fees maintains a product's registration for one *financial* year, and is based on the product's disposals for the previous *calendar* year.

The term 'disposals' refers to:

- Australian products sold, used or given away in Australia by the manufacturer;
- Imported products sold, used or given away in Australia by the importer

A product's disposals equal the value of its gross sales in Australia. Registrants should *not* include sales tax in calculating disposals.

Renewal Fees for 1999-2000 are as follows:

Disposals	Fee
Over $25,000	$1,000
Between $10,000 & $25,000	$600
Less than $10,000 (registered in three or more States/Territories)	$300
Less than $10,000 (registered in one or two States/Territories)	$200
Nil disposals	$200

Levies

The NRA imposes levies on disposals of registered agvet chemical products through three Acts: *Agricultural and Veterinary Chemical Products Levy Imposition (General) Act 1994, Agricultural and Veterinary Chemical Products Levy Imposition (Excise) Act 1994*, and *Agricultural and Veterinary Chemical Products Levy Imposition (Customs) Act 1994*.

Levies are *collected* under the *Agricultural and Veterinary Chemicals Products (Collection of Levies) Act 1994*. The Act's Regulations prescribe the levy rates, which are based on a product's disposals for each calendar year.

As in the case of renewal fees, levies are payable on a product's gross sales, exclusive of sales tax. Registrants should include freight charges when calculating a product's

disposals, where these charges were included in the sale price quoted to the purchaser. Freight charges invoiced as a separate item are not leviable.

Registrants should include trade incentive payments (also known as 'rebates' or 'trade discounts') in calculating a product's disposals, unless:

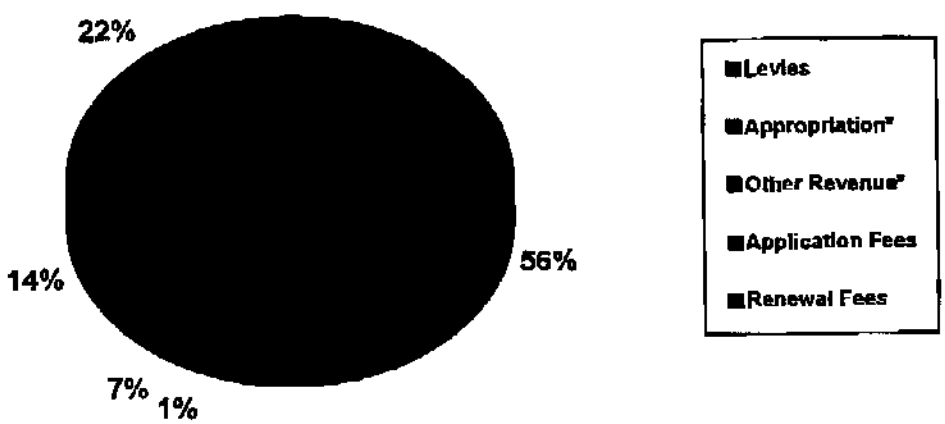
- granting the trade incentive reduces the selling price of a product
- an express or implied condition of the sale contract gives the purchaser the right to receive the trade incentive from the supplier.

An example of this would be where a supplier sells goods at a specified discount because the purchaser has paid by a certain date. However, as with freight charges, such trade discounts will still attract a levy if they are invoiced as part of the unit price. Trade discounts invoiced as a separate item from the gross price and net price are not leviable.

Current levy rates are as follows:

Disposals	Levy
Less than $100,000	Nil
$100,000 or more	0.65% (payable up to maximum of $25,000)

For 1999-2000, the NRA's total revenue was $18.54 million. The source of revenue via fees and levies as a percentage of overall revenue is as follows;



*The NRA obtains an annual appropriation of $108,000 for minor use. Other revenue includes interest and fees for the licensing of veterinary drug manufacturers.

Impact on Cost Recovery

In broad terms, cost recovery has an impact on the NRA itself, the regulated industry, chemical

For the NRA:

The expectation by industry that a fully cost-recovered regulatory agency will have a greater focus on efficiency and overall performance has resulted in the NRA paying considerable attention to performance particularly in meeting legislated timeframes. In excess of 98% of all submissions are now finalised within the appropriate timeframe. This timeliness, coupled with a greater predictability of when a decision will be reached has considerable commercial benefit for industry.

The more predictable source of income that is provided by our model of full cost recovery has allowed the NRA to improve long-term planning and to commence large projects requiring financial commitment over several years. This has helped to improve overall efficiency and in addressing long-standing issues of regulatory concern which may have otherwise not been addressed.

For the Regulated Industry:

The nature of the Australian agrichemical industry is such that there are both very small and very large, multinational, R&D orientated companies. Acceptance of fee-for-service is therefore not universal across the industry, but industry is in general agreement that timeliness and predictability of regulatory outcomes are essential in decision making for successful commercial outcomes.

To ensure fees are closely aligned with the level of service, an extensive schedule of fees and charges has been determined in consultation with the industry and reviewed on several occasions. While there has been some suggestion that the number of fees/charges should be rationalised, this may not be in the best interest of small companies who service niche, yet important agricultural sectors.

Cost recovery has also encouraged industry efficiency through for example, an insistence that only high quality submissions be presented to the NRA. In turn information requirements have been clarified, poor submissions routinely rejected and the use of the NRA resources in a "consultant" role to correct deficiencies in industry submissions largely eliminated.

The industry has supported stronger enforcement effort to ensure that unregistered products are removed from the market. At the same time, however, industry is of the view that compliance activity (which is aimed at poor performers) should not be paid for by the wider industry but preferably by Government (see Anomalies in Cost Recovery Policies below). However, as the major beneficiaries are those that comply, the NRA is of the view that compliance is a legitimate activity to be paid for out of fees and levies imposed on the industry.

For Chemical Users:

Chemical users, in particular primary producers argue that ultimately, regulatory costs fall to them in the form of higher prices for agvet chemical products. However a cost-recovered regulatory system with demonstrated efficiency and effectiveness has brought positive benefits for farmers.

There is now a central approach to the granting of permits for emergency and minor-uses which is provided free of charge for primary producers. The NRA cost recovery model allows for this by cross subsidisation between various programs. This not only assists individual permit applicants but also sunrise industries are being assisted in their pest and disease control needs which, if left to commercial forces alone, may not be accommodated. In these cases, Industry will not commit resources to seek approval for their product use on minor use situations or

accept liability by having uses included on labels. Therefore this may be considered to be a legitimate activity to be funded in part by Government.

Reviews of older products help to ensure that health and safety standards are maintained and that potential trade problems are avoided or minimised

Compliance activity prevents unapproved products entering the marketplace or incorrect/unsubstantiated claims being made which may lead to damage to people, the environment, crops and livestock and unfair competition.

The Wider Community:

The general community benefits through a rigorous and comprehensive registration system by way of greater assurance about agvet product safety with increased levels of confidence being engendered by way of comprehensive surveillance, enforcement and chemical reevaluation efforts. There is also added confidence in the quality of farm produce in terms of food safety.

Comparisons With Overseas Agencies

The NRA has been involved in benchmarking studies with other pesticide regulatory agencies in Canada, USA and the UK. Comparisons of review timeframes, budgets and fees are outlined in Attachment 2. The NRA compares very favourably.

Claims of Industry Capture

From time-to-time it is claimed that full recovery of costs from the regulated industry leads to industry or regulatory capture. This has not been the experience of the NRA. While industry, as do other stakeholders, make their views known to the Authority, there has been no incidence of industry attempting to unduly influence the work of the NRA on the basis that "they pay the fees".

Our experience has been that once industry has seen operational efficiency and productivity improvements, it has supported NRA efforts (often at considerable cost) that continue to ensure Australia has a highly regarded and rigorous registration process.

The NRA's management and consultative arrangements also allay fears of industry capture by being very open and transparent. All assessment reports are made available to the public and decisions are disseminated via the NRA Gazette and other communication vehicles. Strong public input is encouraged.

The NRA Board comprises members having experience in regulatory affairs, consumer interests, OH&S, farming, government and the chemicals industry under an independent Chairperson. This allows a balancing of interests/expertise.

At a technical level, the NRA maintains advisory committees for industry and State consultation and also a Community Consultative Committee which can advise the Board on community issues of concern.

Anomalies in NRA Cost Recovery Arrangements

There are anomalies in cost recovery policies across a number of regulatory authorities which require investigation and possibly harmonisation.

- Not all regulatory agencies are 100% cost recovered or some critical elements are excluded. For example ANZFA and the National Industrial Chemicals Notification Scheme are not fully cost recovered with the latter receiving 10.1% of its costs from government to cover NICNAS being part of a Government Department.

- Regulatory agencies, particularly those established as Statutory Authorities, are still required to have considerable input to the machinery of government. There are extensive efforts required to meet Government policy and reporting requirements for performance purposes. It would appear inappropriate for the cost of meeting Government requirements to be charged to the industry.

- In a similar way, regulatory agencies often possess considerable technical expertise and "grass roots" knowledge of industries and increasingly this is being used by mainstream Government Departments. Advice to government agencies and assistance overall, particularly in framing government policy should not always be charged to the regulated industry.

- Some agencies receive government funding in recognition of the activities they perform as being in the "public good". There appears no consistency across agencies as to what constitutes a public benefit. Since the NRA is fully cost-recovered, the presumption is that there is no public good arising from its activities. This is clearly wrong.

- Enforcement activities are aimed at ensuring that industry complies with legislative requirements. However, elements such as investigation and prosecution are in response to breaches of the law, often by those who do so in a deliberate manner. The costs of expensive investigation and litigation are borne by the industry as a whole through cost-recovery arrangements. We understand that in the Australian Fisheries Management Authority (AFMA), the policing function is funded by the Government, presumably in recognition that those who meet legislative requirements should not be penalised. Unlike the NRA enforcement in the case of AFMA is a Government function.

Regular Review of Cost Recovery Arrangements

The NRA has regularly reviewed its fees and charges to ensure they continue to reflect the costs for individual services. On average about 30% of actual costs are recovered from application fees. However, by having a cost recovery model which have the two components ie up front fees and sales levy, the cost is spread over the life of the product. In this way fees do not unduly disadvantage smaller companies or mitigate against local research and development efforts and the promotion of minor agricultural industries.

The National Competition Policy (NCP) Review of Agricultural and Veterinary Chemicals Legislation recently recommended that the levy charged on industry be changed to a simple flat rate with no exemptions or caps and that application and other registration service fees be cost reflective. These matters are currently being considered by a Commonwealth Working Group under the Chairmanship of the Department of Agriculture, Fisheries and Forestry Australia (AFFA).

The NRA has also conducted an Activity Based Costing Study of its operations in order to advise the Government of possible changes to the fees structure. This study has been referred to AFFA for consultation as part of the NCP Review.

NRA and State Roles in Agvet Chemicals Regulation

It should be noted that the role of the NRA ends at the point of retail sale, following which control-of-use activities become an individual State/Territory responsibility. The overall regulatory system is that exerted by the Commonwealth (through the NRA) and the States.

While the NRA is fully cost recovered, State activities are largely funded by government. Consequently, the costs associated with the whole process of regulation is only partly recovered from industry.

ATTACHMENT 1

Evaluation of Agricultural Chemical Products and Permits

Fees and Assessment Periods

Note: *"Item no." refers to those used in the Agricultural and Veterinary Chemicals Code Regulations. Applications not fitting into the new products or variations to products categories will be assessed under the modular fees list. In addition, where a submission contains several applications it will be assessed under the modular fees list.*

Item no.	Description	Assessment period (mths)	Fee
	New products		
1	New active—primary application	15	$20,620
2	New active—secondary application	15	$2,060
12	New combination, approved actives—primary application	8	$12,370
13	New combination, approved actives—secondary application	8	$1,030
14	New product, approved active, new situation	8	$12,370
15	New product, approved active, new situation, major assessment	13	$12,370
22	New household product, approved active—primary application	8	$6,185
23	New household product, approved active—secondary application	8	$1,030
24	Similar to registered product, bioequivalence	5	$3,095
25	Similar to registered product, bioequivalence, residues	8	$3,095
26	Similar to registered product	3	$1,030
27	Repack	3	$620
28	Major formulation change	8	$12,370
30	Minor change to formulation type	3	$1,030
	Variations to registered products		
32	Major extension	8	$10,310
33	Minor extension	5	$2,060
37	Minor formulation change	3	$1,030
38	Specified administrative label change	3	nil
39	Administrative label change	3	$620
40	Technical label change	8	$2,060

Item no.	Description	Assessment period (mths)	Fee
	Modular		
1	Application	No set period	$620
2	Chemistry assessment	5	$1,030
3	Toxicology (full package)	15	$9,690
4	Toxicology (partial package)	12	$5,980
5	Toxicology (acute studies only)	8	$2,475
6	Residues assessment	8	$2,475
7	Occupational health and safety assessment	5	$1,030
8	Environmental assessment	12	$3,095
9	Efficacy review—Category One	6	$3,095
10	Efficacy review—Category Two	5	$2,060
11	Efficacy review—Category Three	5	$1,030
12	Minor use—requiring one or more MRLs	8	$620
13	Any other assessment	5	$620
	Permits		
42	Off label use—no technical assessment	8	$620
43	Emergency use	No set period	nil
44	Off label use—residue/scheduling required	modular	modular
45	Field trial, new active—residue evaluation required	12	$2,060
46	Field trial, extension of use—residue evaluation required	6	$1,030
47	Experimental trial	3	$620
48	Possession/supply of unregistered product/unapproved active for use/sale outside of Australia	No set period	nil
49	Other uses	3	$620
50	Trial protocol	3	$1,030

Refunds

Applicants may withdraw an application at any time. If an application is withdrawn before a review has begun, the Module Item 1 application fee will apply. If the NRA has begun evaluating an application, all or part of the fee paid may be forfeited to the NRA.

Evaluation of Veterinary Chemical Products and Permits

Fees and Assessment Periods

Note: "Item no." refers to those used in the Agricultural and Veterinary Chemicals Code Regulations. Applications not fitting into the new products or variations to products categories will be assessed under the modular fees list. In addition, where a submission contains several applications it will be assessed under the modular fees list.

Item no.	Description	Assessment period (mths)	Fee
	New products		
1	New active, food producing animal or food and non-food producing animals—primary application	15	$20,620
2	New active, food producing animal or food and non-food producing animals—secondary application	15	$2,060
3	New active, companion animal—primary application	15	$6,185
4	New active, companion animal—secondary application	15	$1,030
5	New active, non-food producing animal other than companion animal—primary application	Modular	Modular
6	New active, non-food producing animal other than companion animal—secondary application	Modular	$620
7	New immunobiological product	8	$4,125
8	New direct-fed microbial or enzyme—Australian efficacy data required	8	$4,125
9	New direct-fed microbial or enzyme for food producing animal—no efficacy data required	5	$2,060
10	New direct-fed microbial or enzyme for companion animal—no Australian efficacy data required	5	$1,030
11	New direct-fed microbial or enzyme for non-food producing animal other than companion animal—no Australian efficacy data required	6	$620
12	New combination of existing active ingredients for food producing or food and non-food producing animals—primary application	8	$12,370
13	New combination of existing active ingredients for animals—secondary application	8	$1,030
14	New product, existing active ingredients, for a different food producing species than currently registered—no toxicology or environmental assessment required	8	$12,370
15	New product, existing active ingredients, for a different food producing species than currently registered—toxicology or environmental assessment required	13	$12,370
29	New product, existing active ingredients, for a non-food producing species—major assessment	8	$5,155

Item no.	Description	Assessment period (mths)	Fee
16	New combination of existing active ingredients for companion animals—no external assessment required—primary application	8	$1,030
17	New combination of existing active ingredients for companion animals—no external assessment required—secondary application	8	$620
18	Not relevant—please refer to Items 5 and 6		
19	New product, existing active ingredients for non-food producing species other than companion animals—no toxicological assessment required	5	$620
20	Medicated lick or block—external assessment required	8	$3,095
21	Medicated lick or block—no external assessment required	5	$1,650
24	New product, similar to a currently registered product—bioequivalence data required	5	$3,095
25	New product, similar to a currently registered product—bioequivalence and residues data required	5	$3,095
26	New product, similar to a currently registered product—no data required	3	$1,030
27	Repack	3	$620
28	New formulation for food producing species, different from registered products	8	$12,370
	Variations to existing registered products		
33	Extension of use to new disease	5	$2,060
34	Extension of use for food producing species—external efficacy and residues assessment required	8	$10,310
35	Extension of use for food producing species—scheduling required	13	$12,370
36	Extension of use or formulation change for an immunobiological product	5	$3,095
37	Minor formulation change	3	$1,030
38	Label change—name/address, new pack size, updating to the current code—specified label changes	3	NIL
39	Label change—any other alteration to the layout/wording	8	$620
40	Technical label change	8	$2,060
50	Trial protocol	3	$1,030

Item no.	Description	Assessment period (mths)	Fee
	Permits		
42	Off label use—no technical assessment	3	$620
43	Emergency use	No set period	NIL
44	Off label use—residues data/scheduling required	Modular	Modular
45	Field trials, new active—residues evaluation required	12	$2,060
46	Field trials, extension of use—residues evaluation required	6	$1,030
47	Experimental trial	3	$620
48	Possession/supply of an unregistered product/unapproved active for use/sale outside Australia	No set period	NIL
49	Other uses	3	$620
	Modular assessments		
1	Application		$620
2	Chemistry assessment	5	$1,030
3	Toxicology assessment (full package)	15	$9,690
4	Toxicology assessment (partial package)	12	$5,980
5	Toxicology assessment (acute studies only)	8	$2,475
6	Residues assessment	8	$2,475
7	Occupational health and safety assessment	5	$1,030
8	Environmental assessment	12	$3,095
9	Efficacy review—Category One	6	$3,095
10	Efficacy review—Category Two	5	$2,060
11	Efficacy review—Category Three	5	$1,030
12	Minor use—requiring one or more MRLs	8	$620
13	Any other assessment	5	$620

Refunds

Applicants may withdraw an application at any time. If an application is withdrawn before a review has begun, the Module Item 1 application fee will apply. If the NRA has begun evaluating an application, all or part of the fee paid may be forfeited to the NRA.

ATTACHMENT 2

Registration Review Time frames - Published standard: total elapsed time for a 'perfect' submission (weeks)

	Canada	Australia	UK	USA (1)	
				AD	regular
A. Registration of a major new product based on a new active					
- screening	7	3	24	--	--
- evaluation and registration					
(normal)	97	65	53	78	78 avg
(priority)	71				104 max
- joint review	61-65				61-65
B. Registration of a new product with a major new use, based on existing active ingredient	66	56	43	40	40 avg 65 max
B. Amendment of a product to add a new host or new pest	66	34	43	40	40 avg 65 max
B. Amendment of a product to change product formulation	66	13	19	15	32
C. Minor label change	26	13	12	13	13
D. Registration of a master copy	7	21	19	13	--
D. export product only	10	not set	--	--	--
D. Minor use label expansion	14	13	12	--	--
E. Research permits, new active, food related	26	52	34		--

1 Data for the USA refers to the Antimicrobial Division (AD),which has legislative standard timeframes and the 'regular' pesticides which has un-published working norms; biopesticides have shorter timeframes.

Agency Budget Comparisons (in C$) - most recent fiscal year

	Canada (1997-98)	Australia (1) (1996-97)	UK (1996-97)	USA (1996-97)
FTE's used	315	94 (1)	244 (2)	860
Salary & Benefit Costs	$19,400,000	$3,600,000	$14,900,000	$68,500,000
Operating Costs (3)	$4,600,000	$4,700,000	$15,800,000	$81,500,000
Capital Costs / Depreciation	$800,000	$100,000	$500,000	
Total Agency Costs	$24,800,000	$8,600,000	$31,200,000	$150,000,000
Rent / accommodation if not included above	$1,000,000	$0	$0	$0
Total Regulatory Cost	$25,800,000	$8,600,000	$31,200,000	$150,000,000
Total External Revenues	$7,500,000	$9,800,000	$19,780,000	$25,400,000

1 Australia data for NRA is adjusted (2/3 of total) to reflect the estimated amounts attributable to non-veterinary chemicals. FTE data includes resources for NRA activities related to non-vet chemicals (est. 68 FTEs) and those used by other departments which provide scientific review functions (est. 26 FTEs).
2. Data for the UK includes FTEs for PSD and for PRS/HSE. Some laboratory services are purchased, but no data is available for the equivalent FTEs.
3. Operating costs include all non-salary and non-capital costs.

Fee Comparisons: Application Fees

	Canada [1]	Australia	UK	USA [3]
A. Registration of a new Active Ingredient				
- product with new active, food use	$228,832	$20,000	$149,000	tol: $95,000
- new product use, non-food	$58,191	$12,000	$97,000	$0
- URMUR (minimum fee)	$22,883	n/a	$1,142	n/a
- exempted products [2]	$262			
B. Amendment, based on an existing registered AI				
-new formulation	$31,500	$10,000	$10,500	$0
-new host / pests	$15,650	$10,000	$10,500	$0
-change in rate / method	$10,910	$1,000	$5,710	$0
- exempted products [2]	$262			
C. Registrations without a need for supporting data				
-minor label change	$154	$600	$700	$0
D. Other				
own use import	$0	$600	$700	$0
export product only	$4,601	$0	$0	$0
private label	$154	$1,000		$0
URMULE	$154	$600	$700	$0
E. Research permits (food related)	$150	$2,000	$4,000	$0

1. The fee indicated for Canada, represents the maximum payable; fee reductions are possible based on the projected sales over the first three years. The minimum fee for a new product based on a new active could be as low as 10% of the amount shown in the table. The fee shown for URMUR reflects the minimum 10%.
2. Several types of products are exempt from most application fees in Canada (see page 6.3).
3. The tolerance processing fee shown for the USA would be the minimum amount payable and could be higher depending on the number of food crops involved (see page 6.4).

Relative Cost of Management and Administration

index	Canada	Australia	UK [1]	USA
FTEs devoted to Management and administration as a % of total costs	12.4%	11.7%	10.7%	13.4%