5.22 THIAMETHOXAM (245)

TOXICOLOGY

Thiamethoxam is the International Organization for Standardization (ISO)–approved name for (*EZ*)-3-(2-chloro-1,3-thiazol-5-ylmethyl)-5-methyl-1,3,5-oxadiazinan-4-ylidene(nitro)amine (International Union of Pure and Applied Chemistry [IUPAC]), with Chemical Abstracts Service (CAS) No. 153719-23-4. It is a neonicotinoid insecticide active against a broad range of commercially important sucking and chewing pests. The biological effects of this chemical class in target species are mediated primarily by an interaction with nicotinic acetylcholine receptor sites.

Thiamethoxam is being reviewed for the first time by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) at the request of the Codex Committee on Pesticide Residues (CCPR). All critical studies complied with good laboratory practice (GLP). Non-GLP studies were identified as such.

Biochemical aspects

In rats given [^{14}C]thiamethoxam labelled in either the thiazole or oxadiazine rings as a single oral dose of 0.5 or 100 mg/kg body weight (bw), the radiolabel was rapidly and completely absorbed, based on the recoveries in excreta. The time to reach maximum concentrations in plasma was 1–4 h. Distribution to the tissues was generally non-selective, but resulted in higher concentrations in liver and blood. Tissue residues in rats amounted to 0.3% of the total applied dose after 7 days.

The depletion from the tissues followed first-order kinetics, with half-lives in all tissues in the range of 2–6 h, independent of the dose level, the site of the label and the sex of the rats. Seven days after oral administration of 0.5 mg/kg bw, the tissue residues were very low. The absorbed material was rapidly excreted from rats, predominantly in the urine. The routes of elimination and the urinary pattern of the rapidly excreted thiamethoxam and its metabolites were complex and independent of the route of administration, the dose level, pretreatment with non-radio-labelled thiamethoxam, the site of label and the sex of the animals.

In rats, about 20–30% of the dose was biotransformed, whereas 70–80% was eliminated as unchanged thiamethoxam. Within 24 h, about 90% of the dose was excreted via kidneys with recovery in urine, and about 4% via the bile with recovery in the faeces; total faecal recovery was about 5%. In mice, 30–60% of the dose was biotransformed and eliminated mainly in urine, but faecal elimination accounted for about 19%.

Twenty-two metabolites were isolated from the excreta of rats and identified. The quantitatively most important metabolite was CGA 322704 (clothianidin), which accounted for about 10% of the dose. The individual contributions of all the other metabolites did not exceed 1% of the dose. Plasma concentrations of two of these minor metabolites, CGA 330050 and CGA 265307, were 15 to 140-fold higher in mouse than in rat. The major reaction involved in the biotransformation of thiamethoxam is cleavage of the oxadiazine ring to the corresponding nitroguanidine compound. Minor pathways are reduction of the nitroguanidine group, yielding a hydrazine, followed by either acylation or further reduction to a guanidine derivative, hydrolysis of the guanidine group to the corresponding urea, demethylation of the guanidine group and substitution of the chlorine of the thiazole ring by glutathione. Cleavage between the thiazole and oxadiazine ring occurs to a small extent and is mediated by either glutathione or oxidative dealkylation. The glutathione derivatives are prone to further degradation. Both the thiazole and oxadiazine moieties are susceptible to oxidative attack. These minor pathways proceed to small molecules and ultimately, probably, to carbon dioxide. The small molecules generated may enter the general metabolism. Metabolic degradation of thiamethoxam in mice proceeded via the same pathway as in rats. All major and almost all minor metabolites found in rat excreta were also detected in mouse excreta.

In vitro comparisons of thiamethoxam metabolism in mouse, rat and human liver microsomal preparations clearly support the significantly higher generation of CGA 330050 and CGA 265307 in mice compared with rats and additionally, demonstrates that human liver microsomes metabolize thiamethoxam in a manner quantitatively similar to and not exceeding that of rats.

Toxicological data

The acute toxicity of thiamethoxam is low, the oral median lethal dose (LD_{50}) being 1563 mg/kg bw in rats and 871 mg/kg bw in mice. Signs of toxicity at high doses included tonic or clonic convulsions, ptosis and reduced locomotor activity. The acute dermal LD_{50} of thiamethoxam in rats was greater than 2000 mg/kg bw. The 4 h acute inhalation median lethal concentration (LC_{50}) of thiamethoxam in rats was greater than 3.72 mg/L (the mean achieved concentration). Thiamethoxam was not irritating to rabbit skin or rabbit eyes. Thiamethoxam was not a skin sensitizer in the Magnusson and Kligman maximization test in guinea-pigs.

The short-term oral toxicity of thiamethoxam administered via the diet was evaluated in mice, rats and dogs. These consisted of 4-week range-finding studies in rats followed by 13-week toxicity studies in rats and dogs and a 52-week toxicity study in dogs. A 13-week range-finding study was also conducted in mice.

The liver was identified as a target organ in mice and rats. Treatment for 13 weeks induced liver hypertrophy, inflammatory cell infiltration and pigmentation of hepatocytes and Kupffer cells in both rodent species. In mice, single-cell necrosis and apoptosis occurred in parallel with these alterations.

The kidney was identified as a target organ in rats, but not in mice or dogs. Both sexes were affected, but there was a difference between the sexes in both morphology and sensitivity. In males, nephrotoxicity was characterized by tubular epithelial hyaline droplet accumulation, acute and chronic tubule lesions, basophilic proliferation and cast formation. The pattern of effects in male rat kidneys resembled α_{2u}-globulin nephropathy, which is generally accepted to be a phenomenon exclusively found in males of some strains of rats. Immunohistochemical studies on kidneys from male rats exposed to thiamethoxam for 28 days or 3, 12 or 24 months with a specific anti-α_{2u}-globulin antibody identified treatment-related increases in renal α_{2u}-globulin accumulation, particularly after 28 days and 3 months of treatment. It was concluded that the renal changes observed in male rats treated with thiamethoxam represent a mild α_{2u}-globulin nephropathy, which is male rat specific and has no human relevance. Renal lesions in females were confined to an increased incidence of chronic tubular lesions and an increase in the severity of nephrocalcinosis. Other observations, particularly basophilic proliferation, tended to be increased in all groups of females at 28 days and may represent the beginnings of chronic progressive nephropathy. However, such observations were not repeated after 3 (or 12) months of exposure. Therefore, the no-observed-adverse-effect levels (NOAELs) of human relevance in rats were derived on the basis of effects in organs other than male kidney in the repeated-dose toxicity studies after 28 days and 3 months of treatment as well as in the 2-year study.

Other target organs and changes in rats were fatty changes in the adrenal cortex, enhanced haemosiderosis or extramedullary haematopoiesis in the spleen and follicular epithelial hypertrophy in the thyroid gland. Thymic and splenic atrophy in dogs and alterations suggestive of delayed maturation of the gonads in dogs and female mice occurred at doses causing substantial growth retardation.

The NOAELs derived from short-term studies, in which thiamethoxam was administered orally, were as follows:

- The NOAEL in the 90-day dietary study in mice with thiamethoxam was 100 ppm (equal to 14.3 mg/kg bw per day), based on raised platelet counts at 1250 ppm (equal to 176 mg/kg bw per day in females). Minimal lymphocytic infiltration and hepatocyte hypertrophy were observed in males at 100 ppm and 1250 ppm; in the absence of any other hepatic changes, these were considered an adaptive response or an early sign of mouse-specific hepatotoxicity.

- The NOAEL in the 28-day dietary study in rats was 100 ppm (equal to 8.0 mg/kg bw per day), based on increased plasma cholesterol concentrations at a dose level of 1000 ppm (equal to 81.7 mg/kg bw per day). The male rat–specific kidney effects have no human relevance, and therefore they are not considered for the NOAEL.
- The NOAEL in the 90-day dietary study in rats was 250 ppm (equal to 17.6 mg/kg bw per day in males), based on reduced body weight gain and histological findings in the adrenals at 1250 ppm (equal to 84.9 mg/kg bw per day). Observation of hyaline droplet accumulation in the kidneys of male rats was considered indicative of α_{2u}-globulin involvement, which is male rat specific and has no human significance.
- The NOAEL in the 90-day oral toxicity study in dogs was 250 ppm (equal to 8.23 mg/kg bw per day), based on prolonged thromboplastin times in both sexes at 1000 ppm (equal to 32 mg/kg bw per day).
- The NOAEL in the 52-week oral toxicity study in dogs was 750 ppm (equal to 21 mg/kg bw per day), based on prolonged thromboplastin times and reductions in testis weights at 1500 ppm (equal to 42 mg/kg bw per day).

Long-term toxicity and carcinogenicity studies were performed in mice and rats. The main target organs were the liver in mice and female rats and the kidneys in male rats. In rats, the principal findings were increased incidences of renal tubule regenerative lesions, which were considered to represent the sequelae of the rat-specific nephropathies observed in short-term studies. Minor and morphologically different changes occurred in the spleen of both rats and mice.

The NOAEL in the 78-week dietary study in mice was 20 ppm (equal to 2.63 mg/kg bw per day), based on hepatotoxic effects (i.e., increased liver weights, hepatocellular hypertrophy, pigment deposition, inflammatory cell infiltration and single-cell necrosis) at 500 ppm (equal to 63.8 mg/kg bw per day). Thiamethoxam was tumorigenic in mice and induced hepatocellular adenomas in male and female mice at a dose level of 500 ppm and hepatocellular adenocarcinomas in male mice at 2500 ppm (equal to 354 mg/kg bw per day).

Special studies on thiamethoxam (the *EZ*-isomer mixture as used in all toxicity studies) were performed to investigate the etiology of adenoma and adenocarcinoma formation in mouse liver during an 18-month oncogenicity study. The hypothesis investigated was that the mouse specificity in this response is due to a very large species difference in metabolism of thiamethoxam, as demonstrated by 15-fold and 140-fold higher plasma concentrations of CGA 330050 and CGA 265307, respectively, in mice than in rats following 10 weeks of dosing with thiamethoxam. This large difference is supported by in vitro comparison of thiamethoxam metabolism by microsomal preparations from mouse, rat and human liver. Although these metabolites also occur with rat microsomes, their concentrations are very much lower than in mice. The data also suggested that humans were likely to be even less susceptible than rats to the hepatic effects of thiamethoxam. The mode of action proposed for development of these tumours is based on the hepatotoxicity of the metabolite CGA 330050 in particular, with CGA 265307 exacerbating its effect, and the subsequent sustained cell proliferation of mouse hepatocytes, leading to the development of a higher incidence of hepatocellular tumours. Not all elements for a mode of action have been identified, but the available data support the contention of a low risk to humans with regard to both hepatotoxicity and carcinogenicity and the absence of any genotoxic involvement. An alternative metabolic pathway to CGA 265307 in both mice and rats is via CGA 322704. The *E*-isomer of CGA 322704 was evaluated at the present Meeting, and it was concluded that it is not carcinogenic in mice or rats.

The NOAEL in this 78-week dietary study in mice for non-hepatic effects is 1250 ppm (equal to 162 mg/kg bw per day), based on reductions in body weight and effects on spleen and stomach at 2500 ppm (equal to 354 mg/kg bw per day).

The NOAEL in the 104-week dietary study in rats was 1000 ppm (equal to 50.3 mg/kg bw per day in females), based on foci of cellular alteration in the liver and increased severity of splenic haemosiderosis at 3000 ppm (equal to 155 mg/kg bw per day). Increased incidences of renal chronic

tubular lesions and basophilic proliferation were observed exclusively in male rats at 500 ppm (equal to 21.0 mg/kg bw per day). These renal lesions were considered to represent the outcome of α_{2u}-globulin-mediated nephropathy, which is widely acknowledged as male rat specific and not relevant in human risk assessment, and therefore they were not used to identify the NOAEL.

Thiamethoxam was tested for genotoxicity and mutagenicity in an adequate range of assays, both in vitro and in vivo. In none of these assays was there any evidence of genotoxic or mutagenic potential.

The Meeting concluded that thiamethoxam is unlikely to be genotoxic.

On the basis of the absence of genotoxicity in vivo, the absence of carcinogenicity in rats and the mode of action by which liver tumours arise in mice, the Meeting concluded that thiamethoxam is unlikely to pose a carcinogenic risk at human dietary exposure levels.

Hyaline change and casts in renal tubules were observed in male rats in the multigeneration studies at 1000 ppm (equal to 45.6 mg/kg bw per day). This observation has no human relevance. Therefore, the relevant NOAEL for parental toxicity is 1000 ppm (equal to 45.6 mg/kg bw per day), based on significantly reduced body weight gain at 2500 ppm (equal to 117.6 mg/kg bw per day in F_0 generation males). The overall NOAEL for reproductive toxicity in the multigeneration studies in rats was 1000 ppm (equal to 74.8 mg/kg bw per day for F_1 males), based on minimal testicular germ cell loss or disorganization, with or without Sertoli cell vacuolization (and unaccompanied by any reduction in epididymal sperm numbers), at 2500 ppm (equal to 191.5 mg/kg bw per day). These effects were not observed in the first study, a difference that could be attributed to a refinement of the methods used for sperm observations between the first and second studies. The overall NOAEL for offspring was 30 ppm (equal to 1.4 mg/kg bw per day for the males), based on marginal reductions in body weight gains of F_{2a} and F_{2b} pups during lactation at 1000 ppm (equal to 45.6 mg/kg bw per day for males) in the first of the two studies.

The NOAEL for maternal toxicity in the developmental toxicity study in rats was 30 mg/kg bw per day, based on slightly decreased body weight gain in dams, providing a lowest-observed-adverse-effect level (LOAEL) of 200 mg/kg bw per day. The NOAEL for fetotoxicity was 200 mg/kg bw per day, based on mild reduction in mean fetal body weight at 750 mg/kg bw per day. Further evidence of fetotoxicity at this dose was increased incidences of skeletal anomalies (irregular or absent ossification of the occipital bone) and skeletal variants (poor ossification of sternebra 5, shortened 13th rib and non-ossification of metatarsal 1).

The NOAEL for maternal toxicity in the developmental toxicity study in rabbits was 15 mg/kg bw per day, based on reduction in body weight gain and food consumption during the treatment period in dams at 50 mg/kg bw per day. The NOAEL for fetotoxicity in rabbits was 50 mg/kg bw per day, based on increased post-implantation loss and reduction in fetal body weights at 150 mg/kg bw per day. Further evidence of fetotoxicity at this dose was increased incidence of delayed and absent ossification as well as an increased incidence of fused sternebrae in fetuses.

The Meeting concluded that thiamethoxam can cause fetotoxicity and skeletal anomalies (malformations and variants), but only at maternally toxic doses.

An acute neurotoxicity study, a 13-week neurotoxicity study and a developmental neurotoxicity study were conducted in rats. A comprehensive set of neurotoxicity end-points was investigated in these studies, including an evaluation of potential to induce neurobehavioural or neuromorphological changes. The studies did not show any specific neurotoxicity after repeated exposure of adult rats or any specific developmental neurotoxicity in the offspring, including at doses causing maternal toxicity. Acute administration of thiamethoxam at dose levels approaching the LD_{50} produces a range of transient neurobehavioural effects, including tonic or clonic convulsions, ptosis and reduced locomotor activity. The NOAEL in the single-dose neurotoxicity study in rats was 100 mg/kg bw, based on transient behavioural changes at 500 mg/kg bw. The NOAEL for systemic toxicity in the 13-week neurotoxicity study was 1500 ppm (equal to 95.4 mg/kg bw per day in males), and the NOAEL for neurotoxicity was 3000 ppm (equal to 216.4 mg/kg bw per day in females), the

highest dose tested, based on the absence of treatment-related effects at these doses. The NOAEL for systemic toxicity in a study of developmental neurotoxicity was 400 ppm (equal to 34.5 mg/kg bw per day), based on decreased body weight gain and food consumption in dams throughout gestation and postpartum, as well as reduced birth weight, reduced pup body weight gain, some evidence of delayed preputial separation and small changes in brain morphometry, but without any quantitative histological or behavioural changes, at 4000 ppm (equal to 298.7 mg/kg bw per day). The NOAEL for developmental neurotoxicity was 4000 ppm (equal to 298.7 mg/kg bw per day), the highest dose tested.

The Meeting concluded that thiamethoxam is not a neurotoxin in mammals at the tested dose levels, although it is a member of the neonicotinoid chemical class, the biological effects of which in target species are mediated primarily by an interaction with nicotinic acetylcholine receptor sites.

No information on medical surveillance or poisoning incidents was available.

The Meeting concluded that the existing database on thiamethoxam was adequate to characterize the potential hazards to fetuses, infants and children.

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) of 0–0.08 mg/kg bw on the basis of a NOAEL of 250 ppm (equal to 8.23 mg/kg bw per day) in a 90-day study of toxicity in dogs, based on prolonged thromboplastin time. A safety factor of 100 was applied. This ADI is protective of the hepatotoxic and hepatocarcinogenic effects observed in mice, which were not observed in rats because of a marked species difference in metabolism. It is also protective of the marginally toxic effects observed in a multigeneration study in rats at 46 mg/kg bw per day.

A number of blood chemistry and haematology parameters in dogs were considered as a basis for the ADI, but the only consistently altered parameter was measures of blood coagulation. Other end-points that received consideration included food consumption reduction in a gavage study of developmental toxicity in rabbits. Renal changes observed in rats arose by processes not relevant for risk assessment at human dietary exposure levels.

An acute reference dose (ARfD) of 1 mg/kg bw was established on the basis of a NOAEL of 100 mg/kg bw in a single-dose study of neurotoxicity in rats. A safety factor of 100 was applied. The transient functional changes in rats appeared to be mild signs of overt toxicity rather than neurotoxicity. The neurotoxicity study was supported by a single-dose study of toxicity in mice, in which clinical signs of toxicity were observed at 500 mg/kg bw, the lowest dose tested.

The metabolite of thiamethoxam, CGA322704 (clothianidin), was evaluated separately by the present Meeting.

A toxicological monograph was prepared.

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL
Mouse	Ninety-day range-finding study of toxicity	Toxicity	100 ppm, equal to 14.3 mg/kg bw per day	1250 ppm, equal to 176 mg/kg bw per day
	Eighteen-month study of toxicity and carcinogenicity	Toxicity[a]	20 ppm, equal to 2.63 mg/kg bw per day	500 ppm, equal to 63.8 mg/kg bw per day
		Carcinogenicity[b]	20 ppm, equal to 2.63 mg/kg bw per day	500 ppm, equal to 63.8 mg/kg bw per day
Rat	Single-dose test of neurotoxicity	Toxicity	100 mg/kg bw	500 mg/kg bw

Species	Study	Effect	NOAEL	LOAEL
	Ninety-day study of toxicity	Toxicity[c]	250 ppm, equal to 17.6 mg/kg bw per day	1250 ppm, equal to 84.9 mg/kg bw per day
	Twenty-four-month studies of toxicity and carcinogenicity	Toxicity[c]	1000 ppm, equal to 50.3 mg/kg bw per day	3000 ppm, equal to 155 mg/kg bw per day
		Carcinogenicity	3000 ppm, equal to 155 mg/kg bw per day[d]	—
	Two-generation study of reproductive toxicity (1)	Reproductive toxicity	2500 ppm, equal to 117.6 mg/kg bw per day[d]	—
		Parental toxicity[c]	1000 ppm, equal to 45.6 mg/kg bw per day	2500 ppm, equal to 117.6 mg/kg bw per day
		Offspring toxicity	30 ppm, equal to 1.4 mg/kg bw per day	1000 ppm, equal to 45.6 mg/kg bw per day[e]
	Two-generation study of reproductive toxicity (2)	Reproductive toxicity	1000 ppm, equal to 74.8 mg/kg bw per day	2500 ppm, equal to 191.5 mg/kg bw per day
		Parental toxicity[c]	1000 ppm, equal to 61.7 mg/kg bw per day	2500 ppm, equal to 155.6 mg/kg bw per day
		Offspring toxicity	1000 ppm, equal to 74.8 mg/kg bw per day	2500 ppm, equal to 191.5 mg/kg bw per day
	Developmental toxicity study	Maternal toxicity	30 mg/kg bw per day	200 mg/kg bw per day
		Embryo and fetal toxicity	200 mg/kg bw per day	750 mg/kg bw per day
Rabbit	Developmental toxicity study	Maternal toxicity	15 mg/kg bw per day	50 mg/kg bw per day
		Embryo and fetal toxicity	50 mg/kg bw per day	150 mg/kg bw per day
Dog	Ninety-day study of toxicity	Toxicity	250 ppm, equal to 8.23 mg/kg bw per day	1000 ppm, equal to 32 mg/kg bw per day

[a] Mouse particularly susceptible to hepatotoxicity, based on the mode of action of thiamethoxam.

[b] No carcinogenicity relevant to humans based on mode of action considerations of tumorigenic effects in mice.

[c] Toxicity relevant to humans, not including nephrotoxicity specific for male rats.

[d] Highest dose tested.

[e] Marginal LOAEL.

Estimate of acceptable daily intake for humans

0–0.08 mg/kg bw

Estimate of acute reference dose

1 mg/kg bw

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

Critical end-points for setting guidance values for exposure to thiamethoxam

Absorption, distribution, excretion and metabolism in mammals	
Rate and extent of oral absorption	Rapid and extensive, > 90%
Distribution	Distributed throughout the body; higher concentrations in liver and blood
Potential for accumulation	None
Rate and extent of excretion	High, > 90% within 24 h
Metabolism in animals	22 metabolites identified in rats
Toxicologically significant compounds (animals, plants and environment)	Parent; CGA330050; CGA322704 (clothianidin)
Acute toxicity	
Rat, LD_{50}, oral	1563 mg/kg bw
Mouse, LD_{50}, oral	871 mg/kg bw
Rat, LC_{50}, inhalation	> 3.7 mg/L (4 h)
Rat, LD_{50}, dermal	> 2000 mg/kg bw
Rabbit, dermal irritation	Not irritating
Rabbit, ocular irritation	Not irritating
Guinea-pig, dermal sensitization	Not sensitizing (Magnusson and Kligman test)
Short-term studies of toxicity	
Target/critical effect	Coagulation in dogs
Lowest relevant oral NOAEL	8.23 mg/kg bw per day (3-month study in dogs)
Lowest relevant dermal NOAEL	60 mg/kg bw per day (liver, 4-week study in rats)
Lowest relevant inhalation NOAEC	No data
Long-term studies of toxicity and carcinogenicity	
Target/critical effect	Liver, spleen, stomach (mice)
Lowest relevant NOAEL	2.63 mg/kg bw per day (18-month study in mice)
Carcinogenicity	Carcinogenic in mice, but unlikely to pose a risk at human dietary exposure levels, based on the proposed mode of action
Genotoxicity	
	Not genotoxic
Reproductive toxicity	
Reproductive target/critical effect	Preweaning weight gain
Lowest relevant reproductive NOAEL	74.8 mg/kg bw per day (rat)
Developmental target/critical effect	Rat: Not teratogenic; reduced live birth weight, delayed ossifications
	Rabbit: Reduced pup body weight, delayed ossifications and increased incidences of skeletal abnormalities
Lowest relevant developmental NOAEL	50 mg/kg bw per day (rabbit)
Neurotoxicity/delayed neurotoxicity	

	No signs of neurotoxicity
Other toxicological studies	
	Mechanistic studies relevant to hepatotoxicity and hepatocarcinogenicity in mice and renal toxicity in rats
Medical data	
	No reports of toxicity in workers exposed during manufacture or use

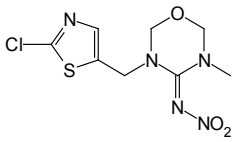
Summary

	Value	Study	Safety factor
ADI	0–0.08 mg/kg bw	Ninety-day study of toxicity in dogs	100
ARfD	1 mg/kg bw	Neurotoxicity study in rats supported by a single-dose toxicity study in mice	100

RESIDUE AND ANALYTICAL ASPECTS

Residue and analytical aspects of thiamethoxam were considered for the first time by the present meeting.

Thiamethoxam (ISO common name), a nicotinoid compound, has broad spectrum activity against sucking and chewing insects in vegetables, ornamentals, field crops, deciduous fruits, citrus, cotton and rice. It possesses contact and stomach activity. Its activity against foliar feeding insects following seed treatment, application to the soil, distribution via irrigation systems, or when applied to the trunks of trees, results from its systemic properties. It is also registered for direct foliar application.



The IUPAC name for thiamethoxam is (EZ)-3-(2-chloro-1,3-thiazol-5-ylmethyl)-5-methyl-1,3,5-oxadiazinan-4-ylidene(nitro)amine and the CA name is 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4*H*-1,3,5-oxadiazin-4-imine.

Thiamethoxam labelled either in the 2-position of the thiazole moiety or on the carbon of the guanidine moiety (4-oxadiazine label) was used in the metabolism and environmental fate studies.

Animal metabolism

Information was available on metabolism of thiamethoxam in laboratory animals, lactating goats and laying hens.

When rats were orally dosed with labelled thiamethoxam, 70–80% of the dose was eliminated in the urine as parent thiamethoxam. The main metabolite in urine was CGA 322704 (*N*-(2-chlorothiazol-5-ylmethyl)-*N*'-methyl-*N*''-nitroguanidine) accounting for approximately 10% of the dose. Numerous low-level metabolites were identified. Metabolism in laboratory animals was summarized and evaluated by the WHO panel of the JMPR in 2010.

When lactating goats were orally dosed with labelled thiamethoxam, approximately 1% of the dose appeared in the milk and 3–4% in the tissues.

Metabolite CGA 322704 was the major component (44% and 45%) of the residue in milk, while parent thiamethoxam was the major component in goat fat (36% and 52%), muscle (51% and 54%) and kidneys (21% and 22%).

Products of further metabolism occurred in the goat liver. NOA 421276 (N-(2-chlorothiazol-5-ylmethyl)-guanidine), NOA 421275 (N-(2-chlorothiazol-5-ylmethyl)-N'-methyl-guanidine), L14 (2-

oxopropionic acid [3-(2-chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidene]-hydrazide) and NOA 407475 (3-(2-chlorothiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidineamine) were metabolites found at levels exceeding 10% TRR in the liver. Parent thiamethoxam and CGA 322704 were present in liver tissue at approximately 1% and 6–7% of TRR respectively.

When laying hens were dosed with labelled thiamethoxam, most of the dose was excreted in the droppings. Eggs accounted for approximately 0.1% of the administered dose and tissues approximately 1–1.5%.

Parent thiamethoxam was not the major component of the residue in any hen tissue or eggs, but did constitute approximately 21% TRR in lean meat, 5–15% in fat + skin, 2–5% in egg white and 11% in egg yolks.

Metabolite CGA 265307 (N-(2-chlorothiazol-5-ylmethyl)-N'-nitroguanidine) was the major residue component in the eggs, both whites (45% and 47%) and yolks (69% and 54%), and also in fat + skin (54% and 57%). Metabolite CGA 322704 was the major residue component in hen liver (34% and 39%) while metabolite MU3 (amino-([(2-chlorothiazol-5-ylmethyl)-amino]-methylene)-hydrazide) was the major component of the lean meat residue (39% and 28%).

Other metabolites present at more than 10% TRR were: NOA 421275 (N-(2-chlorothiazol-5-ylmethyl)-N'-methyl-guanidine) in lean meat, MU3 in hen liver, CGA 322704 and NOA 404617 (1-(2-chloro-thiazol-5-ylmethyl)-3-nitrourea) in egg white and CGA 322704 in egg yolk.

Animal metabolism summary

When animals were orally dosed with labelled thiamethoxam, the ^{14}C was readily excreted in urine and faeces and an array of metabolites was produced.

In lactating goats, metabolite CGA 322704 was the major component of the residue in milk, while parent thiamethoxam was the major component in muscle, fat and kidney. Further degraded metabolites occurred in the liver. Metabolite NOA 421276 was the major identified component of the residue in goat liver.

In laying hens, parent thiamethoxam was not the major component of the residue in any tissue or eggs, but did constitute approximately 21% of the ^{14}C in lean meat. Metabolite CGA 265307 was the major residue component in the eggs and in fat + skin. Metabolite CGA 322704 was the major residue component in liver while metabolite MU3 was the major component of the lean meat residue.

Plant metabolism

Information was available on the metabolism of thiamethoxam in maize, rice, pears, cucumbers, lettuce and potatoes.

When maize seeds treated with [^{14}C-oxadiazin]thiamethoxam were sown and grown through to maturity, ^{14}C residues were detected in whole tops (day 33 after sowing), forage (day 124) and grain and fodder (maturity, day 166). The TRR level of 18 mg/kg in the whole tops with 40% TRR identified as thiamethoxam demonstrated that thiamethoxam is readily taken up and translocated. Parent thiamethoxam was the major identified component of the residues in whole tops and maize grain. Metabolite NOA 421275 (*N*-(2-chlorothiazol-5-ylmethyl)-*N'*-methyl-guanidine) was the major identified component of the forage and fodder. Metabolite CGA 322704 constituted approximately 10% TRR in forage and grain.

In the companion maize seed metabolism study, maize seeds treated with [^{14}C-thiazolyl]thiamethoxam were sown and grown through to maturity. ^{14}C residues were detected in tops (day 33 after sowing), forage (day 124) and grain and fodder (maturity, day 166). Parent thiamethoxam was the major component of residues in the tops (47% TRR). Metabolites appearing as

10% or more of TRR were: NOA 407475 (3-(2-chlorothiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidineamine) in tops, CGA 322704 and NOA 421275 in forage and NOA 421275 in fodder. In the grain, 65% of TRR was unextracted; thiamethoxam and CGA 322704 were the only identified residue components.

In a soil treatment maize experiment, [^{14}C-oxadiazin]thiamethoxam was applied to the soil around maize plants at the 2 leaf stage. Parent thiamethoxam and CGA 322704 were the major identified components of the residues in 89 days forage and grain. Metabolite 1-methyl-3-nitroguanidine at approximately 10% TRR was the major identified component of the fodder.

The companion soil treatment study with [^{14}C-thiazolyl]thiamethoxam again found that thiamethoxam and CGA 322704 were the major identified components in the forage and grain. NOA 421275 at approximately 10% TRR was the major component of the fodder.

In a rice metabolism study, [^{14}C-oxadiazin]thiamethoxam was formulated as granules and applied to the seedling box 24 hours before planting out. A parallel experiment was run with [^{14}C-thiazolyl]thiamethoxam. Release of ^{14}C into the paddy water was rapid and the radiolabel was readily translocated to all parts of the plant. Thiamethoxam was the major component of the residues in the early stages. At maturity, parent thiamethoxam was not identified in the grain, when 88% TRR was unextracted. Metabolites CGA 322704 and *N*-methylurea were the major identified components of the rice grain residues but at only 1–2% TRR. Parent thiamethoxam and CGA 355190 (3-(2-chlorothiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-one) were the main components of the straw residues while thiamethoxam and CGA 322704 were the main components in the husks.

In a separate rice metabolism study, [^{14}C-oxadiazin]thiamethoxam formulated as a WP was applied twice as foliar treatments at booting stage and 50 days later. A parallel experiment was run with [^{14}C-thiazolyl]thiamethoxam. Parent thiamethoxam was the major identified component in grain (13% and 4.5%), husks (65% and71%) and straw (53% and 14.5%) with CGA 322704 the second largest identified component. The non-extracted component in the grain accounted for 63% and 91% of the TRR.

The non-extracted ^{14}C in grains, husk and straw was found to be incorporated into starch, cellulose, hemicellulose or proteins.

Pears were subject to foliar sprays with [^{14}C-oxadiazin]thiamethoxam and [^{14}C-thiazolyl]thiamethoxam formulated as a WP—two cover sprays, 13 days apart with the final spray 15 days before harvest. For each treatment and application rate, thiamethoxam and CGA 322704 were the major identified components of the residues in fruit, together accounting for approximately 50% of the TRR. None of the other metabolites exceeded 10% TRR.

Cucumber plots were subject to foliar sprays with [^{14}C-oxadiazin]thiamethoxam and [^{14}C-thiazolyl]thiamethoxam formulated as a WP—first spray at full flowering and the second 10 days later, 14 days prior to mature harvest. NOA 407475 (3-(2-chlorothiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidineamine) and thiamethoxam were the major identified components of the residues in cucumbers, together accounting for approximately 30–40% the TRR. CGA 322704 and other metabolites were minor components, each accounting for less than 1–2% TRR.

Field grown lettuce were subject to foliar sprays with [^{14}C-oxadiazin]thiamethoxam and [^{14}C-thiazolyl]thiamethoxam formulated as a WG—three times at weekly intervals. Parent thiamethoxam was the major component of the residues accounting for approximately 40% of the residues 14 days after the final treatment. Numerous metabolites were identified, but at day 14 none exceeded 8% of the TRR. The non-extracted residue fraction accounting for 13% and 19% of TRR was subjected to vigorous treatment and extraction, which released ^{14}C material of a very polar nature believed to be derived from natural plant components.

In a potato metabolism study, potato seed-pieces treated with [^{14}C-thiazol]thiamethoxam and [^{14}C-oxadiazin]thiamethoxam were sown and the potatoes were grown to new potato size (84 days after sowing) and maturity (106 days).

Parent thiamethoxam was the major identified residue in the harvested potatoes at 10–27% of TRR. Metabolite CGA 322704 was present at 6–13% of TRR. Metabolite CGA 282149 (3,6-dihydro-3-methyl-*N*-nitro-2H-1,3,5-oxadiazin-4-amine) constituted approximately 6–10% TRR while CGA 349208 (2-chloro-5-thiazolemethanol) and its conjugate also accounted for approximately 6–10% TRR. A number of other metabolites were identified, but none exceeded 10% TRR.

Plant metabolism summary

Thiamethoxam was readily taken up from treated seed, treated soil or sprayed foliage and translocated within the plant and it produced many metabolites. Parent thiamethoxam was usually an important component of the residues.

Metabolic degradation pathways were similar in the various plants tested: maize, rice, pears, cucumbers, lettuce and potatoes.

Parent thiamethoxam and metabolite CGA 322704 appeared in plant metabolism profiles above 10% TRR more often than other metabolites. Other metabolites to appear above 10% TRR at least once were: 1-methylguanidine, CGA 282149, CGA 355190, NOA 407475 and NOA 421275.

N-nitroguanidine was the only plant metabolite (identified in lettuce at 0.3–1.5% TRR) that did not also appear as an animal metabolite. *N*-nitroguanidine may occur from other sources—it is an industrial chemical with uses in the explosives industry and as a chemical intermediate in the manufacture of pharmaceuticals.

Environmental fate in soil

Information was available on aerobic soil metabolism for thiamethoxam, CGA 322704, CGA 355190 (3-(2-chlorothiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-one) and NOA 407475 (3-(2-chlorothiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidineamine). Studies on rice paddy metabolism, soil surface photolysis and rotational crops were also provided.

Soil metabolism and photolysis

When labelled thiamethoxam was incubated in soils under aerobic conditions at 20 °C and 40% max water capacity, its half-life ranged from 80 to 300 days. Higher temperatures or higher moisture levels increased the rate of disappearance. CGA 322704 and CGA 355190 were usually the main identified soil metabolites. After 180 days, approximately 12–20% of the dose had been mineralized and 7–16% was unextracted.

When labelled CGA 322704 was incubated in soils under aerobic conditions at 20 °C and 40% max water capacity, its half-life was approximately 100–300 days. The half-life for labelled CGA 355190 under these same conditions was 15–30 days.

When [^{14}C-thiazol]thiamethoxam was exposed to a paddy soil system at 25 °C, thiamethoxam disappeared with a half-life of approximately 50–70 days. The main metabolite was NOA 407475, produced under the reducing conditions of the paddy soil.

NOA 407475 was quite persistent at 20 °C and 40% max water capacity in soils under aerobic conditions, with 77% and 86% of the dose remaining after a test of 180 days (estimated half-life exceeding 300 days).

In a 30 days study with the soil photolysis of labelled thiamethoxam at 25 °C and 75% field moisture capacity, the amount remaining after photolysis was 66% and 59% compared with the dark controls 83% and 83%. CGA 322704 and CGA 355190 were the main products identified.

Soil metabolism summary

When labelled thiamethoxam was incubated in soils under aerobic conditions at 20 °C, its half-life varied from 80 to 300 days. In 6 months of incubation, the percentage of dose mineralized was approximately 12 to 20% and the percentage that was unextracted was approximately 7 to 16%.

The main soil metabolites identified were: CGA 322704 (N-(2-chlorothiazol-5-ylmethyl)-N'-methyl-N''-nitroguanidine) and CGA 355190 (3-(2-chlorothiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-one). Metabolite NOA 407475 (3-(2-chlorothiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidineamine) was identified under rice paddy conditions. The disappearance of thiamethoxam under soil photolysis conditions was faster than in the dark controls but the main products were CGA 322704 and CGA 355190, the same as for soil metabolism.

Rotational crops

When lettuce, radish and wheat were grown in a rotational crop situation 29, 119 and 362 days after treatment of bare ground with labelled thiamethoxam at 0.2 kg ai/ha, TRR levels were generally low: 0.035 mg/kg and below for lettuce; 0.12 mg/kg and below for radish tops; 0.007 mg/kg and below for radish roots and 0.15 mg/kg and below for wheat grain. Higher TRR levels were found in wheat straw: 0.05–0.75 mg/kg.

Parent thiamethoxam was the most commonly detected component of the residue and was present at higher concentrations (up to 0.023 mg/kg) than other components in lettuce and radish. In wheat straw and grain, parent thiamethoxam (up to 0.038 mg/kg in straw and 0.0002 mg/kg in grain) and metabolite CGA 322704 (up to 0.044 mg/kg in straw and 0.001 mg/kg in grain) were the most commonly detected. However, in some cases other metabolites were present at higher levels: CGA 265307 (N-(2-chlorothiazol-5-ylmethyl)-N'-nitroguanidine) in wheat grain and 1-methylguanidine (CGA 382191), NOA 405217 (N-nitro-N'-methylguanidine), NOA 421275 (N-(2-chlorothiazol-5-ylmethyl)-N'-methyl-guanidine) and CGA 265307 (N-(2-chlorothiazol-5-ylmethyl)-N'-nitroguanidine) in wheat straw.

Residues of parent thiamethoxam and some metabolites could occur in rotational crops, but generally at very low levels. Detections would be unlikely except for residues in commodities such as wheat straw, which will be covered by MRLs in any case because of approved direct uses. Additional information relevant to CGA 322704 fate and behaviour is available in the clothianidin rotational crop studies.

Methods of analysis

Analytical methods and validation data for residues of thiamethoxam and CGA 322704 in animal and plant matrices were made available to the Meeting. Methods had been subjected to independent laboratory validation. Analytical recovery data for thiamethoxam and CGA 322704 at residue concentrations on numerous substrates were available to the Meeting.

Residues of parent thiamethoxam and metabolite CGA 322704 in plant and animal matrices may be analysed by HPLC-MS or HPLC-UV with an LOQ of 0.01 mg/kg after a series of cleanup steps.

In method AG-675, which relies on acetonitrile-water for sample extraction, a microwave extraction procedure is necessary for good extraction of residues from some animal commodities, especially liver. Analysis of residues in liver was not possible with the HPLC-UV finish because of too many interfering peaks, but was successful with the LC-MS/MS finish.

Samples with incurred residues from the metabolism studies were analysed by method AG-675, but interpretation was difficult because of uncertainties in the data (some concentrations below 0.05 mg/kg). For pears and cucumbers, the analytical method concentration of thiamethoxam was approximately 40–90% of the metabolism value. For thiamethoxam in goat meat, the analytical

method result was 56–79% of the metabolism result. The thiamethoxam concentration in goats' milk, measured by method AG-675 was only about 20% of the value from the metabolism study. In each of these tests, the results for CGA 322704 were similar to those for thiamethoxam. However, the data were from different laboratories on samples with different storage histories, making interpretation difficult.

Supporting information relevant to the efficient extraction of CGA 322704 from milk and other matrices by acetonitrile-water is provided in the clothianidin studies on samples with incurred residues from clothianidin metabolism studies. This information on efficient extraction of CGA 322704 residues would also support the efficient extraction of thiamethoxam residues, which had behaved similarly but erratically, in the thiamethoxam studies.

Method REM-179 versions were used for analysis of plant commodities. Samples are homogenized and extracted with water + methanol. Cleanup is affected by solvent partition and cartridge columns.

Pears from the metabolism study were extracted and analysed by method REM 179.3 for comparison with the ^{14}C measurements. Measured concentrations of thiamethoxam in the pear were 0.196, 0.143 and 0.130 mg/kg for the original metabolism study, by radiolabel analysis on the LC fraction and by HPLC-UV respectively. Similarly, measured concentrations of CGA 322704 (expressed as thiamethoxam) were 0.134, 0.0875 and 0.0775 mg/kg for the same three situations.

Thiamethoxam, CGA 322704 and CGA 265307 (N-(2-chlorothiazol-5-ylmethyl)-N'-nitroguanidine) were not suitable analytes for the multiresidue methods tested (DFG Method S 19 and FDA multiresidue methods). In the FDA methods, thiamethoxam was not recovered from the cleanup columns.

Stability of residues in stored analytical samples

The meeting received information on the freezer storage stability of thiamethoxam and metabolite CGA 322704 at residue concentrations in apples, tomatoes, potato tubers, rape seed, maize grain, cranberries, hops, barley grain, barley hay, barley straw, pearled barley and barley flour. For the animal commodities, (beef, liver, milk and eggs), freezer storage stability data were available for thiamethoxam and two metabolites CGA 322704 and CGA 265307.

Thiamethoxam, CGA 322704 and CGA 265307 were apparently stable at residue concentrations in the various substrates tested at the freezer temperatures and test durations. The durations of test were mostly 1–2 years, but some were less. Test temperatures were mostly approximately –18 °C to –20 °C, but other storage temperatures were used in some storage stability tests, e.g., between –26 °C and –4 °C.

Definition of the residue

In animal commodities, parent thiamethoxam was a major component of the residues in goat muscle, fat and kidney, while CGA 322704 was the main component in milk, but thiamethoxam was also a substantial residue component in milk. Thiamethoxam constituted only approximately 1% of the residues in goat liver with CGA 322704 about 6–7%. Some other metabolites were present at higher levels.

In laying hens, parent thiamethoxam was not the major component of the residues in any tissue or eggs, but did constitute approximately 21% TRR in lean meat, 5–15% in fat + skin and 11% in egg yolk. Thiamethoxam was a very minor part of the residues in poultry liver, whereas CGA 322704 constituted 34% and 39% of the liver TRR (8.2 and 9.2 mg/kg) in the poultry metabolism study with ^{14}C labels in the thiazol and oxadiazine positions, respectively. Metabolite CGA 265307 was the major residue component in the eggs, both whites (45% and 47%) and yolks (69% and 54%), and also in fat + skin (54% and 57%). Metabolite MU3 was the major residue component in lean hen meat.

The complexity of the metabolite mixture makes it difficult to select an ideal residue definition for risk assessment in poultry.

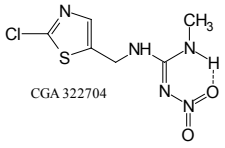
The Meeting decided to include CGA 265307 and MU3 with thiamethoxam in the intake assessment of residues in poultry. Metabolite CGA 322704 will be included in the clothianidin risk assessment.

Because the dietary burden was low and no feeding study was available for poultry, data from the poultry metabolism studies were used in the risk assessment.

For most purposes, thiamethoxam and CGA 322704 are adequate for monitoring residues in animal commodities.

In plant metabolism, parent thiamethoxam is usually an important component of the residues. Metabolite CGA 322704 occurs in plant metabolism profiles above 10% TRR more commonly than do other plant metabolites. For plant commodities thiamethoxam and CGA 322704 are the most important residues.

Thiamethoxam is described as an EZ mixture. It is generally believed that the activation energy for the E↔Z interconversion for the C = N bond is low and that an equilibrium mixture is rapidly established at ambient temperature. The situation is likely to be similar for metabolite CGA 322704. In this case the E form is likely to be favoured in the equilibrium mixture because of possible formation of a hydrogen bond from the secondary amine to the nitro group. The E form of CGA 322704 is equivalent to the compound clothianidin and with E↔Z interconversion, CGA 322704 will appear the same as clothianidin in the analytical methods.



CGA 322704

Clothianidin residues may arise from the use of clothianidin or from the use of thiamethoxam. Separate residue definitions are needed:

- for thiamethoxam
- for clothianidin (from uses of clothianidin) and CGA 322704 (from uses of thiamethoxam), appearing as clothianidin.

The Meeting recommended the following residue definition for thiamethoxam.

Definition of the residue for animal and plant commodities (for compliance with the MRL): *thiamethoxam*.

Definition of the residue for plants and animals (except poultry), (for estimation of dietary intake): *thiamethoxam;* and

CGA 322704 (CGA 322704 to be included with clothianidin and considered separately from thiamethoxam). See also clothianidin.

Definition of the residue for poultry (for estimation of dietary intake): *sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamethoxam;* and

CGA 322704 (CGA 322704 to be included with clothianidin and considered separately from thiamethoxam). See also clothianidin.

The residue is not fat-soluble.

Note that thiamethoxam metabolite CGA 322704 (N-(2-chlorothiazol-5-ylmethyl)-N'-methyl-N''-nitroguanidine) will appear as clothianidin in the analytical method and residues of CGA 322704 occurring in food are included in the clothianidin MRLs.

Metabolite CGA 265307: N-(2-chlorothiazol-5-ylmethyl)-N'-nitroguanidine.

Metabolite MU3: amino-([(2-chlorothiazol-5-ylmethyl)-amino]-methylene)-hydrazide.

Results from supervised trials on crops

The Meeting received supervised field trials data for thiamethoxam uses on citrus, pome fruits, plums, peaches, cherries, strawberries, cranberries, blueberries, caneberries, grapes, bananas, mangoes, papaya, pineapples, broccoli, cabbage, mustard greens, cucumbers, melons, cantaloupes, summer squash, sweet corn, tomatoes, bell peppers, chilli peppers, egg plants, sweet peppers, lettuce, spinach, snap beans, lima beans, succulent peas, dry beans, peas (green pods), peas (dry seed), soya beans, carrots, radishes, potatoes, sugar beets, artichokes, celery, maize, barley, wheat, rice, pecan, sunflower, cotton, oilseed rape, cacao beans, coffee, pea forage and fodder, maize forage and fodder, barley straw and fodder, wheat straw and fodder, rice straw, beet leaves and tops, oilseed rape fodder and forage, hops and tea.

For a specific crop, sets of trials were often available with different methods of application, e.g., foliar, soil treatment and seed treatment, and from different regions. The set of trials with an adequate number of trials and producing the highest residues was selected for maximum residue level estimation. The set of trials selected for thiamethoxam maximum residue level estimation was not necessarily the same set selected for metabolite CGA 322704.

The estimated maximum residue levels for CGA 322704 are transferred to the clothianidin report for integration with the estimates for clothianidin.

Citrus fruits

Supervised trials data for citrus were available from Spain, Indonesia and the USA.

Thiamethoxam may be used in Spain as a single foliar treatment of citrus with a WG formulation at a spray concentration of 0.0075 kg ai/hL and harvest of fruit 28 days later.

In seven thiamethoxam trials on oranges in Spain in accord with Spanish GAP, thiamethoxam residue concentrations in whole oranges in rank order were: < 0.02, 0.02, 0.03, 0.05, 0.05, 0.06 and 0.06 mg/kg. Thiamethoxam residues in orange flesh were: < 0.02 (6) and 0.02 mg/kg. In one Spanish orange trial residues were at measurable levels in both flesh (0.02 mg/kg) and fruit (0.05 mg/kg) providing a factor of 0.4 to estimate thiamethoxam residues in edible portion from residues in whole fruit from foliar treatment. In the same seven orange trials from Spain, residues of CGA 322704 in whole oranges as a metabolite of thiamethoxam were: < 0.02 (5), 0.02 and 0.03 mg/kg. CGA 322704 residues in orange flesh were: < 0.02 (7) mg/kg.

In six thiamethoxam trials on lemons in Spain in accord with Spanish GAP, thiamethoxam residue concentrations in whole lemons in rank order were: 0.02, 0.04, 0.07, 0.07, 0.08 and 0.08 mg/kg. Thiamethoxam residues in lemon flesh were: < 0.02 (5) and 0.02 mg/kg. In the same six lemon trials from Spain, residues of CGA 322704 in whole lemons were: < 0.02, 0.02, 0.02, 0.02, 0.03 and 0.04 mg/kg. CGA 322704 residues in lemon flesh were: < 0.02 (6) mg/kg.

In eight thiamethoxam trials on mandarins in Spain in accord with Spanish GAP, thiamethoxam residue concentrations in whole mandarins in rank order were: < 0.02 (2), 0.02, 0.02, 0.03, 0.04, 0.07 and 0.10 mg/kg. Thiamethoxam residues in mandarin flesh in nine trials were: < 0.02 (7), 0.02 and 0.02 mg/kg. In the same eight mandarin trials from Spain, residues of CGA 322704 in whole mandarins in rank order were: < 0.02 (3), 0.02, 0.02, 0.02, 0.03 and 0.05 mg/kg (NAFTA calculator: 0.057. OECD calculator Mean + 4SD: 0.068). CGA 322704 residues in mandarin flesh in nine trials were: < 0.02 (8) and 0.02 mg/kg. This CGA 322704 data set was selected for maximum residue level estimation.

In Indonesia, thiamethoxam may be applied twice as foliar sprays on citrus with a ZC formulation at 0.085 kg ai/ha and harvest 42 days after the final application. In three trials on oranges in Indonesia in accord with Indonesian GAP, residues of thiamethoxam were : < 0.01, 0.03 and 0.05 mg/kg. Residues of CGA 322704 were not detected.

Thiamethoxam may be used in the USA as a single soil treatment with SL formulations (chemigation in the root zone, drench around tree trunk and out to root zone or band each side of row) at 0.19 kg ai/ha. Thiamethoxam may also be used in two foliar applications with WG at 0.096 kg ai/ha during the production of citrus fruits. Fruit may be harvested on the same day as treatment.

In 12 orange trials in the USA matching the soil surface application GAP, residues of thiamethoxam were all < 0.01 mg/kg. In the same trials, residues of CGA 322704 in the oranges were also all < 0.01 mg/kg.

In six grapefruit trials in the USA matching the soil surface application GAP, residues of thiamethoxam were all < 0.01 mg/kg. In the same trials, residues of CGA 322704 in the grapefruits were also all < 0.01 mg/kg.

In five lemon trials in the USA matching the soil surface application GAP, residues of thiamethoxam were all < 0.01 mg/kg. In the same trials, residues of CGA 322704 in the lemons were also all < 0.01 mg/kg.

In 14 orange trials in the USA matching the US GAP for foliar application with a WG formulation, thiamethoxam residues, in rank order, were: 0.03, 0.04, 0.06, 0.06, 0.06, 0.07, 0.07, 0.08, 0.12, 0.13, 0.13, 0.19, 0.21 and 0.26 mg/kg (NAFTA calculator: 0.393. OECD calculator Mean + 4SD: 0.386). This data set was selected for maximum residue level estimation.

In the same 14 orange trials in the USA, residues of CGA 322704 in rank order were: < 0.01 (8), 0.01, 0.02, 0.02, 0.02, 0.02 and 0.03 mg/kg.

In eight grapefruit trials in the USA matching US GAP for foliar application with a WG formulation, thiamethoxam residues, in rank order, were: 0.02, 0.03, 0.04, 0.06, 0.06, 0.08, 0.10 and 0.17 mg/kg. In the same eight trials, residues of CGA 322704 in rank order were: < 0.01 (6), 0.03 and 0.03 mg/kg.

In six lemon trials in the USA matching US GAP for foliar application with a WG formulation, thiamethoxam residues, in rank order, were: 0.05, 0.06, 0.11, 0.12, 0.14 and 0.17 mg/kg. In the same six trials, residues of CGA 322704 in rank order were: < 0.01, 0.01, 0.01, 0.02, 0.02 and 0.02 mg/kg.

Summary—Citrus fruits

Residue data with suitable GAP were available for oranges, lemons, mandarins and grapefruit. The Meeting noted that thiamethoxam residues were highest in orange trials from the USA and that CGA 322704 residues were highest in mandarin trials from Spain and decided to estimate citrus group maximum residue levels based on these data sets.

On the basis of the foliar applications on oranges in the USA, the Meeting estimated a maximum residue level of 0.5 mg/kg for thiamethoxam on citrus fruits.

The STMR and HR for thiamethoxam in citrus were derived from the median and high residue of the US orange trials and a factor (residues in edible portion ÷ residues in whole fruit = 0.4) from the Spanish trials. The Meeting estimated STMR and HR values of 0.028 and 0.104 mg/kg respectively for thiamethoxam residues in citrus fruits.

On the basis of the CGA 322704 data on mandarins from eight trials with foliar application of thiamethoxam in Spain, the Meeting estimated a maximum residue level of 0.07 mg/kg for CGA 322704 on citrus fruits.

On the basis of the CGA 322704 data on mandarin flesh from nine trials in Spain, the Meeting estimated STMR and HR values of 0.02 and 0.02 mg/kg respectively for CGA 322704 residues in citrus fruits.

Pome fruits

Supervised trials data for pome fruits were available from the USA.

US GAP for pome fruit allows the use of thiamethoxam for foliar application at 0.096 kg ai/ha with a 35 days PHI and 0.048 kg ai/ha with a 14 days PHI.

In 15 apple trials in the USA matching GAP for foliar application and the final rate suitable for a 14 days PHI, thiamethoxam residues in rank order were: 0.03, 0.04, 0.04, 0.05, 0.06, 0.06, 0.06, 0.07, 0.08, 0.08, 0.09, 0.09, 0.10, 0.12 and 0.15 mg/kg (NAFTA calculator: 0.189. OECD calculator 3×Mean: 0.224). In the same 15 trials, residues of CGA 322704 in apples in rank order were: < 0.01 (13), 0.01 and 0.02 mg/kg.

In six pear trials in the USA matching GAP for foliar application and the final rate suitable for a 14 days PHI, thiamethoxam residues in rank order were: 0.03, 0.03, 0.04, 0.05, 0.05 and 0.08 mg/kg. In the same six trials, residues of CGA 322704 in pears in rank order were: 0.01, 0.02, 0.02, 0.03, 0.03 and 0.04 mg/kg (NAFTA calculator: 0.071. OECD calculator 3×Mean: 0.075).

Summary—Pome fruits

Residue data with suitable GAP were available for apples and pears from the USA. The Meeting noted that thiamethoxam residues were higher in the apple trials and that CGA 322704 residues were higher in pears. The Meeting decided to estimate pome fruit group maximum residue levels based on these data sets.

On the basis of the foliar applications on apples in the USA, the Meeting estimated a maximum residue level of 0.3 mg/kg for thiamethoxam on pome fruits. On the basis of the CGA 322704 data on pears from the US trials, the Meeting estimated a maximum residue level of 0.1 mg/kg for CGA 322704 on pome fruits.

The STMR and HR for thiamethoxam in pome fruits were derived from the median and high residues of the US apple trials. The Meeting estimated STMR and HR values of 0.07 and 0.15 mg/kg respectively for thiamethoxam residues in pome fruits. The STMR and HR for CGA 322704 in pome fruits were derived from the median and high residues of the US thiamethoxam pear trials. The Meeting estimated STMR and HR values of 0.025 and 0.04 mg/kg respectively for CGA 322704 residues in pome fruits.

Stone fruits

Supervised trials data were available for plums, peaches and cherries from the USA and cherries from France, Italy, Spain and Switzerland. No suitable GAP was available to evaluate the Swiss trials.

US GAP for stone fruits allows the use of thiamethoxam for foliar application at 0.096 kg ai/ha with a 14 days PHI.

In eight plum trials in the USA matching stone fruit GAP, thiamethoxam residues in plums in rank order were: < 0.01 (5), 0.01, 0.02 and 0.02 mg/kg. In the same eight trials, residues of CGA 322704 in plums in rank order were: < 0.01 (6), 0.01 and 0.02 mg/kg.

In 11 peach trials in the USA matching stone fruit GAP, thiamethoxam residues in peaches in rank order were: 0.01, 0.02, 0.02, 0.02, 0.03, 0.04, 0.04, 0.05, 0.05, 0.06 and 0.19 mg/kg.

In the same 11 peach trials, residues of CGA 322704 in peaches in rank order were: 0.01, 0.02, 0.02, 0.02, 0.02, 0.04, 0.04, 0.04, 0.04, 0.05 and 0.12 mg/kg (NAFTA calculator: 0.144. OECD calculator Mean + 4SD: 0.158). This data set was selected for maximum residue level estimation.

In 10 cherry trials in the USA matching stone fruit GAP, thiamethoxam residues in cherries in rank order were: 0.13, 0.17, 0.19, 0.19, 0.20, 0.21, 0.22, 0.22, 0.24 and 0.28 mg/kg. In the same 10 trials, residues of CGA 322704 in cherries in rank order were: < 0.01, < 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.03, 0.03 and 0.03 mg/kg.

Spanish GAP for cherries allows the use of thiamethoxam for two foliar applications with a spray concentration of 0.0075 kg ai/hL followed by a 7 days PHI.

In 12 cherry trials in France (seven), Italy (three) and Spain (two) matching the Spanish GAP, thiamethoxam residues in cherries in rank order were: 0.13, 0.15, 0.16, 0.16, 0.17, 0.19, 0.20, 0.26, 0.31, 0.49, 0.50 and 0.60 mg/kg (NAFTA calculator: 0.827. OECD calculator Mean + 4SD: 0.927). This data set was selected for maximum residue level estimation.

In the same 12 cherry trials, residues of CGA 322704 in cherries in rank order were: < 0.02 (7), 0.02, 0.02, 0.03, 0.04 and 0.06 mg/kg.

Summary—Stone fruits

Residue data with suitable GAP were available for plums, peaches and cherries. The Meeting noted that thiamethoxam residues were highest in cherry trials from Europe and that CGA 322704 residues were highest in peach trials from the USA and decided to estimate stone fruits group maximum residue levels based on these two data sets.

On the basis of the foliar applications on cherries in 12 trials in France, Italy and Spain, the Meeting estimated a maximum residue level of 1 mg/kg for thiamethoxam on stone fruits. The Meeting estimated STMR and HR values of 0.195 and 0.60 mg/kg respectively for thiamethoxam residues in stone fruits.

On the basis of the CGA 322704 data on peaches from 11 trials in the USA, the Meeting estimated a maximum residue level of 0.2 mg/kg for CGA 322704 on stone fruits. The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.04 and 0.12 mg/kg respectively for CGA 322704 residues in stone fruits.

Berries and other small fruits

Supervised trials data were available for strawberries, cranberries, blueberries, caneberries and grapes.

Cranberry

Supervised trials data were available for cranberries from the USA.

During the production of cranberries in the USA, thiamethoxam as a WG formulation may be used for foliar sprays at 0.070 kg ai/ha with observation of a 30 days PHI.

In six cranberry trials in the USA with a WG formulation and matching the conditions of the foliar treatment GAP, thiamethoxam residues in cranberries were all below LOQ (0.01 mg/kg). In the same six trials, residues of CGA 322704 in cranberries were also all below LOQ (0.01 mg/kg).

Blueberries

Supervised trials data were available for blueberries from the USA.

Thiamethoxam may be used as foliar applications (WG formulation) or a soil-applied surface band (SL formulation) during the production of blueberries in the USA. The application rate is 0.070 kg ai/ha in the foliar use (PHI 3 days) or, for bushberries (includes blueberries), 0.20 kg ai/ha for the band application followed by a PHI of 75 days.

In seven blueberry trials in the USA with an SL formulation and matching the conditions of the soil-applied surface band treatment GAP, thiamethoxam residues in blueberries were all below LOQ (0.01 mg/kg). In the same seven trials, residues of CGA 322704 in blueberries were also all below LOQ (0.01 mg/kg).

In nine blueberry trials in the USA with a WG formulation and matching the conditions of the foliar treatment GAP, thiamethoxam residues in blueberries in rank order were: < 0.01, 0.05, 0.06, 0.06, 0.07, 0.07, 0.07, 0.07 and 0.11 mg/kg. In the same nine trials, residues of CGA 322704 in

blueberries in rank order were: < 0.01 (4), 0.01, 0.01, 0.02, 0.03 and 0.05 mg/kg. This CGA 322704 data set was used as part of the data for maximum residue level estimation for the berry fruits group.

Blackberries, raspberries and boysenberries

Supervised trials data were available from the USA for caneberries: raspberries (four trials), blackberries (one trial) and boysenberries (one trial).

Thiamethoxam may be used as foliar applications (WG formulation) during the production of caneberries in the USA. The application rate is 0.053 kg ai/ha and the crop may be harvested 3 days after an application.

In six caneberry trials in the USA matching the conditions of the foliar treatment GAP, thiamethoxam residues in blackberries, raspberries and boysenberries in rank order were: 0.01, 0.06, 0.10, 0.12, 0.19 and 0.20 mg/kg. In the same six trials, residues of CGA 322704 in blackberries, raspberries and boysenberries in rank order were: < 0.01 (2), 0.01, 0.02, 0.02 and 0.04 mg/kg. This CGA 322704 data set was used as part of the data for maximum residue level estimation for the berry fruits group.

For CGA 322704, the data from nine blueberry trials and six caneberry trials were combined to represent the group: < 0.01 (6), 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.03, 0.04 and 0.05 mg/kg (NAFTA calculator: 0.056. OECD calculator Mean + 4SD: 0.069).

Grapes

Supervised trials data were available for grapes from France, Italy, Spain and Switzerland.

In Spain and Italy, thiamethoxam formulated as WG is approved for foliar application to grapes at 0.050 kg ai/ha, with harvest permitted 21 days later. The trials from France, Italy and Spain were evaluated using the GAP from Spain and Italy. No suitable GAP was available for evaluation of the Swiss trials.

In 11 grape trials in Europe (seven French, one Italian and three Spanish) matching the conditions of the Spanish and Italian GAP, thiamethoxam residues in grapes in rank order were: < 0.02 (2), 0.02, 0.02, 0.02, 0.04, 0.04, 0.07, 0.13, 0.17 and 0.21 mg/kg (NAFTA calculator: 0.276. OECD calculator Mean + 4SD: 0.345). In the same 11 trials, residues of CGA 322704 in grapes were: < 0.02 (10) and 0.02 mg/kg.

On the basis of the foliar applications on grapes in 11 European trials, the Meeting estimated a maximum residue level of 0.4 mg/kg for thiamethoxam in grapes. On the basis of the CGA 322704 data on grapes from the same 11 trials, the Meeting estimated a maximum residue level of 0.05 mg/kg for CGA 322704 on grapes. The residue levels of thiamethoxam and CGA 322704 occurring in grapes allow grapes to be included in the berry fruit group MRLs.

Strawberry

Supervised trials data were available for strawberries from the USA.

During the production of strawberries in the USA, thiamethoxam may be used as a single soil drench treatment (0.20 kg ai/ha) with an SL formulation at the base of the plants followed by harvest 65 days later. Alternatively, a WG formulation may be used for foliar sprays at 0.070 kg ai/ha with observation of a 3 days PHI.

In eight strawberry trials in the USA with an SL formulation and matching the conditions of the drench treatment GAP, but with some flexibility in the PHI, thiamethoxam residues in strawberries in rank order were: < 0.01, < 0.01, 0.01, 0.01, 0.02, 0.02, 0.03 and 0.03 mg/kg. In the same eight trials, residues of CGA 322704 in strawberries were all below LOQ (0.01 mg/kg).

In eight strawberry trials in the USA with a WG formulation and matching the conditions of the foliar treatment GAP, thiamethoxam residues in strawberries in rank order were: 0.02, 0.02, 0.05, 0.05, 0.06, 0.14, 0.22 and 0.26 mg/kg (NAFTA calculator: 0.378. OECD calculator Mean + 4SD:

0.476). This thiamethoxam data set was selected for maximum residue level estimation for the berry fruits group. In the same eight trials, residues of CGA 322704 in strawberries were all below LOQ (0.01 mg/kg).

Summary—Berries and other small fruits

Residue data with suitable GAP were available for strawberries, cranberries, blueberries, caneberries and grapes. The Meeting noted that thiamethoxam residues were highest in strawberries and that CGA 322704 residues were highest in blueberries and caneberries and decided to estimate berry fruit group maximum residue levels based on these two data sets.

Grapes are often evaluated separately because the crop is rarely included in a berries crop group GAP and specific grape data are needed for its important processed commodities. However, the estimated maximum residue level for grapes closely agrees with that estimated for the other berry fruits, so the Meeting agreed to include the grapes with the berry fruits proposals.

On the basis of the foliar applications on strawberries in eight US trials, the Meeting estimated a maximum residue level of 0.5 mg/kg for thiamethoxam in berries and other small fruits.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.055 and 0.26 mg/kg respectively for thiamethoxam residues in berries and other small fruits.

On the basis of the nine blueberry trials and six caneberry trials from the USA, the Meeting estimated a maximum residue level of 0.07 mg/kg for CGA 322704 in berries and other small fruits.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.01 and 0.05 mg/kg respectively for CGA 322704 residues in berries and other small fruits.

Assorted tropical and sub-tropical fruits—inedible peel

Supervised trials data were available for bananas, mangoes, papaya and pineapples.

Banana

Supervised trials data were available for bananas from Cameroon.

In Cameroon, thiamethoxam WG is approved for use as a drench to the banana stem at a concentration of 0.20 kg ai/hL and application volume 100 mL per plant, equivalent to 0.2 g ai per plant, with harvest permitted on the same day.

In three banana trials with thiamethoxam in Cameroon at the approved application rate and one at double rate and with bananas harvested 7–60 days after treatment, thiamethoxam residues in bananas were all below LOQ (0.02 mg/kg). In a further trial at the label rate, banana pulp was analysed but again thiamethoxam residues were below LOQ (0.02 mg/kg). In all these samples, CGA 322704 residues also were all below LOQ (0.02 mg/kg).

The Meeting estimated a maximum residue level of 0.02* mg/kg for thiamethoxam in bananas. On the basis of the CGA 322704 data on bananas from the same 12 trials, the Meeting estimated a maximum residue level of 0.02* mg/kg for CGA 322704 on bananas.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.02 and 0.02 mg/kg for thiamethoxam residues in bananas. The Meeting also estimated STMR and HR values of 0.02 and 0.02 mg/kg for CGA 322704 residues in bananas.

Mango

Supervised trials data were available for mangoes from South Africa.

In South Africa, thiamethoxam is approved for application to mango trees as a drench around the trees or by drip irrigation at a dose of 1.4 g ai per tree. The timing of the application is set by a seasonal instruction: apply from last week in July to mid August. The harvesting season for mangoes would follow in early to mid-summer.

One of the trials was compromised of residues of thiamethoxam (0.02 mg/kg) and CGA 322704 (0.02 mg/kg) appearing in samples from the control plot at similar levels to those from treated plots.

Three of the mango trials followed the label rate for application: 1.4 g ai per tree, resulting in thiamethoxam residues in mangoes, 0.04, 0.10 and 0.11 mg/kg. The same three trials produced CGA 322704 residues in mangoes of < 0.02, 0.02 and 0.02 mg/kg.

Three trials for mangoes are insufficient to support a maximum residue level.

Papaya

Supervised trials data were available for papaya from Brazil and Côte d'Ivoire. No GAP was available to evaluate the Côte d'Ivoire trials.

In Brazil, thiamethoxam is approved as a soil drench application for papaya at a rate equivalent to 0.20 kg ai/ha. A PHI of 14 days is specified.

Four of the papaya trials in Brazil followed the label rate of application, 0.2 kg ai/ha with thiamethoxam residues in papaya fruits all below LOQ (0.01 mg/kg). The same four trials produced CGA 322704 residues in papaya fruits also all below LOQ (0.01 mg/kg).

Four of the papaya trials in Brazil followed a double rate of application, 0.4 kg ai/ha with the same results as the label rate, thiamethoxam residues in papaya fruits all below LOQ (0.01 mg/kg). The same four trials produced CGA 322704 residues in papaya fruits also all below LOQ (0.01 mg/kg).

The Meeting estimated a maximum residue level of 0.01* mg/kg for thiamethoxam in papaya. On the basis of the CGA 322704 data on papaya from the same trials, the Meeting estimated a maximum residue level of 0.01* mg/kg for CGA 322704 on papaya.

The Meeting estimated STMR and HR values of 0 and 0 mg/kg for thiamethoxam residues in papayas. The Meeting also estimated STMR and HR values of 0 and 0 mg/kg for CGA 322704 residues in papayas.

Pineapple

Supervised trials data were available for pineapples from Brazil.

In Brazil, thiamethoxam is approved for pineapples as a pre-seedling transplant immersion in a solution concentration 0.075 kg ai/hL, and as a soil drench at the plant base 45–60 days after transplant at an application rate of 0.20 kg ai/ha.

In the Brazilian trials, this seedling treatment and soil drench usage GAP was followed, but another thiamethoxam soil drench was added 0–60 days before harvest. In the four trials, thiamethoxam residues in pineapples were all below LOQ (0.01 mg/kg). Residues of CGA 322704 were also all below LOQ (0.01 mg/kg).

The Meeting estimated a maximum residue level of 0.01* mg/kg for thiamethoxam in pineapples. On the basis of the CGA 322704 data on pineapples from the same trials, the Meeting estimated a maximum residue level of 0.01* mg/kg for CGA 322704 on pineapples.

The Meeting estimated STMR and HR values of 0 and 0 mg/kg for thiamethoxam residues in pineapples. The Meeting also estimated STMR and HR values of 0 and 0 mg/kg for CGA 322704 residues in pineapples.

Brassica vegetables

Supervised trials data were available for cabbages and broccoli.

Cabbages

Supervised trials data on cabbage were available from the USA.

In the USA, foliar applications of thiamethoxam may be made to head and stem Brassica vegetables (includes cabbage) at 0.096 kg ai/ha, with harvest on the same day.

Soil drench applications of thiamethoxam to Brassica vegetables at 0.19 kg ai/ha with a 30 days PHI are also registered. The soil drench rate in the cabbage trials was 0.14 kg ai/ha and the data were not evaluated.

In eight cabbage trials in the USA matching the foliar GAP conditions, thiamethoxam residues in cabbages (with wrapper leaves) in rank order were: 0.57, 0.59, 0.62, 0.69, 0.78, 0.91, 1.1 and 3.0 mg/kg. In the same eight trials, residues of CGA 322704 in cabbages (with wrapper leaves) in rank order were: 0.02, 0.02, 0.03, 0.03, 0.04, 0.05, 0.06 and 0.08 mg/kg.

In the same eight cabbage trials, residues were also measured on cabbage heads only, i.e., with wrapper leaves removed. Thiamethoxam residues in cabbage heads in rank order were: 0.01, 0.02, 0.03, 0.05, 0.05, 0.09, 0.11 and 0.14 mg/kg. In the same eight trials, residues of CGA 322704 in cabbage heads were: < 0.01 (7) and 0.01 mg/kg.

Two of the cabbage trials matching the foliar GAP conditions were side-by-side trials providing bridging data for the use of WG and SL formulations. Thiamethoxam residues in the head + wrapper leaves were 0.15 and 0.57 mg/kg for SL and 0.69 and 0.58 mg/kg for WG, and for head only the residues were < 0.01 and 0.01 mg/kg for SL and 0.05 and 0.02 mg/kg for WG. CGA 322704 residues in the head + wrapper leaves were < 0.01 and 0.04 mg/kg for SL and 0.04 and 0.05 mg/kg for WG. The results suggest equivalence, so only one of the bridging trials should be included in the dataset for STMR and maximum residue level estimation.

The cabbage datasets become:

Thiamethoxam—head + wrapper leaves (n = 7): 0.59, 0.62, 0.69, 0.78, 0.91, 1.1 and 3.0 mg/kg. (NAFTA calculator: 3.67. OECD calculator Mean + 4SD:4.53)

CGA 322704—head + wrapper leaves (n = 7): 0.02, 0.02, 0.03, 0.03, 0.05, 0.06 and 0.08 mg/kg. (NAFTA calculator: 0.129. OECD calculator Mean + 4SD: 0.132)

Thiamethoxam—head only (n = 7): 0.02, 0.03, 0.05, 0.05, 0.09, 0.11 and 0.14 mg/kg

CGA 322704—head only (n = 7): < 0.01 (6) and 0.01 mg/kg.

Broccoli

Supervised trials data on broccoli were available from the USA.

In the USA, foliar applications of thiamethoxam may be made to head and stem Brassica vegetables (includes broccoli) at 0.096 kg ai/ha, with harvest on the same day.

In 10 broccoli trials in the USA matching the GAP conditions, thiamethoxam residues in broccoli in rank order were: 0.30, 0.30, 0.34, 0.37, 0.41, 0.49, 0.57, 0.66, 1.1 and 1.1 mg/kg. In the same 10 trials, residues of CGA 322704 in broccoli in rank order were: < 0.01 (4), 0.01, 0.02, 0.03, 0.04, 0.04 and 0.04 mg/kg.

Four of the broccoli trials matching the foliar GAP conditions were side-by-side trials providing bridging data for the use of WG and SL formulations. In one pair of trials, from California, thiamethoxam residues in the head + stem were 0.34 and 0.37 g/kg for SL and 0.49 and 0.44 mg/kg for WG. CGA 322704 residues were 0.01 and 0.01 mg/kg for SL and 0.02 and 0.02 mg/kg for WG. In the second pair of trials, from Texas, thiamethoxam residues in the head + stem were 0.38 and 0.41 g/kg for SL and 0.32 and 0.34 mg/kg for WG. CGA 322704 residues were 0.02 and 0.04 mg/kg

for SL and 0.03 and 0.02 mg/kg for WG. The results suggest equivalence, so only one from each pair of the bridging trials should be included in the dataset for STMR and maximum residue level estimation.

The broccoli datasets (n = 8) become:

Thiamethoxam 0.30, 0.30, 0.41, 0.49, 0.57, 0.66, 1.1 and 1.1 mg/kg

CGA 322704 < 0.01 (4), 0.02, 0.04, 0.04 and 0.04 mg/kg.

These data sets were selected for the STMR and HR estimation for the Brassica group.

Summary—Brassica vegetables group

Residue data with suitable GAP were available for broccoli and cabbages. The Meeting noted that residues in cabbage with wrapper leaves had higher residues than the broccoli and decided to use the cabbage data to support Brassica group MRLs.

On the basis of the foliar applications on cabbages in the US trials, the Meeting estimated a maximum residue level of 5 mg/kg for thiamethoxam on Brassica vegetables. On the basis of the CGA 322704 data on cabbages from the same trials, the Meeting estimated a maximum residue level of 0.2 mg/kg for CGA 322704 on Brassica vegetables.

The Meeting noted that residues in broccoli had higher residues than the cabbages (heads only) and decided to use the broccoli data to support Brassica group STMRs and HRs.

On the basis of the foliar applications on broccoli in the eight US trials, the Meeting estimated an STMR and an HR value of 0.53 and 1.1 mg/kg respectively for thiamethoxam on Brassica vegetables. On the basis of the CGA 322704 data on broccoli from the same trials, the Meeting estimated an STMR and an HR value of 0.015 and 0.04 mg/kg respectively for CGA 322704 on Brassica vegetables.

For livestock dietary burden, it is more appropriate to include the cabbage wrapper leaves in the STMR and high residue estimates. In this case the STMR and high residue values for thiamethoxam on cabbages are 0.78 and 3.0 mg/kg respectively. For CGA 322704, the STMR and high residue values on cabbage are 0.03 and 0.08 mg/kg respectively.

Fruiting vegetables, Cucurbits

Supervised trials data were available for cucumbers, melons and cantaloupes and summer squash.

Cucumber

Supervised trials data on cucumbers were available from France, Netherlands, Spain and the USA.

In the USA, foliar applications of thiamethoxam may be made to cucurbit vegetables (includes cucumbers) at 0.096 kg ai/ha, with harvest on the same day.

In-furrow spray or soil surface band applications of thiamethoxam to cucurbit vegetables at 0.19 kg ai/ha with a 30 days PHI are also registered in the USA. The in-furrow and surface band treatment rate in the cucumber trials was 0.14 kg ai/ha and the data could not be evaluated.

In eight cucumber trials in the USA matching the foliar GAP conditions, thiamethoxam residues in cucumbers in rank order were: 0.02, 0.04, 0.05, 0.07, 0.07, 0.08, 0.09 and 0.11 mg/kg. In the same eight trials, residues of CGA 322704 in cucumbers were all below LOQ < 0.01 mg/kg).

In Italy, thiamethoxam may be applied to cucumbers by drip or drench at 0.2 kg ai/ha, with harvest permitted 3 days later. Drip refers to application to the base of each plant through the drip application system. Drench is application by watering soil around plants.

The protected cucumber trials in France, Netherlands and Spain relied on drip, drench and syringe applications. A syringe may be used in an experimental situation to simulate drip application.

In six cucumber trials in France, Netherlands and Spain following Italian GAP, thiamethoxam residues in cucumbers in rank order were: 0.06, 0.06, 0.09, 0.12, 0.14 and 0.29 mg/kg (NAFTA calculator: 0.432. OECD calculator Mean + 4SD: 0.471). The Meeting noted that application at 0.1 kg ai/ha (½ label rate) produced residues of 0.17 and 0.12 mg/kg. In the same six trials, residues of CGA 322704 in cucumbers were all below LOQ < 0.02 mg/kg). These data sets for both thiamethoxam and CGA 322704 were selected for estimation of maximum residue levels for cucurbit fruiting vegetables.

Melons and cantaloupes

Supervised trials data on melons and cantaloupes were available from Italy, Spain and the USA.

Thiamethoxam is approved for use on melons in Spain as a drip irrigation method of application: 0.20 kg ai/ha for indoor production and 0.10 kg ai/ha for outdoor production. A PHI of 3 days is specified.

The two trials from Italy could not be evaluated because no suitable GAP was available.

In four melon trials in Spain matching the drip irrigation GAP conditions (but with allowances on the PHI), thiamethoxam residues in cucumbers in rank order were: < 0.02, 0.02, 0.02 and 0.03 mg/kg. In the same four trials, residues of CGA 322704 in melons were all below LOQ < 0.02 mg/kg).

In the USA, foliar applications of thiamethoxam may be made to cucurbit vegetables (includes cantaloupes) at 0.096 kg ai/ha, with harvest on the same day.

In-furrow spray applications of thiamethoxam to cucurbit vegetables at 0.19 kg ai/ha with a 30 days PHI are also registered in the USA. The in-furrow treatment rate in the cantaloupe trials was 0.14 kg ai/ha and the data could not be evaluated.

In six cantaloupe trials in the USA matching the foliar application GAP conditions, thiamethoxam residues in cantaloupes in rank order were: 0.03, 0.03, 0.04, 0.07, 0.13 and 0.16 mg/kg. In the same six trials, residues of CGA 322704 in cantaloupes were all below LOQ (0.01 mg/kg).

Summer squash

Supervised trials data for thiamethoxam use on summer squash were available from the USA.

In the USA, foliar applications of thiamethoxam as a WG may be made to cucurbit vegetables (includes summer squash) at 0.096 kg ai/ha, with harvest on the same day.

In five summer squash trials in the USA matching the foliar application GAP conditions, thiamethoxam residues in summer squash in rank order were: 0.02, 0.05, 0.06, 0.07 and 0.16 mg/kg. In the same five trials, residues of CGA 322704 in summer squash in rank order were all below LOQ (0.01 mg/kg).

Summary—Fruiting vegetables, Cucurbits

Residue data with suitable GAP were available for cucumbers, melons and cantaloupes and summer squash. The Meeting noted that thiamethoxam residues were highest in cucumbers and that CGA 322704 residues were below LOQ in cucurbit fruiting vegetables. The Meeting decided to estimate cucurbit fruiting vegetables group maximum residue levels based on the cucumber data sets.

On the basis of the drip, drench and syringe applications on cucumbers in six European trials, the Meeting estimated a maximum residue level of 0.5 mg/kg for thiamethoxam on cucurbit fruiting vegetables. On the basis of the CGA 322704 data on cucumbers from the same six trials, the Meeting estimated a maximum residue level of 0.02* mg/kg for CGA 322704 on cucurbit fruiting vegetables.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.105 and 0.29 mg/kg respectively for thiamethoxam residues in cucurbit fruiting

vegetables. The Meeting estimated STMR and HR values of 0.02 and 0.02 mg/kg for CGA 322704 residues in cucurbit fruiting vegetables.

Fruiting vegetables, other than Cucurbits

Supervised trials data were available for sweet corn, tomatoes, peppers, egg plants and okra.

Egg plant

Supervised trials data for thiamethoxam use on egg plants were available from Switzerland and the UK.

Thiamethoxam is approved in Italy for foliar application on egg plants at 0.10 kg ai/ha, two applications at an interval of 7 days, with harvest 3 days after application.

In one greenhouse egg plant trial in the UK matching Italian GAP, thiamethoxam residues in egg plant were 0.12 mg/kg with CGA 322704 residues < 0.02 mg/kg.

Sweet corn

Supervised trials data for thiamethoxam use on sweet corn were available from the USA.

In the USA, thiamethoxam is formulated as an FS seed treatment that may be used on sweet corn at 1.25 mg ai per kernel. This is equivalent to approx 4.5 g ai/kg seed for a single kernel weight of 0.28 g.

In 12 sweet corn trials in the USA where the seed had been treated with thiamethoxam FS at 4.5 g ai/kg seed, thiamethoxam residues and CGA 322704 residues in the harvested sweet corn ears were all below LOQ (0.01 mg/kg).

The Meeting estimated a maximum residue level and STMR and HR values, all at 0.01 mg/kg for thiamethoxam in sweet corn (corn-on-the-cob).

The Meeting estimated a maximum residue level and STMR and HR values, all at 0.01 mg/kg for CGA 322704 in sweet corn (corn-on-the-cob).

Peppers

Supervised trials data for thiamethoxam use on bell peppers and chilli peppers were available from the USA and on sweet peppers from France, Italy, Spain, Switzerland and the UK. No suitable GAP was available to evaluate the data from Switzerland and the UK.

Thiamethoxam is approved in Italy for foliar application on peppers at 0.10 kg ai/ha, with harvest 3 days after application.

In eight sweet pepper field trials in Italy and Spain matching the Italian GAP conditions for peppers, thiamethoxam residues in sweet peppers in rank order were: 0.03, 0.03, 0.06, 0.08, 0.08, 0.09, 0.13 and 0.24 mg/kg. In the same eight trials, residues of CGA 322704 in sweet peppers were all below LOQ (0.02 mg/kg).

In 11 sweet pepper greenhouse trials in France, Italy, Spain, Switzerland and the UK matching the Italian GAP conditions for peppers, thiamethoxam residues in sweet peppers in rank order were: 0.07, 0.07, 0.08, 0.08, 0.08, 0.08, 0.10, 0.12, 0.16, 0.26 and 0.47 mg/kg (NAFTA calculator: 0.510. OECD calculator Mean + 4SD: 0.632). In the same 11 trials, residues of CGA 322704 in sweet peppers were: < 0.02 (9), 0.02 and 0.03 mg/kg. These data sets were selected for maximum residue level estimations for the fruiting vegetables group, except sweet corn.

In the USA, foliar applications of thiamethoxam as a WG may be made to fruiting vegetables (includes peppers) at 0.096 kg ai/ha, with harvest on the same day.

In six bell pepper trials in the USA matching the foliar GAP conditions for fruiting vegetables, thiamethoxam residues in sweet peppers in rank order were: 0.03, 0.06, 0.08, 0.10, 0.13

and 0.18 mg/kg. In the same six trials, residues of CGA 322704 in sweet peppers were: < 0.01 (5) and 0.01 mg/kg.

In three chilli pepper trials in the USA matching the foliar GAP conditions for fruiting vegetables, thiamethoxam residues in chilli peppers in rank order were: 0.06, 0.11 and 0.22 mg/kg. In the same three trials, residues of CGA 322704 in chilli peppers were: < 0.01 (2) and 0.06 mg/kg.

Okra

Supervised trials data for thiamethoxam use on okra were available from Côte d'Ivoire.

In Kenya, foliar applications of thiamethoxam as a WG may be made to okra at 0.10 kg ai/ha, with harvest 3 days later. The Meeting agreed to evaluate the data from Côte d'Ivoire with the Kenyan GAP, allowing that the 2 days PHI in the trials was sufficiently close to the 3 days PHI specified in the Kenyan GAP.

In four okra trials in Côte d'Ivoire at an application rate of 0.10 kg ai/ha and a PHI of 3 days, reported thiamethoxam residues in okra in rank order were: 0.03, 0.07, 0.07 and 0.24 mg/kg. The analytical method used for thiamethoxam residue analysis was an imidacloprid residue analytical method, presumably adapted to thiamethoxam. No validation data were available, but procedural recoveries of 78% and 70% were recorded. Metabolite CGA 322704 residues were not included in the analyses and the reported residues of thiamethoxam include only parent thiamethoxam.

Tomato

Supervised trials data for thiamethoxam use on tomatoes were available from France, Italy, Spain, Switzerland and the USA. No suitable GAP was available to evaluate the Swiss trials.

Thiamethoxam is approved for foliar application on tomatoes in Italy at 0.10 kg ai/ha, with harvest 3 days after application.

In 17 tomato field trials in France, Italy and Spain in accord with the GAP conditions of Italy, thiamethoxam residues in tomatoes in rank order were: < 0.02 (7), 0.02, 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, 0.03, 0.04 and 0.04 mg/kg. In the same 17 trials, residues of CGA 322704 in tomatoes were: < 0.02 (16) and 0.03 mg/kg.

In 10 tomato greenhouse trials in France, Italy, Spain and Switzerland in accord with the GAP conditions of Italy, thiamethoxam residues in tomatoes in rank order were: 0.02, 0.02, 0.02, 0.03, 0.03, 0.03, 0.03, 0.06, 0.07 and 0.12 mg/kg. In the same 10 trials, residues of CGA 322704 in tomatoes were all below LOQ (0.02 mg/kg).

In the USA, foliar applications of thiamethoxam as a WG may be made to fruiting vegetables (includes tomatoes) at 0.096 kg ai/ha, with harvest on the same day.

In 20 tomato trials in the USA matching the foliar GAP conditions, thiamethoxam residues in tomatoes in rank order were: 0.02, 0.03, 0.03, 0.04, 0.04, 0.05, 0.05, 0.06, 0.06, 0.06, 0.06, 0.07, 0.07, 0.07, 0.08, 0.10, 0.10, 0.12, 0.14 and 0.15 mg/kg. In the same 20 trials, residues of CGA 322704 in tomatoes in rank order were: < 0.01 (9), 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, 0.04 and 0.05 mg/kg.

Four of the tomato trials matching the foliar GAP conditions were side-by-side trials providing bridging data for the use of WG and SL formulations. In one pair of trials, from California, thiamethoxam residues in the tomatoes were 0.03 and 0.07 g/kg for SL and 0.06 and 0.02 mg/kg for WG. CGA 322704 residues were < 0.01 and 0.02 mg/kg for SL and < 0.01 and 0.01 mg/kg for WG. In the second pair of trials, from Florida, thiamethoxam residues in the tomatoes were 0.10 and 0.08 g/kg for SL and 0.05 and 0.06 mg/kg for WG. CGA 322704 residues were < 0.01 (2)for both SL and WG. The results suggest equivalence, so only one from each pair of the bridging trials should be included in the dataset for STMR and maximum residue levels estimation.

The tomato datasets become (n = 18): thiamethoxam 0.02, 0.03, 0.03, 0.04, 0.04, 0.05, 0.05, 0.06, 0.06, 0.07, 0.07, 0.07, 0.08, 0.10, 0.10, 0.12, 0.14 and 0.15 mg/kg; CGA 322704 < 0.01 (8), 0.01, 0.01, 0.02, 0.02, 0.02, 0.02, 0.03, 0.03, 0.04 and 0.05 mg/kg.

Summary—Fruiting vegetables, other than Cucurbits

Residue data with suitable GAP were available for sweet corn, tomatoes, peppers, egg plants and okra. The Meeting noted that thiamethoxam residues and CGA 322704 were highest in peppers and decided to estimate fruiting vegetable group maximum residue levels based on the peppers data sets. Residues in sweet corn appeared inconsistent with residues from other members of the commodity group, so the Meeting agreed on separate MRLs for sweet corn. Mushrooms were also excluded from the group MRLs.

On the basis of the foliar applications on sweet peppers in 11 greenhouse trials in France, Italy, Spain, Switzerland and the UK the Meeting estimated a maximum residue level of 0.7 mg/kg for thiamethoxam in fruiting vegetables other than cucurbits, except sweet corn. On the basis of the CGA 322704 data on sweet peppers from the same 11 trials, the Meeting estimated a maximum residue level of 0.05 mg/kg for CGA 322704 in fruiting vegetables other than cucurbits, except sweet corn and mushrooms.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.08 and 0.47 mg/kg respectively for thiamethoxam residues in fruiting vegetables other than cucurbits, except sweet corn and mushrooms. The Meeting estimated STMR and HR values of 0.02 and 0.03 mg/kg for CGA 322704 residues in fruiting vegetables other than cucurbits, except sweet corn and mushrooms.

The JMPR Manual (Section 6.9.2) explains that a generic factor may be used for conversion of residues from fresh peppers to dried chilli peppers. The factor is 10 for the estimation of residue levels of pesticides in dried chilli peppers from the HR values estimated for residues in or on sweet peppers.

The Meeting agreed to apply the default factor of 10 for dried chilli peppers to the STMR (0.08 mg/kg) and HR (0.47 mg/kg) values for thiamethoxam in fruiting vegetables other than cucurbits (based on sweet pepper data) and estimated a maximum residue level, an STMR and an HR for thiamethoxam in dried chilli peppers of 7, 0.8 and 4.7 mg/kg, respectively.

For CGA 322704, the Meeting also agreed to apply the default factor of 10 for dried chilli peppers to the STMR (0.02 mg/kg) and HR (0.03 mg/kg) values based on sweet peppers and estimated a maximum residue level, an STMR and an HR for CGA 322704 in dried chilli peppers of 0.5, 0.2 and 0.3 mg/kg, respectively.

Leafy vegetables

Supervised trials data were available for lettuce, spinach and mustard greens.

Lettuce

Supervised trials data for thiamethoxam use on lettuce were available from the USA.

In the USA, foliar applications of thiamethoxam as a WG may be made to leafy vegetables (includes lettuce) at 0.096 kg ai/ha, with harvest 7 days after treatment.

Thiamethoxam may also be used as a soil treatment at planting (in-furrow spray, surface band or drench) for leafy vegetables at 0.19 kg ai/ha with an expected time to harvest of 65 days. A shanked into root zone after transplanting application at 0.19 kg ai/ha, with a 35 days PHI is also available.

In eight head lettuce trials in the USA matching the foliar GAP conditions, thiamethoxam residues in head lettuces in rank order were: 0.02, 0.04, 0.11, 0.12, 0.20, 0.24, 0.25 and 0.45 mg/kg.

In the same eight trials, residues of CGA 322704 in head lettuces in rank order were: < 0.01 (4), 0.01, 0.01, 0.01 and 0.03 mg/kg.

In 10 leaf lettuce trials in the USA matching the foliar GAP conditions, thiamethoxam residues in leaf lettuces in rank order were: 0.07, 0.13, 0.22, 0.25, 0.53, 0.55, 0.86, 0.88, 1.14 and 1.9 mg/kg (NAFTA calculator: 3.442. OECD calculator Mean + 4SD: 2.914). This data set was selected for a thiamethoxam maximum residue level estimation for the leafy vegetables commodity group.

In the same 10 trials, residues of CGA 322704 in leaf lettuces in rank order were: < 0.01, 0.01, 0.01, 0.01, 0.03, 0.03, 0.04, 0.04, 0.04 and 0.07 mg/kg.

In six leaf lettuce trials in the USA matching the soil treatment GAP conditions, thiamethoxam residues in leaf lettuces in rank order were: 0.03, 0.05, 0.12, 0.36, 0.55 and 0.85 mg/kg.

In the same six trials, residues of CGA 322704 in leaf lettuces in rank order were: < 0.01 (2), 0.03, 0.03, 0.05 and 0.14 mg/kg.

Spinach

Supervised trials data for thiamethoxam use on spinach were available from the USA.

In the USA, foliar applications of thiamethoxam as a WG may be made to leafy vegetables (includes spinach) at 0.096 kg ai/ha, with harvest 7 days after treatment.

In 10 spinach trials in the USA matching the foliar GAP conditions for leafy vegetables, thiamethoxam residues in spinach in rank order were: 0.02, 0.02, 0.05, 0.07, 0.22, 0.28, 0.28, 0.28, 0.62 and 0.66 mg/kg.

In the same 10 trials, residues of CGA 322704 in spinach in rank order were: 0.10, 0.13, 0.21, 0.39, 0.49, 0.54, 0.61, 0.62, 0.77 and 0.80 mg/kg (NAFTA calculator: 2.157. OECD calculator Mean + 4SD: 1.475). This data set was selected for a CGA 322704 maximum residue level estimation for the leafy vegetables commodity group.

Mustard greens

Supervised trials data on mustard greens were available from the USA.

In the USA, foliar applications of thiamethoxam may be made to leafy greens Brassica vegetables (includes mustard greens) at 0.096 kg ai/ha, with harvest 7 days after an application.

In-furrow spray or soil surface band applications of thiamethoxam to Brassica vegetables at 0.19 kg ai/ha with a 30 days PHI are also registered uses. The in-furrow and surface band treatments rate in the mustard greens trials was 0.14 kg ai/ha and the data could not be evaluated.

In six mustard greens trials in the USA matching the foliar GAP conditions, thiamethoxam residues in mustard greens in rank order were: 0.38, 0.42, 0.42, 0.66, 0.69 and 0.75 mg/kg. In the same six trials, residues of CGA 322704 in mustard greens in rank order were: 0.07, 0.08, 0.12, 0.16, 0.23 and 0.29 mg/kg.

Two of the mustard greens trials matching the foliar GAP conditions were side-by-side trials providing bridging data for the use of WG and SL formulations. Thiamethoxam residues in the leaves were 0.69 and 0.60 mg/kg for SL and 0.69 and 0.75 mg/kg for WG. CGA 322704 residues in the leaves were 0.12 and 0.11 mg/kg for SL and 0.18 and 0.23 mg/kg for WG. The results suggest equivalence, so only one of the bridging trials should be included in the dataset for STMR and maximum residue level estimation.

The mustard green datasets become (n = 5): thiamethoxam 038, 0.42, 0.42, 0.66, and 0.75 mg/kg; CGA 322704 0.07, 0.08, 0.16, 0.23 and 0.29 mg/kg.

Summary—Leafy vegetables

Residue data with suitable GAP were available for leaf lettuce, head lettuce, spinach and mustard greens. The Meeting noted that thiamethoxam residues were highest in leaf lettuce and that CGA 322704 residues were highest in spinach and decided to estimate leafy vegetables group maximum residue levels based on these two data sets.

On the basis of the foliar applications on leaf lettuces in 10 US trials, the Meeting estimated a maximum residue level of 3 mg/kg for thiamethoxam on leafy vegetables. The STMR and HR values were 0.54 and 1.9 mg/kg, respectively.

On the basis of the foliar applications on spinach in 10 US trials, the Meeting estimated a maximum residue level of 2 mg/kg for CGA 322704 on leafy vegetables. The STMR and HR values were 0.52 and 0.80 mg/kg, respectively.

Legume vegetables

Supervised trials data were available for beans and peas.

Beans

Supervised trials data for thiamethoxam seed treatment uses on beans were available from the USA.

In the USA, thiamethoxam is registered for use as an FS formulation on bean seed at 50 g ai per 100 kg seed, i.e., 0.5 g ai/kg seed.

In seven snap bean trials in the US with seeds treated at the label rate (0.5 g ai/kg seed) and in seven trials where seeds were treated at 3 × the label rate, residues of thiamethoxam and CGA 322704 did not exceed the LOQ (0.01 mg/kg) in the harvested snap beans (include succulent seeds and pods).

In six lima bean trials in the US with seeds treated at the label rate (0.5 g ai/kg seed) and in six trials where seeds were treated at 3 × the label rate, residues of thiamethoxam and CGA 322704 did not exceed the LOQ (0.01 mg/kg) in the harvested lima beans (include succulent seeds, pods are discarded).

Peas

Supervised trials data for thiamethoxam seed treatment uses on peas were available from the USA.

In the USA, thiamethoxam is registered for use as an FS formulation on pea seeds at 25 g ai per 100 kg seed, i.e., 0.25 g ai/kg seed.

In seven pea trials in the US with seeds treated at 2 × the label rate (0.5 g ai/kg seed) and in seven trials where seeds were treated at 6 × the label rate, residues of thiamethoxam and CGA 322704 did not exceed the LOQ (0.01 mg/kg) in the harvested succulent shelled peas (include succulent seeds, pods are discarded), except for two trials at 6 × where a thiamethoxam residue of 0.01 mg/kg was recorded.

In three pea trials in the US with seeds treated at the 2 × the label rate (0.5 g ai/kg seed) and in three trials where seeds were treated at 6 × the label rate, residues of thiamethoxam and CGA 322704 did not exceed the LOQ (0.01 mg/kg) in the harvested succulent edible pods (include succulent seeds and pods), except for one trial at 6 × where a thiamethoxam residue of 0.01 mg/kg was recorded.

Summary—Legume vegetables

Residue data with suitable GAP were available for snap beans, lima beans, succulent shelled peas and succulent seeds and pods. Residues were below LOQ. The Meeting decided to estimate legume vegetables group maximum residue levels.

On the basis of the seed treatment trials on peas and beans, the Meeting estimated a maximum residue level of 0.01(*) mg/kg for thiamethoxam on legume vegetables. On the basis of the CGA 322704 data from the same trials, the Meeting also estimated a maximum residue level of 0.01(*) mg/kg for CGA 322704 on legume vegetables.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.01 and 0.01 mg/kg for thiamethoxam residues in legume vegetables. The Meeting also estimated STMR and HR values of 0.01 and 0.01 mg/kg for CGA 322704 residues in legume vegetables.

Pulses

Supervised trials data were available for beans, peas and soya beans.

Beans, dry

Supervised trials data for thiamethoxam seed treatment uses on beans were available from the USA.

In the USA, thiamethoxam is registered for use as an FS formulation on bean seed at 50 g ai per 100 kg seed, i.e., 0.5 g ai/kg seed.

In nine bean trials in the US with seeds treated at the label rate (0.5 g ai/kg seed) and in nine trials where seeds were treated at 3 × the label rate, residues of thiamethoxam and CGA 322704 did not exceed the LOQ (0.01 mg/kg) in the harvested dry beans.

Peas, dry

Supervised trials data for thiamethoxam seed treatment uses on peas producing dry peas were available from the USA, Denmark, France and Germany.

In the USA, thiamethoxam is registered for use as an FS formulation on pea seed at 25 g ai per 100 kg seed, i.e., 0.25 g ai/kg seed.

In five pea trials in the US with seeds treated at 2 × the label rate (0.5 g ai/kg seed), residues of thiamethoxam and CGA 322704 did not exceed the LOQ (0.01 mg/kg) in the harvested dry peas. In five pea trials in the US with seeds treated at 6 × the label rate (1.4 g ai/kg seed), residues of thiamethoxam did not exceed the LOQ (0.01 mg/kg) in the harvested dry peas. CGA 322704 residues were: < 0.01 (3), 0.02 and 0.02 mg/kg.

In the Czech Republic, thiamethoxam is registered for use as an FS formulation on pea seed at 53 g ai per 100 kg seed (0.53 g ai/kg seed).

In 20 pea trials in Europe (Denmark—two, France—14 and Germany—four) with seeds treated with thiamethoxam at 0.5 g ai/kg seed (Czech Republic GAP), residues of thiamethoxam in the harvested dry peas at maturity were: < 0.02 (18), 0.02 and < 0.05 mg/kg. In the same 20 trials, residues of CGA 322704 were all below LOQ (0.02 (19) and < 0.05 mg/kg).

The Meeting recognized that residues of thiamethoxam and metabolite CGA 322704 from seed treatment uses were mostly below LOQ, but could sometimes occur in the dry peas.

Soya beans

Supervised trials data for thiamethoxam seed treatment uses on soya beans were available from the USA.

In the USA, thiamethoxam is registered for use as an FS formulation on soya bean seeds at 50 g ai per 100 kg seed, i.e., 0.5 g ai/kg seed.

In 15 soya bean trials in the US with seeds treated at the label rate (0.5 g ai/kg seed), residues of thiamethoxam and CGA 322704 did not exceed the LOQ (0.01 mg/kg) in the harvested soya bean dry seed.

Summary—Pulses

Residue data with suitable GAP were available for dry beans, dry peas and soya beans. Residues were almost all below LOQ. The Meeting decided to estimate pulse group maximum residue levels.

On the basis of the 20 seed treatment trials on peas in Europe, the Meeting estimated a maximum residue level of 0.04 mg/kg for thiamethoxam on pulses. On the basis of the CGA 322704 data from the same trials, the Meeting estimated a maximum residue level of 0.02 mg/kg for CGA 322704 on pulses.

The same data were used for STMR estimates. The Meeting estimated an STMR value of 0.02 mg/kg for thiamethoxam residues in pulses. The Meeting also estimated an STMR value of 0.02 mg/kg for CGA 322704 residues in pulses.

Root and tuber vegetables

Supervised trials data were available for carrots, potatoes, radishes and sugar beet.

Carrots

Supervised trials data for thiamethoxam uses on carrots were available from the USA.

In the USA, thiamethoxam may be used in foliar applications to root vegetables (includes carrot) at 0.070 kg ai/ha, with harvest permitted 7 days after an application. Thiamethoxam may also be used as a soil surface band with incorporation after sowing or in-furrow spray treatments with an application rate of 0.21 kg ai/ha for root vegetables.

In eight carrot trials in the USA matching the foliar GAP conditions, thiamethoxam residues in carrots did not exceed the LOQ (0.01 mg/kg). In the same eight trials, residues of CGA 322704 in carrots also in did not exceed the LOQ (0.01 mg/kg).

In six carrot trials in the USA matching the soil surface band GAP conditions, thiamethoxam residues in carrots in rank order were: < 0.01 (2), 0.01, 0.02, 0.02 and 0.04 mg/kg. In the same six trials, residues of CGA 322704 in carrots did not exceed the LOQ (0.01 mg/kg).

Potatoes

Supervised trials data for thiamethoxam uses on potatoes were available from France, Germany, Spain, Switzerland, the UK and the USA.

In Spain, foliar applications of thiamethoxam may be made to potatoes at 0.025 kg ai/ha, with harvest 7 days after an application. In Hungary, foliar applications of thiamethoxam may be made to potatoes at 0.020 kg ai/ha, with harvest 7 days after an application. These two use patterns are very similar and were used to evaluate the trials from France, Germany, Spain, Switzerland and the UK.

In 13 potato trials in Europe (France—four, Germany—two, Spain—four, Switzerland—two and the UK—one) with foliar application of thiamethoxam at 0.025 kg ai/ha and harvest of tubers 7 days later, residues of thiamethoxam and CGA 322704 did not exceed the LOQs (< 0.02 mg/kg) in any tuber sample.

In the USA, thiamethoxam is registered for foliar application to tuberous and corm vegetables (includes potato) at 0.053 kg ai/ha, with harvest permitted 14 days after an application. Also, potato seed pieces may be treated with thiamethoxam FS at 4.3–6.2 g ai per 100 kg seed.

In 14 potato trials in the USA with foliar application of thiamethoxam at approx 2 × the label rate (0.099 kg ai/ha) and harvest of tubers 14 days later, residues of thiamethoxam and CGA 322704 did not exceed the LOQs (< 0.01 mg/kg) in any tuber sample.

In 16 potato trials in the USA with potato seed pieces treated with thiamethoxam FS and DS at 8 g ai per 100 kg seed pieces, the residues of thiamethoxam in harvested mature tubers were: < 0.01 (11), 0.02, 0.05, 0.14, 0.18 and 0.20 mg/kg (NAFTA calculator: 0.242. OECD calculator Mean + 4SD: 0.308). In the same 16 trials, residues of CGA 322704 in the harvested tubers were: < 0.01

(12), 0.04, 0.04, 0.06 and 0.15 mg/kg (NAFTA calculator: 0.135. OECD calculator Mean+4SD: 0.172). Note that the nominal 8 g ai per 100 kg seed pieces in these trials is 30% higher than the label maximum rate 6.2 g ai per 100 kg seed. These data sets were selected for maximum residue level estimations on the root and tuber vegetables group.

Radish

Supervised trials data for thiamethoxam uses on radishes were available from the USA.

In the USA, thiamethoxam may be used in a single foliar application to radishes at 0.070 kg ai/ha, with harvest permitted 7 days after the application. Thiamethoxam may also be used as a soil surface band with incorporation after sowing with an application rate of 0.11 kg ai/ha for radishes.

In six radish trials in the USA matching the foliar GAP conditions, thiamethoxam residues in radish roots in rank order were: < 0.01 (4), 0.01 and 0.01 mg/kg. In the same six trials, residues of CGA 322704 in radish roots did not exceed the LOQ (0.01 mg/kg).

In six radish trials in the USA matching the foliar GAP conditions, thiamethoxam residues in radish tops in rank order were: 0.07, 0.10, 0.17, 0.18, 0.30 and 0.64 mg/kg. In the same six trials, residues of CGA 322704 in radish tops in rank order were: 0.02, 0.02, 0.03, 0.04, 0.05 and 0.13 mg/kg. The Meeting noted that both the thiamethoxam and CGA 322704 residue concentrations in radish tops fell within the maximum residue levels estimated for the leafy vegetables group.

In four radish trials in the USA matching the soil surface band application GAP conditions, thiamethoxam residues in radish roots in rank order were: < 0.01 (3) and 0.02 mg/kg. In the same four trials, residues of CGA 322704 in radish roots did not exceed the LOQ (0.01 mg/kg).

In four radish trials in the USA matching the soil surface band application GAP conditions, thiamethoxam residues in radish tops in rank order were: < 0.01, 0.09, 0.09 and 0.38 mg/kg. In the same four trials, residues of CGA 322704 in radish tops in rank order were: < 0.01 (2), 0.03 and 0.10 mg/kg.

Sugar beet

Supervised trials data for thiamethoxam uses on sugar beets were available from France, Germany, Italy, Netherlands, Spain, Switzerland and the UK. No suitable GAP information was available to evaluate the trials from Italy, Spain and Switzerland.

In the UK, thiamethoxam is registered for use as an FS formulation on sugar beet seeds at 60 g ai per 100,000 seeds.

In nine sugar beet trials in Europe (France—three, Germany—three, Netherlands—one, Sweden—one and the UK—one) matching UK seed treatment GAP conditions, thiamethoxam residues in harvested sugar beets did not exceed LOQ (0.02 mg/kg). In the same nine trials, residues of CGA 322704 in sugar beets also did not exceed LOQ (0.02 mg/kg).

Summary—Root and tuber vegetables

Residue data with suitable GAP were available for carrots, radishes, potatoes and sugar beets. Residues were highest in potatoes and the Meeting decided to estimate root and tuber vegetables group maximum residue levels based on the potatoes data.

On the basis of the potato seed piece treatment with thiamethoxam FS and DS in 16 US trials, the Meeting estimated a maximum residue level of 0.3 mg/kg for thiamethoxam on root and tuber vegetables. On the basis of the CGA 322704 data on potatoes from the same 16 trials, the Meeting estimated a maximum residue level of 0.2 mg/kg for CGA 322704 on root and tuber vegetables.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.01 and 0.20 mg/kg respectively for thiamethoxam residues in root and tuber

vegetables. The Meeting estimated STMR and HR values of 0.01 and 0.15 mg/kg respectively for CGA 322704 residues in root and tuber vegetables.

Stalk and stem vegetables

Supervised trials data were available for artichokes and celery.

Artichoke, Globe

Supervised trials data for thiamethoxam uses on globe artichokes were available from the USA.

In the USA, thiamethoxam WG may be used in foliar applications to globe artichokes at 0.053 kg ai/ha, with harvest permitted 4 days after an application.

In three globe artichoke trials in the USA matching foliar GAP conditions, thiamethoxam residues in globe artichokes in rank order were: 0.17, 0.23 and 0.24 mg/kg. In the same three trials, residues of CGA 322704 in globe artichokes in rank order were: 0.023, 0.024 and 0.029 mg/kg.

Globe artichoke is a minor crop and the Meeting agreed to evaluate the data. The Meeting estimated a maximum residue level of 0.5 mg/kg for thiamethoxam on globe artichokes. On the basis of the CGA 322704 data on globe artichokes from the same three trials, the Meeting estimated a maximum residue level of 0.05 mg/kg for CGA 322704 on globe artichokes.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.23 and 0.24 mg/kg respectively for thiamethoxam residues in globe artichokes. The Meeting estimated STMR and HR values of 0.024 and 0.029 mg/kg respectively for CGA 322704 residues in globe artichokes.

Celery

Supervised trials data for thiamethoxam uses on celery were available from the USA.

In the USA, thiamethoxam WG may be used in foliar applications on leafy vegetables (includes celery) at 0.096 kg ai/ha, with harvest permitted 7 days after an application. Thiamethoxam may also be used as a soil drench treatment at sowing or planting of leafy vegetables at 0.19 kg ai/ha. Trials with the drench treatment could not be evaluated because the trial rate did not match the GAP rate.

In six celery trials in the USA matching the foliar GAP conditions, thiamethoxam residues in celery in rank order were: 0.09, 0.10, 0.16, 0.25, 0.38 and 0.43 mg/kg (NAFTA calculator: 0.927. OECD calculator Mean + 4SD: 0.812). In the same six trials, residues of CGA 322704 in celery in rank order were: < 0.01 (4), 0.01 and 0.02 mg/kg.

On the basis of the foliar applications on celery in six US trials, the Meeting estimated a maximum residue level of 1 mg/kg for thiamethoxam on celery. On the basis of the CGA 322704 data on celery from the same six trials, the Meeting estimated a maximum residue level of 0.04 mg/kg for CGA 322704 on celery.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.21 and 0.43 mg/kg respectively for thiamethoxam residues in celery. The Meeting estimated STMR and HR values of 0.01 and 0.02 mg/kg respectively for CGA 322704 residues in celery.

Cereal grains

Supervised trials data were available for barley, maize, popcorn, rice and wheat.

Barley

Supervised trials data were available for barley from France, Germany, the UK and the USA.

In the Czech Republic and Romania, thiamethoxam is formulated as an FS seed treatment that may be used on barley at 53 g ai per 100 kg seed, i.e., 0.53 g ai/kg seed.

In 24 barley seed-treatment trials in Europe (France—19, Germany—two and the UK—three) with conditions (application rates 0.53–0.78 g ai/kg seed) approximately aligned with the GAP of the Czech Republic and Romania, thiamethoxam residues in barley grain from 23 trials did not exceed LOQ (0.02 mg/kg), while 0.02 mg/kg was recorded in grain from one trial. In the same 24 trials, residues of CGA 322704 in barley grain also did not exceed LOQ (0.02 mg/kg).

US GAP for barley allows the use of thiamethoxam WG for foliar applications at 0.070 kg ai/ha with a 21 days PHI.

In nine barley trials in the USA matching the foliar GAP conditions, thiamethoxam residues in barley in rank order were: < 0.01 (3), 0.01, 0.12, 0.14, 0.14, 0.15 and 0.21 mg/kg (NAFTA calculator: .0.325. OECD calculator Mean + 4SD: 0.403). In the same nine trials, residues of CGA 322704 in barley in rank order were: < 0.01 (7), 0.01 and 0.02 mg/kg. These data sets were selected for maximum residue level estimations.

On the basis of the foliar applications on barley in nine US trials, the Meeting estimated a maximum residue level of 0.4 mg/kg for thiamethoxam on barley. On the basis of the CGA 322704 data on barley from the same nine trials, the Meeting estimated a maximum residue level of 0.04 mg/kg for CGA 322704 on barley.

The same data were used for STMR estimates. The Meeting estimated an STMR value of 0.12 mg/kg for thiamethoxam residues in barley. The Meeting estimated an STMR value of 0.01 mg/kg for CGA 322704 residues in barley.

Maize

Supervised trials data for thiamethoxam seed treatment uses on maize were available from France, Germany, Spain and the USA.

In the Czech Republic and Romania, thiamethoxam is formulated as an FS seed treatment that may be used on maize at 315 g ai per 100 kg seed, i.e., 3.15 g ai/kg seed.

The European supervised trials on maize were evaluated with the seed treatment GAP of the Czech Republic and Romania.

In 24 maize seed-treatment trials in Europe (France—15, Germany—six, and Spain—three) with conditions aligned with the GAP of the Czech Republic and Romania, thiamethoxam residues in maize grain from 23 trials did not exceed LOQ (0.02 mg/kg), while 0.04 mg/kg was recorded in grain from one trial. In the same 24 trials, residues of CGA 322704 in maize grain also did not exceed LOQ (0.02 mg/kg).

In the USA, thiamethoxam is formulated as an FS seed treatment that may be used on maize at 1.25 mg ai per kernel. This is equivalent to approx 4.5 g ai/kg seed for a single kernel weight of 0.28 g.

In 21 maize trials in the USA matching the US seed treatment GAP conditions, thiamethoxam residues in maize grain did not exceed LOQ (0.01 mg/kg). In the same 21 trials, residues of CGA 322704 in maize grain also did not exceed LOQ (0.01 mg/kg). In two trials with a seed treatment rate of 13.5 g ai/kg seed (3 × the label rate), residues of thiamethoxam and CGA 322704 also did not exceed LOQ (0.01 mg/kg).

The maize metabolism studies showed that very low concentrations of thiamethoxam and metabolite CGA 322704 could occur in the maize grain from a seed treatment.

On the basis of the seed treatment uses on maize in 24 European trials, the Meeting estimated a maximum residue level of 0.05 mg/kg for thiamethoxam on maize. On the basis of the CGA 322704 data on maize from the same 24 trials, the Meeting estimated a maximum residue level of 0.02 mg/kg for CGA 322704 on maize.

The same data were used for STMR estimates. The Meeting estimated an STMR value of 0.02 mg/kg for thiamethoxam residues in maize. The Meeting also estimated an STMR value of 0.02 mg/kg for CGA 322704 residues in maize.

Popcorn

Supervised trials data for thiamethoxam use on popcorn were available from the USA.

In the USA, thiamethoxam is formulated as an FS seed treatment that may be used on popcorn at 1.25 mg ai per kernel. This is equivalent to approx 4.5 g ai/kg seed for a single kernel weight of 0.28 g.

In three popcorn trials in the USA where the seed had been treated with thiamethoxam FS at 4.5 g ai/kg seed, thiamethoxam residues and CGA 322704 residues in the harvested grain were all below LOQ (0.01 mg/kg).

The Meeting estimated a maximum residue level and an STMR value, both at 0.01 mg/kg for thiamethoxam in popcorn.

The Meeting estimated a maximum residue level and an STMR value, both at 0.01 mg/kg for CGA 322704 in popcorn.

Rice

Supervised trials data were available for rice from Brazil and Japan.

In Japan, thiamethoxam formulated as an SC may be applied to rice as foliar sprays at a concentration of 0.0065 kg ai/hL. A 14 days PHI is observed. Thiamethoxam GR may also be used as a seed-box treatment at 0.8 g ai per litre of soil.

In two reverse-decline rice trials in Japan with seed-box treatment and foliar application aligned with GAP, residues of thiamethoxam in hulled rice grain were: 0.064 and 0.092 mg/kg. It should be noted that higher residues occurred at 28 days PHI than at shorter intervals. In the same two trials, CGA 322704 residues in the hulled rice grain were: 0.068 and 0.088 mg/kg.

Brazil has a registered seed treatment use for thiamethoxam FS on rice at 100 g ai per 100 kg seed, i.e., 1 g ai/kg seed. Thiamethoxam as a WG formulation may also be used in foliar applications on rice at 0.0375 kg ai/ha with observation of a 21 days PHI.

In three rice trials in Brazil with application conditions, seed treatment 1.4 g ai/kg seed, and foliar application at 0.05 kg ai/ha (33% higher than label), thiamethoxam residues in rice grain were: < 0.02, < 0.02 and 0.03 mg/kg. In three other trials with application conditions, seed treatment 1.4 g ai/kg seed, and foliar application at 0.028 kg ai/ha (25% lower than label), thiamethoxam residues in rice grain were: 0.27, 0.22 and 0.32 mg/kg. The data are apparently inconsistent with residues from the 0.028 kg ai/ha application rate approximately 10 times as high as residues from the 0.05 kg ai/ha application rate.

Residues of CGA 322704 in the six trials (approximately label rate) from Brazil were < 0.02, < 0.02, < 0.02, 0.02, 0.07 and 0.08 mg/kg.

Six trials for rice are very minimal for a major crop and the Meeting decided not to estimate a maximum residue level.

Wheat

Supervised trials data were available for wheat from France, Germany, Switzerland and the UK.

In the Czech Republic and Romania, thiamethoxam is formulated as an FS seed treatment that may be used on wheat at 53 g ai per 100 kg seed, i.e., 0.53 g ai/kg seed.

In 34 wheat seed-treatment trials in Europe (France—31, Germany—two and the UK—one) with conditions (application rates 0.56–0.64 g ai/kg seed) approximately aligned with the GAP of the Czech Republic and Romania, thiamethoxam residues in wheat grain from 34 trials did not exceed

LOQ (0.02 mg/kg). In the same 34 trials, residues of CGA 322704 in wheat grain also did not exceed LOQ (0.02 mg/kg).

Hungarian GAP for wheat allows the use of thiamethoxam WG for foliar applications at 0.040 kg ai/ha with a 14 days PHI.

In 22 wheat trials in Europe (France—13, Germany—four, Switzerland—two and the UK—three) with conditions aligned with the GAP of Hungary (but application rate 0.050 kg ai/ha instead of 0.040 kg ai/ha and eight trials also included seed treatments), thiamethoxam residues in wheat grain from 22 trials were: < 0.02 (16), 0.02, 0.02, 0.02, 0.03, 0.03 and 0.04 mg/kg (NAFTA calculator: 0.037. OECD calculator Mean + 4SD: 0.042). In the same 22 trials, residues of CGA 322704 in wheat grain did not exceed LOQ (0.02 mg/kg). These data sets were selected for maximum residue level estimations.

On the basis of the foliar applications on wheat in 22 European trials, the Meeting estimated a maximum residue level of 0.05 mg/kg for thiamethoxam on wheat. On the basis of the CGA 322704 data on wheat from the same 22 trials, the Meeting estimated a maximum residue level of 0.02 mg/kg for CGA 322704 on wheat.

The same data were used for STMR estimates. The Meeting estimated STMR values of 0.02 and 0.02 mg/kg respectively for thiamethoxam residues and CGA 322704 residues in wheat.

Tree nuts

Pecans

Supervised trials data were available for pecans from the USA.

In the USA, a ZC (mixed formulation of CS capsule suspension and SC suspension concentrate) is registered for foliar application to pecans at 0.054 kg ai/ha. A 14 days PHI is to be observed.

Eight pecan trials were carried out at five sites in the USA. At three of the sites, application was made with a low-volume concentrated spray to simulate aerial application in one trial and as a high-volume dilute spray in the parallel trial. The remaining two sites had one trial each, one at high volume and the other at low volume. The trials included a second active ingredient, pymetrozine, as a tank mix.

In eight pecan trials at five sites in the USA with foliar application of a thiamethoxam WG formulation at 0.074 kg ai/ha and pecan harvest at 12 or 14 days after the second application, residues of thiamethoxam in pecan kernels did not exceed the LOQ (0.01 mg/kg). In the same eight trials, residues of CGA 322704 in pecan kernels also did not exceed the LOQ (0.01 mg/kg).

On the basis of the foliar applications on pecans in eight US trials, the Meeting estimated a maximum residue level of 0.01 mg/kg for thiamethoxam on pecans. On the basis of the CGA 322704 data on pecans from the same eight trials, the Meeting estimated a maximum residue level of 0.01 mg/kg for CGA 322704 on pecans.

The same data were used for STMR and HR estimates. The Meeting estimated STMR and HR values of 0.01 and 0.01 mg/kg for thiamethoxam residues in pecans. The Meeting also estimated STMR and HR values of 0.01 and 0.01 mg/kg for CGA 322704 residues in pecans.

Oilseed

Supervised trials data were available for cotton seed, oilseed rape and sunflower.

Cotton

Supervised trials data were available for cotton from Greece, Spain and the USA.

In the USA, a thiamethoxam FS formulation is registered for seed-treatment of cotton seed at 0.30–0.34 mg ai per seed. For a 100 mg cotton seed this would translate to 3.0–3.4 g ai/kg seed. Thiamethoxam is also registered for foliar use on cotton at 0.070 kg ai/ha, with observation of a 21 days PHI.

In the cotton trials from the US, the seed treatment rate was in accord with US GAP, but foliar application rates in the trials (0.032, 0.045, 0.05, 0.15 and 0.25 kg ai/ha) were not in accord with the GAP rate, 0.070 kg ai/ha, so it was not possible to evaluate the cotton trials data.

In Spain, a thiamethoxam WG formulation is registered for foliar applications to cotton at 0.050 kg ai/ha with a PHI of 28 days.

In 13 cotton trials in Europe (Greece—eight and Spain—five) matching the foliar GAP conditions of Spain, thiamethoxam residues in cotton seed did not exceed the LOQ (0.02 mg/kg). In the same 13 trials, residues of CGA 322704 in cotton seed also did not exceed the LOQ (0.02 mg/kg). Some of the trials had also included a thiamethoxam seed treatment at 1.9–2.7 g ai/kg seed, but it is expected that the foliar treatment would produce the higher residues; in this case residue levels did not exceed the LOQ from the combined uses. The residue data were reported for dehulled seed and cotton hulls separately. Residues of thiamethoxam and CGA 322704 in cotton hulls were also below LOQ (0.05 mg/kg) in all samples.

Oilseed rape

Supervised trials data were available for seed treatment uses on oilseed rape from France, Germany, Sweden and the UK.

In Germany and the UK, thiamethoxam FS formulations are registered for use as seed treatments on rapeseed at 420 g ai per 100 kg seed.

In 14 trials in France, nine in Germany, one in Sweden and five in the UK where rapeseed was treated with thiamethoxam in WS or FS formulations, then sown and the crop grown to maturity, residues of thiamethoxam in rapeseed were all below LOQ (0.02 mg/kg). Residues of metabolite CGA 322704 in rapeseed were also all below LOQ (0.02 mg/kg) in the same trials.

Sunflowers

Supervised trials data were available for sunflowers from the USA.

In the USA, a thiamethoxam FS formulation is registered for seed-treatment of sunflower seeds at 0.25 mg ai per seed. For a 60–70 mg sunflower seed this would translate to 3.6–4.2 g ai/kg seed.

In eight sunflower trials in the USA matching the GAP conditions, thiamethoxam residues in sunflower seeds did not exceed the LOQ (0.01 mg/kg). In the same eight trials, residues of CGA 322704 in sunflower seeds also did not exceed the LOQ (0.01 mg/kg).

Residues of thiamethoxam and CGA 322704 also did not exceed LOQ (0.01 mg/kg) in two trials where seed treatment rates were 12.2 and 11.3 g ai/kg seed (3 × the label rate), suggesting a nil residue situation.

Summary—Oilseeds

Residue data with suitable GAP were available for sunflowers, cotton and oilseed rape. The Meeting noted that thiamethoxam and CGA 322704 residues were mostly below LOQ, but were highest in cotton seed and decided to estimate oilseed group maximum residue levels based on the cotton seed data set.

On the basis of the foliar applications on cotton in 13 European trials, the Meeting estimated a maximum residue level of 0.02 mg/kg for thiamethoxam on oilseed. On the basis of the

CGA 322704 data on cotton seed from the same 13 trials, the Meeting estimated a maximum residue level of 0.02 mg/kg for CGA 322704 on oilseed.

The same data were used for STMR estimates. The Meeting estimated STMR values of 0.02 and 0.02 mg/kg respectively for thiamethoxam residues and CGA 322704 residues in oilseed.

Seed for beverages and sweets

Cacao

Supervised trials data were available for foliar application of thiamethoxam in the production of cacao beans in Côte d'Ivoire.

In Cameroon, thiamethoxam WG is registered for foliar application to cacao at 0.025 kg ai/ha. A PHI of 30 days is to be observed.

In four cacao trials in Côte d'Ivoire matching the GAP conditions of Cameroon, thiamethoxam residues in fermented dried cacao beans did not exceed the LOQ (0.02 mg/kg). In the same four trials, residues of CGA 322704 in dried cacao beans also did not exceed the LOQ (0.02 mg/kg).

On the basis of the foliar applications on cacao in four Côte d'Ivoire trials, the Meeting estimated a maximum residue level of 0.02 mg/kg for thiamethoxam on dried cacao beans. On the basis of the CGA 322704 data from the same four trials, the Meeting estimated a maximum residue level of 0.02 mg/kg for CGA 322704 on dried cacao beans.

The same data were used for STMR estimates. The Meeting estimated STMR values of 0.02 and 0.02 mg/kg respectively for thiamethoxam residues and CGA 322704 residues in dried cacao beans.

Coffee

Supervised trials data were available for thiamethoxam uses in the production of coffee beans in Brazil.

In Brazil, thiamethoxam may be used in soil treatments in the production of coffee—GR granules applied to the soil at 0.30 kg ai/ha, max annual dose 0.60 kg ai/ha; PHI 90days;WG drench on soil under coffee tree at 0.50 kg ai/ha, PHI 90 days.

In six coffee trials in Brazil matching the GAP conditions of GR treatment of the soil, thiamethoxam residues in coffee beans in rank order were: 0.02, 0.02, 0.02, 0.02, 0.03 and 0.04 mg/kg. In the same six trials, residues of CGA 322704 in coffee beans in rank order were: < 0.01 (4), 0.02 and 0.02 mg/kg.

In six coffee trials in Brazil matching the GAP conditions of WG drench treatment of the soil, thiamethoxam residues in coffee beans in rank order were: 0.02, 0.03, 0.03, 0.04, 0.04 and 0.06 mg/kg (NAFTA calculator: 0.082. OECD calculator 3×Mean: 0.110). In the same six trials, residues of CGA 322704 in coffee beans in rank order were: < 0.01 (3), 0.02, 0.02 and 0.03 mg/kg (NAFTA calculator: 0.046. OECD calculator Mean + 4SD: 0.049). These data sets were selected for maximum residue level estimations.

The Meeting noted that the trials with granular soil treatments produced residues of the same order as those from the drench treatment and provided support for the six soil drench trials.

On the basis of the six Brazilian trials with soil drench treatments, the Meeting estimated a maximum residue level of 0.2 mg/kg for thiamethoxam on coffee beans. On the basis of the CGA 322704 data on coffee beans from the same six trials, the Meeting estimated a maximum residue level of 0.05 mg/kg for CGA 322704 on coffee beans.

The same data were used for STMR estimates. The Meeting estimated STMR values of 0.035 and 0.015 mg/kg respectively for thiamethoxam residues and CGA 322704 residues in coffee beans.

Legume animal feeds

Pea fodder

Supervised trials data for thiamethoxam seed treatment uses on peas producing dry peas were available from the USA, Denmark, France and Germany. Residue data on pea vines and fodder were also provided.

In the Czech Republic, thiamethoxam is registered for use as an FS formulation for pea seed treatment at 53 g ai per 100 kg seed (0.53 g ai/kg seed).

In 12 pea trials in Europe (Denmark—two, France—six and Germany—four) with seeds treated with thiamethoxam at 0.5 g ai/kg seed (Czech Republic GAP), residues of thiamethoxam in the harvested haulm at maturity, i.e., the pea fodder, in rank order were: 0.02 < 0.04, < 0.05 (6), 0.06, 0.11, 0.18 and 0.21 mg/kg. In the same 12 trials, residues of CGA 322704 in the pea fodder were: 0.02, < 0.04 (2), < 0.05 (6), < 0.1 (2) and 0.09 mg/kg.

On a dry-weight basis (DM = 88%), thiamethoxam residues in pea fodder were (n = 12): 0.02, < 0.04, < 0.05 (6), 0.07, 0.13, 0.20 and 0.24 mg/kg (NAFTA calculator: 0.291. OECD calculator Mean + 4SD: 0.361). Residues of CGA 322704 in the pea fodder, dry weight, were (n = 12): 0.02, < 0.04 (2), < 0.05 (6), < 0.1 (2) and 0.10 mg/kg (NAFTA calculator: 0.139).

The Meeting estimated a maximum residue level of 0.3 mg/kg for thiamethoxam on pea fodder. On the basis of the CGA 322704 data from the same 12 trials, the Meeting estimated a maximum residue level of 0.2 mg/kg for CGA 322704 on pea fodder.

The same data were used for STMR and highest residue estimates. The Meeting estimated STMR and highest residue values of 0.05 and 0.24 mg/kg respectively for thiamethoxam residues in pea fodder. The Meeting estimated STMR and highest residue values of 0.05 and 0.10 mg/kg respectively for CGA 322704 residues in pea fodder.

In 11 of the same pea trials in Europe, residue data were available on whole plant (pea vines) sampled approximately 50–70 days after sowing. Residues of thiamethoxam in the pea whole plant, in rank order were: < 0.05(4), 0.02, 0.04, 0.05, 0.05, 0.07, 0.07 and 0.10 mg/kg. In the same 11 trials, residues of CGA 322704 in the pea whole plant were: < 0.04 (4) and < 0.05 (7) mg/kg.

The Meeting estimated STMR and highest residue values of 0.04 and 0.10 mg/kg respectively for thiamethoxam residues in pea vines. The Meeting estimated STMR and highest residue values of 0.05 and 0.05 mg/kg respectively for CGA 322704 residues in pea vines.

Straw, fodder and forage of cereal grains

Maize forage and fodder

Supervised trials data for thiamethoxam seed treatment uses on maize were available from France, Germany, Spain and the USA.

In the Czech Republic and Romania, thiamethoxam is formulated as an FS seed treatment that may be used on maize at 315 g ai per 100 kg seed, i.e., 3.15 g ai/kg seed. The supervised trials on maize from Europe were evaluated with the seed treatment GAP of the Czech Republic and Romania.

In 22 maize seed-treatment trials in Europe (France—15, Germany—six and Spain—one) with conditions aligned with the GAP of the Czech Republic and Romania, thiamethoxam residues in maize fodder from all trials did not exceed LOQ (0.02 (7), 0.04 (8) and 0.05 mg/kg (7)). In the same 22 trials, residues of CGA 322704 in maize fodder also did not exceed LOQ (same LOQs).

In 10 of these trials (France—five and Germany—five), residues were measured on the whole plant at an earlier stage, i.e., maize forage. Thiamethoxam residues in maize forage in these 10 trials did not exceed LOQ (0.02 (5), 0.04 (2) and 0.05 mg/kg (3)). In the same 10 trials, residues of CGA 322704 in maize forage also did not exceed LOQ (same LOQs).

In the USA, thiamethoxam is formulated as an FS seed treatment that may be used on maize or sweet corn at 1.25 mg ai per kernel. This is equivalent to approx 4.5 g ai/kg seed for a single kernel weight of 0.28 g.

In 35 maize and sweet corn trials in the USA matching the US seed treatment GAP conditions, thiamethoxam residues in maize stover (maize fodder) were: < 0.01 (31), 0.01, 0.01, 0.02 and 0.03 mg/kg. In the same 35 trials, residues of CGA 322704 in maize fodder did not exceed LOQ (0.01 mg/kg). On a dry-weight basis (DM = 83%), thiamethoxam residues in maize fodder were (n = 35): < 0.01 (31), 0.01, 0.01, 0.02 and 0.04 mg/kg. These data sets were selected for maximum residue level estimations.

In 33 maize and sweet corn trials in the USA matching the US seed treatment GAP conditions, thiamethoxam residues in maize forage were: < 0.01 (17), 0.01, 0.01, 0.01, 0.01, 0.01, 0.02, 0.02, 0.02, 0.02, 0.02, 0.04, 0.04, 0.04, 0.04, 0.04 and 0.05 mg/kg. In the same 33 trials, residues of CGA 322704 in maize forage were: < 0.01 (30), 0.01, 0.01 and 0.02 mg/kg. The Meeting estimated STMR and highest residue values of 0.01 and 0.05 mg/kg for thiamethoxam in maize forage. The Meeting also estimated STMR and highest residue values of 0.01 and 0.02 respectively for CGA 322704 in maize forage.

On the basis of the seed treatment uses on maize and sweet corn in 35 US trials, the Meeting estimated a maximum residue level of 0.05 mg/kg for thiamethoxam on maize fodder. On the basis of the CGA 322704 data on maize fodder from the same 35 trials, the Meeting estimated a maximum residue level of 0.01 mg/kg for CGA 322704 on maize fodder.

The same data were used for STMR and highest residue estimates. The Meeting estimated STMR and highest residue values of 0.01 and 0.04 mg/kg respectively for thiamethoxam residues in maize fodder. The Meeting estimated STMR and highest residue values of 0.01 and 0.01 mg/kg for CGA 322704 residues in maize fodder.

Barley straw and fodder

Supervised trials data were available for barley from France, Germany, the UK and the USA.

US GAP for barley allows the use of thiamethoxam WG for foliar applications at 0.070 kg ai/ha with a 21 days PHI.

In eight barley trials in the USA matching the foliar GAP conditions, thiamethoxam residues in barley straw in rank order were: < 0.01 (2), 0.03, 0.03, 0.19, 0.26, 0.27 and 0.33 mg/kg. In the same eight trials, residues of CGA 322704 in barley straw in rank order were: < 0.01 (3), 0.01, 0.02, 0.03, 0.03 and 0.03 mg/kg.

In the same eight barley trials in the USA matching the foliar GAP conditions, thiamethoxam residues in barley hay in rank order were: < 0.01 (2), 0.02, 0.02, 0.20, 0.21, 0.25 and 0.27 mg/kg. In the same eight trials, residues of CGA 322704 in barley hay in rank order were: < 0.01 (3), 0.01, 0.02, 0.02, 0.02 and 0.03 mg/kg.

In the Czech Republic and Romania, thiamethoxam is formulated as an FS seed treatment that may be used on barley at 53 g ai per 100 kg seed, i.e., 0.53 g ai/kg seed.

In 24 barley seed treatment trials in Europe (France—19, Germany—two and the UK—three) with conditions (application rates 0.53–0.78 g ai/kg seed) approximately aligned with the GAP of the Czech Republic and Romania, thiamethoxam residues in barley straw from the 24 trials did not exceed LOQ (0.02–0.05 mg/kg). In the same 24 trials, residues of CGA 322704 in barley straw also did not exceed LOQ (0.02–0.05 mg/kg) in 23 of the trials with a CGA 322704 residue of 0.04 mg/kg recorded in one barley straw.

In 10 of the same barley seed-treatment trials in Europe (France—nine and Germany—one), residues were measured on barley whole plant. Thiamethoxam residues in barley whole plant were: < 0.02, < 0.04 (5), < 0.05, 0.05, 0.05 and 0.11 mg/kg. In the same 10 trials, residues of CGA 322704 in barley whole plant did not exceed LOQ (0.02–0.05 mg/kg).

The Meeting estimated STMR and highest residue values of 0.04 and 0.11 mg/kg respectively for thiamethoxam residues in barley whole plant. The Meeting estimated STMR and highest residue values of 0.04 and 0.05 mg/kg respectively for CGA 322704 residues in barley whole plant.

Wheat straw and fodder

Supervised trials data, including data on wheat straw and fodder, were available for wheat from France, Germany, Switzerland and the UK.

In the Czech Republic and Romania, thiamethoxam is formulated as an FS seed treatment that may be used on wheat at 53 g ai per 100 kg seed, i.e., 0.53 g ai/kg seed.

In 34 wheat seed-treatment trials in Europe (France—31, Germany—two and the UK—one) with conditions (application rates 0.56–0.64 g ai/kg seed) approximately aligned with the GAP of the Czech Republic and Romania, thiamethoxam residues in wheat straw from 34 trials did not exceed LOQ (0.04–0.05 mg/kg). In the same 34 trials, residues of CGA 322704 in wheat straw also did not exceed LOQ (0.04–0.05 mg/kg), except for one trial: CGA 322704 residue = 0.05 mg/kg.

In 12 of the same wheat seed-treatment trials in Europe (France—11 and Germany—one), residues were measured on wheat whole plant. Thiamethoxam residues in wheat whole plant were: < 0.02 (4), < 0.04 (5), 0.02, 0.02 and 0.05 mg/kg. In the same 10 trials, residues of CGA 322704 in wheat were: < 0.02 (3), < 0.04 (5), < 0.05, 0.02, 0.02 and 0.02 mg/kg.

Hungarian GAP for wheat allows the use of thiamethoxam WG for foliar applications at 0.040 kg ai/ha with a 14 days PHI.

In 21 wheat trials in Europe (France—14, Germany—two, Switzerland—two and the UK—three) with conditions aligned with the GAP of Hungary (but application rate 0.050 kg ai/ha instead of 0.040 kg ai/ha and six trials also included a seed treatment), thiamethoxam residues in wheat straw from 21 trials were: < 0.04, 0.05, 0.14, 0.15, 0.17, 0.22, 0.25, 0.28, 0.32, 0.33, 0.34, 0.35, 0.37, 0.42, 0.44, 0.51, 0.51, 0.65, 0.80, 1.4 and 1.5 mg/kg. In the same 21 trials, residues of CGA 322704 in wheat straw were: < 0.04 (8), < 0.05 (5), 0.03, 0.04, 0.06, 0.07, 0.08, 0.10, 0.10 and 0.12 mg/kg.

On a dry-weight basis (DM = 88%), thiamethoxam residues in wheat straw were (n = 21): < 0.04, 0.06, 0.16, 0.17, 0.19, 0.25, 0.28, 0.32, 0.36, 0.38, 0.39, 0.40, 0.42, 0.48, 0.50, 0.58, 0.58, 0.74, 0.91, 1.6 and 1.7 mg/kg. On a dry-weight basis (DM=88%), CGA 322704 residues in wheat straw were (n = 21): < 0.04 (8), < 0.05 (5), 0.03, 0.05, 0.07, 0.08, 0.09, 0.11, 0.11 and 0.14 mg/kg. These datasets were used for MRL estimation.

In 12 of these same wheat trials in Europe (France—10 and Germany—two) with conditions aligned with the GAP of Hungary (but application rate 0.050 kg ai/ha instead of 0.040 kg ai/ha and six trials also included a seed treatment), thiamethoxam residues were measured on wheat whole plants or equivalent: < 0.04, 0.28, 0.38, 0.41, 0.50, 0.51, 0.55, 0.58, 0.61, 0.63, 0.66 and 0.73 mg/kg. In the same 12 trials, residues of CGA 322704 in wheat whole plants were: < 0.04 (5), < 0.05 (3), 0.04, 0.05, 0.05 and 0.06 mg/kg.

The Meeting estimated STMR and highest residue values of 0.53 and 0.73 mg/kg respectively for thiamethoxam residues in wheat whole plants. The Meeting estimated STMR and highest residue values of 0.05 and 0.06 mg/kg respectively for CGA 322704 residues in wheat whole plant.

Rice straw

Data were available for rice straw from two supervised trials, but this was insufficient for an evaluation.

Summary of 'Barley straw and fodder' and 'Wheat straw and fodder'

Barley straw and fodder, and wheat straw and fodder, as commodities of trade, may not always be readily distinguishable from each other. It is therefore preferable for the two commodities to have the same MRLs.

Thiamethoxam residues in wheat straw from 21 trials were: < 0.04, 0.05, 0.14, 0.15, 0.17, 0.22, 0.25, 0.28, 0.32, 0.33, 0.34, 0.35, 0.37, 0.42, 0.44, 0.51, 0.51, 0.65, 0.80, 1.4 and 1.5 mg/kg. Thiamethoxam residues in barley straw from eight trials were: < 0.01 (2), 0.03, 0.03, 0.19, 0.26, 0.27 and 0.33 mg/kg.

Residues of CGA 322704 in wheat straw were: < 0.04 (8), < 0.05 (5), 0.03, 0.04, 0.06, 0.07, 0.08, 0.10, 0.10 and 0.12 mg/kg. Residues of CGA 322704 in barley straw were: < 0.01 (3), 0.01, 0.02, 0.03, 0.03 and 0.03 mg/kg.

In this case, residues in wheat straw were higher than in the barley straw. The Meeting agreed to use the wheat straw data for both the barley straw and fodder MRL, and the wheat straw and fodder MRL.

On a dry-weight basis (DM = 88%), thiamethoxam residues in wheat straw were (n = 21): < 0.04, 0.06, 0.16, 0.17, 0.19, 0.25, 0.28, 0.32, 0.36, 0.38, 0.39, 0.40, 0.42, 0.48, 0.50, 0.58, 0.58, 0.74, 0.91, 1.6 and 1.7 mg/kg (NAFTA calculator: 2.974. OECD calculator Mean + 4SD: 2.246). On a dry-weight basis (DM = 88%), CGA 322704 residues in wheat straw were (n = 21): < 0.04 (8), < 0.05 (5), 0.03, 0.05, 0.07, 0.08, 0.09, 0.11, 0.11 and 0.14 mg/kg (NAFTA calculator: 0.149. OECD calculator Mean + 4SD: 0.178).

On the basis of the foliar applications on wheat in 21 European trials, the Meeting estimated a maximum residue level of 2 mg/kg for thiamethoxam on wheat straw and fodder, dry. On the basis of the CGA 322704 data on wheat straw from the same 21 trials, the Meeting estimated a maximum residue level of 0.2 mg/kg for CGA 322704 on wheat straw and fodder, dry.

The same data were used for STMR and highest residue estimates. The Meeting estimated STMR and highest residue values of 0.39 and 1.7 mg/kg respectively for thiamethoxam residues in wheat straw and fodder, dry. The Meeting estimated STMR and highest residue values of 0.05 and 0.14 mg/kg respectively for CGA 322704 residues in wheat straw and fodder, dry.

On the basis of these same wheat data, the Meeting estimated a maximum residue level of 2 mg/kg for thiamethoxam on barley straw and fodder, dry, and a maximum residue level of 0.2 mg/kg for CGA 322704 on barley straw and fodder, dry. The Meeting also estimated STMR and highest residue values of 0.39 and 1.7 mg/kg respectively for thiamethoxam residues in barley straw and fodder, dry, and STMR and highest residue values of 0.05 and 0.14 mg/kg respectively for CGA 322704 residues in barley straw and fodder, dry.

Miscellaneous fodder and forage crops

Sugar beet leaves and tops

Supervised trials data for thiamethoxam uses on sugar beets, including data on leaves and tops, were available from France, Germany, Netherlands, Spain, Switzerland and the UK. No suitable GAP information was available to evaluate the trials from Italy, Spain and Switzerland.

In the UK, thiamethoxam is registered for use as an FS formulation on sugar beet seeds at 60 g ai per 100,000 seeds.

In 10 sugar beet trials in Europe (France—three, Germany—three, Netherlands—one, Spain—one, Sweden—one and the UK—one) matching UK seed treatment GAP conditions (application rate 60 ± 15 g ai per 100,000 seeds), thiamethoxam residues in sugar beet tops or leaves did not exceed LOQ (0.02 mg/kg). CGA 322704 residues in sugar beet tops or leaves also did not exceed LOQ (0.02 mg/kg).

The data were used for STMR and highest residue estimates. The Meeting estimated STMR and highest residue values of 0.02 and 0.02 mg/kg for thiamethoxam residues in sugar beet tops or leaves. The Meeting estimated STMR and highest residue values of 0.02 and 0.02 mg/kg also for CGA 322704 residues in sugar beet tops or leaves.

Rape seed forage and fodder

Supervised trials data were available for seed treatment uses on oilseed rape from France, Germany, Sweden and the UK.

In Germany and the UK, thiamethoxam FS formulations are registered for use as seed treatments on rapeseed at 420 g ai per 100 kg seed.

In four trials in France, seven in Germany, one in Sweden and two in the UK where rapeseed was treated with thiamethoxam at the GAP rate, then sown and the forage sampled 1–7 months later, residues of thiamethoxam in rapeseed plant were all below LOQ (0.05 mg/kg). Residues of metabolite CGA 322704 in rapeseed plant were also all below LOQ (0.05 mg/kg) in the same trials.

In seven trials in Germany and one in Sweden where rapeseed was treated with thiamethoxam at the GAP rate, then sown and the crop grown to maturity, residues of thiamethoxam in rapeseed straw were all below LOQ (0.05 mg/kg). Residues of metabolite CGA 322704 in rapeseed straw were also all below LOQ (0.05 mg/kg) in the same trials.

The data were used for STMR and highest residue estimates. The Meeting estimated STMR and highest residue values of 0.05 and 0.05 mg/kg for thiamethoxam residues in rapeseed forage. The Meeting estimated STMR and highest residue values of 0.05 and 0.05 mg/kg also for CGA 322704 residues in rapeseed forage.

Cotton gin by-products

Supervised trials data were available for seed treatment and foliar uses on cotton from the USA.

In the USA, a thiamethoxam FS formulation is registered for seed-treatment of cotton seed at 0.30–0.34 mg ai per seed. For 100 mg cotton seed this would translate to 3.0–3.4 g ai/kg seed. Thiamethoxam is also registered for foliar use on cotton at 0.070 kg ai/ha, with a 21 day PHI.

In the cotton trials from the US, the seed treatment rate was in accord with US GAP, but foliar application rates in the trials (0.032, 0.045, 0.05, 0.15 and 0.25 kg ai/ha) were not in accord with the GAP rate, 0.070 kg ai/ha, so it was not possible to evaluate the cotton trials residue data on gin trash.

Dried herbs

Hops

Supervised trials data for thiamethoxam use on hops were available from the USA.

Thiamethoxam may be used in the USA as a soil surface band application with incorporation during the production of hops. The application rate is 0.14 kg ai/ha and the PHI is 65 days.

In three hops trials in the USA matching the GAP conditions, thiamethoxam residues in hops dry cones in rank order were: < 0.025, 0.027 and 0.055 mg/kg. In the same three trials, residues of CGA 322704 in hops dry cones in rank order were: < 0.025, 0.025 and 0.028 mg/kg.

The Meeting agreed that three trials are insufficient for maximum residue level estimation on hops.

Teas

Supervised trials data for thiamethoxam use on tea were available from Japan.

In Japan, thiamethoxam SG (soluble granule) formulation is registered for foliar application during the production of tea. The spray concentration is 0.005 kg ai/hL and the PHI is 7 days.

Immediately after harvest in the tea trials in Japan, the leaves were processed with an in-house tea processing machine and then enclosed in aluminium bags for delivery to the laboratory. The processing consisted of drying, breaking the leaves to expose enzymes and tissues to oxidation and allowing a period of oxidation by exposure in the air.

In six tea trials in Japan matching the GAP conditions, thiamethoxam residues in crude processed tea leaves in rank order were: 2.1, 2.3, 2.7, 5.5, 7.1 and 8.6 mg/kg (NAFTA calculator: 16.92. OECD calculator Mean + 4SD: 15.76). In the same six trials, residues of CGA 322704 in crude processed tea leaves in rank order were: 0.06, 0.08, 0.08, 0.16, 0.25 and 0.28 mg/kg (NAFTA calculator: 0.581. OECD calculator Mean + 4SD: 0.531).

The Meeting estimated a maximum residue level of 20 mg/kg for thiamethoxam on tea, green and black. On the basis of the CGA 322704 data on tea from the same six trials, the Meeting estimated a maximum residue level of 0.7 mg/kg for CGA 322704 on tea, green and black.

The same data were used for STMR estimates. The Meeting estimated an STMR value of 4.1 mg/kg for thiamethoxam residues in tea. The Meeting estimated an STMR value of 0.12 mg/kg for CGA 322704 residues in tea.

Fate of residues during processing

The Meeting received information on the fate of thiamethoxam residues during the processing of apples to juice and pomace; barley to pearled barley, barley bran, barley flour, beer, wort and malt; coffee beans to roasted coffee; cotton seed to meal and refined oil; grapes to juice, pomace and wine; maize to grits, flour, oil and starch; oranges to pulp, juice and oil; plums to dried prunes; potato to wet peelings, flakes and chips; tomatoes to juice, pulp, puree and paste; and wheat to semolina, bran, flour and bread.

Also information was provided on hydrolysis studies of thiamethoxam to assist with identification of the nature of the residue during processing.

Thiamethoxam was essentially stable during the hydrolysis conditions simulating food processing conditions.

Processing factors have been calculated for thiamethoxam residues during the following processes: apples processing to juice and wet pomace; barley processing to pearled barley, bran, flour, and beer; coffee beans to roasted coffee; cotton seed to meal and oil; grapes to pomace and wine; oranges to pulp and juice; plums to dried prunes; tomatoes to juice, paste and puree; and wheat to semolina, wheat bran, wheat bread and wheat flour. Processing factors were also calculated for CGA 322704 residues in the following processes: apples to apple juice and wet pomace; coffee beans to roasted coffee; plums to dried prunes; and tomatoes to paste and puree.

Calculated processing factors are summarised in the following table. Factors are indicated with a '<' (less-than) sign when the residue in the processed commodity is below the LOQ of the analytical method. The calculation is then made on the LOQ of the analytical method and the residue concentration of the RAC (raw agricultural commodity). The medians of the observed values or the best estimates of the processing factors are summarized in the final column of the table.

Only those processes are included in the table that lead to STMR-P or HR-P values useful for dietary intake estimations or for livestock dietary burden calculations.

Raw agricultural commodity (RAC)	Processed commodity	Calculated processing factors.	Median or best estimate
THIAMETHOXAM			
Apple	apple juice	0.20, 0.27, 0.38, 0.92, 0.94, 1.00, < 1.00, 1.04	0.93
Apple	wet pomace	1.08, 1.38, 1.41, 1.50, 1.60, 1.67, 1.91, 2.00	1.55
Barley	barley flour	0.08	0.08
Barley	pearled barley	0.25	0.25
Coffee beans	roasted coffee	< 0.14, < 0.14, < 0.17, < 0.20, < 0.20, < 0.20, < 0.25, < 0.25, < 0.25, < 0.33, < 0.33, < 0.50	< 0.14
Cotton seed	cotton seed meal	0.15, 0.20, 0.27, < 0.3, 0.49	0.27
Cotton seed	cotton seed oil refined	< 0.02, < 0.08, < 0.09, < 0.20, < 0.33	< 0.02
Grapes	dry pomace	3.4, 4.4	3.9
Grapes	wet pomace	1.3, 1.5, 4.3	1.5
Grapes	wine	0.70, 0.73, 0.79, 1.00 , 1.05, 1.33, 1.60, 1.60,	1.0
Orange	dried pulp	2.0, 3.25	2.6
Orange	orange juice	< 0.25, < 0.5	< 0.25
Plum	dried prunes	0.60, 0.83, < 1.0	0.83
Tomato	tomato juice	0.67, 1.0	0.67
Tomato	tomato paste	1.25, 2.00, 2.24, 2.40, 2.94, 2.94, 3.10, 3.86, 3.91, 4.21, 4.33, 6.00	3.0
Tomato	tomato pulp	1.0, 1.0	1.0
Tomato	tomato puree	0.40, 0.50, 0.64, 0.91, 1.06, 1.12, 1.13, 1.50, 1.87, 2.00, 2.21, 2.50	1.1
Wheat	semolina	< 0.7	< 0.7
Wheat	wheat bran	1	1
Wheat	wheat bread	< 0.7	< 0.7
Wheat	wheat flour	< 0.7	< 0.7
CGA 322704			
Apple	apple juice	1.0, 1.0, 1.0	1.0
Apple	wet pomace	1.4, 1,5, 1.5	1.5
Coffee beans	roasted coffee	< 0.33, < 0.33, < 0.33, < 0.33, < 0.33, < 0.50, < 0.50, < 0.50, < 0.50, < 0.50	< 0.3
Plum	dried prunes	1.5, 2.0	1.75
Tomato	tomato paste	2.00, 2.38, 3.33, 3.75, 5.50, 5.78, 6.0, 6.0, 6.5, 6.5, 9.7, 11.3	5.9
Tomato	tomato puree	0.50, 0.67, 1.0, 1.19, 1.33, 1.75, 2.50, 2.75, 3.0, 3.44, 3.54, 6.0,	2.1

Thiamethoxam residues in tea were investigated for percentage infusion and, by inference, percentage consumption.

Tea infusions were prepared by adding boiling water to dried and processed tea leaves from a thiamethoxam supervised residue trial and allowed to stand for 5 minutes. The infusion was filtered and analysed and the % infusion (% of residue extracted into the boiling water) was calculated. For thiamethoxam, the average % infusion was 97%, range 68–130%, n = 12. For CGA 322704, average % infusion was 94%, range 80–100%, n = 10.

The processing factors for thiamethoxam residues for oranges → orange juice (0.25) and oranges → orange dry pulp (2.6) were applied to the citrus fruits STMR, 0.028 mg/kg, to produce an orange juice STMR-P of 0.007 mg/kg and an orange dry pulp STMR-P of 0.073 mg/kg.

The processing factors for thiamethoxam residues for apples → apple juice (0.93) and apples → apple pomace (1.55) were applied to the pome fruit STMR, 0.07 mg/kg, to produce an apple juice STMR-P of 0.065 mg/kg and an apple wet pomace STMR-P of 0.11 mg/kg.

The processing factor for thiamethoxam residues for plums → dried prunes (0.83) was applied to the stone fruits STMR and HR, 0.195 and 0.6 mg/kg, to produce a dried prunes STMR-P of 0.16 mg/kg and an HR-P of 0.50 mg/kg.

The processing factors for thiamethoxam residues for grapes → wine (1) and grapes → dry grape pomace (3.9) were applied to the berry fruits STMR, 0.055 mg/kg, to produce a wine STMR-P of 0.055 mg/kg and a dry grape pomace STMR-P of 0.21 mg/kg.

The processing factors for thiamethoxam residues for tomato → tomato juice (0.67), tomato → tomato paste (3), tomato → tomato pulp (1) and tomato → tomato puree (1.1) were applied to the fruiting vegetables STMR, 0.08 mg/kg, to produce a tomato juice STMR-P of 0.054 mg/kg, a tomato paste STMR-P of 0.24 mg/kg, a tomato pulp STMR-P of 0.08 mg/kg and a tomato puree STMR-P of 0.088 mg/kg.

The processing factors for thiamethoxam residues for barley → barley flour (0.08) and barley → pearled barley (0.25) were applied to the barley STMR, 0.12 mg/kg, to produce a barley flour STMR-P of 0.010 mg/kg and a pearled barley STMR-P of 0.030 mg/kg.

The processing factors for thiamethoxam residues for wheat → semolina (0.7), wheat → wheat bran (1), wheat → wheat bread (0.7) and wheat → wheat flour (0.7) were applied to the wheat STMR, 0.02 mg/kg, to produce a semolina STMR-P of 0.014 mg/kg, a wheat bran STMR-P of 0.020 mg/kg, a wheat bread STMR-P of 0.014 mg/kg and a wheat flour STMR-P of 0.014 mg/kg.

The processing factors for thiamethoxam residues for cotton seed → cotton seed meal (0.27) and cotton seed → refined cotton seed oil (0.02) were applied to the oilseed STMR, 0.02 mg/kg, to produce a cotton seed meal STMR-P of 0.0054 mg/kg and a refined cotton seed oil STMR-P of 0.0004 mg/kg.

The processing factor for thiamethoxam residues for coffee beans → roasted coffee (0.14) was applied to the coffee beans STMR, 0.035 mg/kg, to produce a roasted coffee STMR-P of 0.0049 mg/kg.

The fate of CGA 322704 residues during food processing is dealt with in the clothianidin evaluation.

Residues in animal commodities

The Meeting received a lactating dairy cow feeding study, which provided information on likely residues resulting in animal tissues and milk from thiamethoxam residues in the animal diet.

Lactating Holstein dairy cows were dosed for 29 days once daily via gelatin capsule with thiamethoxam at the equivalent of 2, 6 and 20 ppm in the dry-weight diet.

Parent thiamethoxam did not occur above LOQ (0.01 mg/kg) in liver or fat tissues at the highest test dose. Parent thiamethoxam residues were higher in muscle than in other tissues, but residues did not exceed the LOQ at the 2 ppm dosing level.

Metabolite CGA 322704 did not occur above LOQ (0.01 mg/kg) in any of the tissues except liver.

At 2 ppm dosing, the only residues above LOQ in tissues were: CGA 322704 in liver at 0.028–0.049 mg/kg.

At 6 ppm dosing, residues above LOQ in tissues were: thiamethoxam in muscle at 0.01 mg/kg; CGA 322704 in liver at 0.09–0.14 mg/kg.

Residue levels of parent thiamethoxam and metabolite CGA 322704 reached plateau levels in milk approximately 3–5 days after the commencement of dosing. At 2 and 6 ppm dosing, the approximate plateau levels for thiamethoxam in milk were 0.007–0.008 mg/kg and 0.03–0.05 mg/kg,

respectively. For CGA 322704, the plateau levels in milk at 6 ppm dosing were approximately 0.01–0.02 mg/kg.

Livestock dietary burden

The Meeting estimated the dietary burden of thiamethoxam in livestock on the basis of the diets listed in OECD Feed Table 2009 (available from the FAO website: *http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-docs/en/)*.

Calculation from highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating MRLs, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

Some processed and forage commodities do not appear in the *Recommendations Table* (because no maximum residue level is needed) but they are used in estimating livestock dietary burdens. Those commodities are listed here. Also, the terminology for commodities in the OECD feed tables is not always identical to descriptions in the original studies or Codex descriptions and some clarification is needed.

Commodity	Thiamethoxam STMR or STMR-P, mg/kg	High residue, mg/kg
Apple wet pomace	0.11	
Barley whole plant = Barley forage	0.04	0.11
Beans (dry) = Bean seed	See Recommendations Table, pulses	
Cabbages (including wrapper leaves)	0.78	3.0
Cotton seed meal = Cotton meal	0.0054	
Dry grape pomace	0.21	
Maize = Field corn grain	See Recommendations Table	
Maize fodder = Field corn, stover	See Recommendations Table	
Maize forage = Field corn, forage/silage	0.01	0.05
Orange dry pulp = Citrus dried pulp	0.073	
Pea hay or Pea fodder (dry) = Pea hay	See Recommendations Table	
Pea vines	0.04	0.10
Peas (dry) = Pea seed	See Recommendations Table, pulses	
Rapeseed forage	0.05	0.05
Soya bean (dry) = Soya bean seed	See Recommendations Table, pulses	
Sugar beet tops or leaves = Beet, sugar tops	0.02	0.02
Wheat whole plant = Wheat forage	0.53	0.73

The data on CGA 322704 residues in feed materials will be needed for dietary burden calculations for clothianidin.

Commodity	CGA 322704 STMR or STMR-P, mg/kg	High residue, mg/kg
Barley whole plant	0.04	0.05
Beans (dry) = Bean seed	See Recommendations Table	
Cabbages (including wrapper leaves)	0.03	0.08
Maize = Field corn grain	See Recommendations Table	
Maize fodder = Field corn, stover	See Recommendations Table	
Maize forage = Field corn, forage/silage	0.01	0.02
Pea hay or Pea fodder (dry) = Pea hay	See Recommendations Table	
Pea vines	0.05	0.05
Peas (dry) = Pea seed	See Recommendations Table	
Rapeseed forage	0.05	0.05
Soya bean (dry) = Soya bean seed	See Recommendations Table	
Sugar beet tops or leaves = Beet, sugar tops	0.02	0.02

Commodity	CGA 322704 STMR or STMR-P, mg/kg	High residue, mg/kg
Wheat whole plant = Wheat forage	0.05	0.06

Estimated maximum and mean dietary burdens of livestock

Dietary burden calculations for beef cattle, dairy cattle, broilers and laying poultry are provided in Annex 6. The calculations were made according to the livestock diets from US/CAN, EU, Australia and Japan in the OECD Feed Table 2009.

		Livestock dietary burden, thiamethoxam, ppm of dry matter diet			
		US/CAN	EU	Australia	Japan
Max	beef cattle	0.55	5.21	2.92	0.10
	dairy cattle	0.89	5.23[a,c]	2.01	0.12
	Poultry—broiler	0.11	0.27	0.04	0.03
	Poultry—layer	0.11	1.59[e]	0.04	0.02
Mean	beef cattle	0.13	1.60	2.12[b]	0.10
	dairy cattle	0.56	1.59[d]	1.35	0.07
	Poultry—broiler	0.11	0.11	0.04	0.03
	Poultry—layer	0.11	0.59[f]	0.04	0.02

[a] Highest maximum beef or dairy cattle dietary burden suitable for MRL estimates for mammalian meat.

[b] Highest mean beef or dairy cattle dietary burden suitable for STMR estimates for mammalian meat.

[c] Highest maximum dairy cattle dietary burden suitable for MRL estimates for milk.

[d] Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

[e] Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

[f] Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Animal commodities maximum residue level estimation

Cattle

For MRL estimation, the high residues in the tissues were calculated by interpolating the maximum dietary burden (5.23 ppm) between the relevant feeding levels (2 and 6 ppm) from the dairy cow feeding study and using the highest tissue concentrations from individual animals within those feeding groups.

The STMR values for the tissues were calculated by interpolating the STMR dietary burden (2.12 ppm) between the relevant feeding levels (2 and 6 ppm) from the dairy cow feeding study and using the mean tissue concentrations from those feeding groups.

For milk MRL estimation, the high residues in the milk were calculated by interpolating the maximum dietary burden (5.23 ppm) between the relevant feeding levels (2 and 6 ppm) from the dairy cow feeding study and using the mean milk concentrations from those feeding groups.

The STMR value for milk was calculated by interpolating the STMR dietary burden (1.59 ppm) between the relevant feeding levels (0 and 2 ppm) from the dairy cow feeding study and using the mean milk concentrations from those feeding groups.

In the table, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding study are shown in square brackets [] and estimated concentrations related to the dietary burdens are shown without brackets.

Dietary burden (ppm)	Thiamethoxam residues				
Feeding level [ppm]	Milk	Muscle	Liver	Kidney	Fat
MRL					
	mean	highest	highest	highest	highest
MRL beef cattle (5.23) [2, 6]		0.01 [< 0.01, 0.01]	< 0.01 [< 0.01, < 0.01]	< 0.01 [< 0.01, < 0.01]	< 0.01 [< 0.01, < 0.01]
MRL dairy cattle (5.23) [2, 6]	0.028 [0.007, 0.033]				
STMR					
	mean	mean	mean	mean	mean
STMR beef cattle (2.12) [2, 6]		0.01 [< 0.01, 0.01]	< 0.01 [< 0.01, < 0.01]	< 0.01 [< 0.01, < 0.01]	< 0.01 [< 0.01, < 0.01]
STMR dairy cattle (1.59) [0, 2]	0.006 [0, 0.007]				

The data from the cattle feeding studies were used to support the estimation of maximum residue levels for mammalian meat and milk.

Residues in milk were estimated as 0.028 and 0.006 mg/kg resulting from the maximum (5.23 ppm) and STMR (1.59 ppm) dietary burdens respectively.

The Meeting estimated a maximum residue level for thiamethoxam in milks of 0.05 mg/kg. The Meeting also estimated an STMR for milk of 0.006 mg/kg.

The Meeting estimated a maximum residue level for thiamethoxam in edible offal of 0.01* mg/kg. The estimation is based on the liver and kidney data. The Meeting estimated an STMR value and an HR value of 0.01 and 0.01 mg/kg for edible offal.

For muscle, the residue arising from a dietary burden of 5.23 ppm was calculated as 0.01 mg/kg. The Meeting estimated a maximum residue level for meat as 0.02 mg/kg. STMR and HR values for muscle and fat were all estimated as 0.01 mg/kg.

Cattle—CGA 322704 residues

The residues of CGA 322704 were evaluated in the same way as described above for thiamethoxam.

In the table, dietary burdens are shown in round brackets (), feeding levels and residue concentrations from the feeding study are shown in square brackets [] and estimated concentrations related to the dietary burdens are shown without brackets.

Dietary burden, thiamethoxam (ppm) Feeding level [ppm]	CGA 322704 residues Milk	Muscle	Liver	Kidney	Fat
MRL					
	mean	highest	highest	highest	highest
MRL beef cattle (5.23) [2, 6]		< 0.01 [< 0.01, < 0.01]	0.12[a] [0.049, 0.14]	< 0.01 [< 0.01, < 0.01]	< 0.01 [< 0.01, < 0.01 (20 ppm)]
MRL dairy cattle (5.23)	0.011				

Dietary burden, thiamethoxam (ppm)	CGA 322704 residues				
Feeding level [ppm]	Milk	Muscle	Liver	Kidney	Fat
[2, 6]	0.005, 0.013]				
STMR					
	mean	mean	mean	mean	mean
STMR beef cattle (2.12) [2, 6]		< 0.01 [< 0.01, < 0.01]	0.041[b] [0.039, 0.12]	< 0.01 [< 0.01, < 0.01]	< 0.01 [< 0.01, < 0.01 (20 ppm)]
STMR dairy cattle (1.59) [0, 2]	0.004 [0, 0.005]				

[a] Residue 0.12 mg/kg expressed as thiamethoxam is equivalent to 0.10 mg/kg expressed as CGA 322704.

[b] Residue 0.041 mg/kg expressed as thiamethoxam is equivalent to 0.0.035 mg/kg expressed as CGA 322704.

The CGA 322704 data from the thiamethoxam cattle feeding studies were used to support the estimation of maximum residue levels for mammalian meat and milk.

CGA 322704 residues in milk were estimated as 0.011 and 0.004 mg/kg resulting from the maximum (5.23 ppm) and STMR (1.59 ppm) dietary burdens respectively.

The Meeting estimated a maximum residue level for CGA 322704 in milks of 0.02 mg/kg. The Meeting also estimated a CGA 322704 STMR for milk of 0.004 mg/kg.

For liver, the CGA 322704 residues arising from dietary burdens of 5.23 ppm and 1.59 ppm were 0.10 and 0.035 mg/kg, respectively. The Meeting estimated a maximum residue level for CGA 322704 in liver of 0.2 mg/kg. The Meeting estimated an STMR value and an HR value of 0.035 and 0.10 mg/kg, respectively, for CGA 322704 residues in liver.

For kidney, the CGA 322704 residue arising from a dietary burden of 5.23 ppm was calculated as < 0.01 mg/kg. The Meeting agreed to use the kidney data to estimate a maximum residue level for edible offal except liver. The Meeting estimated a maximum residue level for edible offal except liver as 0.01* mg/kg. CGA 322704 STMR and HR values for edible offal except liver were estimated as 0.01 mg/kg.

For muscle, the CGA 322704 residue arising from a dietary burden of 5.23 ppm was calculated as < 0.01 mg/kg. The Meeting estimated a maximum residue level for meat as 0.01* mg/kg. STMR and HR values for muscle and fat were all estimated as 0.01 mg/kg.

Poultry

The thiamethoxam maximum dietary burden for poultry is 1.59 ppm and the mean dietary burden is 0.59 ppm.

No poultry feeding study is available for thiamethoxam, but the metabolism studies suggest that parent thiamethoxam would be unlikely to be present at measurable concentrations in poultry tissues or eggs from a dietary burden of 1.59 ppm.

When laying hens in the metabolism studies were dosed with thiamethoxam at the equivalent of 112 and 98 ppm (^{14}C-thiazolyl and ^{14}C-oxadiazin, respectively) in the feed, parent thiamethoxam was found in lean meat and eggs at concentrations of 0.14–0.19 mg/kg and 0.03 mg/kg respectively. It may be reasonably anticipated that the levels of thiamethoxam in tissues and eggs resulting from a dietary burden of 1.59 mg/kg would be well below the LOQ of the analytical method (0.01 mg/kg).

Thiamethoxam was a very minor part of the residue in poultry liver, whereas CGA 322704 constituted 34% and 39% of the liver TRR (8.2 and 9.2 mg/kg) in the poultry metabolism study with ^{14}C labels in the thiazol and oxadiazine positions, respectively. Metabolite CGA 265307 was the major residue component in the eggs, both whites (45% and 47%) and yolks (69% and 54%), and

also in fat + skin (54% and 57%). The complexity of the metabolite mixture makes it difficult to select an ideal residue definition for risk assessment.

In the two poultry metabolism studies, the lower dosing (equivalent to 98 ppm in diet) produced slightly higher TRR values for tissues and eggs, so was selected for the purpose of exposure assessment.

	Concentrations, mg/kg, expressed as thiamethoxam				
	Lean meat	Fat + skin	Liver	Egg white	Egg yolk
TRR, mg/kg at dose equiv to 98 ppm in metabolism study	0.93	0.42	9.2	0.30	0.30
For max residue level estimation					
Calculated TRR, mg/kg for dietary burden 1.59 ppm = TRR × (1.59/98)	0.015	0.0068	0.149	0.0049	0.0049
Calculated thiamethoxam, mg/kg, for dietary burden 1.59 ppm = TRR × (1.59/98) × (%TRR/100)	0.0032 (21% TRR)	0.0003 (5% TRR)	0.0003 (0.2% TRR)	0.0001 (1.9% TRR)	0.0005 (11.1% TRR)
Calculated CGA 322704, mg/kg for dietary burden 1.59 ppm = TRR × (1.59/98) × (%TRR/100)	0.0002 (1.5% TRR)	0.0005 (7.7% TRR)	0.058 Note[a] (39% TRR)	0.001 (20% TRR)	0.001 (20% TRR)
For STMR estimation					
Calculated TRR, mg/kg for dietary burden 0.59 ppm = TRR × (0.59/98)	0.0056	0.0025	0.055	0.0018	0.0018
Calculated thiamethoxam, mg/kg, for dietary burden 0.59 ppm = TRR × (0.59/98) × (%TRR/100)	0.0012 (21% TRR)	0.0001 (5% TRR)	0.0001 (0.2% TRR)	0.00003 (1.9% TRR)	0.0002 (11.1% TRR)
Calculated CGA 265307, mg/kg for dietary burden 0.59 ppm = TRR × (0.59/98) × (%TRR/100)	0.0005 (8.4% TRR)	0.0014 (57% TRR)	0.0088 (16% TRR)	0.0008 (47% TRR)	0.00097 (54% TRR)
Calculated MU3, mg/kg for dietary burden 0.59 ppm = TRR × (0.59/98) × (%TRR/100)	0.0016 (28% TRR)	0.0001 (3.6% TRR)	0.0066 (12% TRR)		
Total of thiamethoxam + CGA 265307 + MU3 (expressed as thiamethoxam) for dietary burden 0.59 ppm	0.0032 (57.4% TRR)	0.0016 (65.6%)	0.016 (28.2%)	0.001 (48.9%)	0.0012 (65.1%)
Calculated CGA 322704, mg/kg for dietary burden 0.59 ppm = TRR × (0.59/98) × (%TRR/100)	0.0001 (1.5% TRR)	0.0002 (7.7% TRR)	0.021 Note[b] (39% TRR)	0.0004 (20% TRR)	0.0004 (20% TRR)

[a] Residue 0.058 mg/kg expressed as thiamethoxam is equivalent to 0.050 mg/kg expressed as CGA 322704.

[b] Residue 0.021 mg/kg expressed as thiamethoxam is equivalent to 0.018 mg/kg expressed as CGA 322704.

On the basis of the calculated thiamethoxam residues in tissues and eggs (0.0001–0.0032 mg/kg) for a dietary burden of 1.59 ppm, the Meeting estimated maximum residue levels of 0.01* mg/kg for thiamethoxam in poultry meat, offal and eggs.

On the basis of the calculated thiamethoxam + CGA 265307 + MU3 residues (expressed as thiamethoxam) residues in lean meat (0.0032 mg/kg), liver (0.016 mg/kg) and eggs (0.001 mg/kg) for a dietary burden of 0.59 ppm, the Meeting estimated STMR values of 0.01 mg/kg for thiamethoxam in poultry meat and eggs and 0.016 mg/kg for poultry edible offal.

Similar calculations were made for a dietary burden of 1.59 ppm. On the basis of the calculated thiamethoxam + CGA 265307 + MU3 residues (expressed as thiamethoxam) residues in lean meat (0.0088 mg/kg), liver (0.042 mg/kg) and eggs (0.003 mg/kg) for a dietary burden of

1.59 ppm, the Meeting estimated HR values of 0.01 mg/kg for thiamethoxam in poultry meat and eggs and 0.042 mg/kg for poultry edible offal.

On the basis of the calculated CGA 322704 residues in lean meat (0.0002 mg/kg), liver (0.050 mg/kg) and eggs (0.0001 mg/kg) for a thiamethoxam dietary burden of 1.59 ppm, the Meeting estimated maximum residue levels of 0.01* mg/kg for CGA 322704 in poultry meat, 0.1 mg/kg for poultry offal and 0.01* mg/kg for eggs.

On the basis of the calculated CGA 322704 residues in lean meat (0.0001 mg/kg), liver (0.018 mg/kg) and eggs (0.0004 mg/kg) for a thiamethoxam dietary burden of 0.59 ppm, the Meeting estimated STMR values of 0.01 mg/kg for CGA 322704 in poultry meat and eggs and 0.018 mg/kg for poultry edible offal.

On the basis of the calculated CGA 322704 residues in lean meat (0.0002 mg/kg), liver (0.050 mg/kg) and eggs (0.0001 mg/kg) for a thiamethoxam dietary burden of 1.59 ppm, the Meeting estimated HR values of 0.01 mg/kg for CGA 322704 in poultry meat and eggs and 0.050 mg/kg for poultry edible offal.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes of thiamethoxam, based on the STMRs estimated for 66 commodities, for the GEMS/Food regional diets were in the range of 1 to 4% of the maximum ADI (0.08 mg/kg bw) (Annex 3). The Meeting concluded that the long-term intake of residues of thiamethoxam resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short Term Intake (IESTI) for thiamethoxam was calculated for food commodities and their processed fractions for which maximum residue levels were estimated and for which consumption data were available. The results are shown in Annex 4.

The IESTI for the general population represented 0–4% of the ARfD (1 mg/kg bw) and the IESTI for children represented 0–10% of the ARfD. The Meeting concluded that the short-term intake of residues of thiamethoxam, when used in ways that have been considered by the JMPR, is unlikely to present a public health concern.