Criteria for Approving Applications
to add/revise
MRLs / Exempted Substances

20 June 2011
Applications to add/revise MRLs / exempted substances (1)

_lists of MRLs and exempted substances will be included in the proposed legislation

To cater for new MRLs or pesticides not in the above two lists, but are considered acceptable from the public health perspective, an application mechanism for adding/revising the lists of MRLs / exempted substances will be established under the new legislation
Applications to add/revise MRLs / exempted substances (2)

- Applications for adding/revising MRLs / exempted substances are common trade facilitation measure in overseas jurisdictions:
  - e.g., Canada, EU, Japan and USA

- Through a flexible application mechanism:
  - suitably incorporate MRLs or pesticides that have been found to be acceptable from the public health perspective
  - facilitate import of food
How to apply

- A person may apply to the Director of Food and Environmental Hygiene (DFEH)

- Pre-requisite –
  - An MRL/exempted substance is available in Codex or in another jurisdiction, and/or
  - All necessary documentation is provided

- Application fee will be charged on full-cost recovery basis and is not refundable irrespective of the result
Information required for application

- Documents showing that the concerned MRL / exempted substance is currently adopted by Codex or in force in another jurisdiction;
- Any other information that would be required for processing the application, e.g.,
  - Description of the concerned pesticide and food commodity
  - Current or anticipated availability of the concerned food product in Hong Kong
  - Relevant toxicological data and safety reference values
  - Supervised field trial data
  - Analytical method and information on availability of analytical reference standards
  - Reports of available food processing studies
Principles for approval

- The application is submitted in the form and manner specified by DFEH;
- The applicant has provided the specified information as required by DFEH;
- Food permitted under the concerned MRL/exempted substance will not be dangerous or prejudicial to health.
Results after approval

If adopted -

The concerned MRL/exempted substance shall be applicable to the concerned food type from all sources (including both imported and locally produced food)
Dovetailing with Pesticide Registration Mechanism (1)

- Objective – To ensure that a newly registered pesticide for use on food crops under the Pesticides Ordinance (Cap.133) is properly regulated under the proposed Regulation
- The applicant has to provide information related to the setting up of a new MRL/exempted substances together with the application for registration of a pesticide for use on food crops to the Agriculture, Fisheries and Conservation Department (AFCD)
- Application fee will be charged on full-cost recovery basis and is not refundable irrespective of the result
Dovetailing with Pesticide Registration Mechanism (2)

- The information required is the same as those applicable to normal applications to add/revise MRLs/exempted substances and will be collected by AFCD under Regulation 3(1) of the Pesticides Regulation (Cap.133A). Most of them are the same as that currently listed in the application form for registration:
  - Description of the concerned pesticide and food commodity
  - Current or anticipated availability of the concerned food product in Hong Kong
  - Relevant toxicological data and safety reference values
  - Supervised field trial data
  - Analytical method and information on availability of analytical reference standards
  - Reports of available food processing studies
- Principles for approval are the same as those applicable to normal applications to add/revise MRLs/exempted substances
Dovetailing with Pesticide Registration Mechanism (3)

- On the basis of the information submitted by the applicant, DFEH would advise Director of Agriculture, Fisheries and Conservation (DAFC) that the pesticide in question could be regulated by way of setting up a MRL or adopted as an exempted substance in the proposed Regulation.
- If the pesticide could be regulated, DFEH would amend the Schedules in the proposed Regulation to incorporate the new standard.
- The DAFC will, in accordance with the Pesticides Ordinance (Cap.133), decide whether to approve the registration of the pesticide, having regard to relevant considerations (including DFEH’s advice).
Thank You