



**ACVM Group
Data Assessment Service Workshop
To Be Held
4 Nov (Auckland), 6 Nov (Christchurch), 8 Nov (Wellington)**

Agenda

- 1 WHY ARE WE MAKING CHANGES?** (Debbie Morris)
- 2 REGULATORY REVIEW & EVALUATION (R&E) – the new process**
 - ❖ The timelines – stopping the clock?
 - ❖ The new 'rules' – reject or withdraw options, the need for complete applications, priority of work, use of conditions to manage data gaps
 - ❖ The audit process
 - ❖ The use of expert advice
 - ❖ The outcome – the R&E report: a public document.
- 3 THE DATA ASSESSMENT FUNCTION**
 - 3a Third Party Data Assessments**
 - ❖ You don't need to use an independent data assessor, but
 - ❖ What data assessors need to know
 - ❖ Guideline material
 - ❖ Use of experts/CVs
 - ❖ Risks for companies
 - ❖ Risks for assessors
 - ❖ Costs & timelines
 - ❖ The applicant's perspective
 - 3b ACVM Group Data Assessments**
 - ❖ Discretionary service (but covered by the ACVM Act)
 - ❖ Timelines don't apply – the R&E service is priority
 - ❖ Estimates of costs & how we charge
 - ❖ Complete service or parts of the application?
 - ❖ What happens to the data
 - ❖ ACVM contract
 - ❖ Provision of reports
 - ❖ DAS rules – where do information waivers fit?
- 4 OTHER RELATED INFORMATION**
 - ❖ Where do MRLs fit?
 - ❖ What about information waivers
 - ❖ Provision of future training (including residues)
 - ❖ Accrediting assessors
- 5 COMMON PROBLEMS & QUERIES**
 - ❖ Chemistry & manufacturing standards will be covered with the whole group
 - ❖ Split into plant compounds & veterinary medicines to work through any applicant queries or common problems observed by the ACVM Group assessors

NZFSA ACVM Group Data Assessment Service Workshop Registration Form

Please register for the session you wish to attend by **Monday, 28 October 2002**.

A session might be cancelled or rescheduled, so please let us know that you're interested in attending, and how to contact you. If we **do not** have the minimum number (10 -15) by **Monday, 28 October 2002**, the venue will be cancelled.

Refreshments & light lunch will be provided. The cost of the workshop will be \$120.00 (gst incl).

Monday, 4 November 2002

9.30am - 4.00pm

Auckland

Lakeside Convention Centre
Montgomerie Rd
Auckland

Wednesday, 6 November 2002

9.30am - 4.00pm

Christchurch

Russley Hotel
Roydvale Avenue
Christchurch Airport
Christchurch

Friday, 8 November 2002

9.30am - 4.00pm

Wellington

Cameron Room
Level 3, ASB House
The Terrace
Wellington

Name: _____

Organisation: _____

Fax number: _____

E-mail address: _____

City/date of session: _____

Please return completed registration form to Gill Wilson **by Monday, 28 October 2002**

by post:

Gill Wilson
NZFSA
PO Box 2835
WELLINGTON

or fax:

04 463-2501

or send an e-mail to:

gill.wilson@nzfsa.govt.nz
