OUTCOME 1: LABEL CHANGES AND RELATED TOLERANCE ACTIONS

Some risk mitigation can be accomplished through changes in the way pesticides are used. These changes are generally reflected in changes to the label of a pesticide. Some label changes, such as extending pre-harvest intervals and reducing the number of applications or application rates, could reduce the level of pesticide residues in food. Other changes, such as limiting use to situations where pest populations exceed a certain level or to certain geographic locations, could reduce risk by reducing the volume of the pesticide used. Other label changes, such as limiting use of a pesticide to certain soil types or creating buffer zones around bodies of water, could mitigate water-related exposure to the pesticide. If label changes result in a reduction in the maximum amount of pesticide residue that could be found in food (assuming the label is followed), affected tolerances could be lowered accordingly.

REGULATORY TOOLS FOR ACCOMPLISHING OUTCOME 1

If a registrant consents to label changes, the registrant can request that its registration be amended to reflect the new label language. The Agency could grant the request and amend the registration accordingly. The registrant (or some other person) could petition the Agency to modify any existing tolerance where appropriate.

If a registrant does not consent to label changes, the Agency could issue a notice of intent to cancel the affected registrations unless the changes are made. The outcome of such a cancellation action could be the cancellation of the affected registrations (if the registrant continued to decline to accept a registration with the required changes) or the amendment of the registration to reflect the necessary changes (if the registrant eventually consents to the changes). If tolerance revisions were appropriate and no person submitted a petition to revise the affected tolerances, the Agency could issue a proposal on its own initiative to modify the tolerance. Alternatively, the Agency could proceed under the FFDCA and propose to revoke tolerances if the amendments are not made (and the existing risks without the amendments exceed the safety standard). If a tolerance is revoked, the Agency must also obtain a voluntary cancellation or follow-up with an NOIC.

MANDATORY TIMELINES FOR ACCOMPLISHING OUTCOME 1

If a registrant requests that a registration be amended, the amendment can be immediately granted without any required process or notice. There are no statutory requirements concerning the process to be followed when someone requests that a tolerance be modified under FFDCA § 408(d), although in similar circumstances the Agency has generally allowed for 60 days of public comment before acting on other requests submitted under section 408(d).

If consensus is not reached and cancellation is pursued, the Agency must submit a draft notice of intent to cancel to both USDA and the SAP at least 60 days before publishing a notice of intent to cancel. Interested persons are given 30 days to request a hearing after publication of the notice of intent. If EPA proposes on its own initiative to revoke or modify a tolerance, § 408(e) requires

that a 60 day public comment opportunity be provided before a proposed tolerance can be finalized.

OUTCOME 2 - CHANGES TO CONDITIONS OF REGISTRATION

Some risk reduction can be accomplished through changes to the conditions of one or more registrations. Such changes could include limits on the amount of a pesticide that could be produced, or requirements to perform certain studies. It would even be possible to place conditions on registrations that limit some or all use of a pesticide unless certain specified triggers occur (such as the generation of additional data that allows for greater risk refinement or the development of resistance to other pesticides). Such conditions could be accompanied, where appropriate, by tolerance reductions or revocations as well.

REGULATORY TOOLS FOR ACCOMPLISHING OUTCOME 2

Similar to the tools for accomplishing outcome 1.

MANDATORY TIMELINES FOR ACCOMPLISHING OUTCOME 2

Same as for outcome 1.

OUTCOME 3 - DELETIONS OF USES/REVOCATIONS OF AFFECTED TOLERANCES

Another means of reducing risk is to delete certain uses from the registration of a pesticide. These uses could either be agricultural uses or non-agricultural uses (such as residential uses or non-food uses that result in residues in water) that contribute to the inability to make the safety finding. If the deleted uses are food uses, associated tolerances could be proposed to be revoked as well.

REGULATORY TOOLS FOR ACCOMPLISHING OUTCOME 3

If a registrant agrees to the deletion of particular uses, the registrant can submit under section 6(f) of FIFRA a request to delete the uses from the registration. If EPA grants the request, the registration is amended accordingly. A registrant or other person could request that associated tolerances be revoked accordingly.

If a registrant does not agree to the deletion of particular uses, the Agency could issue a notice of intent to cancel the registration unless the uses are removed from the registration. At the conclusion of a cancellation proceeding, the registrant could be left with the option of accepting the deletion of the uses or having the entire registration cancelled. If any food uses are canceled under cancellation procedures because of dietary risk concerns, EPA is required to revoke the associated tolerance (FFDCA § 408(l)(2)).

Alternatively, if a registrant did not agree to delete uses, EPA could propose to revoke the tolerances for the affected uses under the FFDCA. This could initially be done before or without issuance of a Notice of Intent to Cancel. However, if a tolerance is revoked, the Agency must also obtain a voluntary cancellation or follow-up with an NOIC.

MANDATORY TIMELINES FOR ACCOMPLISHING OUTCOME 3

If a request for voluntary deletion of uses is received under section 6(f) of FIFRA, the statute provides for a minimum 30 day comment period before the request can be granted. If EPA determines that the requested revocation would affect the availability of the pesticide for use on a minor agricultural use, a 180 day comment period must be provided unless the registrant requests a shorter comment period or EPA determines the continued use of the pesticide on the use would cause unreasonable adverse effects on the environment. There are no statutory requirements concerning the process to be followed when someone requests that a tolerance be revoked under FFDCA § 408(d), although in similar circumstances the Agency has generally allowed for 60 days of public comment before acting on other requests submitted under section 408(d).

Cancellation timelines are addressed in outcome.

Alternatively, the Agency could issue a proposal to revoke the tolerances. Such a proposal must be accompanied by a comment period of at least 60 days.

OUTCOME 4 - CANCELLATION OF ACTIVE INGREDIENT

Risk reduction can be achieved through cancellation of all products containing an active ingredient. This would likely be accompanied by revocations of associated tolerances.

REGULATORY TOOLS FOR ACCOMPLISHING OUTCOME 4

If registrants agree to the cancellation of all registrations of a particular active ingredient, the registrants can submit under section 6(f) of FIFRA a request to cancel their registrations. If EPA grants the requests, all the registrations are cancelled. A registrant or other person could request that associated tolerances be revoked accordingly.

If a registrant does not agree to the cancellation of its registration, the Agency could issue a notice of intent to cancel all registrations containing the active ingredient. At the conclusion of a cancellation proceeding, all registrations could be cancelled. If the cancellation is in part attributed to dietary risk concerns, EPA is required to revoke the associated tolerances (FFDCA § 408(l)(2)).

Alternatively, EPA could propose under the FFDCA to revoke all tolerances associated with the active ingredient. This could initially be done before or without issuance of a Notice of Intent to Cancel. However, if a tolerance is revoked, the Agency must also obtain a voluntary cancellation or follow-up with an NOIC.

MANDATORY TIMELINES FOR ACCOMPLISHING OUTCOME 4

Timelines would be the same as under outcome 3.

OUTCOME 5 - DELAYED CANCELLATION OF ACTIVE INGREDIENT OR USES

There are circumstances where certain uses or all registrations of an active ingredient could be cancelled at some designated time in the future. Under such a scenario, an agreement or ruling could be made that results in the cancellation of some uses or all of an active ingredient to be effective at a later date. Generally, such "phase outs" are the result of negotiated settlements between registrants and the Agency, although they could conceivably result from formal regulatory proceedings.

REGULATORY TOOLS FOR ACCOMPLISHING OUTCOME 5

Registrants can conditionally request a voluntary cancellation under section 6(f) of FIFRA, with the condition being that the cancellation not take effect for a specified period of time. If the Agency agrees to the condition, the request can be granted and the cancellation will become effective at the specified time. The registrant or other person could request that associated tolerances be revoked accordingly at some time after the cancellation becomes effective.

There may also be circumstances where it is appropriate for the Agency to itself suggest a delayed effectiveness date in a notice of intent to cancel. The Agency could also propose on its own initiative to initiate tolerance revocations effective at some specified date in the future. If the cancellation is in part attributed to dietary risk concerns, EPA is required to revoke the associated tolerances (FFDCA § 408(l)(2)).

MANDATORY TIMELINES FOR ACCOMPLISHING OUTCOME 5

Timelines are the same as with outcome 3.