

**INSTRUCTIONS FOR CARRYING OUT LONG TERM CONSUMER RISK ASSESSMENT USING
CRD'S TEN CONSUMER MODEL.**

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Instructions for carrying out long term consumer risk assessment using CRD's ten consumer model

1. Introduction

These guidance notes are for the CRD's chronic consumer risk assessment spreadsheet version 1.0 <Chronic_consumer_ver1.0.xls>. For further information on the consumer risk assessment methodology that is implemented in the spreadsheets see the Manual on the Submission and Evaluation of Pesticide Residues Data, 2002 (Food and Agricultural Organization of the United Nations) (http://www.fao.org/agriculture/crops/publications/detail/en/item/46006/icode/9/?no_cache=1).

The estimates of long term exposure are calculated based on the supervised trials median residue (STMR) residue level in the treated agricultural commodity, and consumption data for the ten consumer groups as provided by the UK Food Standards Agency (FSA). The intake is then compared to the acceptable daily intake value (ADI) for the active substance in question.

The spreadsheet can be used for calculating both individual commodity National Estimates of Dietary Intakes (NEDIs) and total dietary intake calculations (total NEDIs) using the 'Rees-Day' model as a first estimate of 'long-term' or chronic pesticide intake or as a primary screen of total dietary intake for pesticides. This model sums the two highest 97.5th percentile commodity intakes and the average intakes across all the remaining commodities for each of the consumer sub-groups. A worst case assessment the Theoretical Maximum Daily Intake (TMDI) screen can be calculated by inserting a Maximum Residue Level (MRL) value instead of using the Supervised Trials Median Residue (STMR). For further details on the basis for this 'Rees-Day' model, see Section 8 below.

The spreadsheet enables the intakes of ten consumer groups from the consumption of treated agricultural commodities to be determined. The consumer groups used are: adult ; infant ; toddler ; 4-6 year old child ; 7-10 year old child ; 11-14 year old child ; 15-18 year old child; vegetarian; elderly (own home); elderly (residential). For further information on these consumer sub-groups, please see the sections on the definitions of the consumer groups (Section 6) and on the dietary surveys (Section 7).

2. How the spreadsheet works

You need to enter several values into the spreadsheet: residue levels in the agricultural commodities (either the MRL or the STMR) in which residues occur; any processing factors to account for concentration or reduction in residues during preparation or processing; and an ADI value, specific to an active substance. Primarily, you need to enter residues data for the raw agricultural commodity (RAC), unless processing data are available and an alternate risk assessment is possible on this basis. ADI values can be found at EU Pesticides database:

<http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN>

You also have the option of inputting the active substance name and the source of ADI, if you want these displayed on the output sheet. Once these inputs have been made, a NEDI/TMDI calculation is automatically carried out by the spreadsheet using consumption data provided by the UK FSA.

You can generate outputs that are suitable for use in word documents; instructions for this are given by way of the example in Section 9.

3. System requirements

The spreadsheet should run on all versions of Microsoft® Excel; Screen resolution is best set at 1024 × 768 pixels or higher.

4. How to use the spreadsheet to perform a long term exposure calculation

These steps guide you through the process of using the spreadsheet to perform a risk assessment based on the STMR that returns a NEDI value based on the food consumption and residue levels. The use of an MRL value in place of the STMR results in a TMDI value rather than a NEDI value.

Once the spreadsheet has been opened and saved onto the PC hard-drive it can be used the same as any other Excel spreadsheet.

Open the spreadsheet by double-clicking on the icon. This will result in the following dialogue box being displayed:



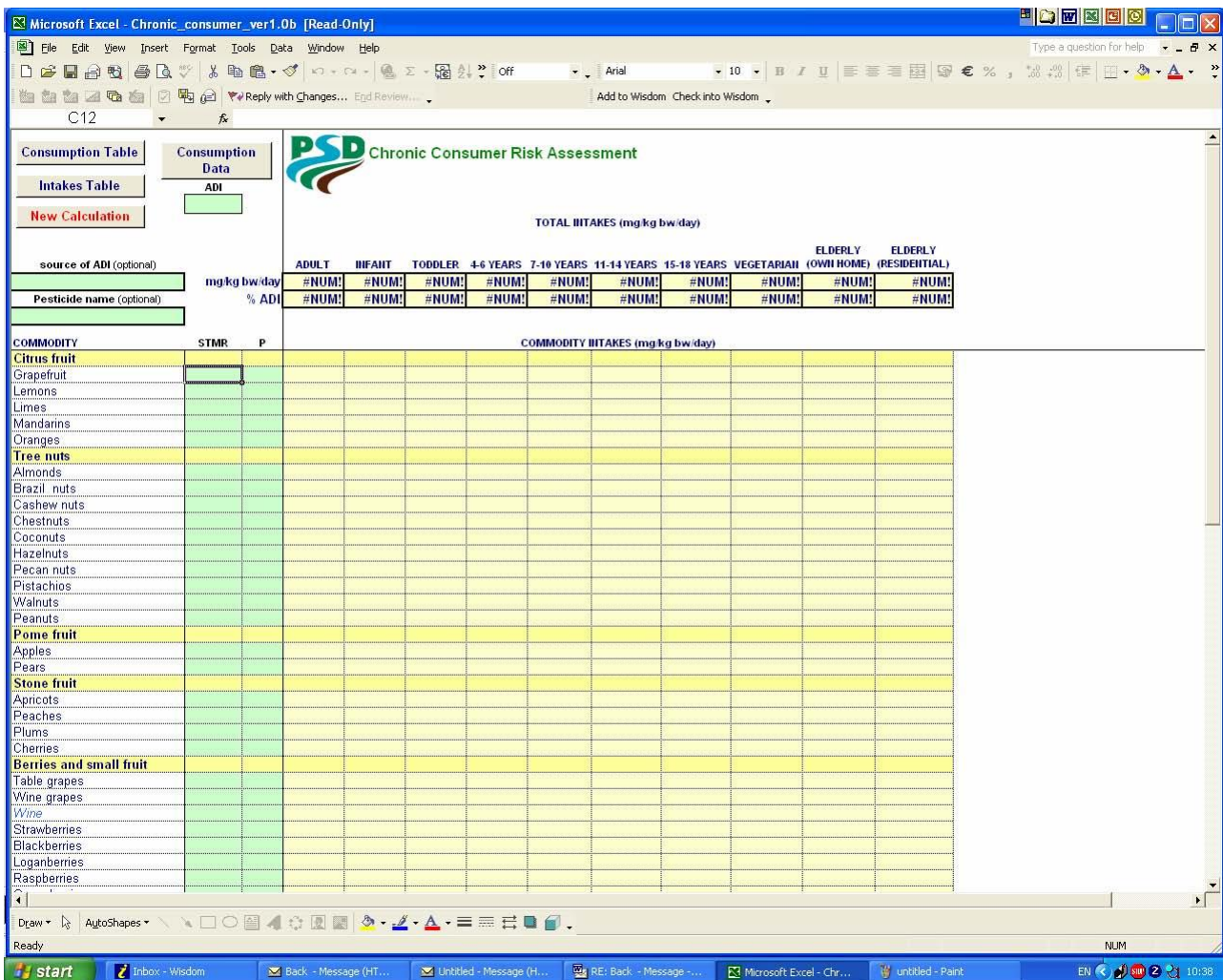
Click Enable Macros All of the macros in this spreadsheet have been virus checked and are safe to use. The spreadsheet will not work if the macros are disabled.

Once the macros have been enabled, a prompt recommending the spreadsheet be opened as read only will be displayed.



It is advisable to open the spreadsheet as read-only and then save any changes under a different file name, as these may lead to incorrect values for total dietary intake values.

Once the spreadsheet is open, the user will see the following screen, with spreadsheet now ready to use



Commodities are grouped in the spreadsheets according to the EU MRL classification rather than in alphabetical order. Only cells with a green background can have data entered into them. From the figure above, it can be seen that the following data can be entered; c) to e) are optional:

- ADI
- STMR
- Processing factor (P)
- Source of ADI
- Pesticide name

An example calculation demonstrating the use of the spreadsheet is outlined in Section 9 below. This is not intended to be a realistic scenario, but rather one that demonstrates the features of the spreadsheet.

5. Notes on required inputs, results and interpretation

This section focuses on the correct use of the spreadsheet and estimates of exposure outputs of the spreadsheet as a consumer risk assessment tool rather than interpretation of the results from a human health perspective taking into account the toxicology of the pesticides. An exceedance of the ADI does not necessarily present a consumer exposure concern. Intakes that are below the ADI inserted are presented in blue type in the input table, and values above the ADI are in red type. In the Intakes table, that is generated and suitable for printing out/cut and pasting, total dietary intakes above the ADI are in red-type.

If you are dealing with only one commodity and wish to have the result expressed as a percentage of the ADI, you will need to insert a zero residue for another commodity as '%ADI' is only calculated for total dietary intakes when there is more than one commodity.

If the number of consumers is less than 60 people, the data should be treated with caution, as the results may not be statistically robust. The chronic exposure spreadsheet provides information on the number of consumers for each commodity and consumer group combination in the consumption worksheet. In the output the results will indicate low consumption as 'LC' where the consumption value is <0.1 g/day or a number of consumers less than 4.

Consumption data are presented in a 'consumption table' and for each commodity a 'mean' and '97.5th percentile' is provided. The mean is a population group mean considering the average consumption across all members of the population group whether or not they consume the commodity item under consideration.

Commodities that are based on RAC are stated in normal type in the commodity list. Those for processed foods are in italics and pale blue type. The use of the data for processed foods e.g. wine depends on the availability of residues data for the processed food itself or a processing or transfer factor, which converts the RAC residue to an appropriate residue for the processed food. The data for processed food can enable a more refined calculation of intake; however, care should be taken not to 'double count' in a total dietary intake calculation. For example, an assessment of total dietary intake should not include a contribution from both 'wine grapes' and 'wine'. To avoid the possibility of 'double counting' it is best to use only the RAC consumption data for commodities (and processing factors as appropriate). Specific advice on further refining calculations to account for residues in processed foods can be sought from CRD.

When considering processing factors note that the Advisory Committee on Pesticides have agreed, and Departments have accepted, when considering if pesticides should be approved for use it will not be assumed that fruit and vegetables will be peeled, see link to ACP statement:

<http://webarchive.nationalarchives.gov.uk/20151023155227/http://webarchive.nationalarchives.gov.uk/20151023155227/http://www.pesticides.gov.uk/guidance/industries/pesticides/advisory-groups/acp/acp-letters/acp-advice-to-the-fsa>. Therefore, intake estimates presented to CRD to support applications for approval should not employ processing factors to take account of edible portions.

The commodity descriptors are the same in both the CRD chronic exposure model (this spreadsheet) and the CRD acute model.

6. Definitions of Consumer Groups

In the following list n=numbers in the survey, and the year given represents the date of the survey:

Adult (n=1724, 2001) – consumers aged 19 to 64 both male and female, with a mean body weight of 76.0 kg. [Please note the survey of adults in previous use by CRD was the 1986/7 [n=2197] survey where the mean bodyweight of consumers was 70.1 kg].

Infant (n=488, 1986) – consumers aged 6-12 months both male and female, with a mean body weight of 8.7 kg

Toddler (n=1675, 1992/3) – consumers aged 18 months to 4 years both male and female with a mean body weight of 14.5 kg

Young people (n= 1701, 1997) split further into

4-6 year old child (n=355) – mean body weight of 20.5 kg

7-10 year old child (n=482) - mean body weight of 30.9 kg

11-14 year old child (n=475) - mean body weight of 48.0 kg

15-18 year old child (n=389) - mean body weight of 63.8 kg

Vegetarian (n= 415, 1994/5) – adult consumers aged 16 to 64 both male and female who are “self declared” vegetarians, although some still eat meat with a mean body weight of 66.7 kg

Elderly (own home) (n= 1275, 1997) – consumers aged over 65 both male and female who live in their own home with a mean body weight of 70.8 kg

Elderly (residential) (n= 412, 1997) – consumers aged over 65 both male and female who receive residential care in a nursing home or similar, with a mean body weight of 61.6 kg.

7. Dietary surveys

In recent years, more data have become available enabling the risks for more consumer sub-groups to be assessed. The data are provided to CRD by the UK FSA and are derived from published dietary surveys (as referenced in Section 10). The field work for the dietary surveys has been conducted over 12 months. A weighed diary record was taken for food consumed over 7 days for all the surveys except for toddlers and elderly which were taken over 4 days. The consumption values for long term consumption are calculated for each individual in the survey by averaging the daily intake for each commodity intake over the course of the survey. The combined data for all of the individuals are then used to derive both the population mean and the 97.5th percentile to derive ‘average’ as well as ‘high level’ consumption values for each of the commodities. The 97.5th percentile is often used to define this upper level of ‘normal dietary behaviour’ and is based on the upper percentile of consumers recorded as consuming a food item. The average intake values used in the chronic exposure estimate, however, takes into account all population members in the survey (i.e. consumers and non-consumers of the food item).

The most recent survey to become available is the National Diet and Nutrition Survey (NDNS) survey of adults conducted in 2001. In order to deduce consumption data for raw agricultural commodities from the variety of foods consumed the FSA apply a recipe analysis to the data assigning different food codes for raw foods and component ingredients of composite foods (such as apple pie). New updated food codes are currently being assigned to ensure that the full potential of the adults 2001 database is realised. As generating refined data based on the new food codes for this analysis is expected to take some time, we have compared the 2001 adults data using the existing food codes data with the previous 1986/87 adults data, and consider that using this 2001 data as an interim position is likely to represent a much more valid estimation of the UK adult diet than continuing to use the ‘old’ 1986/7 survey data. Therefore, information from the 2001 survey of adults is used in this ten consumer group spreadsheet. This will be subject to a future refinement when the further work using newly developed food codes has been completed.

8. The 'Rees-Day' model calculation and assessing long term total dietary intakes.

In conducting total long term dietary intakes it is not appropriate to sum the individual long term intakes from different commodities, as this would result in a gross overestimate. Work on UK data suggests that there were no adults consuming more than five food groups (widely defined) at the 97.5th percentile level and the vast majority consumed less than two food groups at the 'high level' (97.5th percentile) consumption. Therefore, total dietary intakes are estimated by the spreadsheet using the following 'Rees-Day' model equation:

Total NEDI

(based on STMR) Or = \sum 2 highest 97.5th percentile intakes + mean population intakes for other foods
Total TMDI (based on MRL)

It was found that this method estimated the high level intake by 90% to 180% (the vast majority fell between 100% and 130%) of the level estimated using the complete database for individual consumers.

This method gives a 'rough' estimate of the worst case dietary intake whilst incorporating a number of conservative assumptions. Figures for the mean population intakes are provided in the database supporting this model, and can be viewed via the 'consumption' output table.

9. Example Calculation

“Insecticido” is an insecticide for which approval is sought for use on pome fruit, carrots, potato, sugar beet, wheat, oats, and barley. Supervised residue trials have indicated that median levels in the commodities (STMRs) are all 0.05 mg/kg. The JMPR (2004) have established an ADI of 0.003 mg/kg bw/ day.

Enter the ADI in units of mg/kg bw/day and pesticide information as shown in the figure below:

The image shows a spreadsheet interface with several input fields. On the left, there are three buttons: 'Consumption Table', 'Intakes Table', and 'New Calculation'. Below these are three input fields: 'source of ADI (optional)' with the value 'JMPR 2004', 'Pesticide name (optional)' with the value 'Insecticido', and 'ADI' with the value '0.003'. Red circles highlight the 'ADI' field and the 'source of ADI' and 'Pesticide name' fields. A red arrow points from the 'ADI' field to the text 'Input ADI and active ingredient values here'.

The residues from the supervised trials can now be entered in units of mg/kg in the same way. Commodity groupings (e.g. citrus fruit) are present as titles, and are not used in calculations. If, as in this example, it is required to determine the consumption of an entire commodity group such as pome fruit, then residue values for the individual commodities in that group should be entered.

Once the residues levels have been entered, the input sheet should look similar to the one shown below:

Chronic Consumer Risk Assessment

Consumption Table | Intakes Table | New Calculation

source of ADI (optional): JMPR 2004
 Pesticide name (optional): Insecticido
 mg/kg bw/day: 0.003

TOTAL INTAKES (mg/kg bw/day)

	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWHI HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.001052	0.002688	0.004117	0.002791	0.002469	0.001563	0.001430	0.000995	0.000877	0.001105
% ADI	35%	90%	137%	93%	82%	52%	48%	33%	29%	37%

COMMODITY INTAKES (mg/kg bw/day)

COMMODITY	STMR	P	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWHI HOME)	ELDERLY (RESIDENTIAL)
canned/bottled Potatoes	0.05		0.00003	0.00021	0.00014	0.00006	0.00008	0.00004	0.00011	0.00003	0.00007	0.00003
cracked Potatoes	0.05		0.00009	L/C	0.00025	0.00016	0.00015	0.00009	0.00007	0.00011	0.00009	0.00008
misc. Potato products	0.05		0.00004	0.00014	0.00013	0.00014	0.00010	0.00007	0.00006	0.00006	0.00006	0.00005
dried (instant) Potatoes	0.05		0.00001	0.00005	0.00003	0.00003	0.00001	0.00002	0.00001	0.00001	0.00001	0.00001
boiled Potatoes	0.05		0.00009	0.00048	0.00030	0.00021	0.00016	0.00012	0.00011	0.00011	0.00013	0.00011
Crisps	0.05		0.00003	0.00004	0.00011	0.00009	0.00006	0.00004	0.00003	0.00003	0.00002	0.00002
Potato chips	0.05		0.00009	0.00015	0.00029	0.00019	0.00016	0.00017	0.00014	0.00008	0.00008	0.00006
Tea (dried leaves)												
Hops (dried 0.25% of beer)												
Cereals												
Oats	0.05		0.00002	0.00011	0.00006	0.00004	0.00002	0.00002	0.00003	0.00003	0.00003	0.00003
Barley	0.05		0.00001	L/C	0.00002	0.00002	0.00004	0.00001	0.00001	0.00001	0.00001	0.00001
Millet												
Buckwheat												
Cornmeal & Cornflour												
Maize												
Wheat	0.05		0.00018	0.00014	0.00042	0.00044	0.00034	0.00025	0.00020	0.00021	0.00016	0.00017
Rice												
Rye												
Meat												
Poultry												
Meat fat												
Meat excl. poultry & offal												
All types of kidney												
Liver												
Other types of offal												
Eggs												
Milk												
Total all foods												
Sugar beet	0.05		0.00070	0.00167	0.00279	0.00168	0.00157	0.00100	0.00096	0.00060	0.00053	0.00076
Refined sugar												

The values in blue in the yellow columns in the main tables are the NEDI values calculated from the consumption data for each of the consumer group/commodity combinations. The table at the top of the spreadsheet shows the total NEDI value determined using the Rees-Day model, and how this compares to the ADI as a percentage. It can be seen from this example, that the ADI for toddlers is exceeded, and this is flagged up in bold red text. L/C displayed in the main table indicates that consumption of an individual commodity is <0.1 g/day

The outputs suitable for use in word documents can now be generated, by clicking on the consumption table and the intakes table buttons in the top left-hand corner of the sheet. These activate macros that copy the values to new sheets optimised for pasting into word documents. In order for these to be displayed as intended, the page size in the word document should be set to A4 in landscape orientation, with the margins set as 2 cm all round the page. The first table displayed below is that obtained when using the intakes table command, whilst the second table is obtained using the consumption table command.

Slight changes may be required to the formatting of the tables to ensure they fit on a single page, such as wrapping text in the consumption cells or auto-fitting to the window.

The consumption values for each consumer group-commodity combination can be viewed by clicking on the consumption tab at the bottom of the spreadsheet.

The new calculation button clears all of the results and inputs from the spreadsheet, enabling a new calculation to be performed

Active substance: Insecticido

ADI: 0.003 mg/kg bw/day

Source: JMPR 2004

TOTAL INTAKE based on 97.5th percentile										
	ADULT	INFANT	TODDLER	4-6 YEARS	7-10 YEARS	11-14 YEARS	15-18 YEARS	VEGETARIAN	ELDERLY (OWN HOME)	ELDERLY (RESIDENTIAL)
mg/kg bw/day	0.00098	0.00252	0.00394	0.00259	0.00231	0.00144	0.00133	0.00093	0.00081	0.00103
% of ADI	33%	84%	131%	86%	77%	48%	44%	31%	27%	34%

Commodity	STMR (mg/kg)	P	COMMODITY INTAKES (mg/kg bw/day)									
Apples	0.05		0.00013	0.00042	0.00074	0.00047	0.00038	0.00021	0.00018	0.00017	0.00011	0.00005
Pears	0.05		0.00007	0.00013	0.00033	0.00018	0.00011	0.00009	0.00007	0.00009	0.00011	0.00006
Carrots	0.05		0.00004	0.00018	0.00012	0.00010	0.00006	0.00004	0.00005	0.00004	0.00005	0.00004
Potatoes	0.05		0.00016	0.00056	0.00046	0.00041	0.00035	0.00027	0.00023	0.00018	0.00016	0.00016
Oats	0.05		0.00002	0.00011	0.00006	0.00004	0.00002	0.00002	0.00003	0.00003	0.00003	0.00003
Barley	0.05		0.00001	L/C	0.00002	0.00002	0.00004	0.00001	0.00001	0.00001	0.00001	0.00001
Wheat	0.05		0.00018	0.00014	0.00042	0.00044	0.00034	0.00025	0.00020	0.00021	0.00016	0.00017
Sugar beet	0.05		0.00070	0.00167	0.00279	0.00168	0.00157	0.00100	0.00096	0.00060	0.00053	0.00076

* 0.00000 corresponds to <0.000005 mg/kg bw/day (any value ≥0.000005 is rounded to 0.00001)

L/C Low consumption (<0.1 g/day) or low number of consumers (<4)

CONSUMPTION kg/day

Commodity	ADULT		INFANT		TODDLER		4-6 YEARS		7-10 YEARS		11-14 YEARS		15-18 YEARS		VEGETARIAN		ELDERLY (OWN HOME)		ELDERLY (RESIDENTIAL)	
	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%	mean	97.5%
Apples	0.031	0.204	0.014	0.073	0.025	0.216	0.039	0.193	0.042	0.232	0.033	0.197	0.028	0.228	0.040	0.223	0.024	0.155	0.012	0.066
Pears	0.005	0.106	0.002	0.022	0.003	0.095	0.002	0.075	0.003	0.068	0.002	0.089	0.001	0.093	0.005	0.125	0.006	0.161	0.005	0.074
Carrots	0.014	0.053	0.012	0.031	0.008	0.036	0.010	0.039	0.010	0.038	0.010	0.041	0.014	0.063	0.015	0.059	0.015	0.069	0.017	0.048
Potatoes	0.106	0.247	0.028	0.097	0.051	0.133	0.081	0.169	0.101	0.217	0.119	0.256	0.127	0.290	0.091	0.236	0.096	0.232	0.088	0.196
Oats	0.001	0.027	0.002	0.019	0.001	0.018	0.001	0.016	0.001	0.014	0.001	0.017	0.001	0.041	0.003	0.043	0.003	0.037	0.004	0.035
Barley	0.002	0.019	L/C	L/C	0.000	0.005	0.000	0.007	0.000	0.025	0.000	0.009	0.001	0.015	0.001	0.017	0.001	0.018	0.000	0.009
Wheat	0.127	0.274	0.023	0.024	0.057	0.123	0.086	0.182	0.106	0.208	0.117	0.240	0.133	0.258	0.137	0.284	0.112	0.231	0.106	0.213
Sugar beet	0.304	1.060	0.088	0.290	0.334	0.808	0.358	0.690	0.434	0.971	0.467	0.961	0.494	1.229	0.252	0.796	0.248	0.752	0.428	0.935

* <60 consumers in one or more groups.

L/C Low consumption (<0.1 g/day) or low number of consumers (<4).

10. Survey References

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Henderson L, Gregory J, and Swan G Volume 1: Types and quantities of Food consumed TSO (London) 2002
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- 6a) Ministry of Agriculture, Fisheries and Food, Research & Development and Surveillance Report: 181 (October 1996). Dietary Survey of Vegetarians: Final Technical Report. 6b) Ministry of Agriculture, Fisheries and Food, Research & Development and Surveillance Report: 303 (June 1997). Dietary Survey of Vegetarians: Tables of Questionnaire Results. 6c) Ministry of Agriculture, Fisheries and Food, Research & Development and Surveillance Report: 261 (July 1997). Dietary Survey of Vegetarians: Analysis of the Questionnaire Results. 6d) Ministry of Agriculture, Fisheries and Food, Research & Development and Surveillance Report: (March 1999). Vegetarians Dietary Survey: Technical Report on Weighed Intake Diary Data.
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