5.14 GLYPHOSATE (158) AND METABOLITES

TOXICOLOGY

Glyphosate (*N*-(phosphonomethyl)glycine) is a non-selective systemic herbicide that was last evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2004, when a group acceptable daily intake (ADI) for glyphosate and aminomethylphosphonic acid (AMPA), the main metabolite of glyphosate, of 0–1 mg/kg body weight (bw) was established based on a no-observed-adverse-effect level (NOAEL) of 100 mg/kg bw per day for salivary gland alterations in a long-term study of toxicity and carcinogenicity in rats and a safety factor of 100. The 2004 JMPR concluded that it was not necessary to establish an acute reference dose (ARfD) for glyphosate.

Metabolism studies in genetically modified soya beans and maize containing the glyphosate-*N*-acetyltransferase (*GAT*) gene demonstrated that new metabolites are formed that were not observed in conventional crops. The major metabolite in the new maize and soya bean varieties was *N*-acetyl-glyphosate, whereas glyphosate, *N*-acetyl-AMPA and AMPA were found in low concentrations in the edible parts of the crops. The present Meeting was asked by the Codex Committee on Pesticide Residues to evaluate newly submitted studies on toxicokinetics and metabolism, acute oral toxicity, subchronic toxicity and genotoxicity for *N*-acetyl-glyphosate and on acute oral toxicity and genotoxicity for *N*-acetyl-AMPA.

All pivotal studies were certified as complying with good laboratory practice or an approved quality assurance programme.

Biochemical aspects

[^{14}C]*N*-acetyl-glyphosate was rapidly and incompletely (approximately 66%) absorbed in rats following a single oral dose of 15 mg/kg bw. The maximum concentration of radioactivity in plasma was reached after 2 hours, and the half-life for elimination from plasma was 15.6 hours. Elimination was mainly via urine (66.1%) and, to a lesser extent, faeces (26.4%); more than 90% of the total radioactivity was eliminated by 48 hours post-dosing. *N*-Acetyl-glyphosate was metabolized to a very limited extent. One metabolite, glyphosate (< 1% of the total radioactivity), was detected in faeces after a single oral dose of 15 mg/kg bw, whereas glyphosate and *N*-acetyl-AMPA were found in urine following subchronic exposure at dose levels of 56 mg/kg bw per day and above.

Toxicological data

N-Acetyl-glyphosate

N-Acetyl-glyphosate was of low acute oral toxicity; the median lethal dose (LD_{50}) was greater than 5000 mg/kg bw in rats.

In a 90-day study of toxicity with *N*-acetyl-glyphosate in rats, the NOAEL was 4500 ppm (equal to 283 mg/kg bw per day), based on slightly decreased body weight gains in male rats at 18 000 ppm (equal to 1157 mg/kg bw per day).

N-Acetyl-glyphosate was tested for genotoxicity in vitro and in vivo in an adequate range of assays; it was not found to be genotoxic in mammalian and microbial test systems.

The Meeting concluded that *N*-acetyl-glyphosate was unlikely to be genotoxic.

The Meeting concluded that *N*-acetyl-glyphosate is of no greater toxicological concern than the parent glyphosate, based on the structural similarity of *N*-acetyl-glyphosate with glyphosate and supported by the following considerations: 1) *N*-acetylation is a common detoxification pathway of xenobiotic compounds in mammals; therefore, *N*-acetyl-glyphosate is expected to be of similar toxicity to or lower toxicity than glyphosate; 2) a structure–activity relationships analysis indicates that the *N*-acetylated group is not a structural alert for carcinogenicity, mutagenicity or endocrine effects; and 3) the toxicological data for *N*-acetyl-glyphosate show low acute toxicity, low subchronic toxicity (with no organ toxicity in rats at doses up to 1157 mg/kg bw per day) and a lack of genotoxicity.

N-Acetyl-AMPA

N-Acetyl-AMPA was of low acute oral toxicity; the LD_{50} was greater than 5000 mg/kg bw in rats.

N-Acetyl-AMPA was tested for genotoxicity in vitro and in vivo in an adequate range of assays; it was not found to be genotoxic in mammalian or microbial test systems.

The Meeting concluded that *N*-acetyl-AMPA was unlikely to be genotoxic.

The Meeting concluded that the toxicity of *N*-acetyl-AMPA is low and of limited concern, based on the structural similarity of *N*-acetyl-AMPA with AMPA and supported by the following considerations: 1) *N*-acetyl-AMPA is a charged molecule at physiological pH and is expected to be poorly absorbed from the gastrointestinal tract; 2) *N*-acetylation is a common detoxification pathway of xenobiotic compounds in mammals; therefore, *N*-acetyl-AMPA is expected to be of similar toxicity to or lower toxicity than AMPA or glyphosate; and 3) a structure–activity relationships analysis indicates that the *N*-acetylated group is not a structural alert for carcinogenicity, mutagenicity or endocrine effects.

Toxicological evaluation

The Meeting concluded that the group ADI of 0–1 mg/kg bw established by the 2004 JMPR for glyphosate and AMPA may also be applied to *N*-acetyl-glyphosate and *N*-acetyl-AMPA, as the available toxicological data showed that these plant metabolites have no greater toxicity than the parent glyphosate.

The 2004 JMPR decided that an ARfD for glyphosate was unnecessary. The present Meeting confirmed that it is not necessary to establish an ARfD for *N*-acetyl-glyphosate or *N*-acetyl-AMPA in view of their low acute toxicity and the absence of any toxicological effects that would be likely to be elicited by a single dose.

An addendum to the toxicological monograph was prepared.

Estimate of acceptable daily intake for humans

0–1 mg/kg bw (for the sum of glyphosate, *N*-acetyl-glyphosate, AMPA and *N*-acetyl-AMPA)

Estimate of acute reference dose

Unnecessary

Information that would be useful for the continued evaluation of the compound

Results from epidemiological, occupational health and other such observational studies of human exposure

RESIDUE AND ANALYTICAL ASPECTS

Glyphosate is an herbicide with uses on many crops, conventional and glyphosate tolerant. Glyphosate has been evaluated several times with the initial evaluation in 1986 and the latest in 2005 (Periodic re-evaluation Programme of the Thirty-fourth Session of the CCPR for residue review). The Meeting of 2005 established a residue definition for compliance with MRLs as “glyphosate” and a definition of the residue for the estimation of the dietary intake as “sum of glyphosate and AMPA, expressed as glyphosate” for both plant and animal commodities. The toxicology of glyphosate was re-evaluated by the 2004 JMPR which estimated group ADI of 0–1 mg/kg bw for the sum of glyphosate and AMPA. The same Meeting concluded that an ARfD did not need to be derived.

Glyphosate is used on conventional and glyphosate tolerant crops. Different types of glyphosate tolerant crops can be distinguished. Glyphosate tolerant crops containing the modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) gene are referred to here as EPSPS crops and those containing the glyphosate-N-acetyltransferase (*GAT*) gene will be referred to as *gat* crops. EPSPS crops are tolerant to glyphosate but essentially metabolise glyphosate in the same way as conventional crops. Both EPSPS genetically modified crops and conventional crops have been evaluated by the 2005 JMPR. For the current evaluation in addition to data on conventional crops and EPSPS crops, data have been submitted covering the use on genetically modified crops containing the *GAT* trait. These crops inactivate glyphosate by converting it to *N*-acetyl-glyphosate, a different metabolic pathway than for the crops described by the 2005 JMPR.

The Meeting received information on *N*-acetyl-glyphosate (the main metabolite expected to be formed in plants) metabolism in animals, on glyphosate metabolism in genetically modified maize and soya beans containing the *GAT* trait, methods of residue analysis, freezer storage stability, GAP information, supervised residue trials on conventional (dry peas) and EPSPS glyphosate tolerant crops (sweet corn and sugar beets) and *gat* crops (maize and soya beans), fate of residue during storage and processing, and livestock feeding studies with *N*-acetyl-glyphosate.

To assist uniform interpretation of GAP application rates have been expressed in terms of glyphosate acid equivalents (ae), unless indicated otherwise.

Metabolites referred to in the appraisal were addressed by their common names,

N-acetyl-glyphosate	*N*-acetyl-*N*-(phosphonomethyl)glycine
AMPA	aminomethylphosphonic acid
N-acetyl AMPA	[(acetylamino)methyl]phosphonic acid.

Animal metabolism

The metabolism of glyphosate was evaluated by the 2005 JMPR. The current Meeting received metabolism studies for *N*-acetyl-glyphosate, the main glyphosate metabolite in genetically modified maize and soya beans containing the *gat* trait, in lactating goats and laying hens. Metabolism of *N*-acetyl-glyphosate in laboratory animals was summarized and evaluated by the WHO panel of the JMPR 2011.

A lactating goat was orally treated twice daily for 5 consecutive days with [^{14}C]-*N*-acetyl-glyphosate at a dose equivalent to 205 ppm (mg test substance equivalent/kg feed) per day. Approximately 88% of the administered dose was recovered with the majority in the excreta (87.7% of the dose). Faeces, urine and cage wash contained 74, 11 and 2.3% of the total administered dose, respectively. Composite milk (day 1–5), liver and kidney each contained < 0.1% TRR of the administered dose. The radioactivity in the tissues ranged from 0.05 in muscle to 4.69 mg/kg *N*-acetyl-glyphosate equivalents in kidney. TRR values in milk were 0.030 to 0.036 mg/kg *N*-acetyl-glyphosate equivalents during the dosing period. Plateau levels in milk were reached after 24 hours.

Unchanged *N*-acetyl-glyphosate was the major residue in all tissues. Low levels of glyphosate, AMPA and *N*-acetyl AMPA were also detected. *N*-acetyl-glyphosate accounted for 53% TRR in fat, 77% in kidney, 55% in liver, 40% in milk and 17% in muscle. The minor metabolites glyphosate, AMPA and *N*-acetyl AMPA, accounted for no more than 15% TRR in liver, 8.4% liver and 6.6% fat, respectively.

Six laying hens were orally treated twice daily for 7 consecutive days with [^{14}C]-*N*-acetyl-glyphosate at a dose equivalent to 63 ppm (mg test substance equivalent/kg feed) per day and were sacrificed 6 hours after the last dose. The recovery of the total administered dose in excreta, eggs, and tissues was 90.2%. The majority (90.1%) of the dose was eliminated in the excreta. Eggs and edible tissues contained ~ 0.1% of the total administered dose. The radioactivity in the tissues ranged from 0.04 mg/kg *N*-acetyl-glyphosate equivalents in muscle and 0.05 mg/kg *N*-acetyl-glyphosate equivalents in fat, to 0.51 mg/kg *N*-acetyl-glyphosate equivalents in liver. The concentrations in whole eggs ranged from 0.05 mg/kg *N*-acetyl-glyphosate equivalents after 48 hours, to 0.36 mg/kg *N*-acetyl-glyphosate equivalents after 158 hours. Higher levels were observed in the egg yolks than in the whites.

Unchanged *N*-acetyl-glyphosate was the principle residue in egg yolks (68% TRR, 0.16 mg/kg), liver (64% TRR, 0.32 mg/kg), fat and muscle (25 and 23% TRR respectively, both 0.01 mg/kg), and was detected in egg whites in trace levels (41% TRR, < 0.01 mg/kg). Glyphosate was identified in fat (39% TRR, 0.023 mg/kg), egg yolks (5.7% TRR, 0.013 mg/kg) and liver (16% TRR, 0.084 mg/kg), and detected in muscle and egg whites at < 0.01 mg/kg (7.2% TRR and 11% TRR, respectively). AMPA was found in liver (6.7% TRR, 0.03 mg/kg), muscle and fat (17 and 11 %TRR respectively, both 0.01 mg/kg) and egg yolks (0.91 %TRR, < 0.01 mg/kg). *N*-acetyl AMPA was identified in fat and liver at 0.01 and 0.02 mg/kg, 10 and 4.0 %TRR respectively and at trace levels in egg whites, egg yolks and muscle. *N*-acetyl-glyphosate and glyphosate were the only residues eliminated to any significant extent in the excreta.

The absorbed dose of *N*-acetyl-glyphosate was not extensively metabolized in cattle and hens. Two basic metabolic pathways are proposed, both leading to AMPA. One route via de-acetylation to form glyphosate, which can be further metabolized to AMPA and one route where *N*-acetyl-glyphosate is metabolized to *N*-acetyl AMPA, which is further de-acetylated to form AMPA.

The metabolism for *N*-acetyl-glyphosate proposed for ruminants and laying hens is consistent with that for rats with regard to the conversion into glyphosate. A small difference between rats and livestock was that AMPA and *N*-acetyl AMPA were not detected in the rat metabolism studies. However, rats dosed with glyphosate show it can be metabolized in the rat to AMPA. Glyphosate, *N*-acetyl-glyphosate and AMPA are poorly absorbed from the gastrointestinal tract and rapidly and essentially completely excreted. Neither molecule accumulates in mammalian systems. It is predicted that *N*-acetyl AMPA will exhibit similar absorption, distribution and metabolism characteristics as glyphosate and its two metabolites.

Plant metabolism

The Meeting received plant metabolism studies for glyphosate treatments on genetically modified maize and soya beans; both contain the *gat* trait.

The metabolic fate of [^{14}C]glyphosate in *GAT* maize plants was examined following a single pre-emergence soil application followed by three foliar applications (each 1.1 kg ai/ha at three different growth stages). Maize plants were harvested as immature foliage (immediately prior to the first foliar application), then as forage (prior to the last application) and finally at maturity (7 days PHI) whereupon plants were separated into stover, cob and grain fractions.

The TRRs in immature maize foliage were low (0.02 mg/kg glyphosate equivalents) indicating that low levels of radioactive soil residues were incorporated by the developing plant. In maize forage (one pre-emergence application and two foliar applications) the TRR was 3.48 mg/kg glyphosate equivalents. The major components in maize forage were glyphosate (58% TRR) and *N*-acetyl-glyphosate (27% TRR). AMPA and *N*-acetyl-AMPA were present at 4.0% TRR and 1.7% TRR respectively. The major components in maize stover were glyphosate (74.9% TRR) and *N*-acetyl-glyphosate (17.8% TRR) with AMPA and *N*-acetyl AMPA also identified but at much lower levels (4.4% and 1.3% TRR respectively). The major component in maize cobs and grain was *N*-acetyl-glyphosate which accounted for 63.8% TRR (0.44 mg/kg) and 51.2% TRR (0.14 mg/kg) respectively. *N*-acetyl-AMPA was the second most prominent metabolite present in cobs and grains at 5.0% TRR and 9.4% TRR, respectively. Glyphosate and AMPA were detected in grains at 6.1% TRR (0.02 mg/kg) and 0.1% TRR (< 0.01 mg/kg), respectively.

The metabolic fate of [^{14}C]glyphosate in *GAT* soya bean plants was examined following a single pre-emergence soil application of 3.4 kg ai./ha, followed by three foliar applications at 1.4, 2.4 and 0.9 kg ai/ha at three different growth stages. Soya bean plants were harvested at typical forage and hay harvests, immediately prior to the final application and at maturity (PHI 14 days).

AMPA was the major extractable metabolite in soya bean forage, accounting for 39.3% TRR (0.17 mg/kg glyphosate equivalents). Glyphosate and *N*-acetyl-glyphosate were also detected accounting for 9.1% TRR and 1.9% TRR respectively. The TRR in hay (one pre-emergent application and one foliar application) was 13.44 mg/kg glyphosate equivalents. Glyphosate was the major residue in soya bean hay samples, accounting for 72.5% TRR. *N*-acetyl-glyphosate (19.2% TRR), AMPA (5.3% TRR) and N-acetyl-AMPA (0.7% TRR) were also detected.

At early harvest (typical of forage and hay harvest), plants were separated into soya bean seeds (1.90 mg/kg glyphosate equivalents) and soya bean foliage/pods (11.22 mg/kg glyphosate equivalents). *N*-Acetyl-glyphosate was the major radioactive component detected in the early-harvest grain accounting for 60.6% TRR with glyphosate (22.7% TRR) and AMPA (5.3% TRR) also detected. Glyphosate and *N*-acetyl-glyphosate were the major radioactive components detected in the early harvest foliage accounting for 43.6% TRR (4.89 mg/kg) and 42.0% TRR (4.70 mg/kg), respectively. AMPA (7.4% TRR) and N-acetyl-AMPA (2.2% TRR) were also detected.

At mature harvest, plants were separated into grain (3.14 mg/kg glyphosate equivalents), pods (17.75 mg/kg glyphosate equivalents) and foliage (straw) (22.09 mg/kg glyphosate equivalents). *N*-acetyl-glyphosate was the major radioactive component detected in the mature grain accounting for 56.9% TRR. Glyphosate (3.2% TRR), AMPA (11.2% TRR) and N-acetyl AMPA (23.5%) were also detected. Glyphosate was the major radioactive component detected in the mature pods accounting for 56.9% TRR with *N*-acetyl-glyphosate (27.7% TRR), AMPA (10.2% TRR) and *N*-acetyl AMPA (3.3% TRR) also detected. Glyphosate was the major radioactive component detected in the mature foliage accounting for 53.4% TRR, 11.79 mg/kg glyphosate equivalents. *N*-acetyl-glyphosate (31.9% TRR), AMPA (10.3% TRR) and N-acetyl AMPA (1.4% TRR) were also detected.

Low levels of radioactivity that was not extracted were associated with the plants' cellulose and lignin fractions.

The proposed pathway of glyphosate in plants with the *gat* trait is deactivation to *N*-acetyl glyphosate which can be further metabolised to *N*-acetyl-AMPA and AMPA. A smaller part of glyphosate may be directly metabolised to AMPA. The pathway differs from that observed with conventional and EPSPS modified crops, where glyphosate is predominantly metabolised to AMPA. *N*-acetyl-glyphosate is only formed at trace levels, if at all in those crops.

Analytical methods

The Meeting received description and validation data for analytical methods for residue analysis of glyphosate and its metabolites in various plant commodities using LC-MS-MS. The method also quantifies the metabolites resulting from metabolism of glyphosate in genetically modified crops containing the *gat* trait, being *N*-acetyl-glyphosate, AMPA and *N*-acetyl AMPA. The LOQs are 0.05 mg/kg.

For animal commodities an LC/MS/MS method was developed and validated to determine *N*-acetyl-glyphosate and the metabolites glyphosate, *N*-acetyl AMPA and AMPA residues in milk, eggs, muscle, kidney, liver and fat. The LOQ is 0.025 mg/kg glyphosate equivalents for residues in milk, egg and muscle and 0.05 mg/kg glyphosate equivalents for liver, kidney and fat.

Multi-residue methods are currently not validated for glyphosate and its metabolites.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of glyphosate and its residues in samples stored frozen.

It was concluded that glyphosate, *N*-acetyl-glyphosate and AMPA residues are stable for at least 12 months in maize forage, and grain, and for at least 23 months in maize stover when stored frozen at -20 °C. In addition, residues of *N*-acetyl AMPA are stable frozen (-20 °C) for at least 23 months in maize forage, stover, and grain.

Glyphosate, *N*-acetyl-glyphosate and AMPA residues in soya bean forage, seed, and hay are stable when stored at -20 °C for at least 12 months. Residues of *N*-acetyl AMPA in forage, seed and hay have also been shown to be stable for a period of at least 18 months when stored frozen at -20 °C.

The stability of *N*-acetyl-glyphosate, glyphosate, AMPA, and *N*-acetyl AMPA stored frozen (nominal -20 °C) in animal tissues (liver, kidney, fat, and muscle matrices) was also determined. The results indicate that glyphosate, *N*-acetyl-glyphosate, AMPA, and *N*-acetyl AMPA are stable for at least 80 days in animal tissues when stored frozen for a period greater than the longest storage interval prior to analysis of each tissue matrix.

The periods of demonstrated stability cover the frozen storage intervals used in the residue studies.

Definition of the residue

As established at the 2005 JMPR, glyphosate is not metabolised in rats, lactating goats and laying hens and is mainly excreted unchanged. Some traces of AMPA were found, but microbial degradation after oral absorption could have been responsible for that.

Livestock metabolism studies with *N*-acetyl-glyphosate, a major plant metabolite of glyphosate in glyphosate tolerant crops (*GAT* trait), were performed in rats, lactating goats and laying hens. This compound was not extensively metabolised. However, two metabolic pathways could be proposed, both of which lead to AMPA via formation of glyphosate or *N*-acetyl AMPA. As a consequence all four metabolites could be found, with *N*-acetyl-glyphosate being the major residue. These findings are confirmed in the farm animal feeding studies with *N*-acetyl-glyphosate where the only quantifiable residue was *N*-acetyl-glyphosate in tissues, eggs and milk, except in kidney tissue of dairy cows in which case AMPA and *N*-acetyl AMPA were also detected.

When considered together with glyphosate, *N*-acetyl-glyphosate is expected to be a minor component of livestock dietary burden, present only when feed is derived from *GAT* crops and when present to be at levels that are lower than parent glyphosate in animal commodities. The Meeting concluded that the previously derived residue definition for enforcement in animal commodities of "glyphosate" should be replaced by "the sum of glyphosate and N-acetyl-glyphosate".

The 2005 JMPR reviewed glyphosate metabolism studies in conventional coffee, corn, cotton, soya beans, wheat, pasture grasses and alfalfa crops as well as on the glyphosate tolerant (EPSPS varieties) cotton, soya beans and sugar beet crops. The patterns of metabolites were similar in different species of plants as well as in conventional and EPSPS crops. The main component of the residue was glyphosate and the main metabolite found was AMPA. These findings are consistent with the residue distribution as observed in the supervised residue trials with EPSPS sweet corn and sugar beet as well as in the field trials with conventional peas (dry) submitted for the current evaluation.

Radioactivity in tolerant maize and soya beans containing the *GAT* trait treated with [^{14}C]glyphosate was due to glyphosate and AMPA, *N*-acetyl glyphosate and *N*-acetyl-AMPA in both maize and soya beans.

For maize cobs and grain *N*-acetyl-glyphosate is the major component (64% and 51% TRR), followed by *N* acetyl AMPA (5 and 9.4% TRR). In maize forage and stover the major component was parent glyphosate (58% and 75 % TRR), followed by *N*-acetyl-glyphosate (27%and 18% TRR),

In *GAT* soya bean seeds *N*-acetyl-glyphosate was the major component of the residue (61% TRR), followed by glyphosate (23% TRR) and AMPA (5.3% TRR). In *GAT* soya bean forage AMPA was the major metabolite (39% TRR) while in soya bean hay glyphosate (73% TRR) was the major component.

To accommodate the use of glyphosate on plants containing the *GAT* trait the Meeting concluded that the previously established residue definition for enforcement in plants of “glyphosate” should be replaced by “the sum of glyphosate and N-acetyl-glyphosate expressed as glyphosate for soya bean and maize crops and remain “glyphosate” for all other crops.

The 2005 JMPR concluded that in conventional crops and the glyphosate tolerant EPSPS crops, glyphosate together with AMPA should be regarded as the residues of toxicological concern. Based on the available toxicological data for glyphosate, *N*-acetyl glyphosate and AMPA and the structural similarity of *N*-acetyl AMPA with the three other compounds, the Meeting concluded that *N*-acetyl-glyphosate, *N*-acetyl AMPA and AMPA were of no greater toxicological concern than glyphosate and set a group ADI of 0–1 mg/kg bw for the sum of glyphosate, *N*-acetyl-glyphosate, AMPA and *N*-acetyl AMPA. The previously established residue definition for dietary risk assessment for plant and animal commodities of “the sum of glyphosate and AMPA, expressed as glyphosate” should be replaced by “the sum of glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate” for both plant and animal commodities.

Based on the above the Meeting agreed to replace the previous definitions for glyphosate as follows:

For plants and animals:

Definition of the residue for compliance with the MRL (for plant commodities): for soya bean and maize—*sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate.*

for other crops—*glyphosate*.

Definition of the residue for compliance with MRL (for animal commodities): *sum of glyphosate and N-acetyl-glyphosate, expressed as glyphosate*

Definition of glyphosate residue for estimation of dietary intake: *sum of glyphosate, AMPA, N-acetyl-glyphosate and N-acetyl AMPA, expressed as glyphosate.*

The changes in definition of the residues for enforcement and for dietary risk assessment will not influence the maximum residue levels, STMRs and highest residues established so far. The levels derived so far are for conventional and EPSPS crops for which N-acetyl-glyphosate and N-acetyl AMPA, if formed, are only minor components of the residue present at < 2% TRR.

Results of supervised trials on crops

The Meeting received supervised residue trial data for glyphosate on glyphosate tolerant sweet corn (EPSPS trait), glyphosate tolerant soya bean (*GAT* trait), conventional peas (dry), glyphosate tolerant sugar beet (EPSPS trait), glyphosate tolerant maize (*GAT* trait), glyphosate tolerant sweet corn forage and stover (EPSPS trait) and glyphosate tolerant sugar beet tops (EPSPS trait).

Glyphosate may be applied prior to crop emergence (pre-emergence = PRE), shortly after crop emergence (early post emergence = EPO), between EPO and a few weeks before harvest (late post-emergence = LPO), and prior to harvest (pre-harvest = PH).

When applied pre-harvest, residues in the raw agricultural commodity (RAC) are mainly determined by applications made during the growth stages of the plant rather than as a consequence of pre-emergence applications. For commodities that are exposed to glyphosate as pre-emergence, post-emergence and pre-harvest applications, the post-emergence and pre-harvest sprays have the greatest influence on residues. The highest residue from any trial at the location and carried out with different numbers of applications and rates and timings of application, but within the range permitted by GAP, was selected.

The limits of quantification of glyphosate and AMPA are typically 0.05 mg/kg.

In general, data from conventional crops and genetically modified crops cannot be combined since application rates in genetically modified crops are usually higher than in conventional crops. The data were only combined when the GAP-s were similar.

For estimation of maximum residue levels for soya beans and maize crops glyphosate and *N*-acetyl glyphosate levels are summed and expressed as glyphosate equivalents.

The values used for the estimation of maximum residue level are underlined.

For estimation of residue levels for dietary risk assessment in conventional crops and glyphosate tolerant crops (EPSPS varieties) glyphosate and AMPA form the total residue, since *N*-acetyl-glyphosate and *N*-acetyl AMPA are not formed. When glyphosate and AMPA are summed, AMPA was converted to glyphosate acid equivalents (AMPA mg/kg × 1.5). The Meeting concluded that generally if AMPA residues are < 0.05 mg/kg, the LOQ level is not summed with glyphosate because AMPA residues are typically much less than glyphosate. If both glyphosate and AMPA are < LOQ, then the sum is < LOQ of glyphosate. This is also the case for glyphosate tolerant sugar beet (EPSPS variety). The exception is where there is evidence that AMPA residues are comparable to glyphosate residues such as for glyphosate tolerant sweet corn (EPSPS variety). In that situation the LOQs are summed and if both glyphosate and AMPA residues are < LOQ and the level reported as less than the sum of the LOQs for glyphosate and AMPA.

For estimation of the residue levels for dietary risk assessment of glyphosate in *GAT* crops, in general, all four analytes are present in significant amounts. In the *GAT* modified soya beans, *N*-acetyl glyphosate is the major residue found in soya bean seed, followed by *N*-acetyl AMPA and glyphosate. AMPA occurs in lower levels. However, as AMPA does occur in levels above LOQ in a small number of residue trials the LOQ for AMPA is included in the sum of residues when AMPA is reported as < LOQ. In maize with the *GAT* trait *N*-acetyl glyphosate residue levels were found to be the major residue in grain. Since in a small number of trials glyphosate residues were also observed the LOQ for both *N*-acetyl glyphosate and glyphosate were included in the calculation of the total residue when residues were reported as < LOQ. Because all AMPA and *N*-acetyl AMPA residue levels were below LOQ and the metabolism study suggests they are components, when present at < LOQ the LOQs for these metabolites were not included in the calculation of the total residue for dietary risk assessment for maize.

The OECD calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the OECD calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was provided.

Fruiting vegetables

Sweet corn

Field trials involving glyphosate tolerant sweet corn (EPSPS variety) conducted in the USA and Canada were available to the Meeting.

The GAP for sweet corn in the USA is ≥ 1 LPO (late post emergence) applications, maximum of 1.7 kg ai/ha per application (PHI 30 days), with a total in-crop maximum of 5.2 kg ai/ha. In the trials matching this GAP the glyphosate residues reported as free acid equivalent in ranked order were (n = 14) 0.11, 0.12, 0.13, 0.13, 0.14, 0.15, 0.24, 0.24, 0.28, 0.30, 0.60, 0.70, 1.2 and 2.3 mg/kg. The Meeting agreed that the USA and Canadian data set could be used to support a maximum residue level recommendation and estimated a maximum residue level of 3 mg/kg for glyphosate on corn-on-the-cob.

Total residues in ranked order were (n = 14) 0.18, 0.20, 0.20, 0.22, 0.22, 0.23, 0.32, 0.33, 0.43, 0.43, 0.78, 1.0, 1.3 and 2.8 mg/kg. The STMR for total residues is 0.325 mg/kg.

Pulses

The Meeting received a request to re-evaluate previously submitted data on lentils, in combination with the data on dried peas and dried beans and new trials in dried peas, and to consider extrapolation of the pea and bean data to support a maximum residue level recommendation for lentils. The Meeting noted extrapolation based on peas (dry) would lead to a higher maximum residue level estimation. The previously evaluated data for peas (dry) and lentils together with newly submitted data for peas (dry) are summarized below.

Lentils

The 2005 JMPR reviewed two trials on conventional lentils, conducted in Canada and matching the GAP of Canada (1 pre-harvest (PH) application of 0.9 kg ai/ha, when crop has 30% grain moisture content and lowermost pods are brown with seed rattle, PHI 7–14 days). Residues of glyphosate reported were < 0.05 and 3.0 mg/kg and for AMPA < 0.05 mg/kg. The total residues (glyphosate and AMPA) were < 0.05 mg/kg and 3.0 mg/kg.

Peas (dry)

Residue data from trials in conventional peas (dry) in the UK, Belgium, Denmark and Canada were evaluated against the GAPs of the UK and Canada by the 2005 JMPR and combined. GAP in Canada is a single PH application of 0.9 kg glyphosate ai/ha when grain moisture is < 30% (PHI 7–14 days). GAP in the UK is a single PH application of 1.4 kg ai/ha when grain moisture is < 30% (PHI 7 days). Glyphosate residues in ranked order were (n = 11): 0.13, 0.16, 0.17, 0.17, 0.5, 0.5, 0.82, 1.4, 1.7, 1.8, and 2.1 mg/kg. Based on these data an MRL of 5 mg/kg was estimated.

When measured, AMPA residues were all < 0.05 (4) mg/kg. The STMR was estimated to be 0.5 mg/kg.

The current Meeting received five additional field trials in conventional peas (dry), performed in three locations in the USA in 1998, matching the USA GAP for 1 PH application of up to 2.55 kg ai/ha, PHI 7 days, and with grain moisture≤ 30%. Glyphosate residues (glyphosate only) in grains in ranked order were: 0.70, 0.77, 1.1, 3.4, and 4.2 mg/kg (n = 5) at PHI 7. The data are insufficient to estimate a new maximum residue level and STMR for conventional peas (dry) based on the USA GAP.

Data from peas (dry) can both be used to extrapolate to other members of the group pulses that have similar GAP such as lentils. The Meeting proposed to use the dataset from peas that support the Canadian GAP of 1 PH application of 0.9 kg ai/ha, grain moisture≤ 30%, PHI 7–14 days. The Meeting extrapolated the residues on peas (dry) to estimate a maximum residue level of 5 mg/kg, an STMR of 0.5 mg/kg, respectively for lentils.

Soya beans

The 2005 JMPR reviewed field trials conducted according to USA GAP in both conventional and glyphosate tolerant soya beans (EPSPS varieties) and concluded them to be similar residue populations for the purpose of estimating MRLs and combined the datasets. The USA GAP for conventional soya beans was 4.3 kg ai/ha PRE, 4.2 kg ai/ha PH, with a PHI of 7 days. The USA GAP for glyphosate tolerant soya beans (EPSPS variety) was 0.43–4.2 kg ai/ha PRE, 1.7 kg ai/ha LPO, 0.83 kg ai/ha PH (combined LPO + PH < 2.5 kg ai/ha), with a PHI of 14 days. Glyphosate residues in ranked order were (n = 36): 0.27, 0.28, 0.34, 0.37, 0.42, 0.44, 0.45, 0.51, 0.56, 0.60, 0.70, 1.0, 1.1, 1.4, 1.4, 1.5, 1.7, 1.8, 1.9, 1.9, 1.9, 2.0, 2.6, 2.7, 2.7, 3.0, 3.3, 3.5, 3.6, 3.7, 4.4, 5.3, 5.4, 5.6, 13 and 17 mg/kg. The 2005 JMPR used the data to confirm the previous maximum residue level of glyphosate in soya beans of 20 mg/kg.

Total residues (glyphosate and AMPA only) were (n = 36): 0.45, 0.59, 0.78, 0.89, 1.0, 1.1, 1.1, 1.2, 1.2, 1.5, 1.6, 2.4, 3.2, 4.0, 4.0, 4.3, 4.7, 4.9, 5.1, 5.4, 5.7, 6.2, 6.6, 7.1, 7.2, 7.6, 7.6, 7.9, 8.2, 8.5, 11, 11, 11, 16, 17 and 20 mg/kg. The highest residue and STMR for total residues were estimated to be 20 and 5.0, respectively.

The current Meeting received field trials performed in the USA and Canada involving glyphosate tolerant soya beans containing the *GAT* trait. GAP for USA and Canada is for 1 pre-emergence application (0.44–4.2 kg ai/ha PRE), followed by three field applications, with a maximum application of 1.76 kg ai/ha at LPO (late post emergence) and the last application PH (pre harvest) not exceeding 0.88 kg ai/ha (PHI 14 days). The Meeting noted that the pre-emergence applications were conducted at a lower rate (mostly 3.2–3.9 kg ai/ha) than indicated by GAP of 4.2 kg ai/ha. However, as established by the 2005 JMPR the difference in application rates at pre-emergence account for less than 10% difference in the residue at harvest and the later post-emergence sprays determine the residue. At one trial location the crop was damaged due to a hurricane and heavy rain fall. Residues in this trial were considerably higher than samples collected from other sites and the results for this site are not considered further.

Residues in the remaining trials matching USA GAP (late post emergence application 1.76 kg ai/ha and pre-harvest application 0.88 kg ai/ha, PHI 14 days) in soya bean seeds were 0.1, 0.34, 0.49, 0.69, 0.89, 0.92, 1.2, 1.5, 1.7, 1.7, 1.7, 1.8, 2.4, 2.4, 3.1, 3.1, 5, 5, 5.8, 5.9, 6 and 7.8 mg/kg (n = 22). The Meeting noted that the use of glyphosate on soya beans containing the *GAT* trait is covered by the previous recommendation of 20 mg/kg for soya bean (dry).

Root and tuber vegetables

Sugar beets

The current Meeting received field trials involving glyphosate tolerant sugar beets containing the EPSPS gene conducted in Canada and the USA.

GAP for these glyphosate tolerant sugar beets in the USA is ≥ 1 PRE applications, total max 4.2 kg ai/ha, 2 LPO of 1.3 kg ai/ha, and 2 PH applications of 0.9 kg ai/ha, PHI 30 days and total in crop application rate (LPO and PH) of 3.9 kg ai/ha. The Canadian GAP consists of 1 × PRE applications and up to 4 × LPO applications at 0.9 kg ai/ha, PHI 30 days, and a total in crop application rate (for LPO) of 3.6 kg ai/ha. The pre-emergence application was not considered to attribute significantly by the Meeting of 2005.

In trials performed in Canada matching the GAP (4 × 0.9 kg ai/ha, PHI 30 days) glyphosate residues in sugar beet roots in ranked order were (n = 4): 3.1, 3.5, 5.7 and 7.1 mg/kg.

In trials matching the USA GAP (2 × 1.3 kg ai/ha LPO and 2× 0.9 kg ai/ha PH, PHI 30 days) glyphosate residues (glyphosate only) in ranked order were (n = 12): 0.62, 0.90, 2.0, 2.2, 2.6, 2.9, 3.2, 3.3, 4.6, 4.8, 5.0 and 5.5 mg/kg.

The Meeting noted that the last two critical applications of the Canadian and USA GAP were similar and that the trials conducted in Canada with a lower application rate led to higher residues. The Meeting decided to combine the results. Glyphosate residues in ranked order were (n = 16): 0.62, 0.9, 2, 2.2, 2.6, 2.9, 3.1, 3.2, 3.3, 3.5, 4.6, 4.8, 5, 5.5, 5.7 and 7.1 mg/kg. The Meeting estimated a maximum residue level of 15 mg/kg.

The total residues in ranked order were (n = 16) 0.7, 0.98, 2.1, 2.3, 2.7, 3, 3.1, 3.4, 3.4, 3.5, 4.8, 5, 5.3, 5.8, 5.8 and 7.3 mg/kg. The highest residue and STMR for total residues are 7.3 and 3.4 mg/kg for glyphosate tolerant sugar beet.

Maize

The 2005 JMPR reviewed trials on conventional maize conducted in the USA (GAP of 0.43–4.5 kg ai/ha PRE, 0.87 kg ai/ha directed spray when crop > 30 cm tall and 2.5 kg ai/ha PH grain moisture < 35%, with a PHI of 7 days). From 21 trials that approximated the USA GAP, which involved a single pre-harvest application to conventional maize, glyphosate residues of < 0.05 (12), 0.05 (2), 0.06 (2), 0.07, 0.09, 0.54, and 3.0 mg/kg were found. Corresponding total residues were < 0.12 (11), < 0.14 (2), 0.14, < 0.16, 0.19, < 0.23, 0.25, < 0.26, < 0.62 and 3.0 mg/kg, respectively. The 2005 JMPR estimated a maximum residue level for conventional maize of 5 mg/kg, an STMR of < 0.12 and a highest residue of 3.0 mg/kg. None of the submitted trials on glyphosate tolerant maize matched the USA GAP.

The current Meeting received field trials involving glyphosate tolerant maize (containing the *GAT* trait) performed in the USA and Canada.

GAP in the USA and Canada is PRE up to a total of 4.2 kg ai/ha, 1–4 LPO in-crop applications of 0.88–1.3 kg ai/ha (total in-crop max 2.6 kg ai/ha), PH application ≤ 0.88 kg ai/ha (PHI 7 days). In trials from Canada and the USA matching this GAP, total glyphosate residues in maize grains were (n = 27) < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, < 0.1, 0.1, 0.1, 0.11, 0.11, 0.11, 0.12, 0.13, 0.15, 0.2, 0.21, 0.3 and 0.56 mg/kg.

Since the GAPs are different for conventional and glyphosate tolerant crops, the datasets cannot be combined. The dataset of conventional maize gives rise to a higher maximum residue level. The Meeting confirms the previous recommendation of a maximum residue level for glyphosate in maize of 5 mg/kg based on the conventional maize data set. The previously derived highest residue and STMR for total residues in conventional maize of 3.0 and < 0.12 mg/kg, respectively are confirmed.

Animal feedstuffs

Straw, forage and fodder of cereal grains and grasses

Maize forage and stover

For the 2005 JMPR evaluation trials on conventional maize were conducted in the USA (GAP 4.2 kg ai/ha PRE; 0.87 kg ai/ha hooded sprayers; 2.5 kg ai/ha pre-harvest grain moisture < 35%, PHI 7 days). Glyphosate residues in stover/fodder 7 days after a pre-harvest application according to US GAP were (n = 21) 2.1, 2.6, 3.4, 3.7, 4.8, 6.7, 8.4, 8.8, 11, 18, 23, 28, 35, 43, 43, 44, 53, 54, 55, 82, and 92 mg/kg. Total residues were (n = 21) 2.1, 2.6, 3.5, 3.8, 4.8, 6.8, 8.8, 9.0, 11, 18, 24, 29, 36, 44, 45, 45, 54, 55, 56, 83 and 93 mg/kg.

Additionally, the review of 2005 reported trials conducted on glyphosate tolerant maize (EPSPS trait) according to the USA GAP (4.2 kg ai/ha PRE; 1.7 kg ai/ha LPO, allowing a minimum of 50 days between application and harvest of corn forage; 0.87 kg ai/ha PH < 30% grain moisture, combined LPO + PH < 2.5 kg ai/ha, PHI 7 days).

Seventeen trials on forage but no trials on tolerant maize fodder matched GAP. Glyphosate residues in forage were (n = 17): 0.30, 0.50, 0.54, 0.66, 0.73, 0.79, 0.87, 0.92, 1.1, 1.1, 1.2, 1.3, 1.3, 1.8, 1.8, 2.2 and 4.6 mg/kg. Total residues were: 0.35, 0.50, 0.54, 0.75, 0.78, 0.84, 0.92, 0.98, 1.2, 1.2, 1.3, 1.4, 1.4, 1.9, 1.9, 2.4 and 4.7 mg/kg (n = 17).

Using the residue trials for conventional maize crops, the 2005 JMPR recommended a maximum residue level of 150 mg/kg (dry weight basis) for maize fodder based on a highest residue of 111 mg/kg (92 mg/kg ÷ 0.83 default dry matter content). The 2005 JMPR also estimated a highest residue of 93 mg/kg and a median residue of 24 mg/kg for total residues in maize fodder, both on an 'as received' basis. The highest and median residues for total residues in maize forage were 4.7 and 1.2 mg/kg respectively, both on an 'as received' basis.

For the current evaluation the Meeting received field trials involving glyphosate tolerant maize (*GAT* trait) performed in the USA and Canada.

GAP in the USA and Canada:≥ 1 PRE applications up to a total of 4.2 kg ai/ha, 1–4 LPO in crop applications of 0.88–1.3 kg ai/ha (max total in-crop application 2.6 kg ai/ha), pre-harvest application ≤ 0.88 kg ai/ha, PHI 7 days. For forage the last application (LPO) should be made at least 50 days before harvest.

In the trials matching the GAP, glyphosate residues in maize stover (*GAT* trait) on an as received basis were (n = 26): 2.2, 2.6, 2.9, 3.1, 3.7, 4.7, 5.0, 5.1, 5.2, 5.8, 8.4, 9.3, 9.6, 10, 11, 11, 13, 14, 14, 17, 17, 20, 20, 25, 28 and 32 mg/kg.

Residues in stover from glyphosate tolerant maize (*GAT* trait) were lower than previously evaluated for conventional and tolerant (EPSPS trait) maize. The Meeting confirms its previous estimation of a maximum residue level for maize stover (fodder) of 150 mg/kg (dry weight basis) and the estimated highest residue of 93 mg/kg and median of 24 mg/kg, both on as received basis.

For trials matching the USA GAP for glyphosate tolerant (*GAT* trait) maize forage (PHI for harvest for forage of 50 days) glyphosate residue levels (fresh weight basis) in ranked order were 0.37, 0.46, 0.50, 0.64, 0.66, 0.68, 0.70, 0.88, 0.69, 1.1, 1.2, 1.6, 1.6, 3.6, 3.8 and 4.8 mg/kg (n = 16).

The median and highest residues (fresh weight basis) are 0.923 and 4.75 mg/kg respectively.

The Meeting noted the currently estimated median and highest residue values of 0.923 and 4.75 mg/kg (fresh weight basis) are not significantly different to the estimates of the 2005 JMPR (STMR 1.2 mg/kg and highest residue 4.7 mg/kg).

Sweet corn forage

The current Meeting received trials on glyphosate tolerant sweet corn (EPSPS trait) forage and stover performed in the USA and Canada.

No GAP for Canada was available. GAP for (sweet) corn forage in the USA is≥ 1 LPO/PH applications with a maximum of 1.7 kg ai/ha, PHI 30 days, with a total in-crop maximum of 5.2 kg ai/ha. The Meeting agreed that the US and Canadian data could be evaluated against the US GAP. The Meeting considered that the pre-harvest application is the critical application that would give rise to the residues in forage. In the trials matching the USA GAP the total residues (fresh weight basis) in sweet corn forage in ranked order were (n = 14) 0.53, 0.91, 1.3, 1.4, 1.5, 1.8, 1.9, 1.9, 2, 2.5, 2.7, 4, 5.6 and 5.8 mg/kg

The Meeting estimated a median residue of 1.9 mg/kg and a highest residue of 5.8 mg/kg for glyphosate (fresh weight basis) in glyphosate tolerant sweet corn forage containing the EPSPS trait.

Miscellaneous fodder and forage crops

Soya bean forage and fodder

Residue levels occurring in forage and stover of glyphosate tolerant soya beans (*GAT* trait) were evaluated but the USA GAP excludes grazing and harvest of treated crops for forage and hay.

Sugar beet tops

For the evaluation of 2005, trials were provided on sugar beet (glyphosate tolerant) from the US (GAP 0.43–4.2 kg ai/ha PRE, 0.43–1.3 kg ai/ha LPO, 0.43–0.87 kg ai/ha PH, PHI 30 days). No trials matched GAP.

For the current evaluation the Meeting received trials on glyphosate tolerant sugar beet tops (EPSPS trait) performed in the USA and Canada.

USA GAP is ≥ 1 PRE applications, with a total maximum of ≤ 4.2 kg ai/ha, followed by up to 2 LPO applications (≤ 1.3 kg ai/ha, max 2.2 kg ai/ha) and up to two PH applications (≤ 0.87 kg ai/ha, max 1.7 kg ai/ha), PHI 30 days, and total in-crop application rate (LPO and PH combined of 3.9 kg ai/ha). The Canadian GAP consists of up to ≤ 4 LPO/PH at 0.9 kg ai/ha, PHI 30 days, and a total in-crop application rate of 1.8 kg ai/ha.

The pre-emergence application was not considered to contribute significantly by the Meeting of 2005. In trials performed in Canada matching the GAP (4× 0.9 kg ai/ha, PHI 30 days) total glyphosate residues in sugar beet tops (fresh weight basis) in ranked order were (n = 4) 2.3, 2.5, 3.2 and 5.4 mg/kg.

In trials matching the USA GAP (2× 1.3 kg ai/ha post emergence and 2× 0.9 kg ai/ha pre-harvest, PHI 30 days) total glyphosate residues (fresh weight basis) in ranked order were (n = 12) 0.61, 0.89, 1.5, 1.6, 1.7, 1.8, 1.9, 2.2, 2.4, 2.6, 2.7 and 2.8 mg/kg.

The Meeting noted that the last two applications of the Canadian and USA GAP were similar and decided by the Meeting to combine the results. The combined data in ranked order are 0.61, 0.89, 1.5, 1.6, 1.7, 1.8, 1.9, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 3.2 and 5.4 mg/kg (n = 16). A median residue of 2.25 mg/kg and a highest residue of 5.4 mg/kg for glyphosate (fresh weight basis) in glyphosate tolerant sugar beet tops were estimated.

Fate of residues during processing

The Meeting received information on the nature of residues under simulated processing conditions on the fate of incurred residues of glyphosate during the processing of soya bean seeds and corn grain. A study of the nature of the residue of *N*-acetyl-glyphosate under simulated processing conditions (pasteurization, baking/brewing/boiling, sterilization) showed N-acetyl-glyphosate was stable.

Processing studies were available for maize and soya beans genetically modified to contain the *GAT* gene and containing incurred residues. Calculated processing factors for total glyphosate acid equivalents (combined results of the parent compound and three metabolites) are summarized below.

Summary of calculated processing factors for *GAT* crops

Commodity	processing factors (PF)	processing factor (median or best estimate)		Median-P
Soya bean (HR = 20; STMR = 5 mg ai/kg, total residue)				
aspirated grain fraction	6.3, 44	25		125
refined oil	–	–		–
Meal	0.7	0.7		3.5
Hulls	5.1	5.1		25.5
Maize (HR = 3; STMR = 0.12 mg ai/kg, total residue)				

Commodity	processing factors (PF)	processing factor (median or best estimate)		Median-P
Soya bean (HR = 20; STMR = 5 mg ai/kg, total residue)				
aspirated grain fraction	11	11		1.32
Starch	–	–		–
Grits	0.93, 0.74	0.84		0.10
Flour	1.2, 0.85	1.0		0.12
Refined oil (wet milling)	–	–		–
Refined oil (dry milling)	–	–		–
Meal (dry milling)	1.1, 0.97	1.0		0.12

The 2005 JMPR estimated processing factors in glyphosate tolerant sugar beet processed commodities, but did not include the results in the appraisal, since no maximum residue level, HR and STMR could be derived for glyphosate tolerant sugar beet (EPSPS trait) at that time. Since these residue levels are established in the current evaluation, the processing factors as determined in 2005 have been summarized in the table below, including the HR-Ps and STMR-Ps.

Summary of processing factors

Commodity	processing factor	processing factor (median or best estimate		Median-P
Sugar beet (HR = 7.3; STMR = 3.4 mg ai/kg, total residue)				
Wet pulp	0.08, 0.06	0.07		0.24
Dry pulp	0.73, 0.50	0.62		2.1
Molasses	< 0.01	< 0.01	–	–
Sugar, Refined	< 0.01	< 0.01	–	–

Residues in animal commodities

Farm animal dietary burden

The Meeting received information on the residue levels arising in animal tissues and milk when dairy cows were fed *N*-acetyl-glyphosate at total dietary levels of 44, 130, 437 and 1179 ppm *N*-acetyl-glyphosate for 28 consecutive days. No residues were detected in milk (LOQ 0.025 mg/kg) in the samples analysed at all dose levels and time intervals. The highest total residues (mean in brackets) in liver, kidney, fat and muscle from the highest dose animals were 0.52 (0.42), 3.6 (3.2), 0.22 (0.12) and 0.053 (0.051) mg/kg respectively.

The Meeting also received information on the residue levels arising in animal tissues and eggs, when laying hens were fed a diet containing *N*-acetyl-glyphosate at total dietary levels of approximately 22, 77, 214 and 782 ppm dry weight feed for 35 consecutive days.

Residues above LOQ (0.025 mg/kg) were detected in tissues and eggs at all dose levels. The highest total residues (mean in brackets) in liver, fat, muscle and eggs from the highest dose animals were 5.2 (4.3), 1.9 (1.3), 0.58 (0.41) and 0.88 (0.60) mg/kg respectively.

Animal commodity maximum residue levels

The current evaluation has not led to recommendations that would alter the dietary burdens calculated using the livestock intake figures employed by the 2005 JMPR. The glyphosate dietary burdens for cattle (dairy and beef) were based on grass, cotton seed and barley grain while those for poultry were based on barley, soya bean grain and soya bean hulls. The estimates for both the highest and mean residue levels for soya bean grain and hulls have not changed from those used by the 2005 JMPR though crops containing the *GAT* trait may contain some *N*-acetyl-glyphosate. However, calculations indicate the contribution to the dietary burden for estimation of maximum residue levels is less than 10% and as such do not warrant a re-evaluation of animal commodity maximum residues levels.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDI) of glyphosate for the 13 GEMS/Food regional diets, based on estimated STMRs were in the range 0–2% of the maximum ADI of 1 mg/kg bw for the sum of glyphosate, N-acetyl glyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate. The Meeting concluded that the long-term intake of residues of glyphosate, N-acetyl glyphosate, AMPA and N-acetyl AMPA from uses that have been considered by the JMPR is unlikely to present a public health concern. The results are shown in Annex 4 of the JMPR 2011 Report.

Short-term intake

The International Estimated Short Term Intake (IESTI) of glyphosate was not calculated. The 2004 and 2005 JMPR concluded that it was unnecessary to establish an ARfD for glyphosate. The Meeting therefore concluded that short-term dietary of glyphosate residues is unlikely to present a risk to consumers.