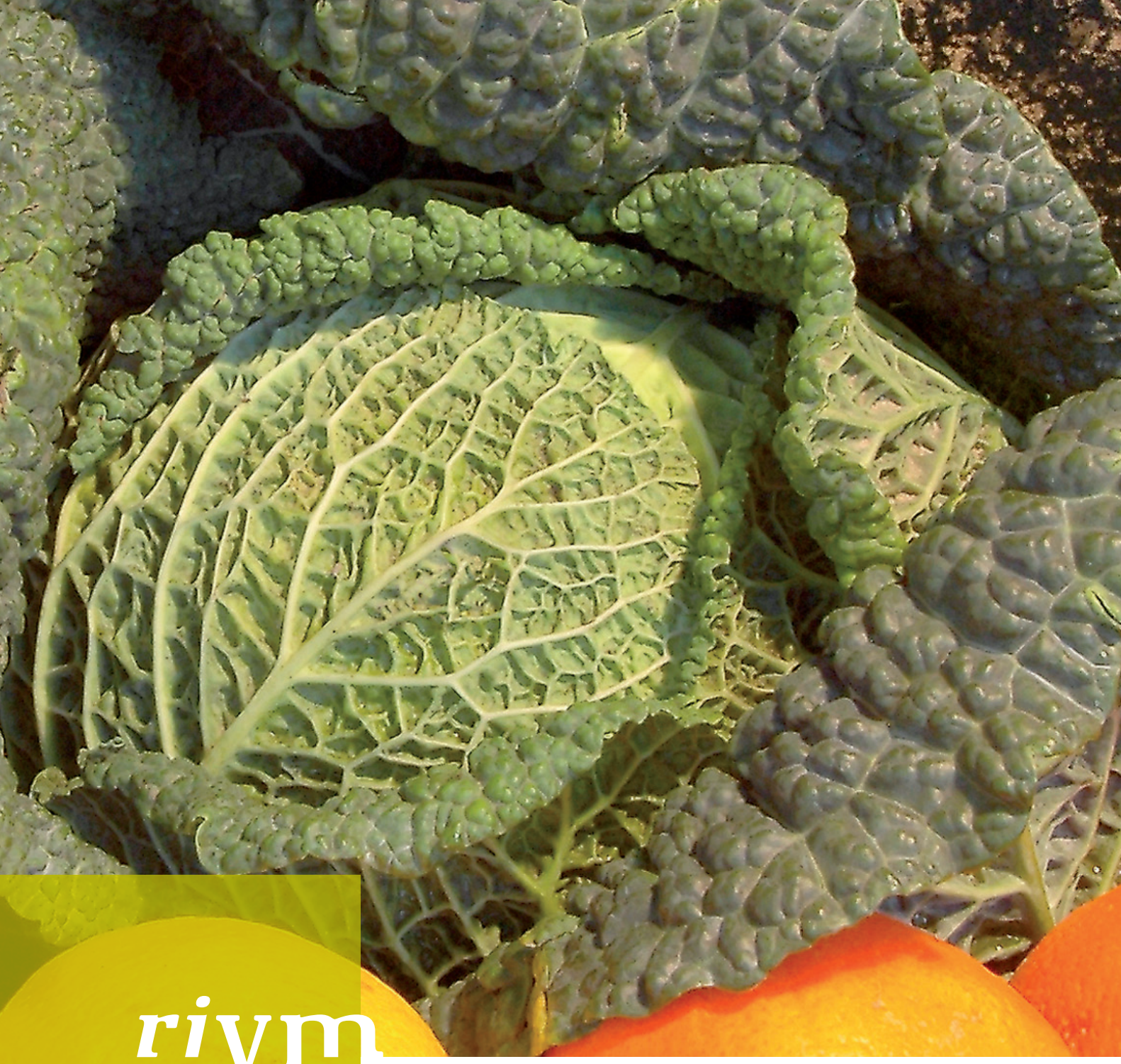

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Revision of Dutch dietary risk assessment models for pesticide authorisation purposes

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This investigation has been performed by order and for the account of VWS, within the framework of 'Advisering Biociden en Bestrijdingsmiddelen'

Abstract

Revision of Dutch dietary risk assessment models for pesticide authorisation purposes

RIVM revised the models for the calculation of consumer risk for pesticide residues at the maximum allowed levels in food; the actual levels are generally lower. The reason for the revision were more recent food consumption data for young children. For a risk assessment, the amount of a food product consumed is combined with the pesticide concentration in or on that product. The resulting pesticide intake is compared to a toxicological reference value. This risk assessment is a default part of the pesticide authorisation procedure.

Using the revised models, the theoretical estimation of the pesticide residue intake of the Dutch population was generally higher than before. Therefore it is possible that some European standards for the maximum allowable amount of pesticide residues (MRLs) will need to be adjusted to lower levels. This should be investigated by incorporating the Dutch data in the European EFSA calculation model, which estimates European consumer risks (PRIMO). The first steps to accomplish this have already been taken.

The revised calculation models now contain consumption data for three target groups: babies/toddlers, young children and the general population. In the previous models no data were available for the first target group. Furthermore, the calculation models contain for the first time consumption data for raw products as well as processed products made thereof (e.g. apple juice from apples and bread from cereals). So far only the consumption data for raw products were available in the models.

Key words:
pesticide residues, dietary risk assessment, food consumption database, NEDI, NESTI, IEDI, IESTI, TMDI, CPAP

Rapport in het kort

Revisie van de Nederlandse dieetrisicobeoordelingsmodellen voor gewasbeschermingsmiddelauthorisatiedoeleinden

Het RIVM heeft de modellen gereviseerd waarmee eventuele risico's voor consumenten worden berekend van restanten van gewasbeschermingsmiddelen die maximaal op voeding worden toegestaan; de reële hoeveelheden zijn doorgaans lager. Aanleiding voor de revisie waren recentere gegevens over het voedingspatroon van jonge kinderen. Om een risico te schatten wordt de geconsumeerde hoeveelheid van een product gecombineerd met de concentratie van het gewasbeschermingsmiddel in of op het product. Hierna wordt deze inname vergeleken met een toxicologische grenswaarde. Deze risicoschatting is een standaard onderdeel van de procedure waarmee gewasbeschermingsmiddelen worden toegelaten, het gewasbeschermingsmiddelautorisatieproces.

Met de gereviseerde rekenmodellen bleken de schattingen van de hoeveelheid gewasbeschermingsmiddelen die Nederlanders via voeding in theorie binnen zouden kunnen krijgen over het algemeen hoger te zijn dan voorheen. Hierdoor kan het mogelijk zijn dat Europese normen voor maximaal toelaatbare hoeveelheden gewasbeschermingmiddelen (MRLs) naar beneden moeten worden bijgesteld. Dit moet nader worden uitgezocht, door de Nederlandse gegevens op te nemen in het Europese EFSA-rekenmodel waarmee Europese risicoschattingen worden gemaakt (PRIMO). Hiervoor zijn inmiddels de eerste stappen gezet.

De gereviseerde rekenmodellen bevatten nu consumptiegegevens van drie doelgroepen: baby's/peuters, jonge kinderen en de bevolking in zijn geheel. Voorheen waren er geen gegevens voor de eerste doelgroep. Daarnaast bevatten de rekenmodellen voor het eerst consumptiegegevens van zowel rauwe producten als van de producten die daarvan worden gemaakt (zoals appelsap van appels en brood van graan). Tot nu toe werd alleen gerekend met de gegevens van het rauwe product.

Trefwoorden:
bestrijdingsmiddel, residu, risicobeoordeling, consumptiedatabase, NEDI, NESTI, IEDI, TMDI, CPAP

Contents

Summary

As part of the pesticide authorisation process, it is required to check whether pesticide residues in food at the level of the Maximum Residue Limit (MRL) could present a health risk to the consumer. For pesticide authorisation purposes, the risk assessment of chronic and acute exposure of the Dutch population to pesticide residues in food is performed with Excel based dietary risk assessment models based on internationally accepted equations (NEDI, NESTI, IEDI, IESTI, TMDI). These dietary risk assessment models needed revision for various reasons, among others new food consumption surveys became available. The revised Dutch dietary risk assessment models contain consumption data for three population groups: babies/toddlers, young children and the general population. The present report describes the process and the choices made to convert foods as recorded during the Dutch food consumption surveys (e.g. pizza) into their raw agricultural commodity ingredients (e.g. wheat, tomato) as used in the revised calculation models.

Five Dutch food consumption databases were available for babies/toddlers, two for young children, and four for adults/general population. The choice of the final food consumption database used in the revised Dutch dietary risk assessment models was determined by the number of consumption days in a particular food consumption database, the ability of the food consumption database to represent the whole Dutch population group, and the age of the data.

Further, whereas the old models only allowed risk assessment for the raw agricultural commodity, the revised Dutch dietary risk assessment models contain consumption data for both raw and processed commodities to accommodate refined dietary risk assessment.

The CPAP model is used to convert foods as listed in the food consumption database into raw or processed agricultural commodities. The consumption value per commodity can be given as g/person/day or as g/kg bw/day. For acute dietary risk assessment, the high end of the commodity consumption distribution as g/person/day is in many cases related to consumers with a higher bodyweight (adults group), while the high end of the commodity consumption distribution as g/kg bw/day is in many cases related to consumers with a lower bodyweight (babies/toddlers group). The g/kg bw/day value was considered to be the most protective and this value was used in the revised Dutch dietary risk assessment models.

Acute dietary exposure assessment was shown to be very sensitive for the unit weight chosen for the raw agricultural commodity. In general, a higher unit weight will lead to higher exposure, but only up to a unit weight of 250 g. A unit weight of 250 g will generally give worst case exposure. To describe a realistic worst case situation, the median unit weight of a commodity was chosen for the revised Dutch acute dietary risk assessment model.

The impact of the changes made in the revised Dutch dietary risk assessment models was investigated for a selected number of pesticides by comparing first tier assessments performed with the old and the revised Dutch dietary risk assessment models. The dietary exposure estimated from the revised Dutch dietary risk assessment models is generally higher than the dietary exposure estimated from the old Dutch dietary risk assessment models. This is caused by one or more of the following reasons: by a change of Dutch food consumption databases, by modifications in the CPAP conversion model, by a change from total commodity consumption to individual commodity consumption, by the use of g/kg bw/day commodity consumption values as starting point instead of g/person/day commodity consumption values, by a change in bodyweight, by introduction of estimated large portions, and by a

change in the unit weights. As a consequence, exposure estimates for some existing EU MRLs may now exceed the toxicological reference values (ADI, ARfD), indicating a potential health risk. It is recommended to start a follow-up investigation for which pesticides, crops and population groups this is the case. In order to investigate this, steps have been taken to include the revised data from the Dutch dietary risk assessment models in the European Food Safety Authority (EFSA) dietary risk assessment model PRIMO.

1 Introduction

From about the mid-1950s, countries began to legislate for pesticide residues in food and feed by the use of maximum residue levels (MRLs). At that time, the residue levels in the raw agricultural commodities (RACs) were enforced and monitored without dietary risk assessment. From 1961 onwards, chronic dietary risk assessment was included based on expert judgement.

From 1989 onwards the methodology for estimating the chronic dietary exposure to pesticide residues was developed by several international meetings (WHO, 1989; WHO, 1995 a/b; WHO, 1997; WHO, 2008a/b). Chronic dietary risk assessment for pesticide authorisation purposes within the EU conforms to international methodology and follows a three step tiered deterministic approach. The first tier is based on a worst case exposure estimation based on maximum residue levels and has been termed Theoretical Maximum Daily Intake (TMDI). If this first tier estimate for dietary exposure is below the toxicological reference value for chronic exposure (ADI, acceptable daily intake), further refinement steps are not necessary, and the pesticide is unlikely to be of safety concern. However, when the first tier results in an estimate of the dietary exposure close to or above the toxicological reference value, a more accurate (refined) risk assessment will usually be necessary. The refined chronic dietary exposure estimation has been termed International Estimated Daily Intake (IEDI) or National Estimated Daily Intake (NEDI). The refined chronic dietary exposure estimate consists of a second tier where the maximum residue level is replaced by a more realistic median residue level and if necessary a third tier where processing is taken into account. If this third tier estimate for dietary exposure still results in exceeding of the toxicological reference value, the MRLs as proposed for pesticide authorisation cannot be set and other measures are required to reduce the chronic dietary risk (e.g. adaptation of the intended use by changing the treated commodities or changing the dose rate).

In the early 1990s, it became apparent that in some cases, pesticide residues could pose risks resulting from a single exposure or at most a few days of exposure (= acute exposure). In recognition of this, the methodology for estimating this acute dietary exposure to pesticide residues was developed during several subsequent international meetings (WHO, 1997; JMPR, 1999a; PSD, 1999). The 1997 Geneva consultation (WHO, 1997) recommended the development of a food consumption database for two population groups: the entire population (general population) and children (ages 6 years and under). Subsequently, the methodology was refined by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) (JMPR 1999b; JMPR 2000; JMPR 2002; JMPR 2003; JMPR 2005; JMPR 2006b; JMPR 2007b) and updated in a FAO/WHO workshop (WHO, 2008a/b). The EU adopted this approach in 1999. For pesticide authorisation purposes acute exposure to pesticides is estimated using a deterministic approach (point estimate). The point estimate is a worst case scenario and is also referred to as the international or national estimate of short-term intake (IESTI or NESTI). In this approach it is assumed that a person consumes a large portion (LP) within a meal or 24 hours, which contains a very high residue level. In this methodology, the acute exposure estimates are performed for each commodity individually (raw or processed), since the probability of two eating events within 24 hours relating to the consumption of a large portion of two different foods both containing a very high residue of the same pesticide is considered to be very low. To assess whether the application of a pesticide has no adverse consequences for public health, the toxicological reference value for acute exposure (ARfD, acute reference dose) is compared to the estimated acute dietary exposure. Although refinement is possible by way of a probabilistic approach, this refinement is not yet performed for pesticide authorisation purposes.

The general equation for both acute and chronic dietary exposure is:

dietary exposure = food chemical concentration x consumption / bodyweight

In the Dutch pesticide authorisation process, commodity consumption data derived from the Dutch food consumption surveys are used to estimate the chronic and acute dietary risk when (a selection of) the Dutch population would consume foods containing pesticide residues at the MRL. The data from the Dutch food consumption surveys as such cannot be used directly since the data listed are processed products like pizza, while MRLs are established for RACs like wheat, tomatoes, olives, mushrooms, oilseeds and milk (in case of a pizza). To use pesticide residues analysed in RACs for estimation of dietary exposure, the RIKILT Institute of Food Safety developed the 'Conversion to Primary Agricultural Product' (CPAP) model in 1995. This model converts foods into their respective RAC ingredients.

Subsequently a commodity consumption distribution is generated for each RAC ingredient by combining the food consumption data and the CPAP model. For chronic dietary risk assessment, average daily commodity consumption values are calculated which are derived from the consumption distribution of individual RAC ingredients for the total population group (consumers and non-consumers). For acute dietary risk assessment models, the 97.5th percentile commodity consumption values are calculated which are derived from the consumption distribution for individual RAC ingredients for consumers-only (i.e. a part of the total population group).

The average daily commodity consumption values are used in the Dutch chronic dietary risk assessment, while the 97.5th percentile commodity consumption values are used in the Dutch acute dietary risk assessment. The Dutch chronic and acute dietary risk assessment was automated in 2000 by using Excel based calculation models developed at the RIVM. These calculation models (i.e. Dutch chronic and acute dietary risk assessment models) contain the equations for dietary exposure as well as consumption values for each individual RAC ingredient for both general population (1-97 years) and children (1-6 yrs). After entering the residue concentrations for relevant RACs, the calculation models compare the dietary exposure to the appropriate toxicological reference value (ADI for chronic risk, ARfD for acute risk) and provide an overview table of commodities for each of the population groups.

In 2006 the Dutch chronic and acute dietary risk assessment models have been updated to incorporate also consumption data for babies (8-12 months). However, these data were never implemented in the Dutch pesticide authorisation process, i.e have not been used in the MRL setting process.

In 2006 a need was identified to update the Dutch chronic and acute dietary risk assessment models for several reasons:

- more recent Dutch food consumption surveys were available for babies/toddlers and for young children;
- the European Union (EU) published a new list of RACs for MRL establishment;
- the European Food Safety Authority (EFSA) formulated the need to convert foods to raw edible portion (EP) in stead of RAC and to use g/kg bw/day commodity consumption values as starting point;
- no consumption values for processed RAC commodities were available. Possible dilution of the pesticide residue levels as a result of processing is especially important for refinement of chronic dietary risk assessment. Possible concentration of the pesticide residue levels as a result of processing is especially important for acute dietary risk assessment.

In 2007, the Dutch Ministry of Health, Welfare and Sport commissioned the RIVM to revise the Excel based calculation models for acute and chronic dietary risk assessment. The project was conducted in cooperation with the RIKILT Institute of Food Safety (the RIKILT group involved in this project moved to RIVM per 1 January 2010). The aimed end products of this project were the revised Dutch chronic and acute risk assessment models and a full documentation of these models. The latter was considered to be necessary to facilitate discussions with other interested parties, since it is known that the general guidance provided by WHO can be interpreted in different ways by different stakeholders.

The full documentation consists of the present report in combination with Excel appendices (available upon request). The present report describes the processes involved to come from the raw data as present in the consumption surveys to the final Excel based Dutch chronic and acute dietary risk assessment models. This process is shown schematically in Figure 1.

- The second chapter describes the available food consumption surveys and the data processing used to translate the food consumption survey into a food consumption database. This chapter describes the choices and assumptions made for the translation.
- The third chapter describes the CPAP model for conversion of foods into RAC ingredients. This chapter describes also the modifications required to adapt the CPAP model to accommodate the required changes. This chapter describes the choices and assumptions made for the conversion.
- The fourth chapter describes the calculation of the commodity consumption values. This chapter describes the choices and assumptions made for the calculation.
- The fifth and sixth chapters describe the Dutch chronic and acute dietary risk assessment models. The equations, commodity consumption values and other parameters required for the exposure estimations are described as well as the choices and assumptions made here.
- The seventh chapter compares the outcomes of the old and revised Dutch chronic and acute dietary risk assessment models.
- In the final chapters a discussion is presented on various items concerning dietary risk assessment.

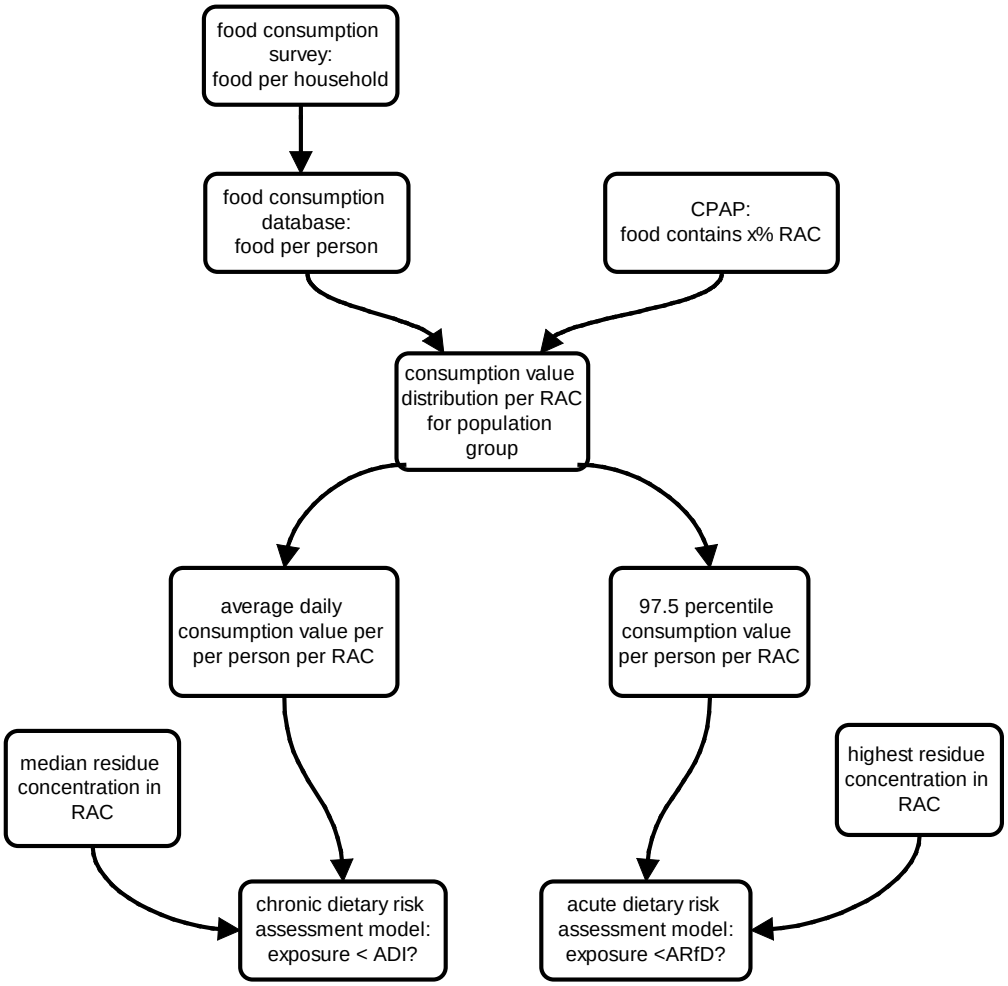

Figure 1 Processes involved in chronic and acute dietary risk assessment

2 Dutch food consumption databases

Commodity consumption data derived from the Dutch food consumption surveys are used to estimate the chronic and acute dietary risk when (a selection of) the Dutch population would consume foods containing pesticide residues at the MRL. This chapter describes the available food consumption surveys and the data processing used to translate the food consumption survey into a food consumption database. This chapter describes the choices and assumptions made for the translation.

2.1 Overview of Dutch food consumption surveys

In 1986 the former Dutch Nutrition Council (Voedingsraad) recommended to perform a food consumption survey and to repeat it on a regular basis to monitor trends in food consumption habits. The first nationwide food consumption survey of the Netherlands was held in 1987-1988 (VCP-1), the second in 1992 (VCP-2) and the third in 1997-1998 (VCP-3).

Subsequent food consumption surveys, initiated by government and industry, focussed on young children (ages below six years): RIKILT-babies (2000-2001), VIO-toddlers (2002) and VCP-kids (2005-2006), particularly because data for children below one year were not available at that time. Exposures to pesticides and contaminants in children are higher than in adults due to higher food consumption levels per kilogram bodyweight. The European Commission estimated a worst case scenario for children aged twelve months (European Commission, 1998).

Because of changes in food policy needs, socio-demographic currents, trends in consumption habits and developments in methodology, the Dutch Ministry of Health, Welfare and Sport (VWS) decided in 2003 that a new approach in national dietary monitoring was needed. The collection method was changed from household food recording during 2 consecutive days to individual sampling by 24-hour dietary recalls on 2 non-consecutive days in combination with a self-administered questionnaire. The decision was in line with the European recommendations of the EFCOSUM-group (Brussaard et al., 2002a/b; De Henauw et al., 2002). A pilot study was held in 2003 among young adults (19-30 years) to test the new way of collecting data. In addition, it was decided to have (semi-)continuous food consumption surveys for age groups 7-69 years and separate surveys for special groups (elderly people, pregnant and lactating women, ethnic groups, young children) and special products (important products consumed by few people). Differences in design and methods do not allow direct comparison of results before and after 2003 (Ocké et al., 2005a).

The databases of the VCP food consumption surveys are owned by VWS and are managed from 2007 onwards by the Dutch National Institute of Public Health and the Environment (RIVM). Information can be found at www.rivm.nl/vcp or www.voedselconsumptiepeiling.nl. The VIO-toddlers 2002 consumption survey is owned by TNO and Numicon and is also managed by the RIVM. These data may only be used to answer questions from public bodies. The RIKILT-babies 2000-2001 consumption survey is owned by the RIKILT Institute of Food Safety in Wageningen and will be transferred to the RIVM from 2010 onwards.

2.1.1 VCP-1, general population, 1987-1988

The first Dutch National Food Consumption Survey (VCP-1) was held in 1987-1988 by assignment of the then Ministry of Welfare, Public Health and Cultural Affairs (WVC) and the then Ministry of Agriculture, Nature Management and Fisheries (LNV), and was conducted by a marketing research institute (AGB Attwood) experienced in nationwide surveys (VCP, 1988; Hulshof and Van Staveren, 1991).

The household was chosen as the unit of observation. A household was defined as a group of one or more persons living in one house and having a meal prepared at home for at least four days a week. Institutionalised individuals (e.g. students, military, persons in hospitals, persons living in homes for the elderly), persons without a permanent address and persons who did not have a thorough command of the Dutch language were excluded from the survey. Households were chosen for which the main housekeeper was younger than 75 years. In a household diary, the food supplied to the members of the household by the main housekeeper were recorded, as well as leftovers and food given to guests and pets. Precise descriptions of methods of cooking, recipes and ingredients were requested as well as amounts of food consumed and moments when the food was taken and by whom. Where possible, product names, product variety (taste, type), brand name, form bought (fresh, canned, frozen) and form of consumption (fresh, peeled, fried, cooked) were recorded. Common household measures (e.g. spoons, cups) and foods regularly used were weighed. In addition to the household diary, a diary was kept by each individual person to record the amount of food consumed outside the house and at what moments. The diaries of children below the age of 13 were completed by one of their parents.

Besides consumption data, also personal data (gender, age, bodyweight, length, education level), household data (number of persons in the household, address data) and personal habits (use of a special diet, mode of life (e.g. vegetarian), use of nutritional supplements, smoking habits, hours of nights rest, meal patterns) were recorded.

Consumption data were collected for two consecutive days from household members of one year and older. The survey was distributed equally over the week and over the year from April 1987 to March 1988, to account for weekly and seasonal effects. Consumption data were collected for a total of 2204 households, comprising 5898 persons aged 1-85 years. Persons of 1-4 years old were overrepresented and persons of 19-22 years old were underrepresented as compared to the Dutch population.

2.1.2 VCP-2, general population, 1992

The second Dutch National Food Consumption Survey (VCP-2) was held in 1992 by assignment of WVC and LNV and was conducted by a marketing research institute (AGB Freshfoods) (VCP, 1993; Kistemaker et al., 1993; Hulshof et al., 1994; Löwik et al., 1998).

Consumption data were collected on two consecutive days from household members of one year and older as described for VCP-1. The survey was distributed equally over the seven days of the week and over a whole year from January up to and including December 1992, to account for weekly and seasonal effects. Consumption data were collected for a total of 2475 households, comprising 6218 persons aged 1-92 years. Persons of 1-7 years old were overrepresented and persons of 19-22 years old were underrepresented as compared to the Dutch population.

2.1.3 VCP-3, general population, 1997-1998

The third Dutch National Food Consumption Survey (VCP-3) was held in 1997-1998 by assignment of the VWS and LNV and was conducted by a marketing research institute (GfK Nederland) (VCP, 1998; GfK, 1998; Kistemaker et al., 1998).

Consumption data were collected on two consecutive days from household members of one year and older as described for VCP-1. In addition, a food frequency questionnaire on fruit and vegetables (VEG) and on milk, meat and fish (ANI) was sent along with the diaries. The survey was distributed equally over the seven days of the week and over a whole year from April 1997 to March 1998, to account for weekly and seasonal effects. Consumption data were collected for a total 2354 households, comprising 5958 persons. In an additional survey, households were chosen for which the main housekeeper was older than 75 years. This resulted in an additional 210 households comprising 292 persons.

In total, consumption data were collected for 2564 households, comprising 6250 persons aged 1-97 years. Persons of 13-22 years old and females of 7-13 and 22-50 years old were overrepresented, while adult males and older women were underrepresented as compared to the Dutch population.

2.1.4 RIKILT-babies, 2000-2001

In 2000-2001, the RIKILT Institute of Food Safety conducted a duplicate diet study among Dutch babies in the age group of 8-12 months to measure the actual intake of pesticides in an age group not covered by the Dutch National Food Consumption Surveys (Boon et al., 2003, 2004).

The sampling strategy was designed to include babies that were fed home-made meals of fruits and vegetables as opposed to industrially prepared baby food. Babies still breast-feeding were excluded from the study. The babies were recruited from three Dutch child health centres in the middle of the Netherlands. Participants were asked to record food consumption during one day and to weigh and record the quantities consumed. In addition, participants were requested to prepare a duplicate portion of all meals consumed by the baby during the study day and to collect this in one vessel for laboratory analysis. Bodyweight was recorded as the weight measured during the last visit at the child health centre prior to the collection day and was corrected for the days between the visit and the measurement.

Consumption data were collected for 373 babies aged 8-12 months (186 girls and 187 boys) with an average bodyweight of 9.3 kg (standard deviation 0.95 kg). Of these, 250 babies consumed only home-made meals (prepared from fresh fruits and vegetables) on the study day, while 123 babies consumed a combination of home-made meals and industrially prepared baby food. Consumption data were collected the whole year round to account for the consumption of seasonal fruits and vegetables. Regional differences may not be accounted for. The study represents Dutch babies given fresh fruits and vegetables and the consumption data will therefore very likely overestimate raw fruit and vegetable consumption when compared to a representative sample of Dutch babies. Although not representative for the whole Dutch baby population, the RIKILT-babies database could have special value for acute dietary risk assessment to estimate LPs for raw fruit and cooked vegetables.

2.1.5 VIO-toddlers, 2002

In 2002 a food survey was conducted among Dutch toddlers aged 8-10, 11-14, and 17-20 months. The survey was initiated by Nutricia Nederland BV and was conducted by TNO (Voedingscentrum, 2002; De Boer et al., 2006).

Toddlers were recruited from 33 Dutch child health centres distributed over the Netherlands. Selected toddlers were healthy at face value, had a birth weight of at least 2500 g and had no congenital defects, no food allergies, no diets prescribed by a physician or a dietician, no vegetarian or veganistic lifestyle, and no (partial) breast feed. Children from persons who did not have a thorough command of the Dutch language were excluded from the survey.

Consumption data were collected on two non-consecutive days. Parents were asked to record food consumption of the child in question in a diary and to record the quantities consumed using standardized spoons and measuring jugs. Precise descriptions of methods of food preparation were requested as well as moments when the food was taken.

Besides consumption data, also personal data (gender, age, bodyweight, length, sleeping times of the child) and family data (address data, number of persons in the family, age of the parents, education of the parents, job situation of the parents, country of birth of the parents, number of years living in the Netherlands for the parents, special diets or lifestyles taken by the parents) were collected.

Consumption data were collected for a total of 941 Dutch toddlers: 333 toddlers aged 9 (8-10) months, 306 toddlers aged 12 (11-14) months and 302 toddlers aged 18 (17-20) months. Food was recorded on one week day and one weekend day by 85 % of the parents and 13 % of the parents recorded food consumption on two week days. Correction for the overrepresentation of weekend days was not required because no difference in nutrient intake was observed. The survey was distributed over a period of five months from January up to and including June 2002, which may not account for all seasonal variations.

2.1.6 VCP-young adults, 2003

In 2003 it was decided to change the data collection method for the Dutch National Food Consumption Surveys from household food recording during 2 consecutive days to individual sampling by 24-hour dietary recalls on 2 non-consecutive days. A pilot study was held in 2003 among young adults (19-30 years) to test the new way of collecting data. The 2003 Dutch National Food Consumption Survey (VCP-young adults) was conducted by TNO and the RIVM in collaboration with GfK Panelservices Benelux for data collection (Ocké et al., 2004 and 2005a/b, Hulshof et al., 2004).

As a pre-selection, postal invitations and questionnaires were sent with questions on gender, age, socio-demographic characteristics (address data, education, degree of urbanisation, household composition), smoking, alcohol consumption, physical activity, a concise food frequency questionnaire with questions on ever or never consumption of 28 selective foods and a standardized food frequency question on vegetable and fruit consumption, pregnancy and lactation. Persons who did not have a thorough command of the Dutch language, pregnant or lactating women and persons that were institutionalized were excluded from the survey.

For each selected participant the dietary survey consisted of 2 independent 24-hour dietary recalls, with 7-14 days in between on different days of the week. The 24-hour recalls were conducted as a computer assisted interview using the EPIC-SOFT computer program. The 24-hour recalls consisted of questions on time/occasion and detailed description of all food and drinks consumed during the past 24 hours. Details included the form in which the foods were consumed (raw or as prepared/processed product) and whether food supplements were used. No information was included on where the food was purchased and where the food was consumed.

Consumption data were collected for 750 Dutch young adults aged 19-30 years. The survey was distributed over a 3-month period from October 2003 up to and including December 2003 and therefore seasonal variations were not accounted for. Although the survey was aimed at equal representation of all days of the week, the Friday was underrepresented for women.

2.1.7 VCP-kids, 2005-2006

In 2005-2006 a food survey was conducted among Dutch infants aged 2-6 years. The survey was conducted by assignment of VWS and was co-ordinated by the RIVM; data were collected by a marketing research institute (GfK Panel Services) (Ocké et al., 2008).

Children whose carers did not have a thorough command of the Dutch language and institutionalized children were excluded from the survey. Children under the age of two were excluded from the survey, because recent food consumption data were available through the VIO-toddlers 2002 database. Per family, only one child was included.

Since a 24-hour recall method is not feasible for young children, a dietary record method was used. Consumption data were reported on two non-consecutive days, separated by 8-13 days, by child carers in pre-structured diaries. The diaries had information on amounts of food and time and place of consumption. In addition to the diaries, home visits were made to collect a self-administered questionnaire and to measure height and weight of the child. The questionnaire addressed background of the child and family, the child's daily rhythm and activities, general characteristics of the child's diet, consumption frequency of certain specific foods, use of dietary supplements, purchase of organic foods, and the volume of cups and glasses used habitually by the child. In addition, information was collected on the household (address, education of the head of the household, urbanisation level).

Consumption data were collected for a total of 1279 infants aged 2-6 years. The survey was distributed equally over the seven days of the week and over a whole year from October 2005 to November 2006, to account for weekly or seasonal effects. The sampling was considered representative with respect to educational level of the head of the household and region of the Netherlands. Children from densely populated areas were slightly underrepresented, as was dietary information for spring and summer.

2.2 Dutch food consumption database construction

The food consumption pattern from the VCP-1, VCP-2, VCP-3, RIKILT-babies and VIO-toddlers Food Consumption Surveys was recorded in diaries and then converted into an electronic database. The data from VCP-young adults and VCP-kids were entered directly into a computer program developed for 24-hour recalls. No changes have been made in these conversions or in these databases for the revised Dutch chronic and acute dietary risk assessment models, but recommendations for improvement are given for future food consumption databases (see sections 3.2 and 4.2.2 and chapter 9).

2.2.1 General methodology

The information in the diaries from VCP-1, -2, and -3 was coded in a standard way and entered in an electronic database by trained dieticians (Hautvast, 1975; GfK, 1998). Individual persons were given a person number consisting of a code for the food survey, a code for the household and an unique number. Foods recorded in the diaries were given a code in accordance with the codes used in the Dutch Food Composition Database (NEVO, NEderlands VOedingsstoffenbestand). NEVO codes have

six numbers like 0001/04 and 1812/28. The Dutch Food Composition Database was updated for each Food Consumption Survey by addition of new foods, addition of nutrients considered relevant or modification of composition of foods (NEVO 1987, 1990, 1993, 1996, 2001, 2006). The 2006 Dutch Food Composition Database contains 1650 foods. Foods were categorized in 24 different food groups based on their nutrient composition.

Amounts of food consumed were recalculated to gram or millilitre per person. For this recalculation conversions were required for net weights of packed food, percentage waste of fresh fruits and vegetables, weights of prepared meat and poultry. Individual portion sizes needed to be assigned for meals consumed collectively within the household using correction factors for leftovers, food given to pets, food given to guests, and food prepared for several days.

For food coding and conversion of portion size to gram or millilitre per person, use has been made of the MGC reference table ('Maten, Gewichten, Codenummers') listing foods with their NEVO code, net weights of packaged foods, percentage waste of fruit and vegetables, and conversion from household measures (spoons, cups) to weights. The MGC reference table was updated up to 2003 (MGC, 1987, 1992, 1997, 2003). Conversion for VCP-1, VCP-2 and VCP-3 is described in more detail in 2.2.2.

The databases for the RIKILT-babies 2000-2001 and VIO-toddlers 2002 consumption surveys were constructed in a similar way. For the RIKILT-babies 2000-2001 consumption survey, temporary food codes have been assigned to special baby foods, which at a later stage were brought in line with the food coding used in the VIO-toddlers 2002 consumption survey.

The data from VCP-young adults, 2003 and VCP-kids, 2005-2006 were entered into an EPIC-SOFT program, specially developed for 24-hour recalls. This system differs from the previously used database structures. Data-entry is done interactively during the interview and checks, food coding and conversion to g/person or ml/person are performed automatically. Individual foods were coded using the NEVO food system, but were classified into 17 different main food groups and 84 subgroups according to the EPIC-SOFT program (Ocké et al., 2008; De Henauw et al., 2002). In future, the MGC reference table will be updated to reflect the data used in the EPIC-SOFT program.

The Dutch Food Composition Database (NEVO) is owned by the 'Stichting NEVO' and is managed by the Netherlands Nutrition Centre in The Hague. The database is available electronically through a licence via www.voedingscentrum.nl. The MGC reference table is owned by Wageningen University and TNO in Zeist and is managed by Wageningen University. The MGC reference table is publicly available.

2.2.2 General conversion rules

The food consumption pattern from the VCP-1, -2, and -3 food consumption surveys was recorded in diaries and then converted into an electronic database using the NEVO coding system and the MGC reference tables. Conversion of the information in the diaries to an electronic database, results in loss of information.

General rules for food coding

1. All foods including water were incorporated in the food consumption database (i.e. got a NEVO code). Only self added herbs (fresh or dry), spices, salt, vinegar, chilli paste ('sambal') and mustard were not included because the contribution of these foods was very difficult to measure within a household.

2. NEVO codes do not make a distinction between brand names and varieties of the same food (e.g. taste). Such foods get one NEVO code.
3. NEVO codes differ when the form of the food is different, e.g. NEVO codes for raw, cooked and canned vegetables are different. When vegetables were heated at any stage during preparation they were coded and recalculated as cooked vegetables.
   Example 1 when scarole (endive) was bought raw and consumed raw, scarole gets the NEVO code for raw scarole (0007/28).
   Example 2: when scarole (endive) was bought raw and consumed cooked, scarole gets the NEVO code for cooked scarole (0008/32).
4. NEVO codes do not make a distinction between different types of mixtures. Such aggregated foods get one NEVO code but with a list of all possible fruit/vegetables found in the different mixtures.
   Example 1: raw mixed vegetables (consumed in a restaurant or sold as such) were not listed separately for each mixture available, but with one NEVO code (e.g. NEVO code 0077/49)
   Example 2: fruit juices consisting of more than one fruit, were listed under one NEVO code (e.g. NEVO code 1463/99).
   Example 3: fruit jams were listed as jam without indication of the fruit type used to make the jam (e.g. NEVO code 0445/40).
5. When composite meals (e.g. fried rice, pizza, hotchpotch) were prepared by the housekeeper, NEVO codes and amounts of individual ingredients were entered in the database. When composite meals were bought as a ready-to-eat meal a special NEVO code was entered. An exception was made for self-prepared soup, which was entered in the database as such.
6. Food ingredients taken during a hot meal were generally coded and recalculated as cooked food: soup, potatoes, rice, pasta, vegetables, dry pulses, eggs (except for raw consumed eggs). Exceptions were made for meat, poultry, fish and game. Meat and poultry were coded as and recalculated to raw food when used with gravy and coded as prepared food when consumed without gravy. Fish was coded as and recalculated to raw food, except for fried fish where the fat used in the preparation was unknown. Game was coded as and recalculated to raw food.
7. Coffee and tea were entered in the food consumption database as liquids (e.g. prepared coffee).
8. When foods recorded in the diaries were not in the NEVO coding system, an alternative was chosen. This alternative might be entering the product as individual ingredients or use a code for a related product.
   Example 1: because for cooked wholemeal pasta no NEVO code existed, cooked wholemeal pasta was recorded as raw wholemeal pasta (for which a NEVO code was available), although pasta was never consumed raw.
   Example 2: pine nuts and pumpkin seeds were coded as sunflower seeds (NEVO code 0872/45), because no NEVO codes are available for these foods.

General rules for conversion to amounts consumed

1. Vegetables and fruits indicated as consumed raw in the diary were only corrected for the percentage waste.
   Example: when 600 g scarole (endive) was bought raw within a household, this was corrected for 15 % waste to 600 x (1-0.15) = 510 g raw edible portion (EP) of scarole per household. This value was divided by the number of persons within that household and the corresponding value was entered in the food consumption database as amount consumed per person.
2. For cooked vegetables, the waste fraction and boil down fraction were taken into account. When vegetables were heated at any stage during preparation, they were coded and recalculated as cooked vegetables. Vegetables recorded as bought fresh in the diaries, but

consumed cooked, were first corrected for the percentage waste and then for the percentage boil down.
Example: When 600 g scarole (endive) was bought raw but consumed cooked per household, this was first corrected for 15 % waste to 600 x (1-0.15) = 510 g EP and then for 33 % boil down to 510 x (1-0.33) = 342 g cooked scarole per household. This value was divided by the number of persons within that household and the corresponding value was entered in the food consumption database as amount consumed per person.

3. For canned vegetables and pulses (in cans or jars), the net weight was entered in the database, i.e. without the liquid, while for canned fruits (in cans or jars) the weight of the fruits plus the weight of the liquid was entered.
4. For aggregated foods like cooked mixed vegetables, one general correction factor for boil down was used (i.e. individual waste and boil down fractions of individual vegetables in the mixture were not taken into account).
Example : for summer vegetables (NEVO code 0077/89, 0l341/22) one general correction factor of 15 % for waste and 18 % for boil down was used.
Example 2: for winter vegetables (NEVO code 0034/25, 0965/56) one general correction factor of 20 % for waste and 18 % for boil down was used.

Recognition codes
As indicated at point 8 of the NEVO coding rules, some foods were coded as a related product. This might have as result that the consumption information of the original food product is lost during translation of the survey to the electronic food consumption database. In the VCP-1 and VCP-2 databases this is indeed the case, the original food cannot be found anymore. In later Dutch food consumption databases this problem was circumvented by the introduction of recognition codes (‘item code’). Recognition codes have numbers between 6000-9000. The combination of NEVO code and recognition code gives the consumption value for that particular food. When using only the NEVO code, the total consumption values are obtained from the underlying foods. Two examples:

- Pine nuts and pumpkin seeds were coded as sunflower seeds (NEVO code 0872/45) without a recognition code. Therefore the consumption of pine nuts and pumpkin seeds cannot be extracted from the Dutch food consumption databases, and the consumption of sunflower seeds is probably an overestimation.
- Cherry tomato and beef tomato were coded as tomato (NEVO code 0060/18) but with a recognition code: 7246 for cherry tomato and 6736 for beef tomato. When using only the NEVO code, the total tomato is obtained, while it is possible to have more detailed results for cherry tomato and beef tomato.

The choice of the related product in NEVO coding very often does not coincide with the EC 178/2006 commodity list which is used for assessment, monitoring and enforcement of pesticide residues in food. For example watercress was coded as cress (NEVO code 0126/32) while watercress and cress are different commodities in the EC 178/2006 commodity list. Another example is lollo biondo (recognition code 7267) which was coded as scarole (endive) in the Dutch food consumption database (NEVO code 0007/28), while lollo biondo is a lettuce in the EC 178/2006 list and the NEVO code for lettuce (0046/36) would be more appropriate. An overview of the commodities for which the NEVO coding is different from EC 178/2006 commodity grouping is indicated in Appendix I.

For some of the commodities listed in the EC 178/2006 commodity list, no NEVO code or recognition code exists (Appendix I). These commodities were not consumed in the random sample taken from the Dutch population. For commodities consumed by the random sample from the Dutch population either a NEVO code exists or an alternative NEVO code or recognition code is used.

3 Commodity conversion

3.1 The need for commodity conversion

Monitoring and control of food safety as well as the dietary risk assessment of pesticide intake are based on raw agricultural commodities (RAC). A RAC is the end product of agricultural production methods that has not undergone any form of processing; it is the raw agricultural part (or parts) of the crops/animal as moving in trade. For pesticide residues, maximum residue levels (MRLs) are established for RACs like fruits, vegetables, cereals, oilseeds, meat, milk and eggs. For example, MRLs for oranges are based on the pesticide residue levels in the whole orange i.e. including the peel. But the RAC is in many cases not the commodity that is actually consumed. Therefore, for chronic dietary risk assessment for pesticide authorisation, a tiered approach is taken:

- As a first step the dietary risk is estimated for intake of pesticide residues in/on the RAC, e.g. orange including peel. To this end, pesticide residue concentrations in the RAC are combined with food consumption data which can either be expressed as RAC or as raw edible portion (EP). Up to now food consumption data have been expressed as RAC. As an example, all orange containing commodities (e.g. raw, juice, marmalade) need to be calculated back to their RAC counterpart and are summed to get the food consumption of orange as RAC (i.e. grams of orange with peel per person).
- As a second step, dietary risk is estimated for intake of pesticide residues in the EP, e.g. orange excluding peel. To this end pesticide residue concentrations in the EP are combined with food consumption data expressed as EP. As an example, all orange containing commodities (e.g. raw, juice, marmalade) need to be calculated back to their EP counterpart and are summed to get the food consumption of orange as EP (i.e. grams of orange without peel per person).
- As a third step, dietary risk is estimated for intake of pesticide residues in the primary processed commodities (PP) or the EP, each individually, e.g. orange consumed raw excluding peel, orange juice, marmalade and others. The PP is the product intended for sale to the consumer, intended for direct use as an ingredient in the manufacture of multi-component foods or intended for further processing. A PP is derived from mechanical or chemical processing of the RAC and is not a multi-component product (OECD, 2008a). To this end, pesticide residue concentrations in the raw or primary processed commodities are combined with food consumption data expressed as EP in case the commodity is consumed raw or expressed as PP in case the commodity is consumed in processed form. As an example the consumption of raw orange is expressed as EP, while the consumption of orange juice is expressed as juice (i.e. grams of juice per person).

None of these steps make use of the foods as listed in the food consumption databases (e.g. pizza, fruit yoghurt, apple pie). In order to use the food consumption databases for chronic and acute dietary risk assessment of pesticides, the foods need to be converted into their RAC ingredients, EP and PP.

3.2 Commodity conversion model (CPAP)

In 1995, the RIKILT Institute for Food Safety developed a computer based CPAP model (Conversion Primary Agricultural Product) to convert foods as recorded in the VCP-1 and VCP-2 food consumption databases into their respective RAC ingredients (Van Dooren et al., 1995, 1996). In total, 1677 foods were converted into their RAC ingredients, resulting in 245 RACs. The list of RACs used for this

conversion was based on legislation then in force for pesticides (Bestrijdingsmiddelenwet 1995, EC 90/642), animal products (Vleeskeuringswet), veterinary drugs (Diergeneesmiddelenwet, EC 2377/90/EC), nuclear energy (Kernenergiewet) and food (Warenwet 1995). Clinical preparations (drip feed, elementary food), aroma's, salt and sweeteners were not converted, since the RAC ingredients were not listed in any of the Dutch and European legislations. The CPAP model is owned by the RIKILT Institute of Food Safety in Wageningen. In the course of 2010 the CPAP model will be transferred to RIVM.

3.2.1 General methodology in the CPAP model

The conversion of foods as recorded in the food consumption databases consists of two steps.

- As a first step, foods are converted into their individual ingredients. For example, pizza consists of flour, tomato puree, olives, vegetables, and cheese.
- As a second step, the individual ingredients are converted into their RAC counterpart. For example, flour is converted into wheat grains; tomato puree is converted to tomatoes, olives are converted to olives including stones, vegetables are converted to raw vegetables, cheese is converted to milk.

The conversion factor listed in the CPAP model is therefore the combined factor for % ingredient (step 1) and conversion to the RAC counterpart (step 2). For example, the CPAP model contains the following conversion factors for fruit and vegetables:

- clean fruit/vegetable fraction (% ingredient plus possible concentration factors);
- peel fraction of fruit (for conversion to fruit with peel);
- core/stone fraction of fruit (for conversion to fruit with core/stone);
- waste fraction of vegetables (for conversion to vegetables with waste);
- boil down fractions for cooked vegetables (for conversion of cooked to raw vegetables).

By using the commodity conversion factors, foods can be converted to their RAC ingredients.

In the 1995 CPAP model, a trained dietician divided each food (NEVO code) into its individual RAC ingredients. Information on conversion factors in the 1995 CPAP model was derived from cookery books, ingredient information in the MGC reference table (version 1992), ingredient information in the Dutch Food Composition Database (NEVO, version 1987, 1989, 1990), literature, labels from foods, information from the manufacturer (Van Dooren et al, 1995). For later versions of the CPAP model also internet was an important source. Both the source and the conversion factor are stored within the CPAP model.

The conversion from foods to RAC in the 1995 CPAP model is based on NEVO codes only; the recognition codes (see section 2.2.2), which are available in the VCP-1, VCP-2 and VCP-3 Dutch food consumption database to give additional information on related foods, are not used. For example if the Dutch food consumption database gives information on tomatoes, this can be divided into consumption for regular tomatoes, cherry tomatoes and beef tomatoes by using their respective recognition codes. In the CPAP model this information is not used: only the total tomato consumption is listed. In the later Dutch food consumption databases (VCP-young adults, VCP-kids) the recognition codes are replaced by the codes used in the EPIC software and for future CPAP models it is intended to use the EPIC coding system (Boon and Ocké, 2008).

The clean fruit/vegetable fraction of the CPAP model is a combination of % ingredient (commodity as such, either raw or processed) and possible concentration factors (e.g. drying). For example, grape-currants in bread (NEVO 0233/25) have a clean fruit fraction of 104.7 %. This factor is the combination of a drying factor of 4.1 and 25 % grape-currants in the bread. If the clean fruit/vegetable fraction includes concentration factors, the % ingredient part in itself cannot be obtained. At present

only a remark is available within the CPAP model as to how the clean fruit/vegetable fraction was obtained. For future use, it is recommended to have a separate entry for the % ingredient and a separate entry for additional conversion factors (e.g. fruit drying, drying of potato and cassava flour, preparation of wine, beer and whisky, oil production, sugar preparation) to be able to verify which conversion factors were used. Further, it is recommended to give an overview of the CPAP conversion factors in a publicly available document. The % ingredient per food can remain confidential in this way.

3.2.2 Conversion procedures in the CPAP model

The conversion factors used to transform the commodities listed in the diaries (VCP-1, VCP-2, VCP-3) to commodities as recorded in the Dutch food consumption database are not always the same as the conversion factors used to transform the commodity in the CPAP model to RAC. Examples are given below. This means that the back calculation to RAC by the CPAP model, may result in a different value than originally recorded in the diaries. When the value is lower than originally recorded, the estimated dietary exposure will be too low; when the value is higher than originally recorded, the estimated dietary exposure will be too high. For future updates it is recommended to harmonize the factors used in the NEVO coding system with the factors used in the CPAP model. A project has already been initiated to match the NEVO coding system with the CPAP model and harmonisation of conversion factors was already listed as a possible point of improvement (Boon and Ocké, 2008).

Aggregated foods
For aggregated foods such as raw or cooked mixed vegetables (NEVO code 0077/49, 0341/22, 0034/25, 0965/56) the NEVO coding system gives information on which vegetables are present in these hypothetical mixtures. In the CPAP model an equal proportion is assumed for each vegetable present in the mixture. Each vegetable present in the mixture is subsequently converted to its RAC counterpart using its own waste and boil down fractions. This is different from the way the food is entered in the Dutch food consumption databases (VCP-1, VCP-2, VCP-3), where a default waste and boil down fraction is used for each vegetable present in the mixture. For future updates it is recommended to harmonize the conversion factors used in the NEVO coding system and the CPAP model.

Cooked and frozen vegetables
Cooked and frozen vegetables are converted to their RAC counterpart using the sum of the boil down fraction and the waste fractions. For example, fried potatoes are converted to raw potatoes by using a multiplication factor of 125 %, consisting of 100 % clean vegetable fraction + 25 % peel fraction + 0 % boil down fraction (Van Dooren et al., 1995). This means that 100 g fried potatoes originate from 125 g raw unpeeled potatoes. This way of calculation is different from the way the foods are entered in the Dutch food consumption databases (VCP-1, VCP-2, VCP-3), where a subsequent correction is made: first from RAC to EP using multiplication by (1-waste fraction) and than from EP to cooked product using multiplication by (1-boil down fraction). Another example is scarole (endive). The CPAP model uses a multiplication factor of 175 %, consisting of 99 % clean vegetable fraction + 26 % waste fraction + 49 % boil down fraction. In the CPAP model, 100 g cooked scarole originates from 175 g raw scarole as marketed. The NEVO coding system uses a 33 % boil down fraction and a 15 % waste fraction, which are subsequently applied. In the NEVO coding system 100 g cooked scarole also originates from 175 g raw scarole as marketed, although different factors were applied. For future updates it is recommended to harmonize the conversion factors used in the NEVO coding system and the CPAP model.

Canned fruits, canned vegetables, canned pulses
For canned fruits (in cans or jars), the weight as recorded in the Dutch food consumption database is the weight of the canned fruits plus the liquid. This means that in the CPAP model, the % ingredient for canned fruits is lower than 100 %. For example, canned strawberries are converted to raw strawberries in the CPAP model by using a multiplication factor of 58 % consisting of 55 % clean fruit fraction + 3 % waste fraction, i.e. 100 g canned strawberries consist of 58 g raw strawberries as marketed. The 55 % clean fruit fraction is the % ingredient fraction of the strawberries in the liquid, no conversion for boil down has been incorporated for canned fruits.
For canned vegetables and canned pulses (in cans or jars), the amount consumed as recorded in the Dutch food consumption database is the net weight, i.e. without the weight of the liquid. This means that in the CPAP model, the % ingredient for canned vegetables is 100 %. In the CPAP model canned vegetables and canned pulses are treated as cooked vegetables and cooked pulses.

Rice, pulses and soybeans
Rice, pulses and soybeans are coded in the Dutch food consumption database from 2003 onwards as cooked commodities. The CPAP models converts cooked rice, cooked pulses, cooked soybeans into dry rice, dry pulses and dry soybeans, because this is the definition of the RAC in the legislation. The CPAP model uses a multiplication factor of 40 % based on the general equation: cooked weight = 2.5 x dry weight as listed in MGC reference table 1992 (MGC, 1992). In the older Dutch food consumption databases (VCP-1, VCP-2, VCP-3) also consumption data for dry rice, dry pulses and dry soybeans may exist. These entries are not converted in the CPAP model.

Coffee, tea, cocoa milk, beer, wine
Coffee, tea, cocoa milk, beer and wine are entered in the Dutch food consumption database as liquids (e.g. prepared coffee and tea). In the CPAP model prepared coffee and tea (as liquid), cocoa milk, beer and wine are converted into their RAC counterparts, because this is the definition of the RAC in the legislation.

- Prepared coffee corresponds to 4.1 % or 4.6 % w/w coffee beans in the CPAP model, similar to the EFSA conversion factor of 25 to convert coffee to coffee beans (6 g coffee powder in 150 ml water) (EFSA, 2007a).
- Prepared tea corresponds to 0.83 % w/w tea leaves in the CPAP model, similar to the EFSA conversion factor of 100 to convert tea infusion to dry tea leaves (2.5 g tea leaves in 250 ml water) (EFSA, 2007a).
- Cocoa milk corresponds to 3.5 % w/w cocoa beans, while cocoa milk from instant powder corresponds to 1.3 %, 2.8 % or 5.0 % w/w cocoa beans.
- Beer corresponds to 13.5 % w/w barley (alcohol free), 19 % w/w barley (0.1-4 % alcohol) or 26.5 % w/w barley (> 7 % alcohol).
- Wine corresponds to 140 % w/w wine grapes in the CPAP model, similar to the EFSA conversion factor of 1.4 to convert wine into wine-grapes (EFSA, 2007a).

Milk products
Milk products like cheese are converted into raw milk, based on the level of one of its constituents: milk-fat part, casein-protein part, whey-protein part, lactose part or water part. The basis for the calculation is documented within the CPAP model (Van Dooren et al., 1995).

3.2.3 Revision of the 1995 CPAP model

When new versions of the Dutch Food Composition Database became available (NEVO 1996, 2001, 2006) corresponding to Dutch food consumption databases VCP-3, VCP-young adults 2003 and VCP-kids 2005-2006, the foods with corresponding NEVO codes were included in the CPAP model. In

addition, new foods recorded in the RIKILT-babies 2000-2001 database and VIO-toddlers 2002 database were also included in the CPAP model. Since the food consumption surveys of RIKILT-babies and VIO-toddlers were not conducted by the regular Food Consumption Survey team, temporary NEVO codes have been given to these foods.

The changes made within the CPAP model have not been documented publicly and no version indication is given for the CPAP model (e.g. CPAP version 1.0). Modifications as introduced in the MGC reference tables have not been incorporated, the MGC 1992 version is still used. For future use, it is recommended that the CPAP model is updated to reflect the data from the latest MGC reference tables and the data in the EPIC-SOFT program and to use version numbers. In addition, the foods corresponding to the temporary NEVO codes should be incorporated in the MGC reference table and NEVO database as well.

3.3 Additional adaptations to the CPAP model

To accommodate the three step tiered approach required for risk assessment (as indicated in section 3.1), foods also need to be converted to their EP counterpart and their PP counterpart in addition to their RAC counterpart as is done in the CPAP model. For this purpose and because of modifications in the authorisation procedures, additional adaptations to the CPAP model were required. These adaptations were not included in the CPAP model itself, but were added using so-called scripts (programming in Pro*Fortran or SQL+).

3.3.1 Modification of the RAC list

The CPAP model uses a list of RACs corresponding to the 1995 Pesticide Regulation: EC 90/642 (European Commission, 1990). Within the EU a new list has been in use since September 2008: EC 178/2006 (European Commission, 2006). For the revised Dutch chronic and acute dietary risk assessment models, the old list of RACs in the CPAP model was replaced by the new list of RACs (by use of scripts).

The differences between the old (EC 90/642) and new list (EC 178/2006) involve changes in the sequence of the commodity groups, introduction of new commodities (additional miscellaneous fruits and herbs) and new commodity groups (herbal infusions), deletion of commodity groups (potatoes are now part of the group root and tuber vegetables) and aggregation of commodities (meat of chicken, duck, turkey and other poultry have been aggregated to poultry, pomelo is included in grapefruit, early and ware potatoes have been aggregated to potatoes, turnip tops were included in spinach). Fish is not yet included in the new list.

Only the RACs from the EC 178/2006 list were included in the revised Dutch chronic and acute dietary risk assessment models. The following ingredients were therefore not included: gelatine, yeast, water, fish varieties, alcoholic drinks (no wine/beer/whisky), human (breast) milk, wild animals (wild rabbit, hare, partridge, pheasant), lemonade water, mineral water, tap water and vitamin preparations.

The Dutch Food and Consumer Product Safety Authority (VWA) has enforcement/monitoring results for pesticide residue levels in commodities not listed in EC 178/2006 (such as tropical fruits, tropical vegetables, herbs and spices). An exceeding of the MRL is found frequently for some of these commodities (Hittenhausen-Gelderblom, 2004). Because no consumption values are available for these commodities, it is not possible to estimate the dietary risk. VWA therefore expressed the wish to have food consumption data for fresh chilli peppers (*Capsicum annuum*), longan (*Euphoria longana*),

sapodilla (*Achras zapota*), bottle gourd (*Lagenaria siceraria*), balsam pear (*Momordica charantia*), fresh yard-long beans (*Vigna unguiculata*), fresh curry leaves (*Murraya koenigii*), fresh coriander leaves (*Coriandrum sativum*) and fresh mint leaves used for herbal infusions. Most of these commodities are not recorded in any of the available Dutch food consumption databases. Therefore, these commodities are not consumed by the Dutch population sampled in the Dutch food consumption databases. Consumption values for fresh yard-long beans can be equated with the consumption value of fresh beans with pods and that of fresh coriander leaves with that of fresh celery leaves, both in accordance with EC 178/2006. Balsam pear is recorded in the Dutch food consumption databases, and is listed as 'other fruiting vegetables with inedible peel' in the revised Dutch chronic and acute dietary risk assessment models, because there is no separate entry in the EC 178/2006 list. To have consumption values for chilli peppers, the commodity peppers as listed in EC 178/2006 is divided in sweet peppers and chilli peppers (fresh) and for commodity conversion foods are assigned to either sweet peppers or chilli peppers.

3.3.2 Change of conversion factors

The conversion factors as available in the 1995 CPAP model were never revised or re-evaluated. However, some conversion factors were erroneous and others were not available. These changes were added by use of so-called scripts.

Erroneous conversion factors

For the revised Dutch chronic and acute dietary risk assessment models, the conversion factors were changed for dried fruit, dried vegetables and dried herbs because conversion factors for the PP (dried fruit, dried vegetables, dried herbs as such) were erroneous. To calculate the RAC counterpart for dried commodities, a drying factor and a waste factor are taken into account. The drying factor is calculated from % moisture levels in dry and raw commodities as indicated in the CPAP model. When both the waste factor and the % moisture levels, as listed in the 1995 CPAP model, were omitted to get the consumption value for the PP (dried fruit, dried vegetables and dried herbs as such), the resulting conversion factor was larger than the expected 100 %. Therefore the drying factors as listed in the 1995 CPAP model were adapted (by use of scripts) to get a 100 % value for the PP (Table 1).

Table 1 Drying factors for dried fruits, dried vegetables and dried herbs

Commodity	% moisture in RAC [a]	% moisture in dry commodity [a]	drying factor used in 1995 CPAP model	drying factor used for revised risk models
apples	84 %	20 %	4.2	4.2
pears	86 %	25 %	3.4	3.4
apricots	87 %	25 %	3.5	3.3
plums	84 %	37 %	2.3	2.8
grapes – raisins	83 %	27 %	3.1	3.1
grapes – currants	83 %	14 %	5.9	4.1
figs	80 %	28 %	2.9	2.0
dates	80 %	28 %	2.9	2.0
banana	-	-	3.0	3.0
potato	77 %	8 %	9.6	9.5
sweet pepper	91 %	10 %	9.1	7.3
chilli pepper	91 %	8 %	11.4	9.1
herbs and other vegetables	90 % [b]	10 % [b]	-	9.0

a Information extracted from 1995 CPAP descriptions

b No information available in the 1995 CPAP model, moisture levels were assumed

Introduction of conversion factors for oils, fats, margarines, sugar, whisky, beer, egg whites, egg yolks
In the 1995 CPAP model, sugar, fats, oils and margarines, whisky, beer, egg whites, egg yolks are not converted to their RAC counterparts (e.g. oilseeds, sugar beets, dry hop cones, whole raw eggs. Since first and second tier dietary risk assessment is based on RACs and EPs and not on PPs (see section 3.1), conversion factors have been established for these commodities.

- Oils, fats and margarines are converted to their RAC counterparts using the information from Table 2. When the oil type is indicated in the CPAP model, e.g. olive oil, the oil is calculated back to olive using the oil contents as listed in Table 2. When the oil type is not indicated in the CPAP model such as ‘vegetable fats and oils’ or ‘animal and vegetable fats and oils’, a distribution of different oil types is estimated based on import levels published by the Dutch Product Board for Margarines, Fats and Oils (MVO, 2008). Subsequently the individual oils or fats are calculated back to the oilseed, oilfruit, coconut, olive, maize, or animal fat in question. For example 100 g ‘vegetable fats and oils’ consist of 14.9 % = 14.9 g coconut fat (see Table 2). Since fresh coconut consists of 36 % coconut fat (see Table 2), 100 g ‘vegetable fats and oils’ corresponds to 100 x 14.9/36 = 41.4 g fresh coconut meat (=RAC). The CPAP oil conversion factor is therefore 0.414, to convert ‘vegetable fats and oils’ to fresh coconut meat. When the percentage ‘vegetable fats and oils’ is 10 % in a certain food, than this oil conversion factor is multiplied by the % ingredient, in this case 0.1 x 0.414 = 0.0414.
- Sugar, glucose syrups and maltodextrines are converted to their RAC counterparts using the following assumptions:
    - all sugar, glucose syrups and maltodextrines come from sugar beets;
    - sugar beet (RAC) contains 7 % (w/w) sugar;
    - the conversion of sugar to glucose syrup or maltodextrines is a factor of 1.
- Whisky is converted to its RAC counterpart using the following assumptions:
    - all whisky comes from barley;
    - 100 g of barley (RAC) amounts to 60 g whisky (based on results from processing studies).

- For dry hop consumption a dilution factor of 500 is used to get the corresponding beer consumption (FAO, 2009).
- Egg white or egg yolks are converted to their RAC counterpart (i.e. whole raw egg without shell) using the assumption that egg yolk represents 1/3 and egg white represents 2/3 of a whole raw egg. This might result in an overestimation of the total egg consumption, because egg white and egg yolk are each calculated back to a whole raw egg.

Table 2 Factors used for conversion of fats and oils into raw edible portion

RAC	Oil distribution within vegetable fats and oils [a]	Oil/fat distribution within animal and vegetable fats and oils [a]	Oil content	Reference oil content
Almond	-	-	50 %	expert judgement [b]
Coconut (fresh meat)	14.9 %	14.4 %	36 %	Coconut Research Centre, 2008
Cotton seed	-	-	20 %	OECD, 2008b
Grape seed	-	-	10 %	expert judgement [b]
Linseed (flax)	-	-	46 %	OECD, 2008b
Maize (corn)	0.1 %	0.1 %	5 %	Ejigui et al., 2005
Olive	0.3 %	0.3 %	50 %	OECD, 2008b
Palm fruit	50.3 %	48.5 %	70 %	OECD, 2008b
Palm kernels	4.2 %	4.0 %	50 %	OECD, 2008b
Peanuts	0.2 %	0.2 %	50 %	Peanuts USA, 2008
Poppy seed	-	-	50 %	expert judgement [b]
Pumpkin seed	-	-	50 %	expert judgement [b]
Rape seed	17.2 %	16.6 %	42 %	OECD, 2008b
Safflower	0.3 %	0.3 %	35 %	OECD, 2008b
Sesame seed	-	-	50 %	expert judgement [b]
Soybean	1.3 %	1.3 %	20 %	OECD, 2008b
Sunflower seed	11.2 %	10.8 %	40 %	OECD, 2008b
Walnut	-	-	60 %	expert judgement [b]
Swine fat	-	1.5 %	100 %	-
Bovine fat	-	2.0 %	100 %	-
	======	======		
Total	100 %	100 %	-	-

[a] based on import levels published by the Dutch Product Board for Margarines, Fats and Oils (MVO, 2008)

b expert judgement was based on internet search (unspecified internet sites)

3.3.3 Conversion to raw edible portions (EP)

Although the RAC is analysed for enforcement and monitoring of pesticide residues, this is in many cases not the commodity that is actually consumed. For example, the MRL is based on whole orange including peel, but only the flesh/pulp is consumed. Consumption levels based on RAC weights will thus overestimate the actual consumption.

In 2006, the European Food Safety Authority (EFSA) developed a model for dietary risk assessment based on all the available consumption data of the individual Member States (EFSA, 2007 a/b). In doing so, the following request was made: '*The consumption figures should be expressed in grams of the edible portion consumed per day or in gram edible portion per kg bodyweight per day*'. Up to now the Dutch chronic dietary risk assessment models were based on total consumption of the RAC. The EFSA requirement means that food consumption for step 1 and step 2 of chronic dietary risk assessment (see section 3.1 and chapter 5) needs to be expressed as EP. As an example, the consumption value for orange is the sum of orange consumed raw, orange juice and orange marmalade, expressed as g EP/person (i.e. grams of orange without peel/person). This means that the consumption figures in the revised Dutch chronic dietary risk assessment models will be lower than before (depending on waste fraction of the RAC, 0 %-65 % lower).

To be able to meet the EFSA requirement, the CPAP model needs to have the possibility to include or exclude conversion factors as needed. The definitions for this inclusion or exclusion are defined in so-called scripts. To get the consumption values expressed as EP, the waste fraction for vegetables, the peel fraction for fruits and the core/stone fractions for fruits are excluded in the commodity conversions. To get the consumption values expressed as EP, clean fruit/vegetable fractions, boil down fractions for vegetables, and conversion factors for drying (raisins to grapes, potato flour to potatoes), oil extraction (rapeseed oil to rapeseed), wine making (wine to grapes), beer brewing (beer to barley) are still included in the commodity conversions. Some worked out examples are given below.

Raw fruits and raw vegetables
For raw fruits and raw vegetables, the waste fraction for vegetables, the peel fractions for fruits and the core/stone fractions for fruits are excluded in the commodity conversions, to get the consumption values expressed as EP. There are a few exceptions:

- For pome fruit (apple, pear) the EP is defined as pome fruit with peel, but without core. For pome fruit commodity conversion, the peel fraction is included and the core fraction is excluded, to get the consumption values expressed as EP.
- For stone fruit (apricots, nectarines/peaches, plums), the EP is defined as the stone fruit with peel, but without stone. For stone fruit commodity conversion, the peel fraction is included and the stone fraction is excluded, to get the consumption values as EP.

Cooked vegetables
For cooked vegetables, the boil down fraction was taken into account to get the consumption values expressed as EP. The waste fraction was excluded in the commodity conversions.

Dried fruits, dried vegetables, dried herbs
For dried fruits, vegetables, and herbs, the drying factor was taken into account to get the consumption values expressed as EP. The waste fraction was excluded.

Oils, fats, sugar, beer, whisky, wine, tea, coffee, egg whites, egg yolk
For oils and fats, sugar, beer, whisky, wine, tea, coffee, egg white, egg yolk the same conversion factors were used as for calculation of the corresponding RAC counterparts.

Concentrated tomato puree and concentrated fruit juice
For concentrated tomato puree and concentrated fruit juice the concentration factor, incorporated in the clean fruit/vegetable fraction, was included. The weight of the resulting undiluted (single) juice or puree was equated to the weight of the EP without a correction for weight change during processing.

For all other foods, the weight of the processed food was equated with the weight of the EP without any correction for weight changes during processing. Examples are: fruit juice, canned fruit (in cans or jars), wheat flour, wheat bran. This gives generally an underestimation of the consumption value expressed as EP for the following reasons:

- For fruit juice the weight loss of the pulp is not taken into account.
- For canned fruit the boil down fraction of the fruit is not taken into account.
- For wheat flour and wheat bran the milling losses are not taken into account and these foods are not calculated back to the whole grain (i.e. EP).

3.3.4 Conversion to primary processed commodities (PP)

A wide range of RACs are processed before consumption. In fact, many RACs are consumed in multiple processed forms such as raw grapes, raisins, grape juice, red wine, and white wine. Information on pesticide residue levels in PPs can be used to refine the chronic and acute dietary risk assessment. Possible dilution of the pesticide residue levels as a result of processing is especially important for refinement of chronic dietary risk assessment. Possible concentration of the pesticide residue levels as a result of processing is especially important for acute dietary risk assessment.

For step 3 of chronic dietary risk assessment (see section 3.1 and chapter 5) and for acute dietary risk assessment (see chapter 6), the individual commodity consumption values (not summed) are required for orange consumed raw (expressed as EP), orange juice and orange marmalade (each expressed as PP). But up to now food consumption data were not available for foods converted to their individual raw and primary processed commodities.

An overview of processing procedures important for the calculation of dietary exposure of humans as listed by OECD is given in Table 3. This list of primary processed commodities, frequently used in dietary risk assessment, was composed from processing lists used in the EU, JMPR and OECD (European Commission, 1995; JMPR, 2007a; OECD, 2008a/b). For pesticide authorisation, processing of animal products like meat, milk and eggs is considered not relevant. These products are therefore listed as their EP. OECD discriminates between cooked vegetables and micro-waved vegetables. Micro-waved vegetables were not specified in any of the Dutch food consumption databases, they were included in cooked vegetables. For future updates, it is recommended to discriminate between cooked and micro-waved vegetables in the food consumption databases.

The consumption of primary processed commodities should be expressed as PP, since residue levels in processing studies are expressed as mg/kg PP. This is generally the way in which the consumption levels per food are entered in the Dutch food consumption databases, e.g. wine is expressed as wine (not as grapes) and oil is expressed as oil (not as oilseeds). Therefore no conversion factors (except % ingredient) are required to convert a food to its processed counterpart.

To have food consumption data for individual commodities expressed as such, the CPAP model needs to have the possibility to include or exclude conversion factors as needed. The definitions for inclusion or exclusion are defined in so-called scripts. To get the consumption values expressed as primary processed commodity, the waste fraction for vegetables, the peel fraction for fruits, the core/stone fractions for fruits and the boil down fractions for vegetables are excluded in the commodity conversions. In addition the conversion factors for drying (raisins to grapes, potato flour to potatoes), oil extraction (rapeseed oil to rapeseed), wine making (wine to grapes) and beer brewing (beer to barley) are excluded. There are a few exceptions:

- For concentrated tomato puree and concentrated fruit juice the concentration factor, incorporated in the clean fruit/vegetable fraction, was included. The weight of the resulting undiluted (single) juice or puree was equated to tomato juice and tomato puree.
- Pulses and soybeans are expressed as cooked pulses and cooked soybeans and therefore no conversion factor is needed. This is in contrast with the conversion to RAC and EP, where pulses and soybeans are expressed as their dry form. In the earlier Dutch food consumption databases (VCP-1, -2, -3), pulses could be expressed as dry pulses. A multiplication factor of 2.5 was used to obtain the cooked counterpart.
- Barley grains, pot barley, buckwheat grains, maize grains, millet grains, oat grains, polished rice, husked rice, rye grains, sorghum grains and wheat grains were expressed as cooked, whereas the EP was expressed as the dry form. A multiplication factor of 2.5 was used to convert the dry commodity to its cooked counterpart.
- Pasta and bulgur were expressed as dry pasta and dry bulgur, not as their cooked counterparts. These dry commodities are seen as milling fractions (i.e. PP). A multiplication factor of 40 % was used to convert the cooked commodity to its dry counterpart.

Table 3 Classification of primary processed commodities

OECD category	OECD category name	CPAP processing code [a]	CPAP processing name	Commodity
I	distribution peel-pulp	1	raw	fruit, tree nuts, vegetables
II	preparation of fruit juice	9	juicing	fruit
		24	coconut milk	coconuts
III	preparation of canned fruit	5	canned	fruit
IV	preparation of other fruit products	11	jam/marmalade/jelly	fruit
		13	sauce/puree	apples
		53	canned baby food	fruit
V	preparation of alcoholic beverages	16	red wine	wine grapes
		54	white wine	wine grapes
		41	beer	cereals
		42	whisky	cereals
VI	cooking of vegetables, pulses and cereal grains in water (including steaming)	3	cooked	vegetables, pulses, cereals
		17	frozen	vegetables
VII	preparation of vegetable juice	9	juicing	vegetables
		13	sauce/puree	tomatoes, rhubarb
VIII	preparation of canned vegetables	5	canned	vegetables
		53	canned baby food	vegetables

OECD category	OECD category name	CPAP processing code [a]	CPAP processing name	Commodity
IX	miscellaneous preparations of other vegetable products	19	deep-frying	potatoes (chips), vegetables
		20	crisps	potatoes
		21	fried	potatoes, vegetables
		27	soymilk	soybeans
		30	tofu	soybeans
X	preparation of oil	12	oil extraction	oilseeds, coconut, maize, olives
		25	peanut butter	peanuts
XI	distribution on milling	23	starch/tapioca	potato, cassava, arrowroot
		28	flour	potato, cassava, dry peas, soybeans, carob
		32	pasta	cereals
		33	bran	cereals
		34	white bread	wheat
		35	wholemeal bread	cereals
		37	bulgur and grits	cereals
		38	germs	cereals
		39	flour (cereals)	cereals
		40	wholemeal flour	cereals
		43	pot barley	barley
		44	flakes	cereals
		46	starch (cereals)	maize
		47	polished rice	rice
		48	husked rice	rice
		50	cocoa powder	cocoa beans
XII	preparation of sugar	52	sugar	sugar beets
XIII	infusions and extractions	31	infusion	tea
		51	extract	coffee beans; cocoa beans
XV	processing of products of animal origin including preparation of meat and fish	-	not required for pesticides	
XVI	dehydration	7	drying	fruit, vegetables, herbs
XVII	fermentation of soybeans, rice and others	18	sauerkraut	white cabbage
		29	soy sauce	soybeans
		26	miso	soybeans

OECD category	OECD category name	CPAP processing code [a]	CPAP processing name	Commodity
XVIII	micro-waved vegetables	-	not specified in any Dutch food consumption database	
XIX	pickling	22	pickled	gherkins, cucumbers, onions, white cabbage
-	not categorized	45	popcorn	maize
		49	chocolate	cocoa beans

a CPAP processing codes 2 (peeling), 14 (cleaning) and 15 (washing/cleaning) were included in code 1 (raw).
CPAP processing code 36 (rye bread) was included in code 35 (wholemeal bread).
CPAP processing codes 4 (making bread), 6 (brewing), 8 (deep-frying and frying), 10 (milling), 16 (wine making) were split up further.

Several foods have undergone more than just the processing procedures as listed in Table 3. These are generally composite foods. Foods that did not fit into any of the processing procedures listed in Table 3 were marked with code 98 for secondary processing. Secondary processing means that a commodity is either a multi-component food and/or the PP is subjected to an additional treatment like pasteurizing, canning, frying, mixing or baking. Secondary processing was assigned to the following foods:

- Fruit, fruit juice and fruit sauce/puree in ready-to-eat desserts (water gruel, ‘vlaflip’, pudding, yoghurt), milkshakes, yoghurt drinks, soya drinks, fruit syrups, biscuits, cakes, health bars, bread, water ice, flan fillings, sauces and composite meals (e.g. chicken-curry salad).
- Jam in biscuits and cakes.
- Vegetables and vegetable sauce/puree in ready-to-eat composite meals (e.g. hotchpotch, fried rice/noodles, chicken curry salad, Russian salad, chop suey, gado gado, ratatouille), salad dressings, and sauces.
- Potatoes, pulses and rice in ready-to-eat composite meals (e.g. hotchpotch, chicken-curry salad, Russian salad, chilli con carne, fried rice).
- Oil in sauces, ready-to-eat composite meals, milk powder, bread, biscuits and cakes.

All other foods not fitting in any of the above were given processing code 99 (unknown). This included only animal products for which no processing data are required.

Although bread and jam/marmalade/jelly are secondary processed commodities, these commodities have been included in the revised Dutch dietary risk assessment models, because they were listed by OECD as being frequently used in dietary risk assessment (see Table 3).

Some composite foods were not marked for secondary processing. Although the foods were multi-component, individual commodities did not receive any additional processing treatment and it was considered that these selected commodities could be treated as primary processed commodities:

- Fruit in muesli was considered as dried fruit (processing code 7).
- Tree nuts in muesli were considered as raw peeled nuts (processing code 1).
- Vegetables, potatoes and pulses in homemade soup were considered as cooked vegetables, cooked potatoes and cooked pulses (processing code 3). If the soup was canned, they were considered as canned vegetables, canned potatoes and canned pulses (processing code 5).
- Vegetables and potatoes in instant hotchpotch and instant soup were considered as dried vegetables and potatoes (processing code 7).

Some fruits and vegetables indicated as raw in the Dutch food consumption database were considered as fruit sauce, fried fruits or cooked vegetables, because it seems highly unlikely that these commodities are consumed raw. It concerns:

- fruit sauce (processing code 13): cowberries;
- fried fruits (processing code 21): cooking bananas;
- cooked vegetables (processing code 3): potatoes, cassava, black salsify, sweet potatoes, eggplants, okra, winter squash (pumpkins), sweet corn, Brussels sprouts, kale, fresh beans with pods, fresh beans without pods, fresh peas with pods, fresh peas without pods, asparagus, artichokes, wild or cultivated fungi and bean sprouts.

4 Commodity consumption value calculation

By linking the Dutch food consumption databases to the CPAP model, a commodity consumption distribution can be generated for raw agricultural commodity (RAC), the raw edible portion (EP) or the primary processed commodity (PP). The commodity consumption value calculation is tailor made (Bakker, 2002). The (SQL+ and Pro*Fortran) scripts for these commodity consumption calculations contain links to the food consumption database, the CPAP model, the additional commodity conversion scripts (see section 3.3), the food-RAC-processing definitions and the equations for the commodity consumption value calculation. Before starting the commodity consumption value calculation, a choice has to be made in the available food consumption databases and the possible food-RAC-processing combinations.

4.1 Choice of food consumption databases

Available food consumption databases are described in chapter 2. A summary of the characteristics of the different Dutch food consumption databases is given in Table 4.

Table 4 Characteristics of Dutch food consumption databases

Dutch food consumption database	Year	Age y=years; m=months	Average bodyweight (kg)	Persons (n)	Consumption days (n)	Coded foods (n)
VCP-1 general population	1987-1988	1-85 y	61.9	5898	11796	907
VCP-2 general population	1992	1-92 y	63.0	6218	12436	1105
VCP-3 general population	1997-1998	1-97 y	65.8	6250	12500	1209
* VCP-3 children	1997-1998	2-6 y	18.1	452	904	718
RIKILT-babies	2000-2001	8-12 m	9.3	373	373	470
VIO-toddlers	2002	8-20 m	10.2	941	1882	693
* VIO-toddlers	2002	8-10 m	9.0	333	666	438
* VIO-toddlers	2002	11-14 m	9.9	306	612	507
* VIO-toddlers	2002	17-20 m	11.5	302	604	530
VCP-young adults	2003	19-30 y	75.1	750	1500	1119
VCP-kids	2005-2006	2-6 y	18.4	1279	2558	1200

* limited selection from the larger database

Up to now acute and chronic exposure to pesticides has been estimated for three age/population groups: general population (age 1-97 years, based on VCP-3 database), children (1-6 years, based on a selection of the VCP-3 database) and babies/toddlers (age 8-12 months, based on RIKILT-babies database).

For nutritional purposes in the Netherlands, the food consumption data are generally divided in more age/population groups: 1-4 years, 4-7 years, 7-10 years, 10-13 years, 13-16 years, 16-19 years, 19-22

years, 22-50 years, 50-65 years, >65 years while for each age group a distinction is made between male and female consumers.

For toxicology assessment purposes, children can be grouped in 6-12 months for babies, 1-2 years for toddlers, 3-4 years for pre-school children and 5-12 years for school children. Such groups are based on development of organs and physiological processes within the child. A pragmatic approach would be to divide children in two groups: 0.5-4 years and 5-12 years, because most of the development will take place in the age group of 5 years and under, mainly in the age group of 6-12 months (VWA, 2008).

For pesticide authorisation purposes, the 1997 Geneva consultation (WHO, 1997) recommended the development of a food consumption database for two population groups: the entire population (general population) and children (ages 6 years and under). The Chemicals Regulation Directorate (CRD) in the UK (formerly Pesticides Safety Directory, PSD) uses age/population groups for infants, toddlers, children 4-6 years, children 7-10 years, children 11-14 years, children 15-18 years, adults and elderly. CRD has no data for the general population. EU uses age/population groups for children and adults. JMPR uses age/population groups for children (varying from <6 years, 1-5 years, 1.5-4.5 years, 1-6 years, 2-6 years, 3-6 years) and general population (varying from >2 years, >3 years, >10 years, 16-64 years).

For dietary risk assessment, it is not considered desirable to divide the food consumption database in small age groups. When the food consumption databases are divided in more subsets based on age, the number of data per subset decreases. For some commodities the number of data might become too low to get an accurate commodity consumption value. Since the accuracy of the commodity consumption values is considered more important than having data for more age/population groups, and since an adult group is not required by international bodies, there is no need to change the age/population groups. When particular interest lies in small age groups (e.g. babies/toddlers) it is better to assess (pesticide) intake as a function of age (i.e. probabilistic). For pesticide authorisations only a deterministic approach is used and a probabilistic approach based on consumption as a function of age is therefore not possible. Therefore commodity consumption values for the revised Dutch chronic and acute dietary risk assessment models will be calculated for the general population, children and babies/toddlers.

4.1.1 Choice of food consumption database for general population

For the general population, three databases are available: VCP-1, VCP-2, VCP-3. The new VCP-young adults database cannot replace the latest VCP-3 database because it only covers a limited age group (19-30 years) and seasonal variations are not accounted for. A larger database could be obtained by combining the VCP-1, VCP-2, VCP-3 and VCP-young adults database, so that more accurate data can be obtained for less represented commodities. But combining the VCP-1, VCP-2 and VCP-3 databases is not common practice and is not desirable, because

- the three surveys were held among the same consumer panels and as such these surveys are not completely independent;
- consumption patterns of fruit, tree nuts, vegetables, cereal products, meat and milk products have changed in time (Health Council, 2002).

The VCP-young adults database was constructed with the EPIC-SOFT program, which leads to technical problems when combining with the earlier VCP-1, VCP-2 and VCP-3 databases.

A more up to date database could be obtained by replacing part of the VCP-3 database by the VCP-kids database (2-6 years) and the VCP-young adults database (19-30 years). Apart from the technical

problems to do so, this is considered not desirable, because the result is an artificial consumption pattern. A disturbance in food consumption pattern might be introduced due to time and methodology.

In conclusion: the VCP-3 database is considered the best choice and the revised Dutch chronic and acute dietary risk assessment models for the general population will still be based on the VCP-3 database.

4.1.2 Choice of food consumption database for children

For children, two databases are available: VCP-3 (2-6 years selection) and VCP-kids (2-6 years). The present Dutch dietary risk assessment models are based on a selection of the VCP-3 database (age 1-6 years). The latest Dutch VCP-kids food consumption survey was conducted in the age group 2-6 years. The lower limit of 2 years was chosen to avoid overlap with the VIO-toddlers database (8-20 months). The higher limit of 6 years was chosen, because at this age children are able to participate in the 24-hour recall method as intended for future food consumption surveys to be performed in the Netherlands (Ocké et al., 2005a). For the revised Dutch chronic and acute dietary risk assessment models it is desirable to replace the 2-6 years VCP-3 database with the VCP-kids database, because the VCP-kids database is based on more consumption days, and more important, contains more up-to-date consumption levels of relevant foods.

In conclusion, the VCP-kids database is considered the best choice and the revised Dutch chronic and acute dietary risk assessment models for children will be based on the VCP-kids database (2-6 years).

4.1.3 Choice of food consumption database for babies/toddlers

For babies/toddlers, five databases are available: the RIKILT-babies database (8-12 months), the VIO-toddlers database (8-20 months) and three selections of the VIO-toddlers database (8-10 months, 11-14 months and 17-20 months). The age group of the RIKILT database is included in the VIO-toddlers database and the RIKILT-babies database can therefore be replaced by the VIO-toddlers database or selections thereof. The RIKILT-babies database is considered not representative for all Dutch babies because the babies were selected from a small area in the Netherlands and only those babies were included which were fed homemade meals of fruits and vegetables and were not breast fed anymore. On the other hand, for the latter reason the RIKILT-babies database could have special value for acute dietary risk assessment purposes to estimate LPs for raw fruit and cooked vegetables. The final choice for the 8-20 month VIO-toddlers database is explained below.

For chronic dietary risk assessment, pesticide intake is compared to an ADI which represents lifelong intake. It seems strange to compare the pesticide intake of a limited age group to an ADI for lifelong intake. A VWA panel has discussed this issue and concluded that an exceeding of 2xADI by children in the age group of 0.5-12 years will generally not result in a health risk, but a case by case assessment is required. A limited (2x) exceeding of the ADI in this age group can generally be compensated for at later age. However, children must not be exposed during their most vulnerable period in life and therefore neurological, endocrine and immunological effects require special attention (VWA, 2008).

A food consumption database for babies/toddlers is therefore relevant for chronic dietary risk assessment. But to avoid a too small age group for comparison with the ADI (lifelong intake) it was considered more appropriate to select the larger age group: either the 8-20 months VIO-toddlers database or the 8-12 months RIKILT-babies database. The RIKILT-babies database was considered not suitable for chronic dietary risk assessment, because it is a one-day survey, because the total number of consumption days was limited and because the database was not representative for all Dutch babies.

For this reasons, the 8-20 months VIO-toddlers database was selected for the revised Dutch chronic dietary risk assessment model.

For acute dietary risk assessment, the g/kg bw/day LPs for commodities consumed raw and processed were calculated for each of the five available databases (LPs not included in this report). When comparing the g/kg bw/day LPs for each of these five groups, the 8-20 months VIO-toddlers database had the highest LP:

- When looking at commodities consumed raw and cooked for 45 % of the 78 commodities available, highest consumption (as g/kg bw/day) was found for the 8-20 months VIO-toddlers database compared to 22 % for the 8-10 months VIO-toddlers database selection, 10 % for the 11-14 months VIO-toddlers database selection, 27 % for the 17-20 months VIO-toddlers database selection, and 35 % for the RIKILT-babies database.
- When looking at other primary processed commodities for 37 % of the 292 commodities, highest consumption (as g/kg bw/day) was found for the 8-20 months VIO-toddlers database compared to 24 % for the 8-10 months VIO-toddlers database selection, 20 % for the 11-14 months VIO-toddlers database selection, 34 % for the 17-20 months VIO-toddlers database selection, and 20 % for the RIKILT-babies database.
- When looking at all commodities (raw plus processed) for 39 % of the 370 commodities available, highest consumption (a g/kg bw/day) was found for the 8-20 months VIO-toddlers database compared to 23 % for the 8-10 months VIO-toddlers database selection, 18 % for the 11-14 months VIO-toddlers database selection, 33 % for the 17-20 months VIO-toddlers database selection, and 23 % for the RIKILT-babies database.

Since the 8-20 months VIO-toddlers database represents the worst case, there is no reason to choose a subselection of this database for acute dietary risk assessment, also because the lower number of consumption days in the subselections compared to the whole 8-20 months VIO-toddlers database results in less accurate LPs.

For acute dietary risk assessment, there are three options:

1. choose the 8-20 months VIO-toddlers database to be in line with the chronic dietary risk assessment and use the most recent data,
2. choose the 8-12 months RIKILT-babies database because these babies were specially selected for the fact that they eat home-made fruit and vegetable meals as opposed to industrially prepared baby food,
3. take the worst case consumption for each of the five databases and the corresponding average bodyweight for the acute exposure estimation; thereby using all the available databases.

The expected higher consumption for raw commodities for the 8-12 months RIKILT-babies database was not found (as was indicated above), therefore, the 8-20 months VIO-toddlers database seems to be a better option, also because this database is more recent, the number of consumption days is higher and the database is considered representative for Dutch babies/toddlers. Taking the worst case consumption from each of the five databases results in an artificial consumption pattern and is not preferred. For the revised Dutch acute dietary risk assessment model the RIKILT-babies database (8-12 months) is replaced by the more recent VIO-toddlers database (8-20 months), because this database reflects more recent consumption data, the number of consumption days is higher and this database is considered representative for the babies/toddlers group.

In conclusion: the 8-20 month VIO-toddlers database is considered the best choice for both chronic and acute dietary risk assessment and the revised Dutch chronic and acute dietary risk assessment models for babies/toddlers will be based on the VIO-toddlers database (8-20 months).

4.2 Food-RAC-processing definition list

For the revised Dutch chronic and acute dietary risk assessment models, the RAC assignment was changed such that the RACs corresponded to the RACs listed in EC 178/2006 (see section 3.3.1). For each RAC ingredient, the corresponding processing code was entered according to Table 3 (see section 3.3.4). This information was entered in the food-RAC-processing definition list (Appendix II).

For each food-RAC-processing combination, two commodity consumption values are calculated: consumption expressed as EP and as PP. Since the % ingredients for a food are confidential and the conversion factors per food are a combination of % ingredient and conversion from one commodity form to another commodity form, the conversion factors for EP and PP are not listed in Appendix II.

4.2.1 Definition list for chronic dietary risk assessment

For chronic dietary risk assessment, average daily commodity consumption values are needed which are derived from the consumption distribution of individual RAC ingredients for the total population (consumers plus non-consumers). For Dutch chronic dietary risk assessment models, all food-RAC combinations are included in the average daily consumption value calculation. In Appendix II a Y at the columns for TMDI indicates that the food-RAC combination is included in the average daily consumption value calculation. For chronic dietary risk assessment, all food-RAC combinations are included as long as the RAC is in the EC 178/2006 list. Ingredients not included are listed in 3.3.1.

4.2.2 Definition list for acute dietary risk assessment

For acute dietary risk assessment models, the 97.5th percentile commodity consumption values are needed which are derived from the consumption distribution for individual RAC ingredients for consumers-only (i.e. a part of the total population). Not all food-RAC-processing combinations were taken into account for acute dietary risk assessment: only food-RAC-processing combinations with a conversion factor for EP of 75 % or higher are included in the LP-calculation to avoid dilution of the 97.5th percentile with foods containing only a few percent of the RAC. The conversion factor of 75 % was chosen because it was thought that a sufficient percentage of RAC should be present in the food. Generally only raw commodities, primary processed commodities that result in concentration of the pesticide residue (e.g. oil, raisins, dried tomatoes, wheat bran) and primary processed commodities that are not consumed in fresh form (e.g. cooked vegetables, cooked pulses, cereal fractions) are relevant for acute dietary risk assessment.

The cut-off limit of 75 % resulted in some unexpected exclusions. Using a cut-off limit of 75 %, no LP values were available for canned fruits, mixed fruit juices, mixed canned fruits, jam/marmalade/jelly, canned baby food, cooked rice/pulses/soybeans, liquids, chocolate, and bread. Therefore the cut-off limit of 75 % for some of these commodities was adapted to be able to calculate LP values for these commodities. An overview is given below.

Canned fruits
Canned fruits (in cans or jars) were coded in the Dutch food consumption databases as fruit including the liquid and therefore the ingredient percentages were about 50 %-60 %. To be able to calculate a LP for canned fruits, canned single fruits were included in the selection irrespective of the conversion factor. Fruit mixtures were excluded. LPs were available for canned vegetables and canned table olives, because these were coded as vegetables without liquid in the Dutch food consumption database. If canned fruits would also have been coded without the liquid, they would have been included in the 75 % cut-off limit selection. In

processing studies on canned fruits, generally the pesticide residue is analysed in the canned fruits without the liquid and therefore a change in coding of canned fruit for Dutch food consumption databases is recommended for future updates.

Mixed fruit juices and mixed canned fruits
Mixed fruit juices and mixed canned fruits (in cans or jars) were recorded via one general code in the Dutch food consumption databases. In the food consumption databases a hypothetical ingredient percentage was given to assign all possible fruits in the mixture, which results in low ingredient percentages (5 %-10 %). When the food would have been coded separately it would be possible to identify the real ingredient levels. For future Dutch food consumption databases, it is recommended that mixed fruit juices and mixed canned fruits are coded according to their ingredients (i.e. individual NEVO codes). Mixed fruit juices and mixed canned fruits were therefore not included in the selection and no LP values were calculated.

Jam/marmalade/jelly
Jam/marmalade/jelly were given one general code in the Dutch food consumption databases, even if the jam contained only one fruit. It concerns NEVO codes 445 (‘huishoudjam’), 457 (‘rozenbotteljam’), 484 (‘jam halfzoet’), 807 (‘jam zonder suiker’) and 9640 (‘broodbeleg kinder Yammie’). In the food consumption databases a hypothetical ingredient percentage was given to assign all possible fruits in the jam, which results in low ingredient percentages (5 %). For future Dutch food consumption databases, it is recommended that jam/marmalade/jelly is coded according to its ingredients (i.e. individual NEVO codes). Jam/marmalade/jelly based on individual fruits was not included in the selection and therefore no LP values were calculated. In stead a total jam/marmalade/jelly value was calculated based on consumption of jam/marmalade/jelly foods itself.

Canned baby food
Canned baby food (in jars) generally consists of mixtures of fruits and/or vegetables and individual % ingredients are below 75 % (except apples and fresh beans with pods). For canned baby food a lower cut-off value of 20 % was therefore chosen to be able to calculate LP values for most commodities.

Cooked rice, cooked pulses and cooked soybeans
Foods like rice, pulses and soybeans were coded in the Dutch food consumption database as cooked rice, cooked pulses and cooked soybeans. It concerns NEVO codes 196 (‘kapucijners in blik/glas’), 197 (‘witte bonen in tomatensaus in blik’), 368 (‘bami goreng in blik’); 470 (‘bami goreng zonder ei’); 610 (‘bamibal bereid’); 658 (‘witte rijst gekookt’), 659 (‘macaroni gekookt’); 660 (‘bruine bonen in blik/glas’); 955 (‘parboiled rijst gekookt’); 969 (‘kapucijners gekookt’), 970 (‘linzen gekookt’), 971 (‘sojabonen gekookt’); 972 (‘groene erwten gekookt’), 1014 (‘zilvervliesrijst, gekookt’), 1095 (‘kikkererwten gekookt’), 2157 (‘volkoren macaroni gekookt’), 2159 (‘gierst gekookt’); 6247 (‘meergranenrijst gekookt’). Because the RAC is defined as dry rice, dry pulses and dry soybeans, a conversion factor of 40 % was used in the CPAP model, which was below the 75 % cut-off limit. Cooked pulses, cooked soybeans and cooked cereals with conversion factors of 30 %-40 % were therefore included in the selection because these foods were calculated back to their dry RAC form.

Liquids, chocolate, popcorn
Foods like coconut milk, miso, soymilk, soy sauce, tofu, tea (infusion), beer, whisky, cocoa milk (extract), and coffee (extract) are recorded in the Dutch food consumption database as

liquids and therefore the commodity conversion factor is below 75 % (e.g. tea corresponds to 0.83 % tea leaves). For chocolate and popcorn the commodity conversion factor is also below 75 %. Because these foods are connected to one single RAC counterpart, all these foods were included in the selection (no cut-off limit).

Bread
For wholemeal bread the commodity conversion factors were below 75 % for individual cereals. Sometimes there is single cereal wholemeal bread (only wheat or only rye), but wholemeal bread may also be based on a mixture of cereals (e.g. wheat + rye or maize + rice or barley + buckwheat + maize + oat + rice + wheat). To be able to calculate LPs, only the single cereal wholemeal breads for wheat and rye were included in the selection irrespective of the conversion factor.
For white bread the only conversion factor above 75 % is for toasted white bread. All other white breads have conversion factors below 75 %. White bread is based on a single cereal (wheat), therefore all commodities coded as white bread were included (no cut-off limit).

When using the approach as described above, no LPs were calculated for those commodities with only ingredient percentages below the cut-off limits. In Appendix II a Y at the columns for LP indicates that the food-RAC combination is included in the LP-calculation with cut-off limit.

4.3 Commodity consumption value calculation

Commodity consumption value calculation is performed by so-called scripts. The Dutch food consumption databases are based on a two-day data collection per person. For each day the amounts of RAC, EP or PP originating from different foods within the selection are summed per person. The data per person are not averaged over the two-day period, but are treated as independent persons (i.e. consumption days). For chronic exposure, days with 0 consumption are taken into account, while for acute exposure days with 0 consumption are not taken into account. This results in a distribution of daily commodity consumption values at the RAC, EP or PP level. Based on this distribution, the average or 97.5th percentile value of this distribution was calculated.

The commodity consumption value calculation for acute dietary risk assessment is in line with the recommendations made by WHO for large portion sizes (WHO, 2008a/b): '*For surveys collecting multiple days of consumption data per person, the individual consumer days are assumed to be independent observations in the derivation of upper and lower percentiles, as follows:*

- *if the survey includes multiple days per participant, only the valid consumer days in which consumption of the food of interest occurs should be used;*
- *if a survey participant has multiple valid consumer days, these consumer days should be considered as independent observations, and not averaged;*
- *the number of consumer days on which the percentile is based should be explicitly stated.'*

4.3.1 Consumption values for chronic dietary risk assessment

Commodity consumption values for chronic dietary risk assessment are based on the average commodity consumption values for the total population (consumers and non-consumers).

For chronic dietary risk assessment, average daily commodity consumption values are calculated which are derived from the consumption distribution of individual RAC ingredients for the total population

(consumers plus non-consumers). Daily average commodity consumption values for the three databases (consumers plus non-consumers) indicated in section 4.1 are listed as g/kg bw/day in Appendix III. For each of the age/population groups, commodity consumption values are both given for the total commodity consumption as well as for individual commodity consumption (commodities consumed raw or processed). The total consumption value of a certain RAC is for example the sum of consumption of orange as raw, as juice and as marmalade, expressed as EP. The individual consumption is for example the consumption of orange as raw commodity or as orange juice or as orange marmalade and may be expressed as PP and as EP.

To be able to calculate relative consumption of individual raw and primary processed commodities to total consumption, all individual raw and primary processed commodities are also expressed as EP and a relative percentage to the total RAC consumption was calculated. The total RAC consumption is equal to the totals calculated from the individual raw and primary processed commodities (and expressed as EP). Differences observed can be explained by rounding differences. An example is given in Table 5 for carrots. Relative percentages can be useful to establish which type of processing studies are required for refinement of the risk assessment.

Table 5 Relative consumption of processed commodities to total RAC consumption

commodity	consumption value (a, b)	relative consumption to total RAC
carrots, total	EP = 14.2 g/pers/day	(sum of raw, cooked, canned, other)
carrots, raw	EP = 1.4 g/pers/day	10 % of total
carrots, cooked	EP = 9.5 g/pers/day	67 % of total
carrots, canned	EP = 2.2 g/pers/day	15 % of total
carrots, other (c)	EP = 1.1 g/pers/day	7 % of total

a Daily average consumption values for VCP-3, general population, expressed as EP

b Calculated from g/kg bw/day consumption value x average bodyweight (63.8 kg)

c Others includes dried carrots, carrot juice, frozen carrots, pickled carrots, canned babyfood and secondary processing

For less consumed commodities, the average commodity consumption value will approach zero, because the number of non-consumers determines the average value. All commodity consumption values in g/kg bw/day are rounded to three decimals; the corresponding g/pers/day values are rounded to one decimal. This may result in values like 0.000 g/kg bw/day for less consumed commodities. For commodities which are listed in the RAC list (EC 178/2006) but which are not mentioned in the Dutch food consumption database, a value of 0.000 g/kg bw/day will be entered. The non-consumption is indicated by a 0 number of consumption days.

4.3.2 Consumption values for acute dietary risk assessment

Commodity consumption values for acute dietary risk assessment are based on the 97.5th percentile commodity consumption values for consumers-only (i.e. part of the population). The number of participants in the current design is adequate for foods which are consumed by (almost) all individuals in the population, while problems may arise when the number of zero consumption days is large. The food consumption databases have originally been set up to get average nutrient intakes, they have not been set up for consumers-only consumption values of less consumed commodities. No guidelines are available at the moment how many consumers are needed per commodity to get an accurate value for the LP.

For acute dietary risk assessment, the 97.5th percentile commodity consumption values are calculated which are derived from the consumption distribution for individual RAC ingredients for consumers-only (i.e. a part of the total population). The 97.5th percentile commodity consumption value (or LP) is derived from records of individual consumer days (i.e. survey days on which the food(s) of interest were consumed) on a g/kg bw/day basis. The procedure to find the 97.5th percentile, used in the present report, consists of listing the commodity consumption values in increasing order, counting the number of consumption days (n) and take the (n+1) x 97.5/100th value. For example if you have 1000 consumption days, the 1001 x 97.5/100 = 976th commodity consumption value is the 97.5th percentile. Figures with decimals below 5 are rounded down, figures with decimals of 5 and higher are rounded up (e.g. the 95.3rd value becomes the 95th value and the 95.5th value becomes the 96th value).

Using the numerical procedure described above, at least 40 consumption days are required to be able technically to calculate/point the 97.5th percentile. This value of 40 consumption days was derived from the assumption that 40x2.5 percentile intervals are required to calculate/point the 97.5th percentile. When the commodity consumption values are based on less than 40 consumption days, these 40 intervals are not available and technically it is not possible to calculate/point a 97.5th percentile. Therefore the following approach was taken:

- the 97.5th percentile was taken for 40 consumption days (100:2.5=40 intervals needed);
- the 95th percentile was taken for 20-39 consumption days (100:5=20 intervals needed);
- the 90th percentile was taken for 10-19 consumption days (100:10=10 intervals needed);
- the maximum consumed value was taken for less than 10 consumption days.

This approach was also used by Belgium and Germany (EFSA, 2007a).

High percentiles may also be estimated by statistical methods like MCRA (Monte Carlo Risk Assessment), which are generally used in probabilistic risk assessment. In this case there are no bounds in the required number of consumption days: the only thing that can be said is that the precision of the estimates will decrease with a lower number of consumption days. These more appropriate statistical methods will also provide the associated confidence intervals, and these indicate the precision that was actually reached.

For acute dietary risk assessment models, a LP may be calculated for the total consumption of a certain RAC (e.g. the sum of consumption of orange as raw as juice and as marmalade) and for each individual raw or processed commodity (e.g. orange as raw commodity, or as orange juice or as orange marmalade). The LP should be matched to the commodity to which the residue data relates (WHO, 2008a/b). For the revised Dutch acute dietary risk assessment models, the LP for individual raw or primary processed commodities is used for products of plant origin, while the LP for total consumption is used for products of animal origin. In the case of commodities that are consumed predominantly fresh as for fruit and vegetables, the LP should be derived for the raw commodity. When a high proportion of the commodity, such as cereal grains, is consumed in a processed form, the LP should relate to the PP e.g., bread, flour, providing matching residue concentration data are also available for the processed food . Since processing data are not considered relevant for products of animal origin (OECD 2008a), the LP for total consumption is used for products of animal origin.

When using the cut-off limit as described in section 4.2.2, no LPs were calculated for those commodities with only ingredient percentages below the cut-off limits. To have LPs for all commodities listed in the food-RAC definition list, two calculations were performed:

- In the first calculation only food-RAC-processing combinations with a commodity conversion factor to EP of 75 % or higher (cut-off limit) were included in the selection. For some

commodities like canned fruits (in cans or jars), canned baby food, cooked rice, cooked pulses, cooked soybeans, liquids, chocolate, popcorn, wholemeal bread and white bread lower conversion factors were taken into account because LP values for these commodities were considered relevant although the conversion factors were lower than 75 %. This selection is indicated in section 4.2.2 and Appendix II.

- In the second calculation, all food-RAC-processing combinations were taken into account (no cut-off limit).

The maximum of each of the two calculations is called LP-max. LP-max for the three databases indicated in section 4.1, is listed as g/kg bw/day in Appendix IV.

Whether the LP-max is derived from the calculation with cut-off factor or from the calculation without cut-off factor can be seen from the number of consumption days used to calculate the LP-max. When Nsel (number of consumption days used to calculate LP-max) is equal to Ntot (total number of consumption days available in the food consumption database), than the LP-max is based on values without cut-off factor. When Nsel is smaller than Ntot, than the LP-max is based on values with cut-off factor. The LP-values with cut-off factor are considered more reliable than the LP-values without cut-off factor, since they relate to consumption of a significant part of the commodity in question.

Each LP-max was converted to a g/person/day value by multiplying the value with the average bodyweight of the population group. All commodity consumption values in g/kg bw/day are rounded to three decimals; the corresponding g/pers/day values are rounded to one decimal.

When the calculated LP-max seemed reasonable when comparing the three selected food consumption databases, this value was used for acute dietary risk assessment (LP-choice = LP-max). Generally this is the case when LP-max is based on the LP with cut-off factor (Nsel < Ntot) and when there are a sufficient number of consumption days (Nsel > 40). When the calculated LP-max seemed too low or too high when comparing the three food consumption databases, or when no consumption days were available, a more reasonable value or estimated value was used for acute dietary risk assessment (LP-choice <> LP-max). Generally this is the case when LP-max is based on the LP without cut-off factor (Nsel = Ntot). The procedure of finding LP-choice is outlined in Figure 2.

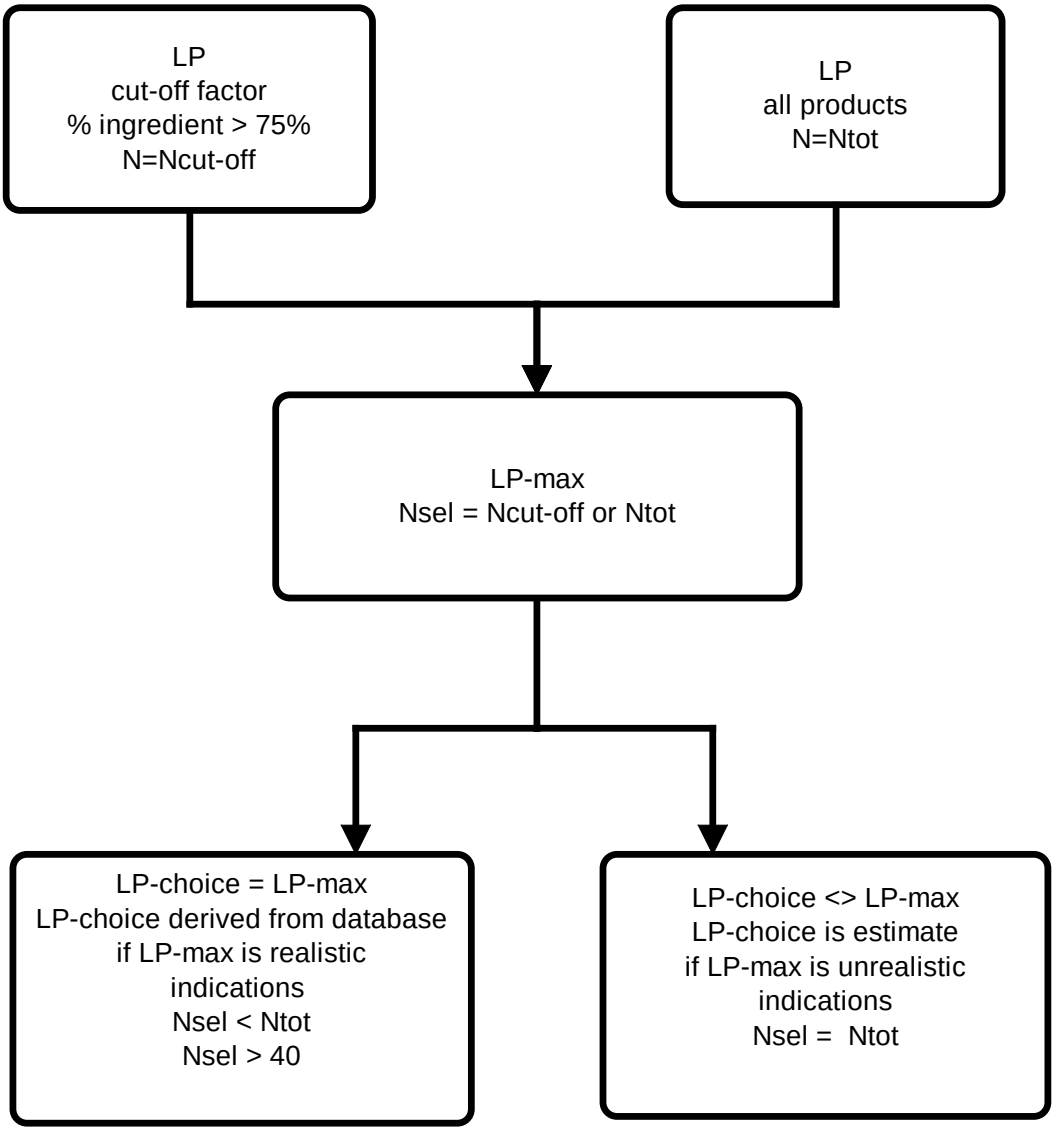

Figure 2 Selection of LP-choice for dietary risk assessment model

The following approach was taken when LP-max seemed too low or too high (LP-choice <> LP-max):

- Extrapolate LP-choice from another database assuming consumption values in VIO-toddlers database (8-20 months), VCP-kids database (2-6 years), VCP-3 database (1-97 years) follows a ratio of 1:2:3 (expressed as g/person/day). This is the ratio as found in the advices by the Netherlands Nutrition Centre (Table 6). For commodities consumed mainly by babies/toddlers as indicated by the total numbers of consumption days (e.g. rose hip juice, canned baby food), the consumption value from the VIO-toddlers database (8-20 months) was also used for the VCP-kids database (if applicable) and VCP-3 database (if applicable) using the bodyweight ratio as conversion factor.
- Take the consumption value (expressed as g/person/day) as recommended by the Netherlands Nutrition Centre (Table 6) as LP-choice, if appropriate. It is known from the Food Consumption Surveys that actual consumption is lower than the consumption values recommended by the Netherlands Nutrition Centre. For those commodities for which no

consumption was found in the consumption databases, 1/4 the value from the Netherlands Nutrition Centre was used as best estimate for the 97.5th percentile of consumers for rarely consumed oils, and 1/2 the value was used as best estimate for cooked soya beans, cooked barley, cooked oats and cooked buckwheat.

- Take the % edible of the unit weight of a commodity as LP-choice (expressed as g/person/day) for those commodities where it can be assumed that one unit is generally consumed by one person, if appropriate. This option is only possible for fruit and vegetables consumed raw.
- Take the size of a commercial package (can, bag, pack) as LP-choice and divide this by the number of persons for which it is intended (expressed as g/person/day). If necessary take the % ingredient on the package in case of mixed vegetables or fruits. This option can be used for canned fruits/vegetables (in cans or jars), frozen vegetables and dried vegetables. This option depends on the package volumes commercially available and the package taken as example from the many packaging volumes available. Packaging volumes are listed in the MGC reference table (MGC, 2003).
- Take 150 or 250 ml as LP-choice for juice and multiply this by the % ingredient for fruit and vegetable juices as given on the lable (expressed as g/person/day).
- Extrapolate the LP-choice from a similar commodity
- Take the amounts as given in recipes of cookery books as LP-choice and divide this by the number of persons for which the recipe is intended (expressed as g/person/day).

The LP-choice values for the three databases (consumers-only) indicated in section 4.1 and used in the revised Dutch acute dietary risk assessment model are listed as g/person/day in Appendix V. For commodities listed in the RAC list (EC 178/2006), for which the number of consumption days is zero and which are considered not to be consumed in the Netherlands, no value was estimated, but a value of NC (no consumption) is used in the revised Dutch acute dietary risk assessment model.

Table 6 Recommended consumption per person per day (Voedingscentrum, 2008)

	1-3 years	**4-8 years**	**9-13 years**	**14-50 years**	**51-70 years**	**>70 years**
Cooked vegetables	50-100 g	100-150 g	150-200 g	200 g	200 g	150 g
Raw fruit	150 g	150 g	200 g	200 g	200 g	200 g
Cooked rice, pasta, pulses or potatoes	50-100 g	100-150 g	150-200 g	200-250 g	150-200 g	125-175 g
Oil	15 g	15 g	15 g	15 g	15 g	15 g
Meat, chicken or eggs	50-60 g	60-80 g	80-100 g	100-125 g	100-125 g	100-125 g

4.4 Choice of commodity consumption value units

The commodity consumption calculation resulted in a distribution of daily commodity consumption values at the RAC, EP or PP level. Based on this distribution, the average or 97.5th percentile value of this distribution was calculated, either expressed as g/person/day or g/kg bw/day.

Both the g/person/day values and the g/kg bw/day values are required in the dietary risk assessment.

- The g/person/day values are required in the acute dietary risk assessment to compare the LP (97.5th percentile) with the unit weight to decide on the equation to be used (see section 6.1).

- The g/kg bw/day values are required in the actual dietary risk assessment to compare the pesticide residue intake with the ADI (for chronic dietary risk assessment) or ARfD (for acute dietary risk assessment), which are each expressed as g/kg bw (see sections 5.1 and 6.1).

The high end of the consumption distribution (output in g/person/day) is in many cases related to consumers with a higher bodyweight (adults group). Therefore EFSA considered that the consumption figures based on individual bodyweights (g/kg bw/day) were more accurate and used the g/kg bw/day commodity consumption values as starting point for its risk assessment (EFSA, 2007a). Since the high end of the consumption distribution (in g/kg bw/day) is related to consumers with a low bodyweight (babies/toddlers group), the g/kg bw/day consumption figures are also more protective.

Since the g/kg bw/day consumption figures are more protective, are required for the actual risk assessment and can be used to compare commodity consumption values of the different age groups, the g/kg bw/day consumption figures are used as starting point in the revised Dutch chronic and acute dietary risk assessment models.

It is important to realize that the g/kg bw/day results (average or 97.5th percentile) cannot be converted to the g/person/day results (average or 97.5th percentile) by using the average bodyweight of the selected age group and vice versa. The g/kg bw/day results (average or 97.5th percentile) were obtained from a distribution consisting of the portion sizes consumed by that particular person in g/person/day divided by its personal bodyweight, which is different from the average bodyweight. The g/person/day results (average or 97.5th percentile) were obtained from a distribution of portion sizes consumed by individual persons irrespective of bodyweight.

In the old Dutch chronic and acute dietary risk assessment models, the g/person/day consumption figures were taken as starting point for the dietary risk assessment, while for the revised Dutch chronic and acute dietary risk assessment models the choice has been made to use the g/kg bw/day consumption figures. To show the impact of this choice, the g/kg bw/day consumption figures were multiplied by the average bodyweight of the food consumption database in question to be able to make a comparison with the g/person/day consumption figures from the same food consumption database. Differences between ‘g/kg bw/day x average bw’ and ‘g/person/day’ values ranged from -48 % to +631 % for the LPs and ranged from 0 % to +400 % for the daily average consumption levels; the ‘g/kg bw/day x bw’ values were generally higher. These differences are higher when the range of bodyweights is more extended like in the VCP-3 general population database where bodyweights are included for 1 year olds up to 97 year olds. Table 7 gives an impression of the largest differences found in this way for the VCP-3 general population. Largest differences are generally found for those commodities consumed by babies or children (low bodyweight), where g/kg bw/day values are multiplied by a large average bodyweight (65.8 kg) to get an unrealistically high g/person/day value. However, this unrealistically high g/person/day value can be calculated back to a realistic g/kg bw/day value by dividing it by the same large average bodyweight (65.8 kg). The final result is therefore related to a realistic exposure, which may originate from low bodyweight persons.

In the revised Dutch chronic and acute dietary risk assessment models, the consumption figures are shown as g/person/day values, although they result from ‘g/kg bw/day x average bw’ calculation. Risk assessors in the pesticide area are used to commodity consumption values expressed as g/person/day. The equations to estimate the exposure require an input as g/person/day (see sections 5.1 and 6.1).

Table 7 Differences originating from g/person/day or g/kg bw/day output for VCP-3 general population data

Commodity	**LP VCP-3, 1-97 years g/person/d output**	**LP VCP-3, 1-97 years * g/kg bw/d output x average bw**	**daily average VCP-3, 1-97 years g/person/d output**	**daily average VCP-3, 1-97 years * g/kg bw/d output x average bw**
orange, canned baby food, PP	46.4	254.4	0.0	0.1
apples, juice, PP	900.0	2193.3	16.3	31.1
apples, sauce, PP	270.0	493.5	6.6	8.8
apples, canned baby food, PP	186.5	1363.5	0.1	0.5
pears, juice, PP	160.0	386.0	0.7	1.0
pears, canned baby food	20.4	111.9	0.0	0.0
table grapes, juice, PP	600.0	1368.6	1.3	1.8
table grapes, can baby food, PP	25.0	164.5	0.0	0.1
strawberry, can baby food, PP	7.0	46.1	0.0	0.0
currants, juice, PP	392.0	839.0	0.8	1.1
currants, canned baby food, PP	7.5	54.8	0.0	0.0
kiwi fruit, raw, EP	150.0	418.8	2.5	3.4
bananas, raw, EP	260.0	611.0	13.4	18.9
bananas, juice, PP	17.2	38.4	0.0	0.1
bananas, canned baby food, PP	24.2	146.2	0.0	0.1
pineapples, juice, PP	378.0	580.6	0.8	1.1
pineapples, can baby food, PP	9.0	49.4	0.0	0.0
potatoes, can baby food, PP	34.3	225.4	0.0	0.2
beetroots, can baby food, PP	4.8	31.3	0.0	0.0
carrots, canned, PP	268.9	536.8	1.5	2.0
carrots, canned baby food, PP	56.5	247.9	0.0	0.2
tomatoes, can baby food, PP	40.0	164.5	0.0	0.1
sweet corn, can baby food, PP	2.0	12.0	0.0	0.0
cauliflower, can baby food, PP	8.2	49.0	0.0	0.1
scarole, can baby food, PP	5.5	36.2	0.0	0.0
beans w pods, baby food, PP	14.3	93.8	0.0	0.1
peas w/o pods, baby food, PP	18.3	75.1	0.0	0.1
rhubarb, sauce, PP	213.0	424.5	0.4	0.5
dry beans, can baby food, PP	12.6	75.3	0.0	0.1
soya beans, soymilk, PP	53.0	232.4	0.1	0.1
maize, popcorn, PP	100.0	204.7	0.2	0.2
rice, flour, PP	70.0	418.8	0.1	0.3
cattle milk, total, EP	1094.5	2537.3	414.7	557.5

* average bodyweight of 65.8 kg for general population in VCP-3

EP = expressed as raw edible portion

PP = expressed as primary processed commodity (e.g. pineapple juice, dry rice flour, canned baby food)

5 Chronic dietary risk assessment models

5.1 Chronic dietary risk assessment

Typically, toxicological studies carried out to examine the health effects resulting from consumption of a chemical substance in the diet are completed over a long period of time (e.g. a year or the lifetime of test animals). These health effects are understood to arise from long-term exposure to the substance being studied. Exposure assessments conducted to be comparable to these long-term toxicological studies have been termed chronic dietary exposure assessments (WHO, 2008a/b).

Chronic exposure assessments may be deterministic (point values) or distributional (also known as probabilistic or stochastic). For pesticide authorisation purposes a deterministic approach is used where a mean dietary exposure is compared to a chronic (long-term) toxicological reference value (ADI, acceptable daily intake, expressed as mg/kg bw). The mean dietary exposure may be calculated by applying a deterministic model using average food consumption levels and the average concentrations in the relevant foods (WHO, 2008 a/b).

The methodology for estimating the chronic dietary exposure to pesticide residues was developed by several international meetings (WHO, 1989; WHO, 1995a/b; WHO, 1997; WHO, 2008a/b).

5.1.1 Current TMDI or IEDI/NEDI equations

Chronic dietary risk assessment for pesticide authorisation purposes with the EU conforms to international methodology and follows a three step tiered deterministic approach, which is shown below.

Step 1. The first step has been termed Theoretical Maximum Daily Intake (TMDI). In this step a worst case scenario is tested, where it is assumed that all consumed products of the commodities in question have been treated, a residue level will be found at the level of the MRL, and all products are consumed raw without taking the decline in residue level by processing into account. If this first step estimate for dietary exposure is below the toxicological reference value (ADI), further refinement steps are not necessary, and the chemical is unlikely to be of safety concern.

$$TMDI = \sum_{i=1}^{n} \frac{MRL_i \times F_i}{bw} \qquad \text{(mg/kg bw/day)}$$

Step 2. When the TMDI-calculation results in an estimate of the dietary exposure at or above the toxicological reference value (ADI), a more accurate (refined) risk assessment will usually be necessary. The refined chronic dietary exposure estimation has been termed International Estimated Daily Intake (IEDI) or National Estimated Daily Intake (NEDI). When the TMDI is found to exceed the ADI, additional data are required for those commodities where the raw edible portion (EP) is different from the raw agricultural commodity (RAC), to estimate the residue levels in the EP. Then a NEDI-calculation is carried out in which the STMR (supervised trials median residue of the EP) is applied as residue level instead of the MRL.

$$NEDI = \sum_{i=1}^{n} \frac{STMR_i \times F_i}{bw} \qquad \text{(mg/kg bw/day)}$$

Step 3. When the NEDI-calculation based on STMRs is found to exceed the ADI, additional processing data are required to show the fate of residues during processing and to estimate the residue levels in primary processed commodities (PP). Then a refined NEDI-calculation is carried out in which processing data are included and the STMR-P (supervised trials median residue of the PP) is applied as residue level instead of the STMR. If this third step estimate for dietary exposure is below the toxicological reference value, further refinement steps are not necessary, and the chemical is unlikely to be of safety concern. If this third step estimate for dietary exposure still results in exceeding of the ADI, the MRLs as proposed cannot be set and other measures are required to reduce the chronic dietary risk (e.g. adaptation of the intended use by changing the treated commodities or changing the dose rate).

$$NEDI = \sum_{i=1}^{n} \frac{STMRP_i \times F_i}{bw} \qquad \text{(mg/kg bw/day)}$$

The following abbreviations were used:

TMDI	= theoretical maximum daily intake (mg/kg bw/day)
NEDI	= national estimated daily intake (mg/kg bw/day)
ADI	= acceptable daily intake (mg/kg bw)
MRL_i	= Maximum Residue Level of a certain RAC (mg/kg)
$STMR_i$	= supervised trial median residue level of a certain EP (mg/kg)
$STMRP_i$	= supervised trial median residue level of a certain PP (mg/kg)
F_i	= consumption of the commodity in question (kg/person/day) for a certain age/population group; obtained from g/kg bw/day commodity consumption value x 0.001 (conversion g to kg) x average bw of an age/population group (in kg).
bw	= average bodyweight of an age/population group (in kg)

As shown above, dietary risk assessment for pesticide authorisation purposes follows a three step tiered deterministic approach. The next step is taken only when the ADI is exceeded. Within JMPR all available data are used without the step wise approach. JMPR may start by using a refined risk assessment for those commodities where STMR or processing data are available.

Note 1
The residue definition for enforcement can be different from the residue definition for risk assessment, since the latter may contain additional toxicologically relevant metabolites.

By definition, an MRL is based on the residue definition for enforcement. But for the purpose of risk assessment, this MRL should be converted into the residue as defined for risk assessment. In the course of pesticide evaluation, a conversion factor is established to convert the residue for enforcement into the residue for risk assessment. The conversion factor may be different for plant and animal commodities, and even for different plant commodities. This conversion factor should be applied to the MRL before using the step 1 equation.

By definition, the STMR and STMR-P in the step 2 and step 3 equations are based on the residue definition for risk assessment. The residue can be determined by analysing the individual components of the residue definition for risk assessment in the commodity in question, or it can be calculated from the STMR or STMR-P based on the residue definition for enforcement multiplied by the conversion factor. Individual analysis is preferred within JMPR, use of conversion factors is preferred within EU.

Note 2
By definition, the STMR is based on the residue level in the EP. In cases where no residue data are available for the distribution between peel and pulp, the $STMR_{RAC}$ (supervised trials median residue of the RAC) is used instead of the STMR. The $STMR_{RAC}$ differs from the STMR for commodities where the EP is not the same as the RAC (e.g. oranges, bananas).

The STMR-P is based on the residue level in the PP. The STMR-P is calculated as $STMR_{RAC}$ x processing factor, where $STMR_{RAC}$ is the supervised trials median residue of the RAC. The $STMR_{RAC}$ differs from the STMR for commodities where the EP is not the same as the RAC (e.g. oranges, bananas).

Note 3
For animal commodities a special procedure is followed (JMPR, 2009).
For *kidney, liver, fat and eggs*, no distinction is made between fat and non-fat soluble pesticides.
For TMDI-calculation, the MRL of the animal commodity is used, together with the consumption value of that product.
For *meat from mammals and poultry*, no distinction is made between fat or non-fat soluble pesticides.
For TMDI-calculation, the MRL values for fat and muscle are used (separately, each). Consumption values for meat have been split into consumption as fat and as muscle. It is assumed that mammalian meat contains 20 % fat and 80 % muscle. It is assumed that poultry meat (with adhering skin) contains 10 % fat and 90 % muscle. The MRL values are therefore combined with meat as 80 %/90 % muscle and with meat as 20 %/10 % fat, and not at meat as total
For *milk*, a distinction is made between fat and non-fat soluble pesticides.
For non-fat soluble pesticides, the MRL values for whole milk are used, together with the consumption values for whole milk. For fat soluble pesticides, the MRL values for cream (milk fat) are used. It is assumed that whole milk contains 4 % fat. The MRL value for cream is recalculated to whole milk by multiplying the MRL (cream) with a factor 0.04. After this correction, the consumption values for whole milk can be used.

For the NEDI-calculation the MRL is replaced by the STMR.

In feeding studies only chickens, cows and sometimes pigs are tested. MRLs for cow tissues and milk are also used for all other ruminants (goats, sheep). MRLs for chicken tissues and eggs are also used for all other poultry (goose, turkey, duck). When there is no difference between the metabolism in poultry and ruminants, than the MRLs for cow tissues are also used for all other slaughter animals.

5.1.2 History of TMDI and IEDI/NEDI estimations

From about the mid-1950s, countries began to legislate for pesticide residues in food and feed by the use of MRLs. The complexity of the pesticide residue problem and its international implications were recognised by the FAO in 1959. As a result the first JMPR was held in 1961 on ‘Principles Governing Consumer Safety in Relation to Pesticide Residues’. At that time chronic dietary exposure estimates were based on expert judgement.

The first methodology for estimating the chronic dietary exposure to pesticide residues was developed by WHO in 1989. At that time, the chronic exposure was calculated by using the TMDI equation in combination with a global diet (WHO, 1989). This calculation greatly overestimated the exposure and was conducted for screening purposes. If the TMDI exceeded the ADI, the Estimated Maximum Daily Intake (EMDI) was calculated based on global and regional diets and might include correction factors

to improve the accuracy of exposure assessments. For example, data on residues in the EP of the commodity in question and the fate of residues during processing was used to make a more accurate calculation of exposure.

The 1995 York consultation (WHO, 1995b) recommended the best use of available data through calculation of an IEDI or NEDI in dietary exposure assessments of pesticide residues, while retaining the TMDI as a priority setting tool. The 1995 York consultation proposed

- the use of median residue levels from supervised field trials;
- separate residue definitions for risk assessment and MRL setting purposes, where appropriate;
- discontinuation of the use of a single global diet and the use of five regional diets for TMDI and IEDI estimations, as developed based on FAO food balance sheets by WHO/GEMS-Food for the regions Africa, Europe, Far East, Latin America and Middle East (WHO, 2005).

Since then no changes have been made to the TMDI and IEDI/NEDI equations itself. Changes involved the diets used for TMDI and IEDI/NEDI estimations, automation of the calculations, and changes in the risk assessment of animal commodities where fat solubility of pesticides was taken into account. The 2006 JMPR (JMPR, 2006a) agreed to replace the five regional diets in its assessments with the 13 global cluster diets developed by WHO/GEMS-Food which are based on cluster analysis approach using major food groups (WHO, 2005).

5.2 Dutch chronic dietary risk assessment models

Within the Netherlands chronic dietary risk assessment of pesticide residues has been performed since 1992, using the consumption data from the VCP-2 general population database. At that time assessments were performed based on consumption data for crop groups like fruits or vegetables. When the 1995 CPAP model became available, it was possible to make more detailed risk assessments based on consumption data for individual fruits and vegetables. When the 1997-1998 VCP-3 database became available, it was possible to make separate risk assessments for children (1-6 years) as well as for the general population (1-97 years).

The Dutch chronic dietary risk assessment was automated in 2000 by using an Excel based calculation model, which is owned and managed by RIVM. This model contains the equations given above as well as the commodity consumption values for the various age groups to be able to estimate dietary risk for the purpose of pesticide authorisation. After entering the residue concentrations for relevant commodities, the model compares the chronic dietary exposure to the appropriate toxicological reference value (ADI for chronic risk) and provides an overview table of relevant commodities for each of the population groups.

The first version of the model was developed in 2000 and contained commodity consumption values for the general population (VCP-3, 1-97 years) and children (VCP-3, 1-6 years). The model was regularly updated to meet the current status of risk assessment procedures.

A revised Dutch chronic dietary risk assessment model (‘Version 03 Dutch TMDI_NEDI calculation.xlt’, see addendum I) was developed to incorporate the updated food consumption data for babies/toddlers, children and general population and consumption data for PPs as described in this report. Considerations in setting-up and using the model are described in 5.2.1 to 5.2.3.

5.2.1 Pesticide residue concentrations (MRL, STMR)

The pesticide residue concentrations (MRL, STMR, $STMR_{RAC}$) needed in the TMDI and NEDI equations and relevant for the Dutch situation, are obtained from supervised field trials conducted in Northern Europe in which the pesticide is applied to the crop in question according to Good Agricultural Practice (GAP) at the maximum permitted dose rate, the maximum permitted number of applications, the minimum permitted interval between applications and the minimum permitted pre-harvest interval.

Processing factors (to estimate STMR-P) are obtained from processing studies where commodities with incurred residues are processed according to industrial or household practices. The processing factor (P-factor) is based on the residue definition for risk assessment (so not the one for enforcement).

$$\text{P - factor} = \frac{\text{Residue in processed product}}{\text{Residue in RAC}}$$

When there is more than one trial, the median P-factor is taken when the P-factors of the different trials are close together (relative standard deviation ≤ 40 %) and the maximum P-factor is taken when the P-factors of the different trials are far off (relative standard deviation > 40 %).

The data on supervised field trials and processing studies are part of the data requirements for pesticide authorisation and are evaluated for the purpose of MRL setting and dietary risk assessment. The way the residue values are obtained from these data are described by EU, FAO and OECD (European Commission, 1995, 1997a/b, 2008; FAO, 2009; OECD, 2008a/b).

5.2.2 Commodity consumption values (F_i) and bodyweights (bw)

Commodity consumption values for chronic dietary risk assessment are based on the average commodity consumption values for the total population (consumers and non-consumers).

Up to now chronic dietary exposure to pesticides has been calculated for two age/population groups: general population (age 1-97 years, based on VCP-3 database) and children (1-6 years, based on a selection of the VCP-3 database). An average bodyweight of 63 kg for general population and 17 kg for children was used in the TMDI/NEDI equations.

In the revised Dutch chronic dietary risk assessment models commodity consumption values are available for general population (age 1-97 years, based on VCP-3 database), children (2-6 years, based on VCP-kids) and babies/toddlers (8-20 months, based on VIO-toddlers database). The reasons behind this choice are presented in section 4.1. Daily average commodity consumption values for each of these databases (consumers plus non-consumers) are listed as g/kg bw/day in Appendix III and are described in section 4.3.1. For each of the age/population groups, commodity consumption values are available for the total commodity consumption as well as for individual commodity consumption (commodities consumed raw or processed). The total commodity consumption for a certain RAC is for example the sum of consumption of orange as raw, as juice and as marmalade, expressed as EP. The individual commodity consumption is for example the consumption of orange as raw commodity or as orange juice or as orange marmalade and may be expressed as PP and as EP.

The average bodyweight for general population was found to be 65.8 kg in stead of the 63 kg which was used up to now. No explanation could be found for this difference in bodyweight. An average

bodyweight of 18.4 kg and 10.2 kg was used for children (VCP-kids database) and babies/toddlers (8-20 months, VIO-toddlers database), respectively.

Up to now, the food consumption was expressed as g/person/day (expressed as RAC). In the revised Dutch chronic dietary risk assessment models, the food consumption is expressed as g/kg bw/day (expressed as EP or as PP, depending on commodity). For further explanation see section 4.4. The g/person/day consumption values in the revised Dutch chronic dietary risk assessment model were calculated from daily average g/kg bw/day consumption x average bodyweight of the population group.

For less consumed commodities, the average commodity consumption value will approach zero, because the number of non-consumers determines the average value. All commodity consumption values (expressed as g/kg bw/day) are rounded to three decimals in the revised Dutch chronic dietary risk assessment models; i.e. the detection limit is set at 0.001 g/kg bw/day. This may result in values like 0.000 g/kg bw/day for less consumed commodities. For commodities which are listed in the RAC list (EC 178/2006) but which are not mentioned in the Dutch food consumption database, a value of 0.000 g/kg bw/day will be entered. The non-consumption is indicated by a zero number of consumption days.

5.2.3 Chronic dietary exposure calculation for primary processed commodities (PP)

When setting up the dietary risk assessment model, problems were encountered when calculating the chronic dietary exposure for PPs.

The TMDI/NEDI-calculation takes place in a tiered approach (see section 5.1.1). In the first and second step, the average consumption of the commodity in question (F_i) is combined with the MRL or STMR and the sum of consumptions for all relevant commodities is compared to the ADI. Since at this stage processing data are not relevant, the MRL or STMR can be combined with the total commodity consumption values (expressed as EP). This total commodity consumption value equals the sum of the individual commodity consumption when expressed as EP (see Table 5 in section 4.3.1). Overestimates of chronic dietary risk occurred when the total commodity consumption includes commodities where only a small proportion is actually consumed (e.g. sugar and oils).

The problem is best illustrated with an example for sugarbeet (calculation 1). Sugar consumption comprises only 7 % (w/w) of sugarbeet root consumption. If no processing data are available, the STMR of sugar beet is combined with the total commodity consumption value for sugarbeet roots (F=1.3478 kg/person/day as EP for VCP-3 general population). If an STMR of 1 mg/kg in the RAC is assumed, this results in the following NEDI:

calculation 1

$$NEDI = \sum \frac{STMR_i \times F_i}{bw} = \frac{1 \times 1.3478}{65.8} = 2.0 \times 10^{-2} \text{ mg/kg bw/day}$$

The same outcome would be obtained if the consumption values of the individual PPs were combined with the STMR for the RAC (expressed as EP) (calculation 2). Total consumption for sugarbeet roots consists of 18 % sugar (F=0.2406 kg/person/day as EP for VCP-3 general population) and 82 % secondary processing (F=1.1073 kg/person/day as EP for VCP-3 general population). If an STMR of 1 mg/kg for each of these commodities is assumed, this results in the following NEDI:

calculation 2

$$NEDI = \sum \frac{STMR_i \times F_i}{bw} = \frac{1 \times (0.2406 + 1.1073)}{65.8} = 2.0 \times 10^{-2} \text{ mg/kg bw/day}$$

But if the actual consumption values of the PPs are combined with the STMR, a lower dietary exposure is calculated (calculation 3). Total consumption for sugarbeet roots than consists of sugar (F=0.0168 kg/person/day as PP for VCP-3 general population) and secondary processing (F = 0.0775 kg/person/day as PP for VCP-3 general population). If an STMR of 1 mg/kg for each of these commodities is assumed, this results in the following NEDI:

calculation 3

$$NEDI = \sum \frac{STMR_i \times F_i}{bw} = \frac{1 \times (0.0168 + 0.0775)}{65.8} = 0.14 \times 10^{-2} \text{ mg/kg bw/day}$$

Conclusion

Since average consumption values expressed as EP overestimate the dietary exposure for commodities where only a small part is actually consumed, only the actual consumption values are relevant. Total commodity consumption values are expressed as EP and therefore overestimate the dietary exposure in such cases.

To solve the problem, the average consumption values for individual raw or primary processed commodities are used for products of plant origin in the revised Dutch chronic dietary risk assessment model; average total commodity consumption values for products of plant origin are not listed anymore. Actual consumption values for commodities consumed raw are expressed as EP, while actual consumption values for commodities consumed in processed form are expressed as PP. Since processing data are not considered relevant for products of animal origin (OECD 2008a), the average total commodity consumption is still used for products of animal origin.

Since combination of RAC residues with consumption values of diluted commodities (like beer, wine, infusions, extracts) will result in overestimation of the dietary exposure if expressed as PP, a default processing factor is used in the revised Dutch chronic dietary risk assessment model to compensate for the dilution (for explanation, see section 6.2.5.2). Processing data will not be required as long as the ADI is not exceeded using this default processing factor. In case processing data are available, the default processing factor should be replaced by the actual processing factor, which is expected to be lower than the default processing factor for dilution because of degradation of the residue.

Since combination of RAC residues with consumption values of concentrated commodities (like dried fruits and dried vegetables) will result in underestimation of the dietary exposure, a default processing factor is used in the Dutch chronic dietary risk assessment models to compensate for the concentration (for explanation see section 6.2.5.3). Processing data will not be required as long as the ADI is not exceeded using this default processing factor. In case processing data are available, the default processing factor should be replaced by the actual processing factor, which is expected to be lower than the default processing factor for concentration because of degradation of the residue.

6 Acute dietary risk assessment models

6.1 Acute dietary exposure estimation

The focus of dietary risk assessment has generally been on the risks arising from chronic (long-term) dietary exposure. However, in the early 1990s, it became apparent that in some cases, pesticide residues could pose risks resulting from a single exposure or at most a few days of exposure (= acute exposure).

Two developments have led to this recent change in focus. First, as chronic dietary exposure methodology has improved, there has been a move away from worst case estimates of chronic dietary exposures. In the past, there were always large conservative assumptions to account for lack of data. Now, with more data available, the chronic dietary exposures are more realistic, and this has directed more attention to a greater need for an explicit consideration of acute dietary exposure (WHO, 2008a/b). Second, research on residues of acutely toxic pesticides (organophosphates and carbamates) in individual fruits and vegetables revealed random occurrences of comparatively high residue levels. Those people who consume significant amounts of such foods are at risk of consuming such a ‘hot’ commodity unit (Harris, 2000).

As for chronic exposure, acute dietary exposure assessments may be deterministic (point values) or distributional. At an international level, a deterministic methodology was developed to address the calculation of the acute dietary exposure for pesticide authorisation purposes. The methodology for estimating the acute dietary exposure to pesticide residues was initially developed by several international meetings (WHO, 1997; JMPR, 1999a; PSD, 1999). The 1997 Geneva consultation (WHO, 1997) recommended the development of a food consumption database for two population groups: the entire population (general population) and children (ages 6 years and under). Subsequently, the methodology was refined by JMPR (JMPR, 1999b, 2000, 2002, 2003, 2005, 2006) and updated in a FAO/WHO workshop (WHO, 2008a/b). The EU has also adopted this approach in 1999, but did not adopt all changes introduced by JMPR subsequently (see section 6.1.3).

For pesticide authorisation purposes acute exposure to pesticides is estimated using a deterministic approach (point estimate). The point estimate is a worst case scenario and is also referred to as the international or national estimate of short-term intake (IESTI or NESTI). In this approach it is assumed that a person consumes a LP within a meal or 24 hours, which contains a very high residue level. In this methodology, the acute exposure estimates are performed for each commodity individually (raw or processed). Acute exposures for the different commodities are not summed as in the chronic exposure, but are each evaluated on their own (point estimate), as it is unlikely that an individual will consume, within a meal or 24 hours, a LP of more than one food containing the highest residue level (the one that incorporates the variability factor). The LP is not a sum of the total consumption of all foods containing a certain commodity, but is linked to the way the food is consumed: as raw, as juice, as cooked etc. To assess whether the application of a pesticide has no adverse consequences for public health, the limit value from the toxicological dossier for acute exposure (ARfD, acute reference dose) is compared to the estimated acute dietary exposure. Although refinement is possible by way of a probabilistic approach, this refinement is not performed for pesticide authorisation purposes.

6.1.1 Current IESTI/NESTI equations

Currently, four different situations are distinguished for the IESTI or NESTI estimation, each with a specific mathematical method: Case 1, Case 2a, Case 2b, Case 3. The outcome of the IESTI or NESTI equation is compared to the ARfD. When the ARfD is exceeded a risk for the consumer cannot be excluded.

The following abbreviations are used in the IESTI/NESTI equations:

U_{RAC} = unit weight of the raw agricultural commodity (RAC), e.g. orange with peel (kg).
U_e = unit weight of the raw edible portion, e.g. orange without peel (kg).
U_P = unit weight of the primary processed commodity, e.g. raisins (kg).
LP = largest consumed portion of a commodity by 97.5th percentile of consumers of an age/population group (kg/person/day); obtained from g/kg bw/day commodity consumption value x 0.001 (conversion g to kg) x average bw of an age/population group (in kg) or set manually if the LP from the database is not considered reliable (see section 4.3.2).
ν = variability factor for a certain commodity.
HR = highest residue level in the raw edible portion (EP) of composite samples for a certain RAC (mg/kg).
HR-P = highest residue level, where processing of the commodity (mg/kg) is taken into account. HR-P is calculated by multiplication of the highest residue in a composite sample of the RAC with the processing factor.
STMR = Supervised Trial Median Residue in the EP of composite samples for a certain commodity (mg/kg).
STMR-P = Supervised Trial Median Residue, where processing of the commodity (mg/kg) is taken into account. STMR-P is calculated by multiplication of the median residue of the RAC with the processing factor.
bw = average bodyweight of an age/population group (in kg).

Case 1

Case 1 is the simple case where the residue concentration in composite samples from residue trials (raw or processed) more or less corresponds with the residue in a meal-sized portion of the commodity; a meal-sized portion consists of several units (U_{RAC} or U_P < 25 g):

$$NESTI = \frac{LP \times HR \times \nu}{bw} \qquad \text{(expressed as mg/kg bw/day)}$$

Case 1 also applies to meat, liver, kidney, edible offal and eggs. Case 1 applies to dry pulses, oilseeds, and cereal grains if a pesticide is applied post-harvest (WHO, 2008 a/b; EFSA, 2007a). HR is replaced by HR-P for primary processed commodities (PP) consisting of individual units (not combined or mixed).

Case 2

Case 2 is the situation where the meal-sized portion as a single fruit or vegetable unit might have a higher residue level than the composite samples from residue trials (U_{RAC} or $U_P \geq 25$ g). A variability factor is introduced to correct for possible higher residues (a default factor or based on available residue data in separate pieces of fruit or vegetable). Case 2 is divided in Case 2a and Case 2b, where the unit size is less than or greater than the LP size, respectively.

Case 2a
Case 2a concerns the U_e that is smaller than the LP: (U_{RAC} or $U_P \geq 25$ g and U_e or $U_P < LP$). This means the LP consists of more than one unit.

$$NESTI = \frac{\{U_e \times HR \times \nu\} + \{(LP - U_e) \times HR\}}{bw} \quad \text{(expressed as mg/kg bw/day)}$$

The Case 2a equation is based on the assumption that the first unit contains residues at the HRxν level and the next ones contain residues at the HR level, which represents the residue in the composite from the same lot as the first one. HR is replaced by HR-P and U_e is replaced by U_P for PPs consisting of individual units (not combined or mixed).

Case 2b
Case 2b concerns the U_e that is larger than the LP: (U_{RAC} or $U_P \geq 25$ g and U_e or $U_P \geq LP$). This means the LP consists of one unit or part of a unit.

$$NESTI = \frac{LP \times HR \times \nu}{bw} \quad \text{(expressed as mg/kg bw/day)}$$

The Case 2 b equation is based on the assumption that there is only one consumed unit and it contains residues at the HRxν level. HR is replaced by HR-P for PPs consisting of individual units (not combined or mixed).

Case 3
Case 3 allows for the likely bulking and blending of PPs such as flour, vegetable oils and fruit juices. Case 3 concerns PPs that have been combined or mixed; the STMR-P value represents the likely highest residue concentration:

$$NESTI = \frac{LP \times STMR_P}{bw} \quad \text{(expressed as mg/kg bw/day)}$$

Case 3 also applies to milk. Case 3 applies to dry pulses, oilseeds and cereal grains when a pesticide is applied pre-harvest (WHO, 2008a/b; EFSA, 2007a).

Note 1
The LP (kg/person/day) should be matched to the commodity to which the HR or STMR relates. In the case of commodities that are consumed as the fresh fruit or vegetable, the LP should relate to the EP (expressed as kg EP/person/day). However, when the commodity is consumed in a processed form (e.g. grains), the LP should relate to the PP like flour or bread (expressed as kg flour/person/day and kg bread/person/day).

Note 2
The residue definition for enforcement can be different from the residue definition for risk assessment, since the latter may contain additional toxicologically relevant metabolites.

By definition, the HR, STMR, STMR-P and HR-P in the equations are based on the residue definition for risk assessment. The residue can be determined by analysing the individual components of the residue definition for risk assessment in the commodity in question, or it can be calculated from the STMR, HR, STMR-P or HR-P based on the residue definition for enforcement multiplied by a conversion factor. The individual analysis is preferred by JMPR, the use of a conversion factor is preferred by EU.

In the course of pesticide evaluation, a conversion factor is established to convert the residue for enforcement into the residue for risk assessment. The conversion factor may be different for plant and animal commodities, and even for different plant commodities.

Note 3
By definition, the STMR and HR is based on the residue level in the EP. In cases where no residue data are available for the distribution between peel and pulp, the $STMR_{RAC}$ (supervised trials median residue of the RAC) or HR_{RAC} (highest residue of the RAC) is used instead of the STMR. The $STMR_{RAC}$ and HR_{RAC} differ from the STMR and HR for commodities where the EP is not the same as the RAC (e.g. oranges, bananas).

The STMR-P and HR-P is based on the residue level in the PP. The STMR-P or HR-P is calculated as $STMR_{RAC}$ x processing factor or HR_{RAC} x processing factor , where $STMR_{RAC}$ is the supervised trials median residue of the RAC and HR_{RAC} is the highest residue of the RAC. Note that the $STMR_{RAC}$ and HR_{RAC} differ from the STMR and HR for commodities where the EP is not the same as the RAC (e.g. oranges, bananas).

Note 4
For animal commodities a special procedure is followed (JMPR, 2009)
For *kidney, liver, fat and eggs*, no distinction is made between fat and non-fat soluble pesticides.
For NESTI calculation, the HR of the animal commodity is used, together with the consumption value of that product.
For *meat from mammals and poultry*, no distinction is made between fat or non-fat soluble pesticides.
For NESTI calculation, the HR values for fat and muscle are used (separately, each). Consumption values for meat have been split into consumption as fat and as muscle. It is assumed that mammalian meat contains 20 % fat and 80 % muscle. It is assumed that poultry meat (with adhering skin) contains 10 % fat and 90 % muscle. The HR values are therefore combined with meat as 80 %/90 % muscle and with meat as 20 %/10 % fat, and not at meat as total
For *milk*, a distinction is made between fat and non-fat soluble pesticides.
For non-fat soluble pesticides, the STMR values for whole milk are used, together with the consumption values for whole milk. For fat soluble pesticides, the STMR values for cream (milk fat) are used. It is assumed that whole milk contains 4 % fat. The STMR value for cream is recalculated to whole milk by multiplying the STMR (cream) with a factor 0.04. After this correction, the consumption values for whole milk can be used.

In feeding studies only chickens, cows and sometimes pigs are tested. HRs for cow tissues and milk are also used for all other ruminants (goats, sheep). HRs for chicken tissues and eggs are also used for all other poultry (goose, turkey, duck). When there is no difference between the metabolism in poultry and ruminants, than the HRs for cow tissues are also used for all other slaughter animals.

6.1.2 History of IESTI/NESTI equations

Since its introduction in 1997, several changes to the IESTI/NESTI equations have been made.

For the Case 1 equation, the MRL-P (MRL in PP) was replaced with HR or HR-P by the 1999 JMPR (JMPR, 1999b). The main reasons for this change were that MRLs as proposed by JMPR may be significantly higher than the highest composite residue level in the residue trials because of the JMPR practice of using a geometric progression when recommending MRLs. This may lead to the IESTI not being sufficiently discriminatory to be used as a screening technique. Also, it was considered to be undesirable to round off values at an intermediate stage in the calculation. Another advantage of using the HR instead of the MRL is the fact that this gives the opportunity to take into account the total toxicologically relevant residue. To enforce MRLs, as many pesticide residues as possible are measured in one single analytical run (multi residue methods). Therefore, the residue definition (indicating the residue of concern) describing the MRL should be as simple as possible. In practice, the residue definition used for enforcement often equals the parent compound, which serves as an 'indicator molecule' but does not necessarily encompass the total residue level, since a significant part of the compound may degrade or metabolize following application. In contrast, for dietary intake calculations, one is interested in the exposure to the total amount of toxicologically relevant residue. Therefore, if necessary, a separate residue definition for dietary risk assessment is defined in which metabolites or degradation products are also included. The HR relates to this residue definition.

For the Case 2a equation, the STMR-P in the second part of the equation was replaced by the HR or HR-P by the 2000 JMPR (JMPR, 2000). In cases where a LP consumed contains more than one individual unit (Case 2a equation), it was initially assumed that the units comprising a portion may be derived from different lots. In that case, the first unit would contain residues at the level of HRxυ, and the subsequent ones would contain residues at the STMR level, which is the median value of residues in different lots. The 2000 JMPR agreed that this assumption might not reflect the actual situation, in which the supply available for consumption is likely to be derived from a single lot. Therefore, the meeting decided to replace the STMR-P in the second part of the IESTI equation by the HR or HR-P.

For the Case 3 equation, the MRL was replaced by the STMR or STMR-P by the 1999 JMPR (JMPR, 1999b, 2000) since the STMR or STMR-P was considered to be the likely highest residue in case of bulking and blending of PPs and milk.

6.1.3 Variability factor

The concept of the variability factor υ was introduced to take into account the different concentrations of residues in the individual units of which a composite sample is composed. The variability factor was defined in an FAO/WHO consultation as 'the ratio of a highest level of residue in the individual commodity unit to the corresponding residue level seen in the composite sample' (WHO, 1997) and refined by an international conference (PSD, 1999) as 'the 97.5th percentile of the residues presented in crop units divided by the mean residue of the lot residue population'.

The 2002 JMPR (JMPR, 2002) proposed variability factors for different types of commodities. The variability factor used for calculation of the acute exposure depends on the unit weight and properties of the commodity and the kind of application of the pesticide or pesticide formulation. Table 8 lists the standard variability factors that were applied (FAO, 2002, JMPR, 2002).

Table 8 Variability factors used by 2002 JMPR

Situation	Variability factor
Unit weight of the RAC $U_{RAC} < 25$ g	1
Head lettuce , head cabbage [a]	3
Unit weight of the RAC $U_{RAC} > 250$ g	5
Unit weight of the RAC 25 g $\leq U_{RAC} \leq$ 250 g	7
Unit weight of the RAC 25 g $\leq U_{RAC} \leq$ 250 g, *and* the commodity is a leafy vegetable [b]	10
Unit weight of the RAC 25 g $\leq U_{RAC} \leq$ 250 g, *and* the pesticide is a granule for soil treatment [c]	10

[a] Head lettuce includes head lettuce ('kropsla') and iceberg lettuce.
Head cabbage includes Savoy cabbage, red cabbage,white cabbage and oxheart cabbage.
[b] JMPR uses the Codex crop group definition. Codex group leafy vegetables (013) includes EU leafy brassicas like kale and Chinese cabbage and EU leafy vegetables like lettuce, scarole (endive), chicory, and fresh herbs.
[c] A variability factor of 10 is only used for granular applications up to or close to harvest, when the consumable part of the crop has started to form and where granules are likely to be retained within the crop. Not many crops may comply with this rule, since leafy vegetables and leafy brassicas have already a variability factor of 10 and when the U_{RAC} is larger than 250 g (like flowering brassicas, head cabbage, lettuce or scarole) the rule does not apply.

The mentioned variability factors are default factors. Generally, these are conservative values, i.e., they are overestimates. Variability can therefore also be calculated from field measurements of a large number of samples taken of the crop in question which has in accordance with GAP been treated with the pesticide in question. Whether the median or a higher percentile value has to be taken from this distribution as variability factor is still under debate in the EU, but a draft proposal has been made by the IUPAC Advisory Committee on Crop Protection Chemistry (Hamilton et al., 2004).

In 2002, the highest residue in a crop unit, from a sample consisting of a number of crop units at or above 90, was considered to represent the 97.5th percentile of the population in the sampled lot. This method overestimated the variability in more than 90 % of the cases, because the highest residue can be much higher than the 97.5th percentile. The Advisory Committee on Crop Protection Chemistry of the International Union of Pure and Applied Chemistry (IUPAC) took another approach to estimate variability factors and selected only those cases where 95 % or higher of the individual units had detectable residues. The initial concern was that the calculated variability would be frustrated if more than a very few of the units were non-detects. The probability of contribution, of individual residue values, to the 97.5th percentile was taken into account in the calculation of the best estimate for the variability factor. Evaluation of a wide range of studies on variability in field studies and in the market place, showed an average variability factor of 2.7 (range 1.5-7.2) for supervised trials involving approximately 8000 unit analyses for a number of pesticides over a range of crops. Based on these studies, the Advisory Committee on Crop Protection Chemistry of the IUPAC recommended that a default variability factor of 3 should be applied in the absence of more accurate information (Hamilton et al., 2004).

After discussing the work of IUPAC, the 2003 JMPR agreed to replace the default variability factors of 5 and 10 by a new default variability factor of 3 for all commodities, except for $U_{RAC} < 25$ g where a variability of factor of 1 is used (JMPR, 2003).

The 2005 JMPR (JMPR, 2005) reviewed the variability factor used in the calculation of short-term intake. Based on this review, involving the consideration of a data set of more than 22000 residue

results, including data from the FAO/IAEA Joint Division, supervised field trials and EFSA, the 2005 JMPR reconfirmed that owing to the inevitable random nature of the variability factor derived from the combined uncertainty associated with sampling and analysis, the best estimate of the default variability factor is the mean of the variability factors derived from samples of various crops. The 2005 JMPR reconfirmed that a default variability factor of 3 should be applied for $U_{RAC} \geq 25$ g if no empirically derived variability factors are available.

When only limited residue data are available, and the distribution of the residue population is not known, the resulting MRL recommendation can be substantially higher than the HR. The 2006 JMPR (JMPR, 2006b) had a concern that conducting the assessment using the HR value might not assure the safety of consumers, when the MRL is much larger than the HR.

Within EU, discussion on the most appropriate variability factor is still ongoing. The current JMPR approach to use a default variability factor of 3 (based on the mean of the variability factor distribution derived from samples of various crops) is not applied as the Member States did not support this view (EFSA, 2007a/b). EU risk managers incline to choose for a higher percentile value from the variability distribution, to cover all uncertainties.

As data collected in the framework of the EU coordinated monitoring programmes 1999 to 2002 indicated that in some cases a higher factor seemed more appropriate, the Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR panel) of EFSA was requested for a scientific opinion whether the available data justify replacing the former used variability factors with the new factor of 3.

The PPR Panel analysed the available data on unit-to-unit variation in pesticide residue estimates and concluded that 2.8 is the average variability factor for supervised trials and about 3.6 for market surveys. The Panel concluded that the ‘true’ variability factor will be underestimated in about one third of intake assessments if a default variability factor of 3 is used (EFSA, 2005).

The controversial discussion on the most suitable variability factor is still ongoing among Member States, whether the variability factors currently used in the EU MRL setting should be replaced by less conservative values. The most recent proposal made by the European Commission (EFSA, 2007c) is to use a default variability of 3 but at the same time also replace the HR in Case 1 and Case 2 equations by the MRL. This proposal is still under discussion and up to now the JMPR 2002 variability factors are still used for acute dietary risk assessments in the EU.

The 2007 JMPR (JMPR, 2007b) reacted on this EFSA opinion. The 2007 JMPR indicated that the HR refers to residues of toxicological concern present in the EP of the crop, while the MRL refers to a residue definition relevant for enforcement purposes related to the commodity in trade. When the residue definitions are the same and the whole food commodity is the EP, the maximum residue level is typically higher than the HR. The JMPR noted that, overall, IESTI using the HR as an input is a satisfactory indicator for assessing the acceptability of MRLs for the assessment of short-term dietary intake. However, from the perspective of public perception there may be benefits in estimating the IESTI from the MRL. If using the MRL in the IESTI equation, adjustments and alternatives would be needed in situations where the EP is different from the commodity to which the MRL applies, where the risk assessment definition is different from the enforcement definition and in situations where there are no detectable residues in the EP.

6.2 Dutch acute dietary risk assessment model

Within the Netherlands acute dietary risk assessment of pesticide residues has been performed since 1999, using the 1997-1998 VCP-3 database for children and general population. The Dutch acute dietary risk assessment was automated in 2000 by using an Excel based calculation model, which is owned and managed by RIVM. This model contains the equations given above as well as the commodity consumption values for the various age groups to be able to estimate dietary risk for the purpose of pesticide authorisation. After entering the residue concentrations for relevant commodities, the model compares the acute dietary exposure to the appropriate toxicological reference value (ARfD for acute risk) and provides an overview table of relevant commodities for each of the population groups.

The first version of the model was developed in 2000 and contained commodity consumption values for the general population (VCP-3, 1-97 years) and children (VCP-3, 1-6 years). The model was regularly updated to meet the current status of risk assessment procedures. In 2006 the Dutch acute dietary risk assessment models have been updated to incorporate also consumption data for babies (RIKILT, 8-12 months). However, these data were never implemented in the authorisation process, i.e. have not been used in the MRL setting process.

A revised Dutch acute dietary risk assessment model (Version 05 Dutch NESTI calculation.xlt, see addendum II) was developed to incorporate the updated food consumption data for babies/toddlers, children and general population consumption data for PPs and updated unit weights as described in the present report. Considerations in setting-up and using the model are described in sections 6.2.1 to 6.2.5.

6.2.1 Pesticide residue concentrations (HR, STMR)

The pesticide residue concentrations (HR, HR_{RAC}, STMR, $STMR_{RAC}$) needed in the NESTI equations and relevant for the Dutch situation, are obtained from supervised field trials conducted in Northern Europe in which the pesticide is applied to the crop in question according to Good Agricultural Practice (GAP) at the maximum permitted dose rate, the maximum permitted number of applications, the minimum permitted interval between applications and the minimum permitted pre-harvest interval.

Processing factors (to estimate STMR-P and HR-P) are obtained from processing studies where commodities with incurred residues are processed according to industrial or household practices. The processing factor (P-factor) is based on the residue definition for risk assessment.

$$\text{P - factor} = \frac{\text{Residue in processed product}}{\text{Residue in RAC}}$$

When there is more than one trial, the median P-factor is taken when the P-factors of the different trials are close together (relative standard deviation ≤ 40 %) and the maximum P-factor is taken when the P-factors of the different trials are far off (relative standard deviation >40 %).

The data on supervised field trials and processing studies are part of the data requirements for pesticide authorisation and are evaluated for the purpose of MRL setting and dietary risk assessment. The way the residue values are obtained from these data are described by EU, FAO and OECD (European Commission, 1995, 1997a/b, 2008; FAO, 2009; OECD, 2008a/b).

6.2.2 Commodity consumption values (LP) and bodyweights

Commodity consumption values for acute dietary risk assessment are based on the 97.5th percentile commodity consumption values for consumers-only (i.e. part of the population).

Up to now acute dietary exposure to pesticides has been calculated for 3 age/population groups: general population (age 1-97 years, based on VCP-3 database), children (age 1-6 years, based on a selection of the VCP-3 database) and babies (age 8-12 months, RIKILT-babies database). An average bodyweight of 63 kg for general population, 17 kg for children and 9.3 kg for babies was used in the NESTI equations.

In the revised Dutch acute dietary risk assessment model, LPs are available for general population (age 1-97 years, based on VCP-3 database), children (2-6 years, based on VCP-kids) and babies/toddlers (8-20 months, based on VIO-toddlers database). The reasons behind this choice are presented in section 4.1. The chosen large portion (LP-choice) for each of these databases (consumers-only) are listed as g/person/day in Appendix V and are described in section 4.3.2. For each of the age/population groups, commodity consumption values are given for individual commodities (consumed raw or processed). The individual consumption is for example the consumption of orange as raw commodity or as orange juice or as orange marmalade and may be expressed as PP and as EP. A total commodity consumption value is generally not required, except for animal products (meat, milk, eggs), since processing data are not required here.

The average bodyweight for general population was found to be 65.8 kg in stead of the 63 kg which was used up to now. No explanation could be found for this difference in bodyweight. An average bodyweight of 18.4 kg and 10.2 kg was used for children (VCP-kids database) and babies/toddlers (8-20 months, VIO-toddlers database), respectively.

Up to now, the food consumption was expressed as g RAC/person/day. In the revised Dutch acute dietary risk assessment model, the food consumption is expressed as g/kg bw/day (either as EP or as PP). For further explanation see section 4.4. The g/person/day consumption values in the revised Dutch acute dietary risk assessment model were calculated from daily average g/kg bw/day consumption x average bodyweight of the population group.

All commodity consumption values in g/kg bw/day are rounded to three decimals; the corresponding g/pers/day values are rounded to one decimal. When no consumption days are available and it is not likely that the commodity is consumed in the Netherlands, the LP is indicated as ‘NC’ (not consumed).

6.2.3 Variability factors (ν)

For commodity items larger than 25 g per unit, a meal-sized portion may contain only one or a few items and residue concentrations might be substantially above the batch average, due to variation between items. Therefore for risk assessment calculations, a variability factor is applied.

For the revised Dutch acute dietary risk assessment model the variability factors as indicated in Table 8 (section 6.1.3) are used, until EU has made a decision on the variability factors to be used.

6.2.4 Unit weights (U_{RAC} and U_e)

6.2.4.1 Unit weights to be used in the equations

For acute exposure estimations, two unit weights are needed: the U_e to be used in the Case 2a/2b calculations and U_{RAC} to decide on the variability factor to be used. The U_e can be calculated by multiplication of U_{RAC} with the edible fraction (= 1 - waste fraction and/or 1 - peel/stone fraction).

Up to now the unit weights of UK (or other European countries if UK data were not available) were used for acute exposure assessments for the Netherlands, because Dutch data were thought not to be available. But the present updated unit weights from UK can no longer be used for the revised Dutch acute dietary risk assessment model, because UK only gives data for the U_e. For estimation of the variability factor also U_{RAC} is required.

EFSA has developed the PRIMO calculation model to calculate NESTIs for different member states (EFSA, 2007a/b). For those countries that had no national unit weights available (like the Netherlands), EFSA used the average U_e from member states that have reported their unit weights. Therefore EFSA acute dietary risk assessment will differ from the risk assessment as performed in the Netherlands because other unit weights are used and this may result in other variability factors to be used. The average unit weights used by EFSA cannot be used for the revised Dutch acute dietary risk assessment model, because EFSA only gives data for the U_e. For estimation of the variability factor also U_{RAC} is required.

Both EFSA and UK use the U_e to decide on the variability factor, which is not correct, since the variability factor is defined for and measured in the RAC (FAO, 2002). The JMPR, at present, only uses the U_e in their calculations because JMPR has decided on commodities which are Case 1 or Case 3 and JMPR uses one variability factor of 3 for all other commodities. Therefore, there is no need anymore to have unit weight data on RACs. But within EU, the decision to use one variability factor of 3 for commodities which are not Case 1 or Case 3, has not been made. So in this stage, there is still a need to have both the U_e as well as the U_{RAC} to decide on which variability factor (5 or 7) to use in the calculations. Therefore, the revised Dutch acute dietary risk assessment model will continue to use both unit weights (U_e and U_{RAC}) in the calculations.

6.2.4.2 Dutch unit weights

Although is was thought that Dutch data on the unit weights were not available, waste/peel fractions and unit weights have been used in the coding of foods in the food consumption databases. These data have been available since the first Food Consumption Survey (VCP-1). Unit weights of the RAC and % edible are available in the MGC reference tables, which is updated up to 2003 (MGC, 1987, 1992, 1997, 2003).

The unit weights listed in the MGC reference table are generally based on the results of three weighings per fruit or vegetable of similar size (small, medium, large). Sometimes weights were estimated based on similar products (e.g. nectarines = peaches). The unit weights, waste/peel/stone fractions and boil down fractions listed in the MGC reference table come from published data (Lassche et al., 1964, Hulshof et al., 1983) as well as from observations made during the Food Consumption Survey collection of data (VCP-1, VCP-2, VCP-3). Different sampling locations and different growing seasons were not taken into account. Data on unit weights and % edible from the MGC 2003 reference table were supplemented with new data generated by RIVM in the period 2003-2009. An overview of these data is given in Appendix VI.

6.2.4.3 Definition of unit weights for raw commodities

EC 178/2006 lists the definition of the RAC. However, for some commodities, the unit weight of the traded commodity may differ from the unit weight of the RAC for MRL setting. The following choices were made for the revised Dutch acute dietary risk assessment model (see Appendix VI).

- *Tree nuts, peanuts and sunflower seeds* are traded as nut/seed in the shell or as nuts/seeds without shell. The RAC for MRL setting and U_{RAC} in the NESTI model refer to the nuts/seeds without shell and therefore RAC = EP. Coconuts, chestnuts and pistachios are an exception.
- *Coconuts* are traded as whole coconuts. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to the coconut without shell (i.e. coconut meat and liquid) and therefore RAC = EP.
- *Chestnuts* are traded as whole chestnuts. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to nuts with shell. The EP for chestnuts is defined as the RAC minus the shell.
- *Pistachios* are traded as nuts with shell. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to nuts without shell and therefore RAC = EP.
- *Pome fruit (apples, pears, quinces), cherries and plums* are traded as fruit with stems. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to fruits without stems. The EP for pome fruit is defined as the RAC minus core but with peel. The EP for cherries is defined as RAC minus stones. The EP for apricots, peaches/nectarines and plums is defined as the RAC minus stones, but with peel.
- *Grapes* are traded as whole bunches of grapes. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to berries without stems. Since stems are removed, RAC = EP.
- *Currants* are traded as whole berry strings. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to the whole berry string including stems. The EP for currants is defined as the RAC minus stems.
- *Strawberries, persimmons ('kaki'), and pineapples* are traded as fruits with caps/crowns/stems. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to the fruits without the green caps/crowns/stems. For strawberries and persimmons, RAC = EP. The EP for pineapples is defined as the RAC minus peels and minus core.
- *Root vegetables* are generally traded as roots with (part of the) leaves. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to the root without leaves and tops. The EP for root vegetables is defined as the RAC minus peel or skin (if applicable).
- *Onions and shallots* are traded as bulbs with dry skins. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to the bulb without easily detachable skin. Since the weight of this skin is negligible, the weight of the traded commodity is equal to U_{RAC}. The EP for onions and shallots is defined as the RAC minus the rest of the dry skin.
- *Spring onions* are traded as onions with green leaves and washed roots. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to the whole product after removal of roots and therefore RAC = EP.
- *Tomatoes, peppers, aubergines, okra's, and courgettes* are traded as fruits with caps/crowns/stems. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to the fruits without the green caps/crowns/stems. Therefore RAC = EP, except for peppers where the EP is defined as the RAC minus seeds.
- *Sweet corn* is traded as corn-on-the-cob with part of the husks still present. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to kernels plus cob without husk. The EP for sweet corn is defined as the RAC minus the cobs.
- *Broccoli* is traded as curd with stalk and adhering leaves. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to broccoli with stalk but without the adhering leaves. The EP for broccoli is defined as the RAC minus the stalk peel.

- *Cauliflower* is traded as curd with stalk and adhering leaves. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to cauliflower without stalk and adhering leaves and therfore RAC = EP.
- *Head brassicas and leafy brassicas* are traded as cabbage with decayed leaves. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to cabbage without decayed leaves. The EP is defined as the RAC minus stalks (head cabbage, kale) or bottom parts (Brussels sprouts, Chinese cabbage), whichever is applicable.
- *Kohlrabi* is traded as bulb without roots but with adhering leaves. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to kohlrabi without roots and adhering leaves. The EP is defined as the RAC minus the skin.
- Several *leafy vegetables* are traded as commodities with decayed leaves and washed roots, e.g. lamb's lettuce, cress, purslane, turnip tops, watercress. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to plants without roots and without decayed leaves and therefore RAC = EP.
- *Fresh beans or peas without pods* are traded as beans or peas with pods. The RAC for MRL setting and the U_{RAC} in the NESTI model refer to the fresh beans or peas without pods and therefore RAC = EP.

6.2.4.4 Unit weights for different size varieties

Within one commodity there are several size varieties. For example for orange, the MGC reference table 2003 lists unit weights for small, medium and large sized varieties: 115 g, 200 g and 285 g, each with 60 % edible. Commodities with extreme size varieties are: tomatoes (cherry tomatoes, medium sized tomatoes, beef tomatoes (‘vleestomaten’), strings of tomatoes (‘trostomaten’)), onions (cocktail onions, one-year onions from seed, two-year onions from planting onions), aubergines (small Thai varieties, large varieties), carrots (small size ‘waspeen’, large size ‘winterpeen’ and bunched-up small size carrots). An example of the outcome for different tomato varieties is given in Table 9.

Table 9 Calculated exposure levels (% ARfD) for different tomato varieties

	HR mg/kg	LP [a] g/person/d	U_{RAC} g	% edible	Ue g	υ	case	% ARfD [b]
tomatoes, small (cherry tomato)	0.1	222.5	12	100%	12	1	1	1.7%
tomatoes, normal sized	0.1	222.5	110	100%	110	7	2a	6.7%
tomatoes, large (‘vleestomaat’)	0.1	222.5	268	100%	268	5	2b	8.5%
1 string 5 tomatoes (‘trostomaten’)	0.1	222.5	864	100%	864	5	2b	8.5%

Abbreviations see equations for Case 1, 2a an 2b in section 6.1.1.

[a] LP was calculated from g/kg bw/day consumption value x average bodyweight for VCP-3 general population;

[b] an ARfD of 0.02 mg/kg and average bw = 65.8 kg was taken to calculate % ARfD.

The worst case outcome of the exposure estimation for commodities with different sized varieties is difficult to predict, because of the different equations used for the different situations. The outcome depends on whether the U_{RAC} is smaller or larger than 25 g (Case 1, Case 2), whether the U_{RAC} is smaller or larger than 250 g (variability factor 7 or 5) and whether the U_e is smaller or larger than the LP (Case 2a or Case 2b). Figure 3 shows the effect on exposure (% ARfD) when U_{RAC} varies from 20-500 g at constant LP, while keeping the ARfD at 0.02 mg/kg, the residue level at 0.2 mg/kg and % edible at 100 % (U_{RAC}=U_e) . The effect was calculated for a LP varying from 20-500 g.

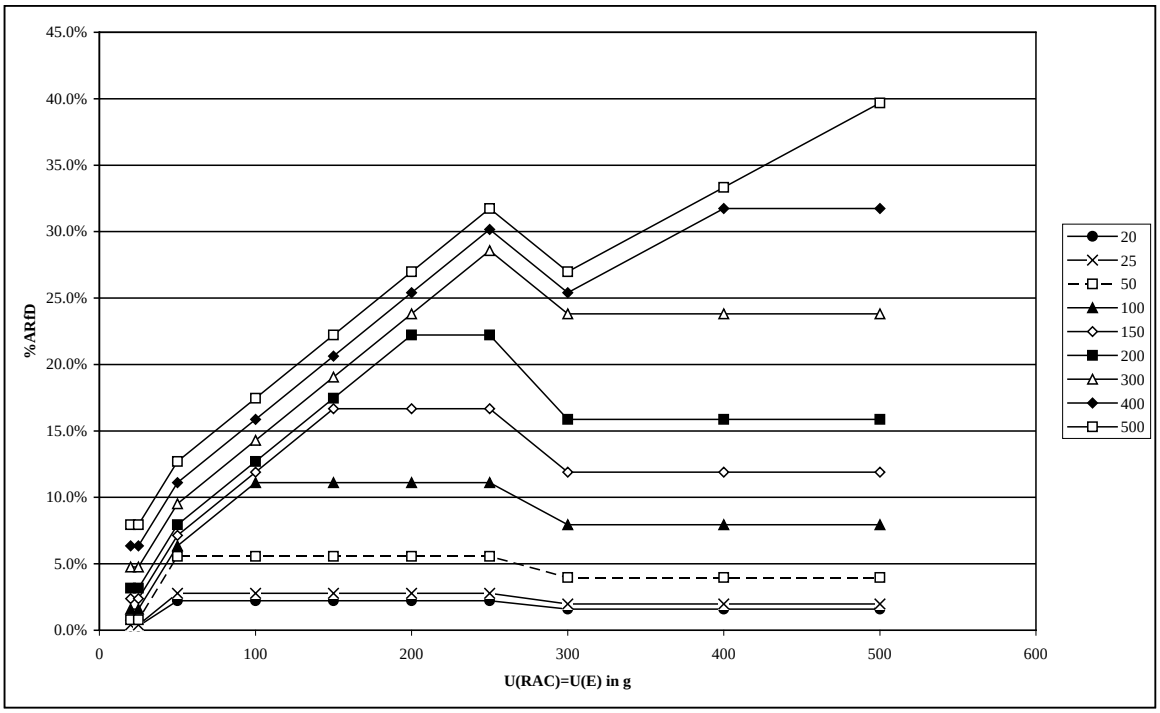

Figure 3 Effect of unit weight (U) on exposure (% ARfD) at different LPs (20-500 g)

The following conclusions can be drawn from these exercises.

- For Case 1 (U_{RAC} < 25 g) U_{RAC} or U_e have no effect on estimated exposure, because they are not included in the calculation.
- For Case 2a ($U_{RAC} \geq 25$ g en U_e < LP) both U_{RAC} and U_e affect the estimated exposure. U_{RAC} determines which variability factor has to be used ($\nu = 5$ for $U_{RAC} > 250$ g and $\nu = 7$ for 25 g < $U_{RAC} \leq 250$ g). Higher υ means higher exposure. Therefore a U_{RAC} lower than 250 g has a more worst case outcome than a U_{RAC} above 250 g. For constant LP and ν, U_e determines the outcome (and not U_{RAC}) and higher U_e means higher exposure.
- For Case 2b ($U_{RAC} \geq 25$ g and $U_e \geq$ LP) U_e has no effect on estimated exposure, but U_{RAC} has. U_{RAC} determines which variability factor has to be used ($\nu = 5$ for $U_{RAC} > 250$ g and $\nu = 7$ for 25 g $\leq U_{RAC} \leq 250$ g). Higher ν means higher exposure. Therefore a U_{RAC} lower than 250 g has a more worst case outcome than a U_{RAC} above 250 g. For constant LP and ν, U_e or U_{RAC} has no influence on the outcome, since U is not incorporated in the Case 2b equation.
- For commodities with U_{RAC} below and above 25 g (Case 1 to Case 2a/b), the commodity with the larger U_{RAC} will result in higher exposure.
- For commodities with unit weights U_{RAC} below and above 250 g (variability factor 7 or 5), the commodity with a U_{RAC} below 250 g will generally result in highest exposure. Generally, the U_{RAC}=250 g itself will result in highest exposure. When the LP is very large ($\geq$ 400 g/person), then the higher unit weights (400 g or higher) will result in higher exposure.

The effect seen in Figure 3 was calculated for a LP at a fixed bodyweight. But in practice, both the bodyweight and the LP differs for babies/toddlers, children, and general population. A lower bodyweight (babies/toddlers) will result in higher % ARfD, but a lower LP (babies/toddlers) will result in a lower % ARfD. Since lower LP may outweigh lower bodyweight, it is difficult to predict which of the three groups (babies/toddlers, children, general population) will result in highest risk.

In general, higher unit weight will lead to higher exposure. At the International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment in York in 1998 it was decided that the median unit weight should be used in the IESTI equation (PSD, 1999). The unit weight in the IESTI equation was defined as the median U_e, in kg, provided by the country in the region where the trials which gave the highest residue were carried out. But frequently other values are used like the mean or an approximate value.

In 2001, Australia aimed to gather information on the unit weight of the most commonly sold size fruits and vegetables (Bowles and Hamilton, 2001). Seasonable influences and subsequent availability may influence unit weight. Variability in unit weight was noted for oranges, beetroot, cauliflower, eggplant, fennel, leeks, radish and squash. In general, Australia selected the median values, reflecting the fact that the medium size of each commodity was commonly the most representative in the marketplace.

Because the NESTI model aims to represent a realistic worst case, the median value of the unit weights available was taken as unit weight for the risk assessment (Appendix VII). Old UK data and data from WHO GEMS/food are incorporated in Appendix VII for comparison only; they were not used in the revised Dutch acute dietary risk assessment model. In the revised Dutch acute dietary risk model the following choices were made as indicated in Appendix VII:

- *Grapes* are traded as whole bunches of grapes. The U_{RAC} refers to the berries belonging to the whole bunch of grapes and not to individual grape berries, which is in agreement with the EFSA approach (EFSA, 2007a). Bunches of about 100-125 g seem too low for the Dutch situation. Bunches are general 1-2 kg in size when sold on the market. Supermarkets generally sell grape bunches in plastic boxes of about 500 g. A unit weight of 500 g was chosen.
- *Currants* are traded as whole berry strings. The U_{RAC} refers to the whole berry string including stems and not to individual currant berries.
- *Bananas* are traded as hands of bananas. The U_{RAC} refers to a single banana, which is in agreement with the EFSA PRIMO model (EFSA, 2007b). This is however different from the WHO approach, where a hand of bananas is used as unit weight (WHO, 2003).
- *Beetroots and carrots* are traded as roots without leaves, but also as bunched-up roots with leaves (‘bosbiet’ and ‘bospeen’), usually as 10-20 carrots/bunch or 3-5 beetroots/bunch. The U_{RAC} is defined as the single root without leaves and tops.
- *Carrots* are traded as small size carrots (‘waspeen’ = wash carrot) and as large size carrots (‘winterpeen’ = winter carrot). The large size carrots are generally available in the winter period, while the small size carrots are available year-round. Because hotchpotch (prepared from winter carrots) is a favourite Dutch meal in the winter period, and therefore the large sized carrots will be on the menu very often in this season, the large sized carrots are taken as unit weight.
- *Radishes* are traded as bunched-up roots with leaves (usually 20 radishes/bunch). The U_{RAC} refers to a bunch of 20 roots without leaves. In this way, also the larger radish varieties which are mentioned in the EC 178/2006 list (black radish, Japanese radish) are covered by the unit weight.
- *Spring onions* are traded as bunches of 3-5 onions. The U_{RAC} refers to a single onion with leaves.
- *Tomatoes* are traded as single units or as tomatoes on a string (‘trostomaten’). The U_{RAC} refers to single units. Single tomatoes are traded as small sized tomatoes (cherry tomatoes), medium sized tomatoes (regular tomatoes) and large sized tomatoes (beef tomatoes, ‘vleestomaten’). The U_{RAC} refers to the median value of single units of medium and large sized tomatoes.
- *Garlic* is traded as a bulb with several cloves. The U_{RAC} refers to the single clove and not to the bulb of the garlic, which is in agreement with the EFSA approach (EFSA, 2007a).

- *Spinach* is traded as single leaves or as individual plants without roots. The U_{RAC} refers to the single leaves without roots as is in agreement with the EFSA approach (EFSA, 2007a). Most EU Member States assume that spinach is usually harvested as individual leaves (U_{RAC} < 25 g) and not as a whole crop.
- *Watercress* is traded as a bunch of plants with washed roots. The U_{RAC} refers to single plants without roots as is in agreement with the EFSA approach (EFSA, 2007a).
- *Fresh herbs* are traded as plants in pots with soil or as bunches of leaves/branches. The U_{RAC} in the NESTI model refers to single leaves/branches.
- *Bleach celery* is traded as plant with part of the leaves and without roots. The RAC for MRL setting and the U_{RAC} in the NESTI model refers to the plant as traded and not to individual stalks as some countries do (WHO, 2003).

6.2.4.5 Unit weights for related commodities

The EC 178/2006 list includes also related commodities for which the same MRL applies. For example grapefruit includes sweetie, ugli and pomelo. Each of these related commodities has its own unit weight. In the MGC reference table 2003, the following unit weights are listed: grapefruit 250 g, 60 % edible; sweetie 240 g, 70 % edible; ugli 400 g, 65 % edible and pomelo 645 g, 59 % edible. As a general rule, the U_{RAC} and % edible for the default commodity as stated in the EC 178/2006 list is used in the exposure estimations, in this case the U_{RAC} and % edible for grapefruit. EFSA has taken the same approach by using only the unit weight for grapefruit and excluding the unit weight of pomelo reported by Belgium (EFSA, 2007a). For some commodities like head cabbage, Chinese cabbage, lettuce, cultivated mushrooms and wild mushrooms there is no default variety defined in the EC 178/2006 list. The following choices were made in the revised Dutch acute dietary risk assessment model as indicated in Appendix VII:

- For *head cabbage and Chinese cabbage*, the unit weight has no influence on the outcome of the acute dietary risk assessment. For head cabbage, the median value for all head cabbages is taken. For Chinese cabbage, the unit weight for the pe-tsai type cabbage is taken.
- *Lettuce* includes both head forming lettuces like head lettuce and iceberg lettuce as well as leafy lettuces like oak leaf lettuce, lollo biondo and lollo rosso. Although the unit weight for head forming lettuces is much larger than for leafy lettuces, the leafy lettuces have variability factors of 10 because of unit weights below 250 g, while head forming lettuces have a default variability factor of 3. Therefore exposure is worst case for leafy lettuces. In the revised Dutch acute dietary risk assessment model the median unit weight for all lettuce types is taken, which happens to be 302 g and corresponds to a variability factor of 5 for leafy vegetables with U_{RAC} > 250 g. This corresponds with the EFSA approach. In the EFSA dietary intake model (PRIMO) a variability factor of 5 was used for lettuce, because U_{RAC} > 250 g and lettuce in EU includes head lettuce and open leaf varieties (EFSA, 2007a).
- *Cultivated mushrooms* include smaller sized varieties like common mushrooms and larger sized varieties like oyster mushrooms and portobello mushrooms. Since common mushrooms are the mushrooms which are consumed most in the Netherlands, they are set as default variety.
- *Wild mushrooms* include several types of mushrooms. Since chanterelles are the mushrooms which are consumed most in the Netherlands, chanterelles are set as default variety.

6.2.4.6 Raw commodities for which no unit weight is required (Case 1 and Case 3)

For some commodities unit weight data are not required, since they are considered Case 1 or Case 3. Case 1 applies to meat, liver, kidney, edible offal and eggs. Case 1 also applies to dry pulses, oilseeds and cereal grains if a pesticide is applied post-harvest (WHO, 2008 a/b; EFSA, 2007a; FAO 2009).

Case 1 is also applicable to tree nuts (except coconut), cherries, berries and small fruits (except grapes and elderberries), dates, olives, kumquats, lychees, passion fruits, garlic single cloves, okra, Brussels sprouts, lamb's lettuce, cress single plants, land cress single plants, rucola single leaves, single leaves and sprouts of Brassica, spinach single leaves, purslane individual plants, watercress individual plants, herbs single leaves/branches, fresh legume vegetables, dried tea leaves, coffee beans, dried herbs for infusions, hops, spices (except root spice), because the U_{RAC} is < 25 g.

- Case 1 is often used for strawberries. But Case 1 was not confirmed for strawberries, since the U_{RAC} ranges from 11 to 41 g for small and large strawberries. Since unit weights above 25 g combine with variability factors of 7 and give much higher exposure estimates, the unit weight for the medium sized strawberries (18 g) was chosen (Case 1).
- Case 1 is often used for asparagus. But Case 1 was not confirmed for asparagus, since the U_{RAC} ranges from 20 to 86 g for thin and thick asparagus. For the revised Dutch acute dietary risk assessment model the median unit weight of 53 g is used.
- Case 1 is used for cultivated mushrooms. This is based on small sized common mushrooms, although larger varieties may exist (see section 6.2.4.5).
- Case 1 is used for wild mushrooms. This is based on chanterelles, although larger varieties may exist (see section 6.2.4.5).

Case 3 applies to milk (WHO, 2008 a/b; EFSA, 2007a; FAO, 2009).

Case 3 also applies to dry pulses, oilseeds and cereal grains when a pesticide is applied pre-harvest (WHO, 2008 a/b; EFSA, 2007a; FAO, 2009). Since post-harvest use on dry pulses, oilseeds and cereal grains requires Case 1, and Case 1 represents the worst case situation, Case 1 is the default value in the revised Dutch acute dietary risk assessment models for dry pulses, oilseeds and cereal grains. The same rationale may be applicable to dried tea leaves, dried herbs for infusion, coffee beans and hops.

6.2.4.7 Unit weights for primary processed commodities (PP)

Unit weights for PPs are generally not necessary, since it can be assumed that commodities are bulked or blended and Case 3 will apply. In the revised Dutch acute dietary risk assessment model, Case 3 is applied to fruit juice, coconut milk, jam/marmalade/jelly, fruit sauce/puree, canned baby food, red wine, white wine, beer, whisky, frozen vegetables, vegetable juice, vegetable sauce/puree, deep fried potatoes (chips), crisps, soymilk, tofu, vegetable oil, peanut butter, tapioca, flour (soybean/potato/carob), pasta, bran, white bread, wholemeal bread, bulgur and grits, germs, flour (cereals), wholemeal flour, pot barley, flakes, starch (maize), polished rice, husked rice, cocoa powder, sugar, tea infusions, herbal infusions, extracts (coffee, cocoa), dried vegetables, sauerkraut, soy sauce, miso, popcorn, chocolate. There are a few exceptions:

- Canned fruits (in cans or jars) can result from individual fruits with U_{RAC} < 25 g (berries) where Case 1 will apply. Canned fruits may also result from fruits which are cut into cubes/slices/pieces and which are mixed and blended before canning, for which Case 3 will apply. Exceptions are halved pears and peaches, with $U_{RAC} \geq 25$ g, which can be considered as individual fruits.
- U_{RAC} for individual dried fruits are generally below 25 g and therefore Case 1 will apply. Exceptions are dried pineapple slices, dried and candied papaya slices and dried and candied melon slices ($U_{RAC} \geq 25$ g) for which Case 3 will apply, because they are mixed/blended.
- Cooked vegetables result from household processing. Cooked vegetables may either be eaten as single units (e.g. potatoes, small carrots, Brussels sprouts) or consumed in small pieces (e.g. shred cabbage, sliced courgette, diced celeriac). It depends on the number of persons within a household and the unit weight itself, whether shred/sliced/diced commodities are consumed as single units by individual persons. For two-person households and commodities with unit

weights above 300-400 g, consuming a shred/sliced/diced commodity derived from a single unit by each of these two persons is very likely. For three-person households this unit weight threshold is increased to 450-600 g. Because it is very likely that shred/sliced/diced commodities are consumed as single units, unit weights are relevant here. Therefore unit weights for cooked vegetables are considered to be the same as the U_e corrected for a boiling factor (BF), if available. For example the U_e for celeriac is 660 x 77 % (% edible) is 508 g, while the unit weight for the cooked commodity is 508 g x 86 % (boiling factor) = 437 g. Boiling factors for several commodities are listed in Table 10 (MCG, 2003). For those commodities where boiling factors are available, no boil down is assumed.

- Canned vegetables (in cans or jars) are generally cut into small pieces and are mixed and blended before canning, for which Case 3 will apply. Exceptions are canned tomatoes, canned sweet peppers, canned asparagus and canned artichokes, with $U_P \geq 25$ g, which can be considered as individual vegetables.
- Pickled vegetables (in cans or jars) are generally cut into small pieces and are mixed and blended before canning, for which Case 3 will apply. Exceptions are gherkins, with $U_P \geq 25$ g, which can be considered as individual vegetables.

Table 10 Overview of boiling factors

Commodity	boiling factor [a]	Commodity	boiling factor [a]
pears	80 %	Chinese cabbage	70 %
beet root	85 % (boiled with peel)	kale	80 %
carrots	90 %	kohlrabi	90 %
celeriac	86 %	lamb's lettuce	58 %
Jerusalem artichokes	87 %	lettuce	67 %
parsnips	87 %	scarole	67 %
salsify	87 %	spinach	60 %
swedes	92 %	purslane	60 %
turnips	87 %	beet leaves (chard)	60 %
onions	81 %	witloof	80 %
shallots	81 %	fresh beans with pods	91 %
spring onions	80 %	fresh beans w/o pods	94 %
tomatoes	78 %	fresh peas with pods	91 %
sweet peppers	87 %	fresh peas w/o pods	92 %
aubergines	93 %	asparagus	91 %
okra	87 %	bleach celery	83 %
cucumbers	88 %	bulb fennel	83 %
courgettes	88 %	artichokes	90 %
broccoli	94 %	leeks	81 %
cauliflower	94 %	cultivated fungi	60 %
head cabbage	93 %	wild fungi	57 %
		tauge	80 %

[a] the boiling factor (MCG, 2003) needs to be multiplied with the U_e to get the unit weight of the cooked/boiled/stewed commodity

6.2.5 Acute dietary exposure calculation for primary processed commodities (PP)

When setting up the dietary risk assessment model, problems were encountered when calculating the acute dietary exposure for PPs.

6.2.5.1 NESTI calculation for PPs in case no processing data are available

Consumption values for primary processed commodities may be expressed as EP or as PP. The idea was to combine the residues in the RAC with consumption values for the EP if no processing data were available and to combine the residues in the PP (residue in RAC x processing factor) with consumption values for the PP if processing data were available. But then some problems in calculations in the NESTI were encountered, which are best illustrated by calculation of the NESTI for cooked parsnips.

NESTI calculation in case processing data are available
In case residue data are available for cooked parsnips (from processing studies), the unit weight of the cooked commodity (U_P = 0.227 kg) is combined with the consumption value for cooked parsnips (LP = 0.2000 kg/pers/day as PP for VCP-3 general population). Since U_P > LP, Case 2b applies and since U_P < 250 g, a variability factor of 7 applies. If an HR of 0.1 mg/kg in the RAC and a processing factor of 0.5 is assumed, than the residue in the cooked parsnips is 0.05 mg/kg (HR-P). This results in the following NESTI:

Calculation 1

$$NESTI = \frac{LP \times HRP \times v}{bw} = \frac{0.2000 \times 0.05 \times 7}{65.8} = 1.06 \text{ x } 10^{-3} \text{ mg/kg bw/day}$$

NESTI calculation in case no processing data are available
In case residue data are not available for cooked parsnips but only for the raw commodity, it seems logical to combine the residue of the RAC with the consumption value for the EP counterpart of cooked parsnips (LP = 0.2300 kg/person/day as EP for VCP-3 general population). But which unit weight to choose in this case? At first instance it seems logical to use the unit weights corresponding to the raw commodity (U_{RAC} = 0.272 kg; U_e = 0.261 kg). Since U_e > LP, Case 2b applies and since U_{RAC} > 250 g, a variability factor of 5 applies. If an HR of 0.1 mg/kg in the RAC is assumed this results in the following NESTI:

Calculation 2

$$NESTI = \frac{LP \times HR \times v}{bw} = \frac{0.2300 \times 0.1 \times 5}{65.8} = 1.75 \text{ x } 10^{-3} \text{ mg/kg bw/day}$$

The outcome of calculation 2 is lower than expected. A value of 2.44 x 10^{-3} mg/kg bw/day was expected based on the higher residue (residue 0.1 mg/kg in stead of 0.05 mg/kg) and the higher consumption value (0.2300 kg/person/day instead of 0.2000 kg/person/day). This is not the case because the unit weight difference results in a difference in variability factor and thus the NESTI formula has changed. Since this seems not right, at second instance, the consumption value for the EP counterpart of cooked parsnips (LP = 0.2300 kg/person/day as EP for VCP-3 general population) was combined with U_P = 0.227 kg. Since U_P < LP, Case 2a applies and since U_P < 250 g, a variability factor of 7 applies. If an HR of 0.1 mg/kg in the RAC is assumed, this results in the following NESTI:

Calculation 3

$$NESTI = \frac{\{U_e \times HR \times v\} + \{(LP - U_e) \times HR\}}{bw} = \frac{\{0.227 \times 0.10 \times 7\} + \{(0.2300 - 0.227) \times 0.1\}}{65.8} = 2.42 \text{ x } 10^{-3} \text{ mg/kg bw/day}$$

The outcome of calculation 3 lies closer to the expected value of 2.44 x 10^{-3} mg/kg bw/day, but still it seems not right that a totally different NESTI formula is used to calculate the exposure (Case 2a in stead of Case 2b). Therefore at third instance, it seems better to combine the residue of the RAC with the consumption value for cooked parsnips (LP = 0.2000 kg/person/day as PP for VCP-3 general

population) and the unit weight for cooked parsnips (U_P = 0.227 kg). In this case the same formula is used for both the residue in the RAC and the residue in the PP and the outcome of the results is only related to a difference in residue value. The consumption value represents the actual consumption of the commodity in question, it is not calculated back to the raw edible commodity. Since U_P > LP, Case 2b applies and since U_P < 250 g, a variability factor of 7 applies. If an HR of 0.1 mg/kg in the RAC is assumed, this results in the following NESTI:

Calculation 4

$$NESTI = \frac{LP \times HR \times v}{bw} = \frac{0.2000 \times 0.1 \times 7}{65.8} = 2.13 \text{ x } 10^{-3} \text{ mg/kg bw/day}$$

In this case the NESTI is exactly twice as high as for calculation 1. This difference is as expected and can be explained by the residue value used: 0.05 mg/kg if processing data are available (calculation 1) and 0.1 mg/kg if no processing data are available (calculation 4). The same formula and the same consumption values are applied in both cases.

Conclusion
Since a change in consumption value (expressed as EP or PP) and a change in unit weight (for EP or PP) can be accompanied by a change in the NESTI formula, a different exposure might be calculated for the same PP. Therefore only the unit weights corresponding to the PP and the actual consumption values are relevant.

To solve the problem, the large portion consumption values for PPs are combined with unit weights for PPs in the revised Dutch acute dietary risk assessment model. Actual consumption values for commodities consumed in raw form are expressed as EP, while actual consumption values for commodities consumed in processed form are expressed as (PP). Since processing data are not considered relevant for products of animal origin (OECD 2008a), the average total commodity consumption is still used for products of animal origin.

6.2.5.2 NESTI calculation for diluted PPs

The conclusion to use only the consumption values expressed as PP as indicated for chronic and acute exposure (see sections 5.2.3 and 6.2.5.1) had some consequences for highly diluted PPs. The consequences are best illustrated by calculation of the NESTI for tea infusion.

NESTI calculation for diluted PPs in case no processing data are available
In case residue data are not available for tea infusion but only for the raw commodity (i.e. dry tea leaves), normally the residue of the RAC would be combined with the consumption value for the EP counterpart of tea infusion (LP = 0.0129 kg/person/day as EP for VCP-3 general population). For tea infusion Case 3 applies. If we assume an STMR of 1.0 mg/kg in the RAC this results in the following NESTI:

Calculation 1

$$NESTI = \frac{STMR \times LP}{bw} = \frac{1.0 \times 0.0129}{65.8} = 1.96 \text{ x } 10^{-4} \text{ mg/kg bw/day}$$

But in sections 5.2.3 and 6.2.5.1 it was decided to use only the consumption values for the PPs since these represent the actual consumption value. For tea infusion, this implies that the consumption value for tea infusion (LP = 1.3353 kg/person/day as PP for VCP-3 general population) is combined with the

residue value for the RAC (dry tea leaves). For tea infusion Case 3 applies, so in this case there is no change in NESTI formula. If an STMR of 1.0 mg/kg in the RAC is assumed, this results in the following NESTI:

Calculation 2

$$NESTI = \frac{STMR \times LP}{bw} = \frac{1.0 \times 1.3353}{65.8} = 203 \text{ x } 10^{-4} \text{ mg/kg bw/day}$$

The outcome of calculation 2 is a factor 100 higher than for calculation 1, which is attributed to dilution only. The dietary exposure is overestimated by expressing the consumption value as PP. By using a default processing factor of 0.01, equal to the dilution factor, a more realistic outcome will be calculated. For tea infusion, this implies that the consumption value for tea infusion (LP = 1.3353 kg/person/day as PP for VCP-3 general population) is combined with the residue value for the RAC (dry tea leaves) and a default processing factor of 0.01. If an STMR of 1.0 mg/kg in the RAC is assumed, this results in the following NESTI:

Calculation 3

$$NESTI = \frac{STMR \times PF \times LP}{bw} = \frac{1.0 \times 0.01 \times 1.3353}{65.8} = 2.03 \text{ x } 10^{-4} \text{ mg/kg bw/day}$$

In this way the outcome of the RAC residue combined with the consumption value for the PP (calculation 3) will be the same as for the RAC residue combined with the consumption value for the EP counterpart of the primary processed commodity (calculation 1).

Conclusion

Since combination of RAC residues with consumption values for diluted commodities (expressed as PP) will overestimate the dietary intake of pesticide residues, a default processing factor is used in the revised Dutch chronic and acute dietary risk assessment models to compensate for the dilution. Processing data will not be required as long as the ADI or ARfD is not exceeded using this default processing factor. In case processing data are available, the default processing factor should be replaced by the actual processing factor, which is expected to be lower than the default processing factor for dilution because of degradation of the residue. Table 11 lists the default processing factors for diluted PPs in case they are expressed as PP and need to be combined with a residue for the raw commodity.

Table 11 Default processing factors (PF) for diluted primary processed commodities

RAC	processing	PF [a]	RAC	processing	PF [a]
barley	whisky	0.03	oats	cooked	0.40
barley	beer	0.19	rice	polished (cooked)	0.40
maize	beer	0.19	rice	husked (cooked)	0.40
millet	beer	0.19	rye	cooked	0.40
rice	beer	0.19	sorghum	cooked	0.40
rye	beer	0.19	wheat	cooked	0.40
sorghum	beer	0.19	dry hop cones	beer	0.002
wheat	beer	0.19	coffee beans	extract	0.04
dry beans	cooked	0.40	cocoa beans	extract	0.03
dry beans	canned	0.40	dry tea leaves	infusion	0.01
dry beans	canned babyfood	0.40	dry camomille flowers	infusion	0.01
dry lentils	cooked	0.40	dry hybiscus flowers	infusion	0.01
dry peas	cooked	0.40	dry rose petals	infusion	0.01
dry peas	canned	0.40	dry jasmin flowers	infusion	0.01
dry lupins	cooked	0.40	dry lime (linden)	infusion	0.01
dry soyabean	cooked	0.40	dry strawberry leaves	infusion	0.01
barley	cooked	0.40	dry rooibos leaves	infusion	0.01
barley	pot barley (cooked)	0.40	dry mate	infusion	0.01
buckwheat	cooked	0.40	dry valerian roots	infusion	0.01
maize	cooked	0.40	dry ginseng roots	infusion	0.01
millet	cooked	0.40	other herbal infusions	infusion	0.01

[a] the default processing factor is equal to the dilution factor, which is calculated from the consumption value expressed as EP divided by the consumption value expressed as PP.

6.2.5.3 NESTI calculation for concentrated PPs

The conclusion to use only the consumption values expressed as PP as indicated for chronic and acute exposure (see sections 5.2.3 and 6.2.5.1) had some consequences for highly concentrated PPs. The consequences are best illustrated by calculation of the NESTI for raisins (dried table grapes).

NESTI calculation for diluted commodities in case no processing data are available
In case residue data are not available for raisins (dried table grapes) but only for the raw commodity (i.e. table grapes), normally the residue of the RAC would be combined with the consumption value for the EP counterpart of raisins (LP = 0.2499 kg/person/day as EP for VCP-3 general population). For raisins Case 1 applies, U < 25 g, ν = 1. If an HR of 0.5 mg/kg in the RAC is assumed, this results in the following NESTI:

Calculation 1

$$NESTI = \frac{HR \times LP \times \nu}{bw} = \frac{0.5 \times 0.2499 \times 1}{65.8} = 1.9 \text{ x } 10^{-3} \text{ mg/kg bw/day}$$

But in sections 5.2.3 and 6.2.5.1 it was decided to use only the consumption values for the PPs since these represent the actual consumption. For raisins, this implies that the consumption value for raisins (LP = 0.0806 kg/person/day as PP for VCP-3 general population) is combined with the residue value for the RAC (grapes). For raisins Case 1 applies, U < 25 g, υ = 1. If an HR of 0.5 mg/kg in the RAC is assumed, this results in the following NESTI:

Calculation 2

$$NESTI = \frac{HR \times LP \times \nu}{bw} = \frac{0.5 \times 0.0806 \times 1}{65.8} = 0.61 \text{x } 10^{-3} \text{ mg/kg bw/day}$$

The outcome of calculation 2 is a factor 3.1 lower than for calculation 1, which is attributed to concentration only. The dietary intake of pesticide residues is underestimated by expressing the consumption value as PP. By using a default processing factor of 3.10, equal to the concentration factor, a more realistic outcome will be calculated. For raisins, this implies that the consumption value for raisins (LP = 0.0806 kg/person/day as PP for VCP-3 general population) is combined with the residue value for the RAC (grapes) and a default processing factor of 3.10. If an STMR of 0.5 mg/kg in the RAC is assumed, this results in the following NESTI:

Calculation 3

$$NESTI = \frac{HR \times PF \times LP \times \nu}{bw} = \frac{0.5 \times 3.10 \times 0.0806 \times 1}{65.8} = 1.9 \text{ x } 10^{-3} \text{ mg/kg bw/day}$$

In this way the outcome of the RAC residue combined with the consumption value for the PP (calculation 3) will be the same as for the RAC residue combined with the consumption value for the EP counterpart of the primary processed commodity (calculation 1).

Conclusion

Since combination of RAC residues with consumption values for concentrated primary processed commodities (expressed as PP) will underestimate the dietary intake of pesticide residues, a default processing factor is used in the revised Dutch chronic and acute dietary risk assessment models to compensate for the concentration. Processing data will not be required as long as the ADI or ARfD is not exceeded using this default processing factor. In case processing data are available, the default processing factor should be replaced by the actual processing factor, which is expected to be lower than the default processing factor for concentration because of degradation of the residue. Table 12 lists the default processing factors for concentrated PPs.

Table 12 Default processing factors (PF) for concentrated primary processed commodities

RAC	processing	PF [a]	RAC	processing	PF [a]
apples	dried	4.73	chili peppers	dried	7.00
pears	dried	4.04	aubergines	dried	5.00
apricots	dried	4.11	courgettes	dried	5.00
cherries	dried	3.00	melons	dried and candied	2.00
peaches	dried	3.00	sweet corn	dried	5.00
plums	dried	3.09	broccoli	dried	5.00
table grapes	dried	3.10	cauliflower	dried	5.00
strawberrries	dried	3.00	head cabbage	dried	5.00
blueberries	dried	3.00	kale	dried	5.00
cranberries	dried	3.00	spinach	dried	5.00
currants	dried	3.00	chervil	dried	5.18
dates	dried	2.00	celery leaves	dried	5.00
figs	dried	2.00	parsley	dried	5.18
table olives	dried	2.00	sage	dried	9.80
carambola	dried	5.00	rosemary	dried	9.80
persimmon	dried	5.00	thyme	dried	9.80
lychee	dried	5.00	basil	dried	5.18
bananas	dried	3.00	tarragon	dried	9.80
mangoes	dried	3.00	other fresh herbs	dried	7.00
papaya	dried and candied	2.00	fresh beans with pods	dried	5.00
pineapple	dried	3.00	fresh peas w/o pods	dried	5.00
potatoes	dried (granules/flakes)	9.50	asparagus	dried	5.00
carrots	dried	5.00	leeks	dried	5.00
celeriac	dried	9.74	cultivated fungi	dried	5.00
parsnips	dried	5.00	wild fungi	dried	4.00
garlic	dried	9.80	ginger	dried and candied	2.00
onions	dried	5.00	turmeric	dried	5.00
tomatoes	dried	5.00	other root spices	dried	5.00
sweet peppers	dried	5.00			

[a] the default processing factor is equal to the concentration factor, which is calculated from the consumption value expressed as EP divided by the consumption value expressed as PP.

7 Impact of model revision on dietary risk assessment

7.1 Overview of changes introduced

To assess the impact of the changes introduced in the revised Dutch dietary risk assesment models on dietary risk assessment for pesticide authorisation purposes, the outcome of the old Dutch chronic and acute dietary risk assessment models was compared to the outcome of the revised Dutch chronic and acute dietary risk assessment models.

Four changes in the consumption value calculations can be distinguished which have impact on the outcome of the dietary risk assessment:

1. change in food consumption database;
2. changes in commodity conversion;
3. change from total to individual commodity consumption values;
4. change of g/person/day to g/kg bw/day as starting point.

In addition three other changes have been made which have impact on the outcome of the dietary risk assessment:

5. change in average bodyweight;
6. manual adaptation of calculated large portions;
7. change in unit weights.

Point 6 and 7 are only relevant for acute dietary risk assessment.

7.1.1 Change in food consumption database

In the old Dutch chronic and acute dietary risk assessment models, the consumption values are based on three age/population groups: the RIKILT-babies database (age 8-12 months), the VCP-3 children database (age 1-6 years) and the VCP-3 general population database (age 1-97 years). In the revised Dutch chronic and acute dietary risk assessment models, the consumption values are based on the same age/population groups, but resulting from different food consumption databases for babies/toddlers and children: the VIO-toddlers database (age 8-20 months), the VCP-kids database (2-6 years). For more details see sections 2.1 and 4.1.

Note. Although consumption values for babies/toddlers were available in the old Dutch acute dietary risk assessment models, they were never implemented in the actual Dutch pesticide authorisation process, and as such have not been used in the MRL setting process. The old Dutch chronic dietary risk assessment model did not contain babies/toddlers data at all.

7.1.2 Changes in commodity conversion

In the old Dutch chronic and acute dietary risk assessment models foods are converted back to their RAC counterparts, while in the revised Dutch chronic and acute dietary risk assessment models foods are converted back to their EP counterparts or to their PP counterparts. In the old Dutch chronic and acute dietary risk assessment models, fats and oils are not converted back to their RAC counterparts, but are listed as such without specification of origin (i.e. total fats and oils). In the revised Dutch chronic and acute dietary risk assessment models, oils and fats are listed according to their origin (i.e. sunflower oil is listed under sunflower seed). In the old Dutch chronic and acute dietary risk

assessment models commodities are listed according to EC 90/642, while in the revised Dutch chronic and acute dietary risk assessment models, commodities are listed according to EC 178/2006. This may have impact on commodities which are taken as individual commodities in the old Dutch chronic and acute dietary risk assesment models and are taken as grouped commodities in the revised Dutch chronic and acute dietary risk assessment models, e.g. peaches and nectarines, spinach and turnip tops, and meat of chicken, duck and turkey. For more details see sections 3.2 and 3.3.

7.1.3 Change from total to individual commodity consumption values

In the old Dutch chronic and acute dietary risk assessment models, the consumption values are based on the total commodity consumption values only: expressed as RAC in the chronic dietary risk assessment models and expressed as EP in the acute dietary risk assessment models. In the revised Dutch chronic dietary risk assessment models, the consumption values are based on individual commodity consumption values, if necessary corrected for dilution or concentration. Individual consumption values for commodities consumed in raw form are expressed as EP, while individual consumption values for commodities consumed in processed form are expressed as PP. Since processing data are not considered relevant for products of animal origin (OECD 2008a), the average total commodity consumption is still used for products of animal origin. For more details see sections 4.3, 5.2.3 and 6.2.5.

7.1.4 Change of g/person/day to g/kg bw/day as starting point

In the old Dutch chronic and acute dietary risk assessment models the g/person/day distribution of consumption values is used as starting point, while in the revised Dutch chronic and acute dietary risk assessment models the g/kg bw/day distribution of consumption values is used as starting point. For chronic exposure the average value of these distributions is taken, while for acute exposure the 97.5^{th} percentile value of these distributions is taken. For more details see section 4.4.

7.1.5 Change in average bodyweight

A change in food consumption database corresponds with a change in average bodyweight. In the old Dutch chronic and acute dietary risk assessment models, bodyweights are 9.3 kg for the RIKILT-babies database (age 8-12 months), 17 kg for the VCP-3 children database (age 1-6 years) and 63 kg for the VCP-3 general population database (age 1-97 years). In the revised Dutch chronic and acute dietary risk assessment models, bodyweights are 10.2 kg for VIO-toddlers database (age 8-20 months) and 18.4 kg for the VCP-kids database (2-6 years). Unexpectantly also the bodyweight for the VCP-3 general population database (1-97 years) changed from 63 kg to 65.8 kg. No explanation could be found for this change in bodyweight.

7.1.6 Adaptation of calculated large portions

In the old Dutch acute dietary risk assessment model, the calculated large portions as derived from the food consumption databases are used as such. For the revised Dutch acute dietary risk assessment model, the calculated large portions (LP-max) as derived from the food consumption databases are assessed before use. When there was reason to believe that the calculated large portions (LP-max) derived from the food consumption databases were too low or too high or when no consumption data were available, a more reasonable or estimated value is used in the revised Dutch acute dietary risk assessment model. For more details see section 4.3.2.

7.1.7 Change in unit weight

In the old Dutch acute dietary risk assessment model, unit weights derived from UK are used. In the revised Dutch acute dietary risk assessment model, national Dutch unit weights are used. A change in unit weight may be accompanied by a change in variability factor and a change in NESTI equations. For more details see section 6.2.4.

7.2 Impact of the changes introduced

To assess the impact of the changes introduced in the revised Dutch dietary risk assesment models on dietary risk assessment for pesticide authorisation purposes, the outcome of the old Dutch chronic and acute dietary risk assessment models was compared to the outcome of the revised Dutch chronic and acute dietary risk assessment models. The comparison between the old and revised models was made in two ways:

a) using default residue values for all commodities;
b) using existing pesticide MRLs for authorised uses only.

7.2.1 TMDI and NESTI calculation using default residue values

Default residue values can be entered in each of the models to assess whether the revised models will have impact on existing MRLs, which commodities are expected to contribute most to pesticide intake and which commodities differ most between the old and revised Dutch chronic and acute dietary risk assessment models.

For chronic dietary risk assessment, a residue value of 0.1 mg/kg (MRL) was entered for each commodity in the old and revised Dutch chronic dietary risk assessment models and the TMDI obtained (for all commodities) was compared to an ADI of 0.01 mg/kg. There is no old model for babies/toddlers. Results are shown in Table 13.

For acute dietary risk assessment, a residue value of 0.1 mg/kg (either STMR or HR) was entered for each commodity in the old and revised Dutch acute dietary risk assessment models and the individual NESTIs obtained were compared to an ARfD of 0.1 mg/kg. Results are shown in Table 13.

As is shown in Table 13, TMDIs and maximum NESTIs for the revised Dutch chronic and acute dietary risk assessment models are similar or slightly lower than those for the old Dutch chronic and acute dietary risk assessment models. Based on these results, no impact on existing MRLs is expected for the revised model. It should however be noted that babies/toddlers have not been included in the dietary risk assessment up to now and, based on the results in Table 13, consumer risk for babies is expected to be a factor 1.5-2.0 higher than for children. If babies/toddlers are included in the consumer risk assessment, this may have impact on existing MRLs for those pesticides for which TMDIs > 50 % ADI or NESTIs > 50 % ARfD have been estimated for children.

Table 13 Dietary risk assessment using default values

	Babies old	Babies revised	Children old	Children revised	Gen pop old	Gen pop revised
Chronic						
TMDI [a]	-	11.051	7.262	5.813	2.505	2.514
% ADI	-	110.5%	72.6%	58.1%	25.0%	25.1%
Acute						
maximum NESTI [a]	12.366	13.849	8.947	8.870	5.294	5.522
maximum % ARfD	12.4%	13.8%	8.9%	8.9%	5.3%	5.5%

- no dietary risk assessment model available

[a] expressed as µg/kg bw/day

Table 14 and 15 show the top ten commodities for which TMDIs and NESTIs are highest in the revised Dutch chronic and acute dietary risk assessment models. For chronic exposure, TMDI's per commodity have been calculated based on summed individuals of the commodity in question (whether expressed as EP or as PP and corrected for dilution or concentration) to get a commodity based overview. For acute exposure, if a particular commodity has two NESTI's in the top ten list (e.g. potatoes fried and potatoes boiled), then only the highest of these two is listed in Table 15, to get a commodity based overview. The top ten commodities have the highest impact on the outcome of dietary risk assessments, although this may depend on proposed MRLs for individual commodities.

Table 14 Top ten commodities in revised Dutch chronic dietary risk assessment model

TMDI (µg/kg bw/d) and % ADI VIO-toddlers (8-20 months)		**TMDI (µg/kg bw/d) and % ADI VCP-kids (2-6 years)**		**TMDI (µg/kg bw/d) and % ADI VCP-3 general population (1-97 years)**	
cattle milk	5.973, 59.7%	cattle milk	2.444, 24.4%	cattle milk	0.847, 8.5%
apples	0.985, 9.8%	apples	0.541, 5.4%	potatoes	0.208, 2.1%
bananas	0.536, 5.4%	sugarbeet roots	0.422, 4.2%	wheat	0.193, 1.9%
potatoes	0.410, 4.1%	wheat	0.411, 4.1%	sugarbeet roots	0.143, 1.4%
wheat	0.396, 4.0%	potatoes	0.289, 2.9%	apples	0.137, 1.4%
pears	0.391, 3.9%	bananas	0.193, 1.9%	oranges	0.101, 1.0%
sugarbeet roots	0.263, 2.6%	oranges	0.142, 1.4%	swine meat	0.095, 1.0%
oranges	0.222, 2.2%	swine meat	0.110, 1.1%	bovine meat	0.073, 0.7%
table grapes	0.154, 1.5%	pears	0.109, 1.1%	wine grapes	0.044, 0.4%
bovine meat	0.105, 1.0%	table grapes	0.103, 1.0%	tomatoes	0.037, 0.4%

* TMDI and % ADI calculated using 0.1 mg/kg as pesticide residue value and 0.01 mg/kg as ADI, based on summed individuals of commodity in question (corrected for default dilution/concentration)

Table 15 Top ten commodities in revised Dutch acute dietary risk assessment model

NESTI (µg/kg bw/d) and % ARfD babies/toddlers (VIO-toddlers, 8-20 months)		**NESTI (µg/kg bw/d) and % ARfD children (VCP-kids, 2-6 years)**		**NESTI (µg/kg bw/d) and % ARfD general population (VCP-3, 1-97 years)**	
pears, raw	13.849, 13.8%	pumpkins, cooked	8.870, 8.9%	pumpkins, cooked	5.522, 5.5%
witloof, cooked	12.517, 12.5%	pears, raw	7.931, 7.9%	cauliflower, cooked	4.166, 4.2%
apples, raw	10.778, 10.8%	pineapples, raw	7.875, 7.9%	cattle milk, total	3.856, 3.9%
cattle milk, total	10.399, 10.4%	oranges, raw	7.119, 7.1%	melons, raw	3.750, 3.8%
bananas, raw	9.706, 9.7%	witloof, cooked	6.860, 6.9%	table grapes, raw	3.391, 3.4%
oranges, raw	9.546, 9.5%	table grapes, raw	6.777, 6.8%	bleach celery	3.376, 3.4%
peaches, raw	9.503, 9.5%	melons, raw	6.451, 6.5%	apples, juice	3.333, 3.3%
potatoes, fried	9.338, 9.3%	apples, raw	6.236, 6.2%	watermelons, raw	3.290, 3.3%
pumpkins, cooked	8.000, 8.0%	cattle milk	6.074, 6.1%	pears, raw	3.054, 3.1%
broccoli, cooked	7.877, 7.9%	peaches, raw	5.930, 5.9%	lettuce, cooked	2.989, 3.0%

* NESTI and % ARfD calculated using 0.1 mg/kg as pesticide residue value and 0.1 mg/kg as ARfD

To assess the impact of the changes on individual commodity results, the change is defined as revised/old, where old is the TMDI or NESTI from the old Dutch chronic and acute dietary risk assessment models and revised is the TMDI or NESTI from the revised Dutch chronic and acute dietary risk assessment models using default values. Because the revised Dutch chronic dietary risk assessment model only contained individual commodity entries, the TMDI's per commodity have been calculated based on summed individuals of the commodity in question (whether expressed as EP or as PP and corrected for dilution or concentration) to be able to make a comparison with the old Dutch chronic dietary risk assessment model. There is no old model for babies/toddlers. Because the revised Dutch acute dietary risk assessment model only contained individual commodity entries, the NESTI of the old model is compared to the maximum NESTI per commodity for the revised model.

For children in the revised Dutch chronic dietary risk assesment models a change larger than a factor 1.5 in the TMDI outcome is found for rape seed (32.1), goat's milk (16.2), sunflower seed (14.0), coconuts (12.8), limes (3.4), sheep meat (3.4), peas with pods (3.0), courgettes (2.6), pears (2.6), guava (2.6), passionfruit (2.0), currants (1.9), dry soyabean (1.7), wine grapes (1.7), table olives (1.7), mangoes (1.7), cassava and tannia (1.7), lamb's lettuce (1.7), hazelnuts (1.6), and rhubarb (1.6).

For the general population in the revised Dutch chronic dietary risk assessment model a change larger than a factor 1.5 in the TMDI outcome is found for rape seed (69.3), sunflower seed (15.2), coconuts (13.1), dates (3.2), dry soyabean (2.7), millet (2.4), elderberries (2.1), rose hips (2.0), gooseberries (1.6) and raspberries (1.5).

For babies/toddlers in the revised Dutch acute dietary risk assesment model a change larger than a factor 1.5 in the NESTI outcome is found for horses meat (25.3), goat's milk (23.6), buckwheat (9.4), fresh beans without pods (7.2), oats (3.4), cherries (3.0), barley (2.9), mangoes (2.5), dry lentils (2.4), leeks (2.2), lettuce (2.2), rice (2.1), swine liver (2.1), pumpkins (2.0), rye (2.0), swedes (2.0), table grapes (2.0), sugarbeet roots (1.9), Brussels sprouts (1.9), peanuts (1.9), sunflower seed (1.7), maize (1.6), bovine liver (1.6), swine meat (1.6), cucumbers (1.5), chicken's eggs (1.5), grapefruit (1.5), dry beans (1.5), bananas (1.5) and dry soyabean (1.5).

For children in the revised Dutch acute dietary risk assessment model a change larger than a factor 1.5 in the NESTI outcome is found for radishes (26.1), currants (16.2), pineapples (10.7), millet (9.9), fresh peas with pods (6.6), goat's milk (6.6), gherkins (5.8), maize (3.9), dry peas (3.4), barley (3.3), lettuce (3.0), lemons (2.5), sweet potatoes (2.4), apricots (2.4), rye (2.1), sheep's milk (2.0), rice (1.9), leeks (1.9), beetroot (1.8), bleach celery (1.7), cashew nuts (1.7), fresh beans without pods (1.7), mangoes (1.6) and sweet peppers (1.6).

For the general population in the revised Dutch acute dietary risk assessment model a change larger than a factor 1.5 in the NESTI outcome is found for pistachios (33.6), dry soyabean (9.6), millet (8.9), bovine liver (7.0), radishes (6.5), maize (6.0), lettuce (4.9), currants (4.8), bleach celery (4.3), gherkins (3.9), bovine fat (2.8), beetroot (2.8), horses meat (2.6), rice (2.5), swine liver (2.5), cattle milk (2.2), buckwheat (2.2), apples (2.1), broccoli (2.1), rye (2.0), sugarbeet roots (1.9), carrots (1.8), sweet chestnuts (1.8), sweet potatoes (1.7), swine fat (1.7), chicken's eggs (1.6), oats (1.5), kiwi fruit (1.5), sweet corn (1.5) and fresh beans with pods (1.5).

In addition to this, the revised Dutch acute dietary risk assesment model contains consumption and/or unit weight data for commodities, for which no data were available in the old Dutch acute dietary risk assessment model. This resulted in NESTI values in the revised Dutch acute dietary risk assessment models, which were not available in the old Dutch acute dietary risk assessment model. Only those commodities are listed where the NESTI is larger than 1 µg/kg bw/day (in parentheses), using default values of 0.1 mg/kg for pesticide residues in each commodity. This corresponds to 100 % ARfD when the ARfD is 0.001 mg/kg bw.

Babies/toddlers: scarole (6.6), papaya (3.8), asparagus (2.9), currants (2.6), gherkins (2.3), apricots (2.0), shallots (1.6), rhubarb (1.4) and aubergines (1.3).
Children: pumpkins (8.9), pomegranates (5.5), turnips (5.1), parsnips (5.1), bulb fennel (4.5), papaya (4.2), carambola (3.9), persimmon and sharonfruit (3.9), scarole (3.6), kale (2.8), salsify (2.6), Jerusalem artichokes (2.6), artichokes (2.3), watermelons (2.3), cactusfruit (2.2), guava (2.2), asparagus (2.0), shallots (1.6), coconuts (1.4) and kohlrabi (1.3).
General population: scarole (2.5), kale (2.3), parsnips (2.1), turnips (1.9), cassava and tannia (1.9), pomegranates (1.8), carambola (1.6), yams (1.4) and other spinach and similar (1.2).

7.2.2 TMDI and NESTI calculation using existing pesticide MRLs

As shown in 7.2.1, the outcome of the revised Dutch chronic and acute dietary risk assessment models is different from the old Dutch chronic and acute dietary risk assessment models. As a consequence, exposure estimates for some existing EU MRLs may now exceed the toxicological reference values (ADI, ARfD), indicating a potential health risk.

Dietary exposure depends on the pesticide and because of the various parameters involved (toxicological reference values, number of pesticide treated commodities, commodity consumption value, population group) it is not possible to say beforehand which pesticide MRLs need to be re-evaluated. Usually the acute dietary exposure is more critical than the chronic dietary exposure and dietary exposure for babies/toddlers and children is more critical than for general population. Pesticides with a low toxicological reference value (ARfD), with a large number of pesticide treated commodities, and with MRLs on commodities for which largest changes between old and revised Dutch acute dietary risk assessment models were found, are the most likely candidates for re-evaluation.

For the present report some critical pesticides were selected based on the following criteria:

- the pesticide is a fungicide, insecticide or growth regulator;
- and the pesticide is listed in Annex I of Directive 91/414/EC;
- and the pesticide has MRLs, which are listed in Annex II of Regulation EC 396/2006;,
- and the pesticide has an ARfD, which is established by EFSA;
- and the pesticide is authorized for use in the Netherlands on more than 3 crop groups;
- or the pesticide is freqently found in foods at levels exceeding the MRL in monitoring programs conducted by the Dutch Food Safety Authority (VWA).

The following pesticides were selected based on these criteria:

fungicides:	captan, chlorothalonil, famoxadone, imazalil, dithiocarbamates (maneb, mancozeb), metalaxyl-M, pyraclostrobin and thiophanate-methyl;
growth regulators:	ethephon;
insecticides:	acetamiprid, deltamethrin, fenvalerate and esfenvalerate (RR and SS), indoxacarb, lambda-cyhalothrin, pymetrozine, thiacloprid.

To assess the impact of the changes on existing MRLs the % ADI and % ARfD was calculated using the old and revised Dutch chronic and acute dietary risk assessment models.

- Residue values used in the calculation were the MRLs as listed on the EU pesticides database (European Commission, 2009) for the selected pesticides. STMRs or HRs were not used. For the dithiocarbamates, the EU Pesticides database indicates which MRLs are specific for a certain dithiocarbamate. For the present comparison all MRLs were included, irrespective of the dithiocarbamate in question. Only those MRLs were included in the dietary risk assessment, which were above the LOQ, since the EU Pesticides database does not indicate which LOQs originate from authorised use.
- The residue is based on the residue definition for enforcement. Conversion factors to convert the residue for enforcement to the residue for risk assessment were not used.
- Default processing factors as defined in the old and revised Dutch chronic and acute dietary risk assessment models were used. Processing data were not taken into account.
- The ADI and ARfD values were obtained from the EU pesticides database (European Commission, 2009) for the selected pesticides.

Results are shown in Table 16 and 17. The use of MRLs instead of STMRs or HRs, the use of the residue definition for enforcement and the omission of processing data will have an impact on the numerical outcome of the dietary exposure. **Therefore the calculations in Table 16 and 17 should be seen as a first tier assessment and should NOT be interpreted to mean that current MRLs are not safe.** To assess the safety of current MRLs, refined dietary exposure calculations would be needed. Because the aim of this exercise is to compare the old and the revised Dutch chronic and acute dietary risk assessment models, the numerical outcome of the dietary exposure is not relevant. Conclusions can be drawn from the relative differences between the old and revised Dutch chronic and acute dietary risk assessment models, as long as the same input parameters are used for both models.

Table 16 TMDI based on existing MRLs

Pesticide	% ADI Babies old	% ADI Babies revised	% ADI Children old	% ADI Children revised	% ADI Gen pop old	% ADI Gen pop revised
acetamiprid	-	7.9 %	9.4 %	5.7 %	4.8 %	3.4 %
captan	-	49.3 %	26.6 %	24.7 %	7.0 %	7.2 %
chlorothalonil	-	235.6 %	165.6 %	132.1 %	81.3 %	67.0 %
deltamethrin	-	225.4 %	195.3 %	163.8 %	93.7 %	89.1 %
(es)fenvalerate (RR and SS)	-	21.8 %	27.8 %	27.3 %	8.9 %	10.9 %
ethephon	-	35.9 %	24.0 %	23.4 %	10.2 %	9.4 %
famoxadone	-	37.0 %	23.2 %	23.3 %	21.9 %	17.0 %
imazalil	-	260.7 %	223.3 %	150.7 %	84.7 %	66.3 %
indoxacarb	-	245.3 %	152.1 %	131.7 %	74.3 %	63.6 %
λ cyhalothrin	-	161.7 %	116.6 %	91.6 %	51.0 %	47.7 %
maneb (dithiocarbamates)	-	254.7 %	181.3 %	155.2 %	67.9 %	60.4 %
metalaxyl-M	-	24.8 %	15.6 %	13.9 %	5.8 %	5.2 %
pymetrozine	-	15.5 %	15.7 %	9.7 %	7.9 %	5.9 %
pyraclostrobin	-	38.4 %	32.3 %	24.9 %	17.5 %	13.6 %
thiacloprid	-	107.4 %	69.1 %	57.4 %	28.6 %	26.9 %
thiophanate-methyl	-	12.9 %	7.3 %	6.8 %	5.0 %	4.2 %

- no dietary risk assesment model available

Table 17 Maximum NESTI based on existing MRLs

Pesticide	% ARfD Babies old[a]	% ARfD Babies revised	% ARfD Children old	% ARfD Children revised	% ARfD Gen pop old	% ARfD Gen pop revised
acetamiprid	79.0 %	331.4 %	68.3 %	190.4 %	67.2 %	149.5 %
captan	117.4 %	138.5 %	72.6 %	79.3 %	22.6 %	33.3 %
chlorothalonil	53.1 %	127.6 %	50.3 %	141.4 %	25.5 %	56.3 %
deltamethrin	489.7 %	331.4 %	335.9 %	190.4 %	178.5 %	149.5 %
(es)fenvalerate (RR and SS)	17.0 %	19.0 %	18.6 %	18.4 %	6.3 %	11.3 %
ethephon	215.1 %	257.7 %	117.6 %	315.0 %	76.7 %	127.5 %
famoxadone	33.1 %	69.1 %	58.8 %	67.8 %	31.7 %	33.9 %
imazalil	790.3 %	954.6 %	683.4 %	711.9 %	206.6 %	226.9 %
indoxacarb	156.7 %	106.0 %	107.5 %	108.4 %	50.8 %	54.3 %
λ cyhalothrin	652.9 %	883.7 %	498.4 %	483.0 %	476.0 %	327.0 %
maneb (dithiocarbamates)	293.5 %	346.2 %	181.5 %	198.3 %	79.4 %	84.8 %
metalaxyl-M	23.5 %	27.7 %	23.5 %	27.1 %	12.7 %	13.6 %
pymetrozine	44.0 %	132.5 %	29.4 %	76.1 %	26.9 %	59.8 %
pyraclostrobin	263.4 %	441.8 %	227.8 %	253.8 %	447.7 %	199.3 %
thiacloprid	117.4 %	441.8 %	124.6 %	253.8 %	119.0 %	199.3 %
thiophanate-methyl	85.0 %	95.0 %	47.9 %	59.3 %	24.8 %	22.1 %

[a] These data were never implemented in the authorisation process, i.e. have not been used in the MRL setting process.

For the pesticides investigated, chronic dietary exposure is similar between the old and revised Dutch chronic dietary risk assessment models for children and general population. But since in the old models the babies/toddlers group was not included, the babies/toddlers group may result in exceeding of the ADI, since the dietary exposure may be a factor 1.5-2.0 higher than for children. Therefore, cases where pesticide exposure to children was estimated to be 50 % of the ADI, could indicate a potential health risk for babies/toddlers.

For the pesticides investigated in Table 17, acute dietary exposure for the revised Dutch acute dietary risk assessment model is similar or higher for babies/toddlers, children and general population as compared to the old Dutch acute dietary risk assessment model. Exceeding of the ARfD and a factor 1.5 or higher increase in maximum NESTIs were found for acetamiprid (all age groups), chlorothalonil (babies/toddlers and children), ethephon (children and general population), pymetrozine (babies/toddlers), pyraclostrobine (babies/toddlers) and thiacloprid (babies/toddlers).

For the pesticides investigated in Table 17, the following commodities were responsible for exceeding of the ARfD and a factor 1.5 or higher increase in individual NESTIs in the revised Dutch acute dietary risk assessment model: grapefruit raw (babies/toddlers), apple juice (general population), table grapes raw (babies/toddlers), currant juice (all age groups), banana raw (babies/toddlers), mango raw (babies/toddlers), papaya raw (babies/toddlers and children), pineapple raw (children), sweet peppers raw (children), pumpkins cooked (babies/toddlers and children), kale cooked (children, general population), kale canned (children), kale frozen (children), kale sec processing (babies/toddlers and children), lettuce raw (children), lettuce cooked (general population), scarole raw (all age groups), scarole cooked (all age groups), scarole frozen (children), red mustard raw (general population), bleach celery cooked (children and general population), fennel cooked (children), leeks cooked (babies/toddlers and children), buckwheat grits (babies/toddlers), millet cooked (children), polished rice cooked (babies/toddlers), rice flour (children and general population).

For papaya, kale, scarole and red mustard the change is attributed to absence of data in the old Dutch acute dietary risk assessment model. For kale, scarole and red mustard no NESTI was calculated in the old models because no unit weights were available and for papaya no NESTI was calculated because papaya was not listed in the commodity list of that time. For grapefruit, apples, table grapes, currants, bananas, mangoes, pineapples, sweet peppers, pumpkins, lettuce, bleach celery, fennel, leeks, buckwheat and rice, the change is attributed to the changes introduced in the revised Dutch acute dietary risk assessment model (see section 7.1).

7.2.3 Conclusions

As shown in sections 7.2.1 and 7.2.2, the outcome of the revised Dutch chronic and acute dietary risk assessment models results in a higher estimated pesticide exposure as compared to the old Dutch chronic and acute dietary risk assessment models and this could have an impact on the risk assessments underlying some existing pesticide MRLs. In this context it should be noted that risk assessments underlying the EU MRLs are based on the worst case consumption data available from the EU Member States. Obviously, the Dutch data have not been the critical data in all calculations. However, in some instances the new Dutch data may now have become the most critical. Generally MRLs are re-evaluated every ten years. Risk managers may wish to make an inventory of critical cases for which an earlier re-evaluation might be necessary.

In the old Dutch chronic and acute dietary risk assessment models the babies/toddlers data were never implemented in the Dutch pesticide authorisation process and as such have not been used in the MRL setting process. Consumer risk for babies is expected to be a factor 1.5-2.0 higher than for children. Therefore risk managers may wish to re-evaluate existing pesticide MRLs, for which pesticide exposure to children was estimated to be > 50 % of the ADI or ARfD.

The impact on chronic dietary exposure for children and general population is considered negligible, when taking into account the uncertainty of results. The impact on acute dietary exposure for children and general population is relevant for several commodities. Risk managers may wish to re-evaluate pesticide MRLs for those pesticides where the NESTI is > 50 % of the ARfD and for which there is use on those commodities for which NESTI increases above a factor 1.5 were found or for which data have now become available in the revised Dutch acute dietary risk assessment model. As is shown in 7.2.1, this concerns at least MRLs for the following commodities: apples, currants, papaya, pineapples, sweet peppers, pumpkins, kale, lettuce, scarole, bleach celery, bulb fennel, leeks, millet, and rice. Other commodities for which MRLs may be re-evaluated are: lemons, cashew nuts, sweet chestnuts, coconuts, pistachios, apricots, carambola, persimmon and sharonfruit, kiwi fruit, cactusfruit, mangoes, pomegranates, guava, cassava and tannia, sweet potatoes, yams, beetroot, carrots, Jerusalem artichokes, parsnips, radishes, salsify, turnips, shallots, gherkins, watermelons, sweet corn, broccoli, kohlrabi, other spinach and similar, fresh beans with pods, fresh beans without pods, fresh peas with pods, asparagus, artichokes, dry peas, dry soyabean, barley, buckwheat, maize, oats, rye, sugarbeet roots, swine fat, swine liver, bovine fat, bovine liver, horses meat, cattle milk, sheep's milk, goat's milk, and chicken's eggs.

In order to accommodate a re-evaluation of existing EU-MRLs, steps have been taken to include the revised data from the Dutch dietary risk assessment models (consumption data, unit weights, bodyweights) into the EFSA dietary risk assessment model PRIMO.

8 Discussion

In the previous chapters detailed discussions were presented on the commodity conversion model (see chapter 3), the choices of the food consumption databases (see chapter 4) and the commodity consumption value calculation (see chapter 4). In addition, problems encountered in chronic and acute dietary exposure calculations when using consumption data for primary processed commodities (PP) were discussed in chapters 5 and 6. The reader is referred to those chapters for these discussions. In this chapter, more general issues regarding the current TMDI, IEDI/NEDI and IESTI/NESTI models are discussed.

8.1 TMDI and IEDI/NEDI-calculations

The concept of the TMDI and IEDI/NEDI equations was developed by WHO. The consumption levels used in the TMDI and IEDI/NEDI equations by WHO are average consumption levels based on food balance sheets (FBS). Consumption values resulting from FBS are based on a country's annual food production plus imports and minus exports, divided by the number of people in a certain country (WHO, 1997). Consumption values resulting from FBS represent an overestimate of consumption levels per person as compared to average consumption values obtained by food consumption surveys (WHO, 1997). This is because wastes, resulting from cleaning the fruits or vegetables, table scraps or excess supply, have not been taken into account. When developing the TMDI and IEDI/NEDI equations it was assumed that this overestimation using the FBS data was of such a magnitude that it compensated for a lack of information regarding the above average consumption data. However, using the IEDI/NEDI equations based on more realistic food consumption data, as is generally the case in the EU, this compensation is lost. It is noted that in the IEDI/NEDI equations this underestimation on the consumption side is compensated by very conservative assumptions on the residue side. There is however no quantitative information on whether this balances out, and this should be further investigated (EFSA, 2009).

Consumption values in the old Dutch chronic dietary risk assessment model to calculate the TMDI and NEDI were based on consumption of RACs (i.e. including waste), but the consumption values in the revised Dutch chronic dietary risk assessment models are based on consumption of the commodities as such (i.e. EP or PP). This is less worst case than the consumption values derived from FBS. As indicated above, there is concern that the average consumption value is not sufficiently protective. It could be considered to use a higher percentile of the consumption distribution in the IEDI/NEDI equation. However, since MRL-legislation is EU-harmonized and therefore also the IEDI/NEDI equation should be used in a harmonized way, such a discussion should take place at the EU level.

It should be noted that CRD in the UK already uses another approach. When making a risk assessment for chronic intake of pesticides (i.e. intake in the diet over a lifetime) estimates are made for high level rather than the average consumer in order to protect the population as a whole. CRD uses the 97.5th percentile to define such high level consumption i.e. 97.5 % of the population eats amounts of food equivalent to or lower than this level. The assumption is that dietary habits that give rise to consumption higher than this 97.5th percentile level are unlikely to be maintained over a significant part of any individual’s lifetime.

Another possibility would be to take the 97.5th percentile for critical commodities and to take the 50th percentile for all other commodities. It is recommended to have an international discussion on this subject.

8.2 IESTI/NESTI calculations

8.2.1 Default variability factor

The outcome of the IESTI/NESTI equation was shown to be very sensitive for the unit weight chosen in combination with the variability factor (see section 6.2.4). In general, a higher unit weight will lead to a higher exposure. A unit weight of 250 g gives the worst case exposure, because of the variability factor of 7 which is chosen at this unit weight. When the unit weight is higher than 250 g, the variability factor is 5, which results in lower exposure.

When a default variability factor of 3 is used for all commodities ≥ 25 g, this abrupt difference in exposure between commodities > 250 g and < 250 g will disappear. This is shown in Figure 4 where the exposure (% ARfD) was calculated as a function of unit weight ($U_{RAC}=U_e$) for 2 LPs (100 and 200 g/person/day) when using the equations for variability factors of 1, 5 or 7 and the equations for a variability factor of only 1 or 3. Then in general it can be said, that the larger the U_e, the higher the exposure. When the unit weight exceeds the LP, than there is no effect anymore of the unit weight. Since at present within the EU the default variability factors of 1, 3, 5 and 7 are maintained, this strange course of theoretical acute dietary exposure will remain.

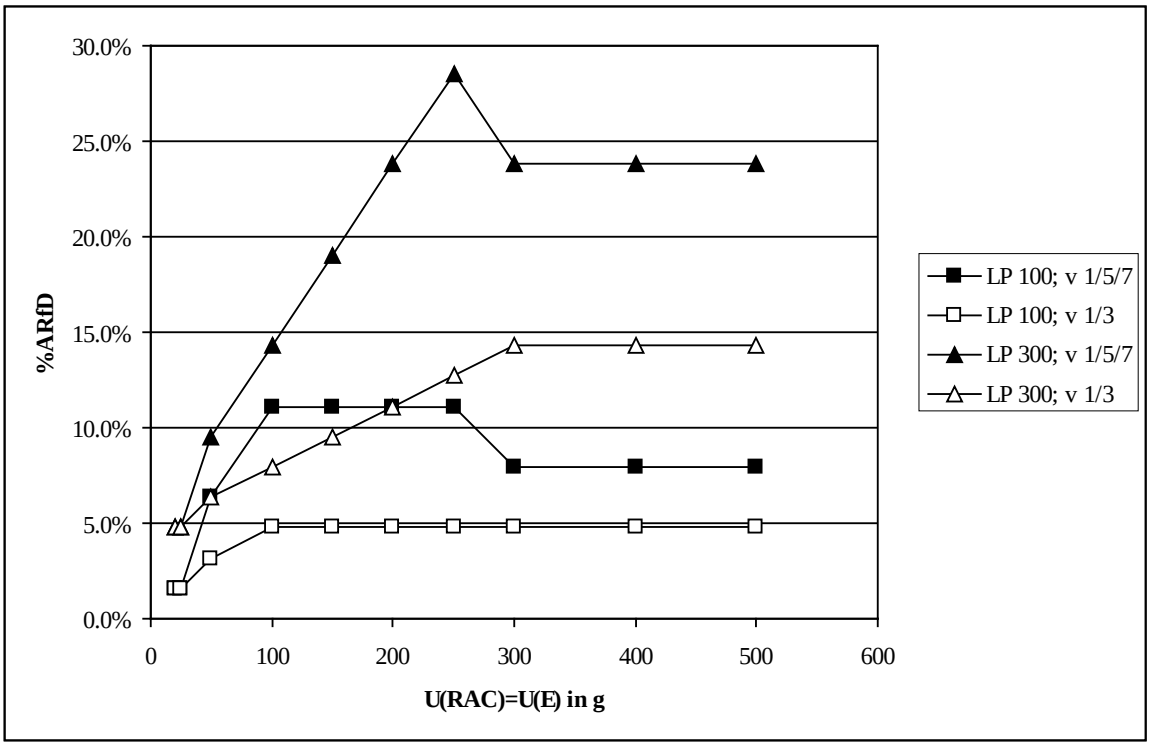

Figure 4 Effect of unit weight (U) on exposure (% ARfD) at different LPs (LP = 100 or 300 g/person) and different variability factors (**v** = 1/3 or **v** = 1/5/7)

8.2.2 Unit weights for vegetables

For vegetables, U_e is used in the IESTI/NESTI equations. However, it could be questioned whether this unit weight approach is appropriate for vegetables. Most vegetables are shredded, sliced or cut before being consumed as raw or cooked vegetable, and therefore Case 3 seems more appropriate. However, when shredded, sliced or cut, the amount consumed may still be originating from one single unit. The likelihood for this event depends on the magnitude of the household:

- For vegetables having a unit weight > 1000 g, it is likely that this is consumed as part of a single unit (LP < U) in shredded, sliced or cut form by each person in a household. Case 2 would apply.
- For vegetables having a unit weight of 500-1000 g, they might be consumed as a part of a single unit (LP < U) in shredded, sliced or cut form by each person in a one- to four-person household. Case 2 would apply. For larger households, it is likely that the vegetables are consumed mixed and therefore Case 3 would apply.
- For vegetables having a unit weight of 250-500 g, they might be consumed as part of a single unit (LP < U) in shredded, sliced or cut form by each person in a one- to two-person household. Case 2 would apply. For larger households, it is likely that the vegetables are consumed mixed and therefore Case 3 would apply.
- For vegetables having a unit weight of 100-250 g, they might be consumed as single units in shredded, sliced or cut form by one person in a one-person household. Case 2 would apply. For larger households, it is likely that the vegetables are consumed mixed and therefore Case 3 would apply.
- For vegetables having a unit weight < 100 g, it is unlikely that they are consumed as single units in shredded, sliced or cut form by one person. Case 3 would apply.

For vegetables, a cut-off unit weight limit based on a default household magnitude is needed to decide whether Case 2 or Case 3 applies. There might be some exceptions for vegetables consumed as a whole commodity, i.e. without cutting, for which the unit weight approach might be valid (e.g. potatoes, carrots, radishes, tomatoes).

The above should also be addressed at EU level.

8.2.3 Residue levels in small or large sized commodities

According to the equations used for IESTI/NESTI equation, a higher unit weight will generally lead to higher exposure. For post-harvest treatments, this may be true. But for pre-harvest treatments this seems not to be correct. For pre-harvest treatments early in the growing season, a higher unit weight of a certain commodity generally indicates longer growing periods resulting in dilution of the residue or further break down of the residue. So lower residue levels are expected in the large sized varieties compared to the small sized varieties. For pre-harvest treatments close to harvest, when the commodity has reached its final size, the volume/surface ratio determines the residue levels. Higher residues are generally found for cherry tomatoes than for normal sized tomatoes and for silver skin onions than for onions. This residue difference is found for the 1-2 kg mixed field samples of cherry tomatoes and 1-2 kg mixed field samples of normal sized tomatoes, required for supervised residue field trials, and can therefore not be ascribed to variability of one single unit within a batch. Therefore, you would expect a higher risk in consuming smaller sized varieties than in consuming larger sized varieties of a certain commodity. This risk is not reflected in the IESTI/NESTI equation.

MRLs are based on worst case residues. In case small sized varieties have higher residues, MRLs will be based on the residues in/on the smaller sized varieties. When the residues corresponding to small sized varieties are combined with unit weights for larger sized varieties in the IESTI/NESTI equation, exposure is highly overestimated. For commodities that come in very different sizes, the IESTI/NESTI equations do not seem to describe the actual situation correctly. For pre-harvest treatments a small sized Case 1 commodity should result in higher exposure than a larger sized Case 2 commodity. For post-harvest treatment variability factors of 5 or 7 seem to be too high, since variability of post-harvest treatment is generally much lower than for pre-harvest treatments. It is recommended to discuss in an international workshop the option of changing the IESTI/NESTI equations in such a way that only the residue levels are corrected, not the LP/bw ratio or U/bw ratio (as happens in Case 2a equations).

Up to now only the variability factor within a sampling lot has been investigated without any indication of the corresponding unit weight or the time period between application and harvest. It is recommended to collect data where the relationship between unit weight and residue level in combination with the variability factor within a sampling lot and time period between application and harvest is investigated. It is also recommended that for pesticide authorisation, the average unit weight of the sampling lot from supervised residue trials is recorded, to have an indication of the representativeness of the residue values which are selected from supervised residue trials. A requirement for authorisation could then be that the unit weights corresponding to selected residue values are sufficiently different in order to establish an MRL. A different outcome is expected for post-harvest treatments, pre-harvest treatments close to harvest and pre-harvest treatments early in the growing season.

A possible way forward could be to adapt the IESTI/NESTI equation as follows:

$$NESTI = F \times (HR + A)$$, where

F = commodity consumption value as g/kg bw/day;
HR = highest residue level found in a composite sample in mg/kg;
A = additional residue required based on variability within sampling lots, taking into account the actual unit weight of the composite samples and the time period between application and harvest.

8.2.4 Population groups

The large portion consumption values in the revised Dutch acute dietary risk assessment models are now based on three population groups: babies/toddlers, children and general population. The consumption values are based on the 97.5th percentile distributions expressed as g/kg bw/day.

Since the extreme g/kg bw/day consumption values in the general population group are probably derived from the low bodyweight persons (babies/toddlers, children), there is an overlap between babies/toddlers and general population and between children and general population. For future use it is suggested to take out the 1-6 years old population group from the general population group to avoid overlap in acute dietary risk assessment.

8.3 Uncertainty in dietary risk assessment

All risk assessments are subject to uncertainty. It is important to characterise the degree of uncertainty associated with risk estimates, so that it can be taken into account in risk management. Each element of the dietary risk assessment should be examined systematically for potential sources and types of uncertainty, to maximise the likelihood that important uncertainties are recognized. EFSA published guidance for dealing with uncertainty in dietary exposure assessment (EFSA, 2006).

It will be efficient to use a tiered approach to analysing uncertainties (EFSA, 2006). Each individual source of uncertainty may be analysed at one of three levels: qualitative, deterministic or probabilistic. Note that it is not necessary to treat all uncertainties in an assessment at the same level; on the contrary, it is likely to be more efficient to quantify only the most substantial uncertainties. Initially, all significant uncertainties may be analysed qualitatively. This may be sufficient, if the outcome is clear enough for risk managers to reach a decision. Otherwise, those uncertainties that appear critical to the outcome may be analysed deterministically or probabilistically. Treating the most significant uncertainties at higher tiers (deterministic and probabilistic) progressively refines the characterisation of uncertainty, and provides an increasingly clear picture of the likelihood of adverse effects.

It is important to communicate the strengths of the assessment (what is known) as well as the uncertainties. The aim should be to provide a balanced picture of what is known and what is uncertain, and avoid giving an exaggerated impression of either certainty and uncertainty.

EFSA suggests a tabular approach to help with this task. Table 18 lists uncertainties that are likely to be relevant in dietary exposure for pesticide authorisation purposes. The table was taken from an EFSA opinon on cumulative risk assessment (EFSA, 2008) and was adapted for pesticide authorisation purposes. For this reason uncertainties associated with monitoring data were either left out or changed to uncertainties associated with supervised field trials. Sources of uncertainty rated +++ or --- warrant sensitivity analysis and provide the greatest scope for refinement of the assessment.

Table 18 Qualitative influence of uncertainties on dietary exposure for pesticide authorisation purposes

Source of uncertainty/variability	**Direction and magnitude**
Residues	
* Sampling uncertainties due to limited number of supervised field trials per commodity (generally 4 or 8).	---/+++
* Sampling uncertainty due to limited number of units per composite sample.	-/+
* Measurement uncertainties in pesticide concentrations.	-/+
* Handling of data below the LOQ.	-/+
* Extrapolation to commodities for which no field trials are available.	-/+
* Residue data from supervised field trials tend to overestimate the real exposure of the consumer, due to the fact that sampling is done immediately after harvest and that at the time of consumption the residue may have declined.	+/++
* Supervised field trial data will tend to overestimate concentrations in treated produce, because field trial conditions are supposed to tend towards a worst case (e.g. maximum number and rate of applications, minimum intervals between and after treatment). This will tend to overestimate consumer exposure.	+/++
* Data on the effect of processing on residues (e.g. peeling, canning, cooking) are absent, rather limited, or incomplete and frequently based on a limited number of measurements. During the pesticide authorisation process, (additional) processing data can be requested if needed and dietary exposure can be refined.	---/+++
* Residue data for raw agricultural commodities may overestimate the real exposure of the consumer, if the concentrations in edible and non-edible parts of the raw agricultural commodities differ. During the pesticide authorisation, data on the distribution between edible and non-edible parts of the commodity can be requested and dietary exposure can be refined.	0/+++

Source of uncertainty/variability	Direction and magnitude
* Omission of potential contribution of residues from preceding rotational crops. This is generally not an issue at pesticide authorisation, since the pesticide use label will be adapted to contain restrictions to prevent residues in succeeding crops: e.g. time periods for replanting or restrictions on which rotational crops to use.	-/0
* Omission of potential contribution of residues in animal products. During the pesticide authorisation process, data on the residue distribution in livestock can be requested if needed and dietary exposure can be refined.	---/0
* Use of residue as defined for enforcement/monitoring to represent all residues of toxicological concern. If residues of toxicological concern are not included, this will underestimate the dietary exposure. However, this is only an issue if two residue definitions are needed, one for enforcement/monitoring and one for risk assessment. During the pesticide authorisation process, residue data for all relevant metabolites can be requested if needed and dietary exposure can be refined.	---/0
* Using a conversion factor to correct residues as defined for enforcement/monitoring to represent all residues of toxicological concern. This is only an issue if two residue definitions are needed, one for enforcement/monitoring and one for risk assessment. During the pesticide authorisation process, residue data for all relevant metabolites can be requested if needed and dietary exposure can be refined.	-/+
* Choice of unit weight in acute risk assessment.	--/++
* Treatment of unit to unit variation (e.g. choice of variability factor: default variability factors or variability factors from field data).	--/++
* Future change of pesticide usage/residue levels.	---/+++
Consumption data	
* Influence of survey design (method used, season, days of week).	---/++
* Use of old food consumption survey data.	--/++
* Statistical uncertainty due to limited number of persons surveyed (especially for rarely consumed commodities).	-/+
* Measurement/reporting uncertainty in consumption surveys.	-/+
* Uncertainty in estimation of food weights.	-/+
* Ambiguity in food coding descriptions.	-/+
* Extrapolation from food as consumed to commodities: the recipes used for this may include both underestimates and overestimates in different cases.	--/++
* Relation of consumption to bodyweight.	-/+
* Estimation of average daily consumption or 97.5th percentile commodity consumption value.	-/+

+, ++, +++ = uncertainty with potential to cause small, medium or large overestimation of risk (i.e.: overestimation of the ratio of exposure to ADI or ARfD, hence increased conservatism);

-, --, --- = uncertainty with potential to cause small, medium or large underestimation of risk (i.e.: underestimation of the ratio of exposure to ADI or ARfD, hence reduced conservatism).

The relative importance of these and also of other uncertainties not listed here may vary from one dietary risk assessment to the next, and should be considered case by case.

The current exercise is not a definitive assessment, since many parameters depend on the use pattern of the substance in question and the data available during the pesticide authorisation process (e.g. processing data, livestock data, rotational crop data). In a definitive risk assessment it would be essential for the risk assessor to review the uncertainties identified in Table 18 as well as uncertainties

in the toxicological assessment and arrive at a conclusion regarding the overall level of uncertainty in the risk assessment. This should be expressed in terms of the overall influence of the uncertainties on the final outcome of the assessment (e.g. can it be considered to be conservative or unconservative overall). The consumption data are generally fixed (default calculation model), but the residue data offer the possibility to refine the dietary risk assessment and decrease the level of uncertainty/variability. Since the current exercise is not a definitive assessment, such an overall evaluation has not been undertaken. However, the table above is presented as an indication of the uncertainties that will need to be considered in future assessments.

8.4 Use of the dietary risk assessment models for other purposes

The revised Dutch chronic and acute dietary risk assessment models are intended for pesticide authorisation purposes (i.e. MRL setting). But in practice, the Dutch dietary risk assessment models are also used for enforcement purposes by official competent Food Safety authorities (VWA in the Netherlands), supermarkets, and auctions to assess the safety of food and to decide on the acceptability of a lot on the market or for monitoring purposes to assess the actual exposure. Some remarks have to be made regarding the use of the dietary risk assessment models for these purposes, since some of the assumptions made for dietary risk assessment for pesticide authorisation purposes (i.e. theoretical worst case exposure calculation) do not apply to dietary risk assessment for enforcement purposes (i.e. verification of residue levels for trade and consumer safety) or for monitoring purposes (i.e. assessment of actual exposure).

8.4.1 Enforcement purposes

It is not appropriate to use the revised Dutch chronic dietary risk assessment models for enforcement purposes, since these models assume life long consumption of commodities with realistic pesticide residues. A single lot with residue levels exceeding the MRL will not be consumed life long. The only model that could be used with caution for enforcement purposes is the revised Dutch acute dietary risk assessment model.

The JMPR concludes in its 2005 report that ‘the JMPR IESTI procedure should only be used for estimation of short-term intake from residues found in crop units taken from a single lot as defined in the Codex sampling procedure. It is not applicable for residue data obtained from market samples, where the commodities offered for sale are of mixed lots, which may result in a variability factor three to four times higher than the one in the treated lot. Consequently it is not appropriate to attempt to derive a variability factor using residue data of uncertain origin or those clearly indicating that the sampled commodity originated from a mixed lot, i.e. a high CV value, in the estimation of short-term intake based on data from supervised trials’ (JMPR, 2005). The JMPR concludes in its 2006 report that a discussion should be started on ‘the adequacy of the IESTI equations when residues for monitoring/enforcement data are used or the need of a specific methodology for this application’ (JMPR, 2006b).

Banasiak et al. concluded that food control laboratories should only evaluate the acute dietary exposure (Banasiak et al., 2007). Problems in exposure estimation of residues in surveillance samples are:

- The residue definition. For enforcement/monitoring residues are measured according to the residue definition for enforcement/monitoring, which may not be the same as the residue definition for risk assessment. The residue definition for risk assessment is normally not published (except by JMPR). It is available on request at EFSA.

- The commodity part. For enforcement/monitoring residue values are only available for the RAC, while dietary risk assessment should be performed using the residues found in the EP or the PP. The highest residues (HR), median residues (STMR) and processing factors are derived from supervised field trials or processing studies within registration procedures and these are normally not published.
- The variability factor. For enforcement/monitoring residues are measured in mixed lots, while the variability factor for authorisation purposes is based on the variability in single lots. The standard variability factors can be transferred to surveillance data.
- The measurement uncertainty. Uncertainty is found in all the parameters of the acute dietary risk assessment model (ARfD, LP, U, bw, residue value) and consideration of the uncertainty of only one parameter (residue value) is not appropriate. Therefore the calculations should be made with the analytically measured value without consideration of the analytical measurement uncertainty.

In addition to the problems indicated by Banasiak et al. some further remarks should be made.

- The dietary risk is highly dependent on the unit weight of the RAC (U_{RAC}). For surveillance samples the unit weight as listed in the acute dietary risk assessment model is best replaced by the maximum unit weight of the lot. The % edible can be maintained to get the corresponding unit weight of the raw edible portion (U_e).
- The ARfD is evaluated for each commodity as such. It is not appropriate to add % ARfD for different commodities with residues of the same pesticide. It is highly unlikely that the highest portion of more than one commodity with the highest residue is consumed by the same 97.5^{th} percentile of consumers. For an estimate of dietary risk for residues on several commodities, probabilistic risk assessment procedures are more appropriate.
- Very often more than one pesticide is detected in enforcement samples, making cumulative risk assessment relevant for such type of samples. EFSA has made an opinion on the methodology to assess cumulative risk assessment (EFSA, 2008) and has presented a worked example (EFSA, 2009). Acute and chronic exposure scenarios for risk assessments have been considered, both in the context of MRL setting, and also in relation to actual exposures that result form the patterns of usage that occur in practice (i.e. based on monitoring data).

When exceeding of the ARfD is found for a surveillance sample lot, an estimation could be made as to the probability of the dietary risk in order to help risk managers to decide on the appropriate action. The current guidance on dietary risk assessment for surveillance samples (European Commission, 2004) is not intended to estimate the probability of dietary risk for a specific part (percentage or regional area) of the population. It should be kept in mind that LPs are deduced for the 97.5^{th} percentile of consumers for the whole country (based on a random sample). It is difficult to translate the meaning of an exceeding of the ARfD for a surveillance sample lot compared to the 97.5^{th} percentile for the whole country. It is important to realize that the hypothetical consumers of this surveillance sample represent a specific part (percentage) of the population, not the consumers in the whole country. Risk managers may wish to consider which part (percentage) of the population needs to be protected. An unknown is the surveillance sample lot in comparison to the whole amount of this particular commodity that is consumed on one day within this specific population group or within the whole country. It is also unknown how many people will consume the surveillance sample lot in comparison to the consumers within the specific population group or within the whole country. It should also be known in what form (processed or raw) and in what amounts the surveillance sample is consumed per day. No appropriate guidance is available at present, where the probability of dietary risk is estimated for a specific part (percentage or regional area) of the population. It is recommended to develop such guidance.

8.4.2 Monitoring purposes

The use of the dietary risk assessment models for monitoring purposes is very limited. The models can be used as a first worst case tier, but generally probabilistic methods, like MCRA, are used to estimate dietary risk from monitoring results. Very often more than one pesticide is detected in monitoring samples, making cumulative risk assessment relevant for such type of samples, as discussed in the previous section on enforcement samples (EFSA, 2008 and 2009).

Dietary risk assessment can be performed to assess the actual exposure to pesticide residues, veterinary drugs and contaminants by linking the CPAP model to databases containing monitoring information on actual levels of these chemicals (Bakker, 2002). Dutch monitoring data are available in the KAP (Kwaliteitsprogramma Agrarische Producten) database for levels of residues in raw agricultural commodities (Van Klaveren et al., 1994). The CPAP model and the monitoring database KAP were previously owned by the RIKILT Institute of Food Safety in Wageningen, but are transferred to the RIVM in the course of 2010.

9 Recommendations for future work

For some RACs, the NEVO coding system is not consistent with the classification as given in the RAC list in EC 178/2006. For instance, lollo rosso (a lettuce variety) is coded in the NEVO coding system as scarole (endive), while it is classified as lettuce in EC 178/2006. Recommendations are given in Appendix I for improvement of the NEVO coding system in this regard. Since the CPAP model uses presently only the NEVO codes as input for the conversion of foods to RAC levels, this inconsistency is also found in the outcome of the CPAP model. For future food consumption survey databases, the EPIC-SOFT program will be used to record food consumption data. This gives the opportunity to include more details when converting foods to RAC level in the CPAP model, e.g. brand of the food (Boon and Ocké, 2008). For future updates it is recommended to match the NEVO coding system with the EC 178/2006 classification and to include more detailed food information in the CPAP model.

Several other recommendations were made to improve gaps between the NEVO coding system and pesticide risk assessment procedures (see sections 3.2 and 4.2.2). In processing studies on canned fruits, generally the pesticide residue is analysed in canned fruits without the liquid and therefore a change in coding of canned fruits is recommended, since Dutch food consumption surveys include the liquid. Mixed fruit juices, mixed canned fruits, jam/marmalade/jelly are recommended to be coded according to their ingredients (i.e. individual NEVO codes for different mixtures). Further it is recommended to discriminate between cooked and micro-waved vegetables in the food consumption surveys.

The conversion factors available in the CPAP model are very often not the same as the conversion factors used to construct the Dutch food consumption databases (see section 3.2.2). The difference in conversion factors may work out in two directions. The original amounts consumed may be higher than the consumption values used to calculate average or 97.5th percentile consumption values or they may be lower. For future updates it is recommended to harmonize the conversion factors used in the NEVO coding system and the MGC reference tables with the conversion factors used in the CPAP model, since they have impact on the dietary risk assessment. In addition it is recommended to document the processing factors used in the CPAP model in a publicly available document. Furthermore, it is recommended that the Dutch Food Composition Database (NEVO) is updated to incorporate the temporary NEVO codes which are used in the current CPAP model. It also recommended to use version numbers for the CPAP model and the NEVO database to be able to define which conversions were used when. A project has already been initiated to match the NEVO coding system with the CPAP model and harmonisation of conversion factors was already listed as a possible point of improvement (Boon and Ocké, 2008).

The clean fruit/vegetable fraction of the CPAP model is a combination of % ingredient (commodity as such, either raw or processed) and possible concentration factors (e.g. drying). If the clean fruit/vegetable fraction includes concentration factors, the % ingredient part in itself cannot be obtained. At present only a remark is available within the CPAP model as to how the clean fruit/vegetable fraction was obtained. For future use, it is recommended to have a separate entry for the % ingredient and a separate entry for additional conversion factors (fruit drying, drying of potato and cassava flour, preparation of wine, beer and whisky, oil production, sugar preparation) to be able to verify which conversion factors were used.

For future Dutch dietary risk assessment models it is desirable to have food consumption data for special groups like pregnant and lactating women, vegetarians, ethnic groups and elderly people (WHO, 2008a/b). In the latest Food Consumption Survey on general population (VCP-3, 6250 persons) 50 persons were pregnant, 170 persons had a diet without meat (vegetarian or veganistic), 182 persons were immigrants (including people who had not indicated their place of birth). These numbers are too small to get accurate food consumption data. The group of elderly people is larger (923 persons > 60 years and 670 persons > 65 years) and these data could be used to get accurate food consumption data. For future food consumption surveys it is anticipated to collect data on pregnant and lactating women, ethnic groups and elderly people (Ocké et al., 2005a).

Finally, the 2006 and 2007 JMPR (JMPR, 2006b, 2007b) recommended that FAO and WHO should host a consultation to address the issues on acute dietary risk assessment. JMPR indicated that the discussion should include the following specific issues:

- Uncertainty and variability of the parameters in the IESTI/NESTI estimation
- The investigation of the practicalities of using the MRL in IESTI/NESTI equations
- Ways to improve the consumption, unit weight and bodyweight data for the IESTI/NESTI estimation
- Identification of additional subgroups of the population for which the assessment should be conducted, e.g. toddlers
- The adequacy of the IESTI/NESTI equations when residues from monitoring/enforcement are used or the need of a specific methodology for this application
- How to improve the communication between risk assessors and risk managers and the public on the output of the risk assessment

The present authors would like to emphasize the need for such an international discussion, both at EU level and at FAO/WHO level, since the IESTI/NESTI equations do not seem to describe pre-harvest situations correctly in case of small and large commodity varieties (see section 8.2.3) and IESTI/NESTI equations do not seem to be appropriate for enforcement purposes (see section 8.4). Furthermore, a re-evaluation of the IEDI/NEDI equation is also warranted as indicated in section 8.1.

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List of abbreviations

CPAP	Conversion to Primary Agricultural Product i.e. a model to convert foods into their raw agricultural product ingredients
CRD	Chemicals Regulation Directorate, UK (formerly PSD, see below)
EFSA	European Food Safety Authority
EP	raw edible portion
EU	European Union
FAO	Food and Agricultural Organisation of the United Nations
FBS	Food Balance Sheets
IEDI	International Estimated Daily Intake, i.e. refined chronic exposure calculation for pesticides
IESTI	International Estimated Short-term Intake, i.e. acute exposure calculation for pesticides
JMPR	FAO/WHO Joint Meeting on Pesticide Residues
MGC	Measures, Weights, Codes reference table (‘Maten, Gewichten, Codenummers’)
MRL	Maximum Residue Limit, i.e. maximum allowed concentration of a pesticide in a RAC
NEDI	National Estimated Daily Intake, i.e. refined chronic exposure to pesticides
NESTI	National Estimated Short-term Intake, i.e. acute exposure calculation for pesticides
NEVO	Dutch Food Composition Database (NEderlands VOedingsstoffenbestand)
PP	(primary) processed product or (primary) processed commodity
PSD	Pesticide Safety Directory, UK
RAC	Raw Agricultural Commodity, i.e. the end product of agricultural production methods that has not undergone any form of processing, e.g. raw orange including peel
RIVM	Dutch National Institute for Public Health and the Environment
STMR	Supervised Trial Median Residue level of the raw edible portion of a certain commodity
TMDI	Theoretical Maximum Daily Intake, i.e. worst case chronic exposure calculation for pesticides
VCP	VoedselConsumptiePeiling, i.e. Dutch National Food Consumption Survey (DNFCS)
VIO	VoedingsInnameOnderzoek, i.e. Dutch food consumption survey for babies/toddlers
VWA	Dutch Food and Consumer Product Safety Authority
VWS	Dutch Ministry of Health, Welfare and Sport
WHO	World Health Organisation of the United Nations
WVC	former Dutch Ministry of Welfare, Public Health and Cultural Affairs
LNV	Dutch Ministry of Agriculture, Nature Management and Fisheries – former name of current Dutch Ministry of Agriculture, Nature and Food Quality

Other terms used

commodity	Part of a crop or animal moving in trade for which residue levels are derived. E.g. a crop like wheat can consist of two commodities: wheat grains for human consumption and wheat straw for livestock consumption. For an animal like cow, several different commodities exist: milk, meat, fat, kidney, liver, edible offal.
raw agricultural commodity (RAC)	The end product of agricultural production methods that has not undergone any form of processing, e.g. raw orange including peel. The product is intended for processing into food for sale to the consumer or as a food without further processing.
raw edible portion (EP)	The end product of agricultural production methods that has not undergone any form of processing, but the inedible parts have been removed, e.g. orange flesh (raw orange excluding the peel).

primary processed commodity (PP)	A primary processed commodity is derived from mechanical or chemical processing of the RAC and is not a multi-component product. The product intended for sale to the consumer, for direct use as an ingredient in the manufacture or for further processing. Examples are fruit juices and cooked vegetables.
secondary processed commodity	A secondary processed commodity is a multi-component product or a product which was subjected to two or more processing treatment(s). The product is intended for sale to the consumer. Examples are bread, fruit in ready-to-eat dessert, vegetables in ready-to-eat meals.
food	Commercial product e.g. raw oranges, a pack of orange juice, a box containing a frozen pizza, a can of strawberries.
RAC ingredient	The part of a food that can be attributed to a RAC, e.g. tomato puree on a pizza can be attributed to tomatoes.

Appendices and addenda

Appendices and addenda are available as Excel files only. They are available electronically upon request, as it was not possible to incorporate them in this Word document.

Appendix I: An overview of the commodities for which the NEVO coding is different from EC 178/2006 commodity grouping.

Appendix II: Food-RAC-processing definition list for Dutch dietary risk assessment models.

Appendix III: Average commodity consumption values for the selected three Dutch food consumption databases for the total age group (i.e. consumers plus non-consumers).

Appendix IV: Calculated large portions (LP-max) for the selected three Dutch food consumption databases (for consumers-only).

Appendix V: Large portion choice for the selected three Dutch food consumption databases (for consumers-only).

Appendix VI: Dutch unit weights.

Appendix VII: Choice of Dutch unit weights.

Addendum I: revised Dutch chronic dietary risk assessment model (Version 03 Dutch TMDI_NEDI-calculation.xlt)

Addendum II: revised Dutch acute dietary risk assessment model (Version 05 Dutch NESTI calculation.xlt)

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