

Crop	Processing type	Products
Carrots	Cooking vegetable in water	Washed, topped and peeled carrots, <u>cooked carrots</u> , cooking liquid
Head cabbage		Inner and outer leaves, <u>cooked head cabbage</u> , cooking liquid
Asparagus		<u>Peeled</u> and <u>cooked asparagus</u> , cooking liquid
Peas without pods		<u>Cooked peas</u> , cooking liquid
Spinach		<u>Cooked spinach</u>
Carrots	Preparation of vegetable juice	<u>Juice</u>
Tomatoes		<u>Juice</u>
Carrots	Preparation of canned vegetable	<u>Canned</u>
Asparagus		<u>Canned</u>
Peas without pods		<u>Canned</u>
Gherkins		<u>Canned</u>
Tomatoes		Washed and peeled tomatoes, <u>canned</u>
Mushrooms		<u>Canned</u>
Melon	Distribution in the edible/non edible portion	Peel, Pulp
Onions	Preparation of other vegetable products	Dried onions, peeled onions
Mushrooms		Dried mushrooms
Head cabbage (white)		<u>Sauerkraut</u> , sauerkraut juice
Tomatoes		<u>Puree</u>
Lettuce		Inner and outer leaves, washing

3 Potatoes

Fried potatoes should only be investigated in the case of postharvest use of plant protection products or in the case of plant growth regulators shortly before harvest

Crop	Processing type	Products
Potatoes	Cooking in water	Peeled potatoes, peel, (...), <u>micro-waved boiled (...)</u> potatoes (unpeeled), cooking liquid.
Potatoes	Preparation of other products	<u>Fried potatoes</u> , (...), crisps, (...)

4 Hops

Crop	Processing type	Products
Hops	Preparation of beer	<u>Beer</u> , brewer's yeast, spent hops and flocs

The report must state the dilution factor.

5 Oilseeds

<u>Crop</u>	<u>Processing type</u>	<u>Products</u>
Rape seed	Preparation of oil	<u>Crude oil</u> , <u>refined oil</u> , solvent-extracted meal/press cake

6 Cereals

Wheat and rye in particular, and also barley (in the form of malting barley), are included here among the plant products which are of special nutritional importance.

<u>Crop</u>	<u>Processing type</u>	<u>Products</u>
Wheat or rye	Distribution on milling and preparation of bread	<u>Whole-meal flour</u> , <u>whole-grain bread</u> , middlings, <u>total bran (coarse bran, fine bran)</u> , <u>flour</u> including <u>toppings (Type 550 or Type 997)</u> , <u>wheat germ</u>
Maize	Distribution on milling (and preparation of bread)	Flour, bran, middlings, <u>starch</u> , <u>germ</u> (residues in germ should also be determined in follow-up studies in order to answer questions concerning residues in oil derived from the germ)
Barley	preparation of beer	<u>Brewing malt</u> , malt sprouts, <u>beer</u> , spent grains and flocs, brewer's yeast
Barley		Pot barley
Oats		Oat husk and oat dust, <u>oat flakes</u>

7 Sugar beets

<u>Crop</u>	<u>Processing type</u>	<u>Products</u>
Sugar beets	Preparation of sugar	Pulp, press water, raw juice, thin juice, lime sludge, <u>thick juice</u> , raw sugar, <u>white sugar</u> , <u>molasses</u>

資料 4

Residue Guideline No. 7 - Processing Studies

February 2000

Background

Processing studies are used to support a raw commodity MRL proposal and in some cases the setting of a processed commodity MRL. These guidelines give advice on when processing studies should be provided to support the MRL.

There is an increasing need for information about the effects of storage, peeling, washing, cooking and food processing on the fate of agricultural and veterinary chemical residues in foods/animal feeds both from a regulatory and public concern perspective. Consequently in some situations residue levels determined from processing studies allow a more realistic estimation of dietary intake of residues resulting from the use of an agricultural or veterinary chemical.

It should be noted, however, that for many pesticide products no data will be required since residues in raw agricultural or animal commodities are not significant or are non-detectable. In such cases MRLs in the processed foods are covered by the entries for the raw agricultural/animal commodities.

It is intended that this guideline should be in harmony with those used in other countries such as European Union (EU)[1], the United States[2] and Canada[3], where processing studies are also conditionally required, and with Codex[4].

Data from relevant studies conducted in other countries, along with appropriate argument, will normally be acceptable for Australia. Completed processing studies conducted overseas should be submitted with an application for registration.

This guideline gives only general advice on when, and what type of processing study may need to be carried out. In some situations it may be necessary to produce a protocol in consultation with the National Registration Authority. Further detailed information about the conduct of processing studies can be obtained from Codex[4], EU1 and the US EPA guidelines[2].

Situations in which Processing Studies may be required:

Processing studies may be required in the following situations:

- when the theoretical maximum daily intake (TMDI) exceeds the acceptable daily intake (ADI) so as to determine the level of residue in the consumed food relative to the raw commodity and thus calculate a processing factor (relative concentration or reduction of residues) to allow a better estimate of actual daily intake of residues;
- when there is a possibility that processing may convert residues into a metabolite that has toxicological significance;
- when it is evident that residue levels in the processed food/feed will be greater than in the raw agricultural commodity and hence there is a need to set MRLs for various processed foodstuffs; and
- when the commodity contains residues above the limit of quantitation and processing studies are mandatory, e.g. wheat;

It is expected that processing studies will be required when significant (>0.1 mg/kg) residues are present in the following raw commodities: cereals, oil seeds, citrus, grapes, apples, potatoes and dried fruit and sugarcane.

Requirement for Processing Studies

The decision on whether processing studies (rather than reasoned argument) are necessary to support an MRL proposal for a particular crop/animal commodity will depend on a combination of factors.

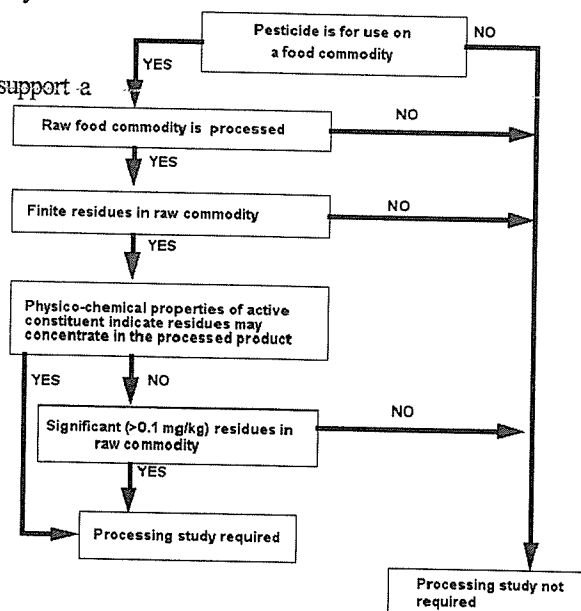
The importance of the level of intake of the processed product in the human or animal diet should be considered when considering whether to do processing studies for TMDI

calculations. When the commodity is not widely consumed the impact on the TMDI could be small and a

- processing study on one commodity in a group can be extrapolated to cover a range of foods. The importance of the processed product to the human diet can be determined from national dietary surveys conducted by the Australia New Zealand Food Authority (survey last done in 1983). In the case of animal diets, consultation with appropriate animal nutrition experts may be required.
- Physicochemical properties of the active ingredient can be used to assist in determining whether residues in processed commodities might be higher than those in raw agricultural commodities. The likely behaviour of the active ingredient and/or its metabolites can be drawn from the:
 - octanol/water distribution coefficient - e.g. when $\log K_{ow}$ is greater than 3 it is probable the residue will be concentrated in oil;
 - hydrolysis stability - e.g. when stable to hydrolysis the residue is not readily degraded by storage;
 - heat stability - e.g. residue not readily degraded by cooking;
 - solubility behaviour - e.g. good water solubility indicates residues may concentrate in juices including wine.
- The level of residues in the raw commodity. Processing studies are not usually necessary to support the proposed MRL if:
 - the commodity is mainly eaten raw;
 - there are no significant (below 0.1 mg/kg) or toxicologically-active residues;
 - there is adequate evidence that residue levels in processed foods/feeds will not exceed the level in a raw agricultural commodity.

Decision tree for data requirements

The process for deciding what data is appropriate to support a proposed MRL is provided in Figure 1. It must be read in conjunction with the accompanying guideline notes.



Conduct of Processing Studies

Processing studies should only be conducted on commodities containing weathered (aged) residues. Using fortified samples is *generally* not acceptable unless the raw commodity residue consists entirely of a surface residue. If processing results in alteration of the residue, then a radiolabelled processing study to determine the nature of the residue in the food/feed should be carried out on one of the major food processing procedures that involves the use of heat. It will not be necessary to carry out a radiolabel study on every crop/crop group.

When designing a residue program, all raw commodities that are processed should be considered. Lists of commonly processed animal and crops commodities that should be considered are given in Tables 1 and 2.

Processing trials should be considered for all raw commodities which are processed. Applicants who are in doubt about a particular situation should consult with the APVMA before conducting the study(s).

Number of Studies and Products to be Analysed

The number of studies needed will depend on the use pattern proposed and the number of crop and livestock species involved. Data should be developed for representative foods. One study per crop or animal or no more than two studies per crop or animal *group* is generally sufficient, although if the processed products play an important part in dietary intakes additional studies may be required (*if in doubt consult with APVMA prior to conducting trials*).

Where the raw commodity undergoes a number of processes (e.g. cereals) the initial major primary processed products should be examined first (e.g. flour, bran). Studies on secondary processed and cooked products will only be required if there is reason to believe residues in those commodities could be higher than those occurring in primary processed products. When a number of similar crops are to be included on the label, studies on one representative from each crop group will normally be acceptable.

Studies conducted overseas to determine processing factors will be acceptable provided the processing methods are similar to those used in Australia. Normally the processes and cooking techniques used in Australia are not significantly different from those used in Europe and North America.

Table 1. Commonly processed animal commodities

Animal	Commodities
Cattle	Cooked edible offal; cooked meat; pasteurised milk; meat meal
Sheep	Cooked edible offal; cooked meat, meat meal
Pig	Cooked edible offal, cooked meat, meat meal
Poultry	Cooked edible offal, cooked meat, cooked eggs, meat meal

If the label contains more than one animal species then data on one species will normally be sufficient.

Table 2. Commonly processed crop commodities

Raw commodity	Primary processed food	Secondary processed food	Raw commodity	Primary processed food	Secondary processed food
Canola	oil(a)		Potato	chips, dried, boiled	
Cereals (small grain)			Rice	polished, flour	
Wheat/rye	flour, bran wheat germ	bread,	Safflower	oil(a)	
Barley	malts	beer	Sorghum	flour, meal	
Oats	flakes		Soybean	oil(a), meal	
			Spices	dried	
Cotton seed	oil(a)		Sugarcane	raw sugar juice	refined sugar, syrup
Fruits(b)				molasses, bagasse	
Berries (currant strawberry)	jam, juice		Sunflower	oil(a),meal	
Citrus (orange)	juice, pulp, peel		Vegetables		
Pome (apple)	juice, dried, sauce		Root & tuber (carrots)	juice, cooked	
Stone (plum, peach)	preserved, jam, dried		Bulbs (onions)	peeled,	
Sub tropical	juice, preserved		Brassicas (cabbage)	inner & outer leaves	

Tropical (pineapple)	juice, preserved		Stem (asparagus)	cooked preserved,	
Grapes	juice, dried,	wine	Legumes (peas)	whole, podded,	
Hops	dried, spent			cooked	
Maize/corn	flour, meal	flakes	Fruiting		
Mungbeans	sprouts		(tomatoes)	juice, preserved, cooked	
Mustard seeds	powder		Leafy (lettuce) (spinach)	inner & outer leaves cooked	
Peanut	oil(a)		Mushrooms (cultivated)	cooked	
Peppermint	oil(a)				

(a) If it is likely that a higher residue will be present in refined oil than in raw oil, studies should also be conducted on the refined oil.

(b) If the label contains a wide range of fruit crops, one study containing a fruit juice (e.g. apple), a preserved fruit (e.g. peach), a cooked fruit (e.g. peach), a jam (e.g. strawberry) and a dried fruit (e.g. prune) will normally be sufficient.

Processing Technology

The technology used in processing studies should correspond as closely as possible to the actual conditions in common usage (in the home or commercially). Extended periods of storage should be considered as a processing practice. Where more than one process can occur, then data should be produced for the worst case situation. It is not expected that studies using every conceivable type of processing or cooking will be needed, but a limited number using typical conditions is desirable.

Evaluation of Results Data from processing studies will allow:

- recognition of reductions and concentrations of residues;
- estimation of transfer factors;
- recognition of significant alterations in residues.

The appropriate MRL can normally be set by multiplying all available raw commodity results for the crop/animal by the relevant transfer factor (from processing study) and the estimated residue levels evaluated in the normal manner.

Reporting of Results

A full laboratory report including all relevant data should be written using the standard format for residue reports (see Residue Guideline No. 11; *Reporting of residue trials*). The report must include a full description of the processing practice used.

[1] Lundehehn JR. *Guidelines for the Establishment of Community Maximum Residue Levels (MRLs) of Plant Protection Products in Food and Feedstuffs of Plant and Animal Origin - Final Report*. For the Commission of the European Communities, Directorate-General for Agriculture. January 1993.

[2] US Environmental Protection Agency (US EPA). *Pesticide Assessment Guideline: Residue Chemistry* Subdivision O PB83-153981. October 1982; Technical Guidance, December 1989; Addendum on data reporting PB88-117270. November 1987; Standard Evaluation Procedure PB88-243209, July 1988.

[3] Health and Welfare Canada, Health Protection Branch. *Guidelines for Developing Pesticide Residue Data in Foods as Consumed*. July 22 1988.

[4] Correspondence from Chief, Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission. August 1993

Ⅱ. 研究成果の刊行に関する一覧表

雑誌

発表者氏名	論文タイトル	雑誌名	巻号	頁	出版年
該当なし	該当なし	該当なし			

Ⅲ. 研究成果の刊行物・別刷り

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