Act No. 182 of 1989

STOCK MEDICINES BILL 1989

NEW SOUTH WALES

EXPLANATORY NOTE

(This Explanatory Note relates to this Bill as introduced into Parliament)

The following Bills are cognate with this Bill:

Pesticides and Allied Chemicals (Amendment) Bill 1989;
Stock Foods and Medicines (Amendment) Bill 1989.

The object of this Bill is to replace the provisions in the Stock Foods and Medicines Act 1940 ("the 1940 Act") relating to stock medicines with updated legislation which deals exclusively with stock medicines and which gives effect in New South Wales to a national scheme for clearance of stock medicines (and other chemicals) for use in participating States and Territories.

Principal objectives of the national scheme include improving Australia's international trade in primary products, protecting the environment and safeguarding the health of the public. The Agricultural and Veterinary Chemicals Act 1988 of the Commonwealth ("the Commonwealth Act") establishes the Australian Agricultural and Veterinary Chemicals Council, which has the function of clearing agricultural and veterinary chemical products for registration in States and Territories participating in the scheme. It is proposed that chemical products will not be registered for use in those States and Territories unless the products have first been cleared by the national Council.

The proposed Act will re-enact the 1940 Act with the following modifications:

(a) provisions to ensure that the Director-General of the Department of Agriculture and Fisheries ("the Director-General") registers stock medicines cleared by the national "clearance authority";

(b) new offences relating to the use and possession of unregistered stock medicines;

(c) increased penalties for offences relating to stock medicines;

(d) expansion of inspectors' powers to investigate possible offences relating to stock medicines.

PART 1 - PRELIMINARY

Clause 1 specifies the short title of the proposed Act.

Clause 2 provides for the proposed Act to commence on a day or days to be appointed by proclamation.

Clause 3 contains definitions for the purposes of the proposed Act. "Stock medicine" is defined in similar terms to those used in the definition of "veterinary chemical product" in the Commonwealth Act. However, the Commonwealth term does not include a vaccine whereas "stock medicine" does.

Clause 4 empowers the Minister, by order published in the Government Gazette, to declare a person or body of a national character to be the "clearance authority" for the purposes of the proposed Act. It is intended to declare the Australian Agricultural and Veterinary Chemicals Council the clearance authority.

Clause 5 makes it clear that if a substance or organism is registered as a stock medicine under the proposed Act, it is not required to be registered also as a pesticide under the Pesticides and Allied Chemicals Act 1978 (to be renamed the Pesticides Act 1978).

Clause 6 makes it clear that if an activity is expressly authorised or permitted by or under the Poisons Act 1966 or the Pesticides and Allied Chemicals Act 1978, the activity cannot constitute an offence against the proposed Act. For example, possession of an unregistered stock medicine, which would otherwise be an offence under the proposed Act, will not be an offence if authorised by the Secretary of the Department of Health under the Poisons Act 1966.

PART 2 - REGISTRATION OF STOCK MEDICINES

Division 1 - General

Proposed Division 1 substantially follows section 13 (1)-(2B) (registration of stock medicines) and section 15 (applications for registration) of the 1940 Act.

Clause 7 provides for applications for registration of stock medicines to be made to the Director-General.

An application is to be accompanied by an application fee and a fee for the relevant 3 year registration period (or a proportion of that fee if registration is sought after the first year of the registration period).

Clause 8 provides for applications for renewal of registration to be made to the Director-General. Generally, applications for renewal of registration must be made

at least 60 days before a new registration period of 3 years commences, but the Director-General has a discretion to accept late applications.

Clause 9 enables the Director-General to obtain advice from the Stock Medicines Board about applications for registration or renewal of registration. The Board must state its reasons if it recommends refusal of an application.

Clause 10 authorises the Director-General to register or refuse to register or renew the registration of a stock medicine.

Division 2 - Additional requirements for registration when there is a clearance authority

Proposed Division 2 provides the legislative framework for giving effect to the scheme for national assessment of the suitability of stock medicines for use in participating States and Territories.

Clause 11 provides that the proposed Division applies to registration of a stock medicine only when there is a clearance authority and application may be made to that authority for clearance of the stock medicine. (It appears that the proposed clearance authority, the Australian Agricultural and Veterinary Chemicals Council, will not be concerned with clearance of medicines for domestic animals).

Clause 12 restricts the Director-General's discretion in deciding applications for registration of stock medicines when there is a clearance authority declared under proposed section 4. Generally, the Director-General may register a stock medicine only if it has first been cleared for registration. This does not apply, however, if the Minister considers registration is in the interests of New South Wales having regard to:

* whether the control or eradication of the disease or pest at which it is aimed is of economic significance to New South Wales;
* whether the stock medicine will reduce the population of organisms resistant to similar stock medicines;
* whether use of the stock medicine is desirable because of climatic or soil conditions or farming practices in New South Wales.

Clause 13 requires the Director-General to register a stock medicine that has been cleared for registration by the clearance authority. Again, if the Minister considers refusal of registration in the interests of New South Wales after taking into account considerations similar to those mentioned above or because of human health or environmental considerations notified to the Minister, the Director-General may refuse to register the stock medicine.

Clause 14 enables the Director-General, when registering a stock medicine, to approve an experimental or small scale use of the stock medicine even though its certificate of clearance does not indicate that such a use has been approved by the clearance authority.

Division 3 - Duration of registration

Clause 15 provides for registration of stock medicines, in general, for 3 year periods (following section 13 (5) of 1940 Act). However, if the clearance authority

has cleared the stock medicine only for a shorter period, the stock medicine may be registered only for that period.

Clause 16 provides for review of registration of stock medicines by the Stock Medicines Board. The Board may recommend cancellation of registration if it would not have recommended registration had an application for registration been made at the time of review. It may also recommend suspension of registration until cancellation takes effect. Clause 16 basically follows section 15A (1), (2) and (5) of the 1940 Act.

Clause 17 authorises the Director-General to cancel registration of a stock medicine on the recommendation of the Stock Medicines Board (following section 15A (3) and (4) of the 1940 Act). However, the Director-General may not cancel any registration if there is a current clearance of the stock medicine for registration, except where the Minister determines that it is in the interests of New South Wales to do so.

Clause 18 provides (as does section 15A (4) of the 1940 Act) that cancellation of registration of a stock medicine takes effect at the end of the period allowed for an appeal against the cancellation or, if an appeal is lodged, when it is dismissed or withdrawn.

Clause 19 empowers (as does section 15A (6) of the 1940 Act) the Director-General, on the recommendation of the Stock Medicines Board, to suspend the registration of a stock medicine for not more than 90 days.

Clause 20 requires the Director-General to cancel the registration of a stock medicine following withdrawal of clearance for the stock medicine by the clearance authority. Again, an exception is provided where the Minister determines it is in the interests of New South Wales that the stock medicine remain registered.

Clause 21 imposes a new requirement on the Director-General to publish a notice of cancellation of registration of a stock medicine in at least one newspaper circulating generally throughout New South Wales, together with instructions and warnings for disposing of the stock medicine. Clause 21 is similar to provisions in the Pesticides and Allied Chemicals Act 1978.

Clause 22 requires the Director-General also to publish notice of suspension of registration of a stock medicine in at least one newspaper.

Division 4 - Appeals

Clause 23 requires the Director-General to serve written notice of a refusal to register or to renew the registration of a stock medicine, or of a cancellation of registration, on the applicant (or last applicant) for registration or its renewal. Clause 23 follows section 16 (1) of the 1940 Act.

Clause 24 confers on an applicant for registration or renewal of registration the right to appeal to the District Court against a refusal to register a stock medicine or a cancellation of registration of a stock medicine. There is no right of appeal against a refusal to register when there is a clearance authority and the clearance authority has refused to clear the stock medicine.

Clause 25 provides for the District Court Judge hearing an appeal under proposed Division 4 to be assisted by 2 assessors who are to be the Dean of the Faculty of Veterinary Science at Sydney University and a veterinary surgeon appointed by the Minister. Clause 25 follows section 16 (3), (6), (7) and (8) of the 1940 Act.

Clause 26 empowers the District Court to award costs in an appeal under proposed Division 4 (following section 16 (5) of the 1940 Act).

Clause 27 provides that a decision of the District Court on an appeal under proposed Division 4 is binding on the Director-General and the appellant and is to be given effect to accordingly (following section 16 (4) of the 1940 Act).

Division 5 - Supplementary

Clause 28 creates an offence (with a maximum penalty of 50 penalty units ($5,000)) of providing false or misleading information in an application for registration of a stock medicine.

Clause 29 requires anyone concerned in the distribution of a stock medicine to notify the Director-General if it is found to be defective.

Clause 30 empowers the Director-General to require an applicant for registration or renewal of registration to provide further information in connection with the application. Failure to provide the information may result in the Director-General's refusing the application. It will be an offence (with a maximum penalty of 50 penalty units) to provide information that is false or misleading in response to a requirement of the Director-General. Clause 30 is basically the same as section 13B of the 1940 Act.

Clause 31 prohibits the disclosure of any information relating to the composition of a stock medicine which is obtained in the course of administering the proposed Act. Contravention of the prohibition will be an offence with a maximum penalty of 200 penalty units ($20,000). Clause 31 is based on section 14 of the 1940 Act.

PART 3 - PERMITS AND OTHER AUTHORISATIONS

Proposed Part 3 contains new provisions which empower the Director-General to issue permits and to make orders that authorise activities which would otherwise constitute offences against the proposed Act. The new provisions are similar to those contained in the Pesticides and Allied Chemicals Act 1978 and are included as a consequence of the creation of new offences relating to the possession and use of unregistered stock medicines.

Clause 32 authorises the Director-General to issue a permit to do or omit to do anything which would otherwise constitute an offence against the proposed Act or regulations made under it.

Clause 33 enables any person to whom a permit applies to do anything that is specified in the permit. A permit will apply to:

* the person to whom the permit is issued;
* an employee of the person;
* if the person is a corporation, a director of the corporation.

Clause 34 authorises the Director-General, with the Minister's consent, to make an order (to be known as a stock medicines order) that authorises everyone or persons of a specified class to do or omit to do anything that would otherwise constitute an offence against the proposed Act or regulations made under it.

Clause 35 enables any person to whom an order relates to do anything specified in the order.

PART 4 - STOCK MEDICINES BOARD

Proposed Part 4 (**clause 36**) establishes a Stock Medicines Board, comprising the same persons as those on the present Board established by the 1940 Act, namely specified officers of the Department of Agriculture and Fisheries, the Chief Pharmacist of the Department of Health and a veterinary surgeon appointed by the Minister.

Clause 36 also gives effect to Schedule 1 which contains provisions relating to the members and procedure of the Board. The provisions of clause 36 and proposed Schedule 1 basically follow section 12 of the 1940 Act.

PART 5 - CONTROL OF STOCK MEDICINES

Clause 37 creates new offences (with a maximum penalty of 200 penalty units ($20,000) or 400 penalty units ($40,000) for a corporation) relating to possession of stock medicines. Possession of an unregistered stock medicine will be an offence unless it has been prescribed by a veterinary surgeon to treat a particular animal under his or her care. Also, veterinary surgeons and pharmacists will be able to keep unregistered stock medicines. It will also be an offence for a person to possess any stock medicine that is or contains a substance contained in Schedule 4 of the Poisons List if it was supplied in contravention of the Poisons Act 1966.

Clause 38 makes it an offence (with a maximum penalty of 200 penalty units or 400 penalty units for a corporation):

(a) for anyone to use an unregistered stock medicine on an animal that is of a food producing species; or

(b) for a person other than a veterinary surgeon to use an unregistered stock medicine on any other stock, unless the stock medicine has been prescribed by a veterinary surgeon to treat a particular animal and the person uses the stock medicine in accordance with the veterinary surgeon's instructions.

Clause 39 makes it an offence (with a maximum penalty of 200 penalty units):

(a) for anyone to use a registered stock medicine on an animal that is labelled "not for use in food producing animals" contrary to the label unless authorised by a permit or an order; or

(b) for a person other than a veterinary surgeon to use a registered stock medicine contrary to any other instructions that the stock medicine is required or permitted to have on it, unless the person uses the stock medicine in accordance with the instructions of a veterinary surgeon or as required by an order made under the proposed Act.

Clause 40 makes it an offence (with a maximum penalty of 200 penalty units) for a veterinary surgeon to prescribe or supply an unregistered stock medicine or a registered stock medicine for use in a manner contrary to the instructions that the stock medicine is required to have on it, unless the veterinary surgeon gives instructions relating to specified matters (such as the withholding period, frequency of treatment and manner of administration).

Clause 41 creates offences relating to the sale of stock medicines (with maximum penalties of 200 penalty units or 400 penalty units for a corporation). Clause 41 substantially follows section 18 of the 1940 Act. The following will be offences:

* sale of an unregistered stock medicine (other than one prescribed by a veterinary surgeon);
* sale of an adulterated stock medicine;
* sale of a stock medicine that does not comply with a standard prescribed for the stock medicine by the regulations;
* sale of a stock medicine with a claim as to its efficacy for a use that is not required or permitted under the proposed Act to be specified on its label when sold.

Clause 42 provides that it is a defence to certain prosecutions under the proposed Act relating to unregistered stock medicines that the defendant did not know the stock medicine concerned was unregistered.

Clause 43 creates offences (with maximum penalties of 200 penalty units or 400 penalty units for a corporation) relating to advertising of stock medicines. Clause 43 substantially follows section 19 of the 1940 Act. The following will be offences:

* contravention of a prohibition or requirement made by the regulations relating to advertising;
* making or publishing a claim as to the efficacy of a stock medicine for a use other than a use for which it is registered;
* making or publishing a claim about a stock medicine that is false or misleading.

Clause 44 makes it an offence (with a maximum penalty of 50 penalty units ($5,000)) to sell a package of a registered stock medicine unless the package has on it the particulars prescribed by the regulations. Where the clearance authority has issued a certificate of clearance for the stock medicine, the stock medicine must also have on it when sold details relating to its use (including warnings) set out in the certificate. Clause 44 is based on section 17 (1) and (3) (a) of the 1940 Act.

Clause 45 makes it an offence (with a maximum penalty of 50 penalty units) to sell a package of a registered stock medicine which has on it, or to publish material which contains, words or other matter that is prohibited by the regulations or a

reference to the proposed Act. Clause 44 has the same effect as section 17 (2) and (3) (b) of the 1940 Act.

Clause 46 empowers the Director-General to make orders that ban or control the supply of stock medicines, or their use, or require suppliers to recall stock medicines if the Director-General believes that the stock medicines are endangering the health of the public, consumers of food or persons exposed to the stock medicines, are causing undue hazard to the environment or are making stock ill. The clause follows section 19A of the 1940 Act, except in the following respects:

* orders may be made prohibiting use of stock medicines;
* orders can be made because of danger caused by stock medicines to the environment;
* orders which apply generally are to be published in at least one newspaper circulating generally throughout New South Wales;
* the penalty for contravening an order is increased from $1,000 to 200 penalty units or 400 penalty units for a corporation.

Clause 47 provides that an order made under proposed section 46 is to remain in force for the period specified in the order or until revoked.

Notice of such an order must be laid before each House of Parliament and each such order is subject to disallowance in the same way as a regulation or other statutory rule.

PART 6 - GENERAL

Proposed Part 6 substantially follows the provisions of Part 4 (general provisions) of the 1940 Act.

Clause 48 empowers the Director-General to authorise New South Wales or Commonwealth public servants or members of the Police Force to be inspectors for the purposes of the proposed Act. Clause 48 is equivalent to section 20 (1) (a) of the 1940 Act.

Clause 49 empowers the Director-General to authorise suitably qualified and experienced persons to be analysts for the purposes of the proposed Act. Clause 49 is equivalent to section 20 (1) (b) of the 1940 Act, but also provides that an analysis carried out under the supervision of an analyst is to be treated as having been carried out by the analyst.

Clause 50 confers powers on inspectors, such as powers of entry and search. The proposed section substantially follows section 21 of the 1940 Act, but also confers the following additional powers on inspectors:

* power to seize and remove any substance or article that the inspector believes to be a stock medicine or container for a stock medicine involved in a contravention of the proposed Act or regulations;
* power to direct certain persons to keep a seized substance or article in a place where the danger of the stock medicine to people or the environment is minimised;

- power to destroy, with the consent of the Minister, a stock medicine that is considered dangerous;
- power to destroy a stock medicine without the consent of the Minister where there is imminent danger to people, animals or the environment.

Clause 51 provides for the issue of a search warrant, which will be necessary if an inspector intends to enter a dwelling to carry out investigations into a suspected contravention of the proposed Act or regulations made under it.

Clause 52 provides for the retention and disposal of property seized by an inspector under proposed section 50. During the 6 month period after seizure, the property concerned may be retained or returned to the person from whom it was seized. At the end of that period, the property must be returned to its apparent owner unless it has been forfeited to the Crown or an application for its forfeiture has been advertised.

Clause 53 makes it an offence (with a maximum penalty of 200 penalty units or 400 penalty units for a corporation) to tamper with a sample of a stock medicine taken for analysis (following section 23 of the 1940 Act) or to tamper with an inspector's seal or fastening.

Clause 54 empowers (as does section 24 of the 1940 Act) an inspector to require a buyer or seller of stock medicine to provide information concerning any sale of stock medicine and makes it an offence (with a maximum penalty of 100 penalty units) for the buyer or seller to fail to provide the information.

Clause 55 provides that a certificate of an analyst as to the results of an analysis of a stock medicine is to be evidence of those results without proof of the signature of the person who apparently signed the certificate. Clause 55 follows section 25 of the 1940 Act.

Clause 56 provides (as does section 26 of the 1940 Act) that a court may order forfeiture to the Crown of any stock medicine concerned in an offence against the proposed Act.

Clause 57 empowers (as does section 27 of the 1940 Act) a court, on convicting a defendant for an offence against the proposed Act, to order the defendant to pay the costs of any analysis of the stock medicine concerned.

Clause 58 makes it an offence (with a maximum penalty of 50 penalty units) to obstruct an inspector in the exercise of the inspector's functions under the proposed Act (following section 28 of the 1940 Act). A new offence of failure to obey a direction of an inspector (with a maximum penalty of 50 penalty units) is also created.

Clause 59 makes it an offence (with a maximum penalty of 50 penalty units) to take back any stock medicine seized by an inspector (following section 30 of the 1940 Act).

Clause 60 provides for proceedings for offences against the proposed Act or regulations to be brought in a Local Court constituted by a Magistrate sitting alone or in the Supreme Court. The maximum penalty that may be imposed by a Local Court is 50 penalty units (unless the maximum penalty specified for the offence is

a lesser amount). Clause 60 allows proceedings for an offence to be commenced in a Local Court up to 12 months after its alleged commission.

Clause 61 provides (as does section 34 of the 1940 Act) that a certificate, apparently signed by the Director-General, that a stock medicine is, or is not, registered under the proposed Act is evidence of that fact without proof of the Director-General's signature.

Clause 62 provides for service of notices and orders under the proposed Act. It is similar to section 37 of the 1940 Act.

Clause 63 provides (as does section 36 of the 1940 Act) for the refund of fees on refusal of an application for registration or cancellation of registration of a stock medicine. In addition, clause 63 provides for refund of part of a fee paid on applying for registration if the fee is disproportionate to the period for which the stock medicine is registered.

Clause 64 provides (as does section 38 of the 1940 Act) for delegation by the Director-General of the Director-General's functions under the proposed Act.

Clause 65 provides for the making of regulations and is equivalent to section 35 of the 1940 Act except that it increases the maximum penalty that may be imposed by the regulations from $1,000 to 50 penalty units ($5,000).

Clause 66 gives effect to Schedule 2 which sets out savings and transitional provisions.

Clause 67 repeals provisions of the Stock Foods and Medicines Regulations that relate to stock medicines.

Clause 68 amends the Search Warrants Act 1985 so as to apply the provisions of Part 3 of that Act to search warrants issued under proposed section 51.

Schedule 1 contains provisions relating to the members and procedure of the Stock Medicines Board.

Schedule 2 contains savings and transitional provisions consequent on the proposed repeal of the provisions in the 1940 Act dealing with stock medicines.