

Reconsideration work plan

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|-----------------------------------|--------------------------------------|----------------------|
| CHEMICAL | Fenamiphos | |
| REMAINING SCOPE | Finalisation [11.2] | |
| RECONSIDERATION ASSESSMENT PERIOD | 10 months, see Attachment 1 | |
| TIMEFRAME | START: 1 July 2015 | FINISH: 23 July 2015 |
| WORK PLAN DATE | 1 July 2015: amended on 29 July 2015 | |

| Stage | Details | Timeline |
|---------------------------------------|---|----------------------------|
| 1. Nomination | Invitation to nominate agricultural and veterinary chemicals for review – Gazetted on 1 November 1994. | |
| 2. Prioritisation | Prioritised by high concerns regarding public health and environment, and medium concerns regarding work health and safety. | |
| 3. Scoping and work plan | Scope – toxicology, OHS, environment, residues and trade concerns. Link to fenamiphos scoping document – 2003. Work plan – Published on 1 July 2015. | |
| 4. Notice of reconsideration | s32(1) notices sent to holders upon commencement of the review – 2003. Additional s32 notices sent prior to the publication of the preliminary review findings in February 2013 and March 2015. Link to gazette. Notice of reconsideration – Published on 1 April 2003. | |
| 5. Assessment | <u>Component assessment reports published prior to 1 July 2015</u> Toxicology, OHS, residues and environment assessments – Published in 2013. Link to component assessment reports. | |
| 6. Draft regulatory measure | <u>Draft regulatory measures proposed prior to 1 July 2015</u> Link to preliminary review findings report – 2013. | |
| 7. Consultation | <u>Details of consultation undertaken to date</u> A 3-month public consultation period ended on 31 May 2013. All additional data or information submitted during consultation will be considered before making the final regulatory decision. | |
| START DATE (clock starts) | | 01/07/2015 |
| 8. Regulatory decision | <u>Regulatory decisions to be made</u> The APVMA has determined: <ul style="list-style-type: none"> 15 product labels have been varied, one product has been cancelled Actives and products with new labels are affirmed | Completed July 2015 |
| END DATE (regulatory decision) | | 23/07/2015 |
| 9. Implementation | The APVMA published details of the phase out periods that apply to the cancelled product and the cancelled previous approved labels for 15 products. The maximum phase out period specified in the legislation is one year, and ends on 23 July 2016. | |

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Attachment 1

| AGRICULTURAL AND VETERINARY CHEMICALS CODE REGULATIONS 1995 – S78B | | | |
|---|---|------------------------------|--------------|
| PERIOD WITHIN WHICH APVMA IS TO CONCLUDE RECONSIDERATIONS | | | |
| A + B + 2E + 3C + J + D + X | | | |
| A = the longest of the following periods (in months) relevant to the scope of the reconsideration | | | |
| <i>Item</i> | <i>Module level or type</i> | <i>Period for completion</i> | <i>Scope</i> |
| 3.1 | Toxicology – Level 1 | 13 | |
| 3.2 | Toxicology – Level 2 | 9 | |
| 3.3 | Toxicology – Level 3 | 5 | |
| 4.1 | Toxicology (requiring poison schedule classification) | 13 | |
| 7.1 | Environment – Level 1 | 13 | |
| 7.2 | Environment – Level 2 | 7 | |
| 7.3 | Environment – Level 3 | 4 | |
| TOTAL TIME FOR A | | 0 | |
| B = the longest of the following periods (in months) relevant to the scope of the reconsideration | | | |
| <i>Item</i> | <i>Module level or type</i> | <i>Period for completion</i> | <i>Scope</i> |
| 2.1 | Chemistry – Level 1 | 13 | |
| 2.2 | Chemistry – Level 2 | 9 | |
| 2.3 | Chemistry – Level 3 | 6 | |
| 5.1 | Residues – Level 1 | 13 | |
| 5.2 | Residues – Level 2 | 8 | |
| 5.4 | Residues – Level 4 | 4 | |
| 6.1 | Occupational Health and Safety – Level 1 | 13 | |
| 6.2 | Occupational Health and Safety – Level 2 | 7 | |
| 6.3 | Occupational Health and Safety – Level 3 | 4 | |
| 9 | Non-food trade | 6 | |
| 10.1 | Special data – Level 1 | 13 | |
| 10.2 | Special data – Level 2 | 7 | |
| 10.3 | Special data – Level 3 | 7 | |
| TOTAL TIME FOR B | | 0 | |
| 2E = the longest of the following periods (in months) relevant to the scope of the reconsideration | | | |
| <i>Item</i> | <i>Module level or type</i> | <i>Period for completion</i> | <i>Scope</i> |
| 8.1 | Efficacy and safety – Level 1 | 6 | |
| 8.2 | Efficacy and safety – Level 2 | 4 | |
| 8.3 | Efficacy and safety – Level 3 | 3 | |
| TOTAL TIME FOR E | | | |
| 3C = the longest of the following periods (in months) relevant to the scope of the reconsideration | | | |
| <i>Item</i> | <i>Module level or type</i> | <i>Period for completion</i> | <i>Scope</i> |
| 11.1 | Finalisation – type 1 | 3 | |
| 11.2 | Finalisation – type 2 | 2 | ● |
| 11.3 | Finalisation – type 3 | 2 | |
| TOTAL TIME FOR C | | 3 x 2 = 6 | |
| J = whichever is relevant | | | |
| | Consultation with jurisdictional coordinator | 3 | |
| | In any other case | 0 | |
| TOTAL TIME FOR J | | 3 | |
| D | TOTAL TIME FOR D | 4 | ● |
| X = whichever is relevant | | | |
| | Appointment of an arbitrator under s.64 | 3 | |
| | In any other case | 0 | ● |
| TOTAL TIME FOR X | | 0 | |
| TOTAL TIMEFRAME | | 10 months | |