5. EVALUATION OF DATA FOR ACCEPTABLE DAILY INTAKE AND ACUTE DIETARY INTAKE FOR HUMANS, MAXIMUM RESIDUE LEVELS AND SUPERVISED TRIAL MEDIAN RESIDUE VALUES

5.1 AZOXYSTROBIN (229)

TOXICOLOGY

Azoxystrobin is the International Organization for Standardization (ISO) approved name for methyl (*E*)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate, International Union of Pure and Applied Chemistry (IUPAC), for which the Chemical Abstracts Service (CAS) No. is 131860-33-8. Azoxystrobin is a β -methacrylate compound that is structurally related to the naturally occurring strobilurins, which are compounds derived from some fungal species. Azoxystrobin is a broad-spectrum, systemic fungicide that acts by inhibiting electron transport in pathogenic fungi. It has the ability to provide protection against the fungal diseases caused by *Ascomycota*, *Deuteromycota*, *Basidiomycota* and *Oomycota* groups.

Azoxystrobin has not been evaluated previously by JMPR and was evaluated by the present Meeting at the request of the 40th Session of the Codex Committee on Pesticide Residues (CCPR). All pivotal studies with azoxystrobin were certified as complying with good laboratory practice (GLP).

Biochemical aspects

In a autoradiography study in rats, groups of one male and one female were given azoxystrobin labelled with ¹⁴C in either the cyanophenyl, pyrimidinyl or phenylacrylate ring as a single dose at 1 mg/kg bw by gavage. The results of this study indicated that the position of the radiolabel had no significant effect on the rates and routes of excretion or tissue distribution of azoxystrobin, therefore, further metabolism studies were conducted using azoxystrobin labelled in the pyrimidinyl position. In studies in rats given a single oral dose of radiolabelled azoxystrobin, 73-89% of the administered dose was recovered in the faeces and 9-18% in the urine (1 and 100 mg/kg bw) after 7 days. The extent of oral absorption at 1 mg/kg bw was nearly complete since no parent compound was found in the excreta. At least 74-81% of the administered dose was absorbed at 100 mg/kg bw, based on recoveries of radioactivity in the bile and urine. Between 82% and 96% of the administered dose was excreted within the first 48 h. Regardless of the dose administered, residues remaining in the carcass (including organs and tissues) were between 0.31% and 0.62% of the administered dose after 7 days. The highest concentrations were found in the liver $(0.009-0.72 \,\mu\text{g} \text{ equivalents/g})$ and in the kidneys $(0.023-1.12 \,\mu g \text{ equivalents/g})$ at 7 days. No significant quantities of radiolabel were detected in exhaled air. In a study of biliary excretion, about 57-74% of the administered dose was recovered in the bile within 48 h after administration of a single dose at 100 mg/kg bw by gavage. No parent compound was detected in the bile.

Systemically absorbed azoxystrobin was extensively metabolized. The mass balance for the metabolism study indicated that a substantial percentage (45.6-73.6%) of the radiolabel was unextracted, although the excretion studies showed a total recovery of 91.8–104%, with 72.6–89.3% being in the faeces. Fifteen metabolites were identified in the excreta and seven additional metabolites were detected but not identified (< 4.9% of the administered dose). The major metabolites of azoxystrobin in the bile, urine and faeces resulted from hydrolysis followed by glucuronide conjugation. Azoxystrobin was also hydroxylated at the 8 and 10 positions on the cyanophenyl ring, followed by glucuronide conjugation. A minor pathway involving the cleavage of the ether linkage was identified. Approximately 15–32% of the unchanged azoxystrobin was detected in the faeces of bile-duct cannulated rats and rats at the highest dose. Absorption, distribution, excretion and metabolite profiles were essentially similar in males and females, but sex-specific

differences in biotransformation were observed, with the number of metabolites produced being greater in females than in males.

Toxicological data

Azoxystrobin has low acute toxicity when administered by the oral, dermal or inhalation routes. The median lethal dose (LD_{50}) in rats treated orally was > 5000 mg/kg bw. The LD_{50} in rats treated dermally was > 2000 mg/kg bw. The median lethal concentration (LC_{50}) in rats treated by inhalation (nose only) was 0.7 mg/L. Azoxystrobin was slightly irritating to the eyes and skin of rabbits. Azoxystrobin was not a skin sensitizer as determined by the Magnusson & Kligman (maximization) test in guinea-pigs.

In short-term studies in rats and dogs and long-term studies in mice and rats, the major toxicological findings included decreased body weight and body-weight gains, often accompanied by decreased food consumption and utilization. The major target organs in rats were the liver, kidney and bile duct as shown by changes in organ weights, histopathology, and clinical chemistry parameters. Changes in liver weights, often accompanied by changes in clinical chemistry, were also observed in dogs and mice. Kidney-weight changes in mice were not accompanied by any histopathological findings.

In a 90-day dietary study of toxicity in rats, decreased body weights and body-weight gains were seen at 2000 ppm (equal to 221.0 mg/kg bw per day) and 4000 ppm (equal to 443.8 mg/kg bw per day). At 4000 ppm, decreased food consumption, food utilization, changes in clinical chemistry parameters, increased liver and kidney weights, hepatocellular hyperplasia and enlarged lymph nodes, and reduction in total urinary protein were seen in males. The no-observed-adverse-effect level (NOAEL) was 200 ppm, equal to 20.4 mg/kg bw per day.

In a 90-day and a 1-year study in dogs, clinical observations included increased salivation at dosing, and increased incidences of salivation, vomiting, regurgitation and fluid faeces, beginning in week 1 and occurring throughout the study in some cases. These signs were considered to be treatment-related; however, they were not considered to be relevant for establishment of a NOAEL for systemic toxicity because these effects were secondary to local gastrointestinal irritation/disturbances and bolus dosing (capsules). In a 90-day study of toxicity in dogs, decreases in body weights were observed in males and females at 250 mg/kg bw per day, the highest dose tested. Changes in liver weights and in clinical chemistry parameters were observed at the intermediate and the highest dose, indicating adverse effects on the liver and possibly on biliary function. The changes in the liver at 50 mg/kg bw per day were small and without histological correlates, therefore, the Meeting considered that they were not toxicologically relevant. In a 90-day study in dogs, the NOAEL was 50 mg/kg bw per day on the basis of alterations in clinical chemistry (cholesterol, triglycerides and alkaline phosphatase activity), and decreases in body weights seen at the lowestobserved-adverse-effect level (LOAEL) of 250 mg/kg bw per day, the highest dose tested. Similar findings were observed in a 1-year study of toxicity in dogs but were mainly confined to the highest dose of 200 mg/kg bw per day. In a 1-year study of toxicity in dogs, the NOAEL was 25 mg/kg bw per day on the basis of changes in clinical chemistry and increases in liver weights seen at 200 mg/kg bw per day. The overall NOAEL in dogs was 50 mg/kg bw per day on the basis of the similarity of effects in the two studies in dogs.

The carcinogenic potential of azoxystrobin was studied in mice and rats. In a study of carcinogenicity in mice, reduced body weights were observed at 2000 ppm, equal to 272.4 mg/kg bw per day. The NOAEL was 300 ppm, equal to 37.5 mg/kg bw per day. There were no treatment-related neoplastic findings in the bioassay in mice.

In a long-term combined study of toxicity and carcinogenicity in rats, the highest dose of 1500 ppm, equal to 108.6 mg/kg bw per day, was excessively toxic in males and was reduced to 750 ppm, equal to 34 mg/kg bw per day, after 1 year. Reduced body weights, food consumption, and food-conversion efficiency was observed in males and females at the highest dose tested. In the

common bile duct of males at the highest dose only, there were significant increases in the incidences of distension, cholangitis, thickening of the wall, and epithelial hyperplasia. The NOAEL was 300 ppm, equal to 18.2 mg/kg bw per day. There were no treatment-related neoplastic findings in rats.

Azoxystrobin gave a mixed response in a battery of tests for genotoxicity. It gave a weak positive response in two studies in mammalian cells (mouse lymphoma cells and human lymphocytes). The latter findings suggest that azoxystrobin has a clastogenic potential in vitro since the increased occurrence of small colonies observed in the mouse lymphoma-cell assay is considered to be indicative of chromosome aberrations rather than of point mutations. However, azoxystrobin has been shown to give negative results in assays for chromosomal damage in vivo (i.e., clastogenicity) and for general DNA damage at high doses of 2000 mg/kg bw or above. Therefore, the Meeting concluded that the clastogenic effects seen in vitro are not expressed in the whole animal.

The Meeting concluded that azoxystrobin is unlikely to be genotoxic.

In view of the lack of evidence for a genotoxic potential in vivo and the absence of carcinogenicity in rats and mice, the Meeting concluded that azoxystrobin is unlikely to pose a carcinogenic risk to humans.

In a two-generation study of reproductive toxicity in rats, reproductive parameters were not affected at the highest dose tested (1500 ppm, equal to 165.4 mg/kg bw per day). The NOAEL for parental systemic toxicity was 300 ppm, equal to 32.3 mg/kg bw per day, on the basis of reduced adjusted body weight, feed consumption, feed utilization, and an increase in liver weights and the frequency of histopathological findings in the liver (males only). Offspring toxicity was manifested as a decrease in pup body weights, and a decrease in adjusted mean liver weights was observed in pups of both generations at 1500 ppm, equal to 165.4 mg/kg bw per day. The NOAEL for offspring toxicity was 300 ppm, equal to 32.3 mg/kg bw per day.

In a study of developmental toxicity in rats, treatment at the highest dose (300 mg/kg bw per day) was terminated as this dose was toxic; at this dose, three rats died and one was killed in extremis after two doses. Clinical signs of diarrhoea, salivation and urinary incontinence were seen at 25 and/or at 100 mg/kg bw per day. The Meeting considered these effects to be treatment-related but not relevant for the identification of a NOAEL for systemic toxicity, being considered to be secondary to local gastrointestinal irritation/disturbances and dosing by gavage. There were no effects on fetuses at any doses tested. The NOAEL for maternal and developmental toxicity was 100 mg/kg bw per day, the highest dose tested.

Two studies of developmental toxicity in rabbits were conducted. The results of the first study were considered to be invalid because of the adverse effects of administration of high volumes of corn oil as a vehicle. Several special studies were conducted in pregnant and non-pregnant rabbits to evaluate the influence of the type and volume of vehicle used for administration by gavage. The results of these studies showed that corn oil at volumes greater than 2 mL/kg bw was harmful. The NOAEL for maternal toxicity in rabbits was 150 mg/kg bw per day (identified in the study using the lowest volume of corn oil for dosing) based on decreased body-weight gain seen at the LOAEL of 500 mg/kg bw per day. There were no effects on fetuses. The NOAEL for developmental toxicity in rabbits was 500 mg/kg bw per day, the highest dose tested.

Azoxystrobin was not embryotoxic, fetotoxic or teratogenic at doses of up to 300 and 500 mg/kg bw per day in rats and rabbits, respectively.

The Meeting concluded that azoxystrobin is not teratogenic.

In a study of acute neurotoxicity in rats, no treatment-related effects on motor activity parameters, brain measurements (weight, length and width) or neurohistopathology were observed at doses of up to and including 2000 mg/kg bw. Increased incidences of transient diarrhoea, tip-toe gait, hunched posture and landing-foot splay were observed in all groups receiving azoxystrobin, although

these effects were not dose-related. They were considered to be treatment-related but not relevant for identification of a NOAEL for systemic toxicity, being considered to be secondary to local gastrointestinal irritation/disturbances and bolus dosing by gavage. The NOAEL for systemic toxicity was 2000 mg/kg bw, the highest dose tested. In a short-term study of neurotoxicity in rats, no treatment-related changes in mortality, clinical signs, functional observational battery (FOB), motor activity, brain measurements (weight, length, and width), gross necropsy, or neurohistopathology were observed at doses of up to 2000 ppm, equal to 161 mg/kg bw per day, the highest dose tested. The NOAEL for systemic toxicity was 500 ppm, equal to 38.5 mg/kg bw per day, on the basis of decreased body weight and body-weight gain and food utilization in males and females seen at the LOAEL of 2000 ppm, equal to 161 mg/kg bw per day.

Azoxystrobin was not considered to be neurotoxic on the basis of the available data.

No significant adverse effects were reported in personnel working in plants producing azoxystrobin.

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

Toxicological evaluation

The Meeting established an acceptable daily intake (ADI) of 0–0.2 mg/kg bw based on a NOAEL of 300 ppm (equal to 18.2 mg/kg bw per day) in a 2-year study of carcinogenicity in rats, identified on the basis of reduced body weights, food consumption and food efficiency, and bile-duct lesions seen at 750 ppm (equal to 34 mg/kg bw per day) and above, and using a safety factor of 100.

The Meeting concluded that it was unnecessary to establish an acute reference dose (ARfD) for azoxystrobin because no toxicity could be attributable to a single exposure in the available database, including a study of developmental toxicity in rats and rabbits and a study of acute neurotoxicity in rats. The mortality seen in the study of developmental toxicity in pregnant rats at 300 mg/kg bw per day was associated with gross local gastrointestinal pathology and was not seen in pregnant rabbits. The Meeting considered that clinical signs observed in dogs and rats were related to local gastrointestinal effects seen after bolus dosing by gavage in rats or bolus dosing (capsules) in dogs, since these signs were not seen in the dietary studies. Therefore, the Meeting considered that these effects were not relevant for the establishment of an ARfD.

A toxicological monograph was prepared.

Species	Study	Effect	NOAEL	LOAEL
Mouse	104-week study of toxicity and	Toxicity	300 ppm, equal to 37.5 mg/kg bw per day	2000 ppm, equal to 272.4 mg/kg bw per day
	carcinogenicity ^a	Carcinogenicity	2000 ppm, equal to 272.4 mg/kg bw per day ^c	—
Rat	Two-year study of toxicity and carcinogenicity ^a	Toxicity	300 ppm, equal to 18.2 mg/kg bw per day	750 ppm, equal to 34 mg/kg bw per day ^c
		Carcinogenicity	750 ppm, equal to 34 mg/kg bw per day ^c	—
	Multigeneration study of reproductive toxicity ^a	Parental toxicity	300 ppm, equal to 32.3 mg/kg bw per day	1500 ppm, equal to 165.4 mg/kg bw per day ^c
		Offspring toxicity	300 ppm equal to 32.3 mg/kg bw per day	1500 ppm, equal to 165.4 mg/kg bw per day ^c

Levels relevant to risk assessment

Species	Study	Effect	NOAEL	LOAEL	
	Developmental toxicity ^b	Maternal toxicity	100 mg/kg bw per day ^c	—	
		Embryo and fetal toxicity	100 mg/kg bw per day ^c	—	
Rabbit	Developmental toxicity ^b	Maternal toxicity	150 mg/kg bw per day	500 mg/kg bw per day ^c	
		Embryo and fetal toxicity	500 mg/kg bw per day ^c	_	

^a Dietary administration.

^bGavage administration.

^c Highest dose tested.

Estimate of acceptable daily intake for humans

0-0.2 mg/kg bw per day

Estimate of acute reference dose

Unnecessary

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

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

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

Absorption, distribution, excretion, and metabolism in mammals					
Rate and extent of oral absorption	Rapid and nearly complete absorption				
Distribution	Widely distributed in tissues				
Potential for accumulation	Low, no evidence of significant accumulation				
Rate and extent of excretion	Approximately 82–90% (73–89% in faeces and 9–18% in urine) within 48 h				
Metabolism in animals	Extensive; metabolic pathways include hydrolysis followed by glucuronide conjugation and minor pathway included cleavage of the ether				
Toxicologically significant compounds (animals, plants and environment)	Azoxystrobin				
Toxicologically significant compounds (animals, plants and environment) Acute toxicity	Azoxystrobin				
Toxicologically significant compounds (animals, plants and environment) Acute toxicity Rat, LD ₅₀ , oral	Azoxystrobin > 5000 mg/kg bw				
Toxicologically significant compounds (animals, plants and environment) Acute toxicity Rat, LD ₅₀ , oral Rat, LD ₅₀ , dermal	Azoxystrobin > 5000 mg/kg bw > 2000 mg/kg bw				
Toxicologically significant compounds (animals, plants and environment) Acute toxicity Rat, LD ₅₀ , oral Rat, LD ₅₀ , dermal Rat, LC ₅₀ , inhalation	Azoxystrobin > 5000 mg/kg bw > 2000 mg/kg bw 0.7 mg/L , dust (4 h exposure, nose only)				
Toxicologically significant compounds (animals, plants and environment) Acute toxicity Rat, LD ₅₀ , oral Rat, LD ₅₀ , dermal Rat, LC ₅₀ , inhalation Rabbit, dermal irritation	Azoxystrobin > 5000 mg/kg bw > 2000 mg/kg bw 0.7 mg/L , dust (4 h exposure, nose only) Slight irritation				

Guinea-pig, dermal	l sensitization	Not a sensitizer (Magnus	sson & Kligman test)	
Short-term studies	of toxicity			
Target/critical effe	ct	Body-weight effects		
Lowest relevant or	al NOAEL	20.4 mg/kg bw per day (90-day study in rats)	
Lowest relevant de	rmal NOAEL	1000 mg/kg bw per day; highest dose tested (21-day repeated dermal toxicity study in rat)		
Lowest relevant inh	nalation NOAEL	No data		
Genotoxicity				
		Unlikely to be genotoxic		
Long-term studies	of toxicity and carcinogenicity			
Target/critical effe	ct	Liver-weight increases a	nd bile-duct lesions	
Lowest relevant NO	DAEL	18.2 mg/kg bw per day (2-year study in rats)	
Carcinogenicity		Not carcinogenic in mice	e and rats	
Reproductive toxic	ity			
Reproduction target/critical effect		No toxicologically relevant effects		
Lowest relevant reproductive NOAEL		165.4 mg/kg bw per day (rats; highest dose tested)		
Developmental target/critical effect		No developmental toxici	ity in rats and rabbits	
Lowest relevant de	velopmental NOAEL	100 mg/kg bw per day (1	rats; highest dose tested)	
Neurotoxicity/delay	yed neurotoxicity			
Acute neurotoxicity	у	No sign of specific neuro	otoxicity	
Mechanistic data				
		No studies were submitte	ed	
Medical data				
		No significant adverse health effects reported		
Summary			~	
	Value	Study	Safety factor	
ADI	0–0.2 mg/kg bw per day	Rat, 2-year study of toxicity	100	
ARfD	Unnecessary	_	_	

RESIDUE AND ANALYTICAL ASPECTS

Azoxystrobin is a broad-spectrum fungicide belonging to the class of methoxyacrylates, which are synthetic analogues from the naturally-occurring strobilurin fungi. It exerts its fungicidal activity by inhibiting mitochondrial respiration in fungi. At the 39th Session³⁵ of the CCPR, azoxystrobin was scheduled for the evaluation as a new compound by the 2008 JMPR.

Chemical name

ISO common name:	Azoxystrobin
IUPAC:	Methyl (<i>E</i>)-2-{2 [6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3- methoxyacrylate
CA:	Methyl(E)-2-[[6-(2-cyanophenoxy)-4-pyrimidinyl]oxy]- α -(methoxymethylene)benzeneacetate



Animal metabolism

The Meeting received results of animal metabolism studies in lactating goats and laying hens.

Lactating goats were dosed twice daily at each milking with either cyanophenyl-, pyrimidinyl, or phenylacrylate-[¹⁴C]labelled azoxystrobin in gelatine capsules at a nominal rate of 25 ppm in the diet (on a dry weight basis) for seven consecutive days, corresponding to a daily dose of approximately 1 mg/kg bw. The actual dose rate was equivalent to 23–33 mg/kg in the diet. The majority (90–93%) of the administered radiolabelled doses were recovered. The primary route of excretion was via the faeces (62–72% of the administered doses). Excretion via the urine accounted for a further 18–24% of the administered doses, resulting in total of 83–92% of the administered doses being excreted in faeces and urine. The TRR in milk, muscle and fat were very low (0.004–0.025 mg/kg of azoxystrobin equivalents), corresponding to < 0.01% of the administered doses. Characterization of these radioactive residues by fractionation showed that they were unlikely to be attributed to any individual compound at a significant level. Radioactivity in milk reached a plateau of only 0.01 mg/L after 3–4 days of dosing.

In tissues and organs, most of the radioactivity was recovered in the liver (0.58-1.2 mg/kg) and kidney (0.18-0.25 mg/kg), corresponding to 0.2-0.4% and 0.06-0.08%, respectively, of the administered doses, reflecting the role of these organs in metabolism and excretion. In goat kidney, the major metabolites included 2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenylacetic acid (0.01-0.05 mg/kg, 6.9-20% TRR), a glucuronide conjugate of a phenylacrylate ring hydroxy-derivative of azoxystrobin (0.02-0.03 mg/kg, 8.2-16% TRR), and (E)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid (0.005-0.02 mg/kg and 2.0-11% TRR). These metabolites were also present in goat liver but not as major metabolites (only 0.2-0.9, 0.5-1.9, and 0.7-1.9% TRR, respectively). The major metabolite detected in liver of goats dosed with [cyanophenyl-¹⁴C]

³⁵ Codex Alimentarius Commission. Report of the 40th Session of the Codex Committee on Pesticides Residues, 14–19 April 2008, Hangzhou, China, (ALINORM 08/31/24)

labelled azoxystrobin was ring hydroxyl-derivative of S-(2-cyanophenyl)cysteine (compound L4: 0.35 mg/kg and 29% TRR), whereas 4-(2-cyanophenoxy)-6-hydroxypyrimidine was the major metabolite in liver of goats dosed with [pyrimidinyl-¹⁴C] labelled azoxystrobin (0.13 mg/kg and 20% TRR). Compound L4 was not detected in kidney, and 4-(2-cyanophenoxy)-6-hydroxypyrimidine accounted for only 5.0% TRR in kidney of goats dosed with [pyrimidinyl-¹⁴C] labelled azoxystrobin. Azoxystrobin parent was present at low levels in both the kidney (0.002–0.008 mg/kg and 0.8 to 2.0% TRR) and the liver 0.007–0.02 mg/kg and 0.6–1.8% TRR). In general, there was no significant difference in metabolism observed using the three different radiolabels.

<u>Laying hens</u> were dosed once daily with either cyanophenyl-, pyrimidinyl-, or phenylacrylate- $[^{14}C]$ labelled azoxystrobin in gelatine capsules at a nominal rate of 1.5 mg/day for ten consecutive days, corresponding to a daily dose of approximately 0.75 mg/kg bw. The dose was equivalent to an intake of approximately 11–12 ppm in the diet.

The recovery of the administered radiolabelled dose was 93–98%. The majority of the administered dose was excreted in faeces (91–97%). The cage washings accounted for no more than 2.0% of the administered dose. Radioactive residues in tissues and eggs accounted for $\leq 0.2\%$ of the dose. Residues in muscle, egg white, skin with underlying fat, and peritoneal fat were in the range of 0.004–0.039 mg/kg. The highest radioactive residues were in egg yolk (0.040–0.14 mg/kg) and liver (0.082–0.11 mg/kg), both of these representing $\leq 0.1\%$ of the administered dose. The fractionation of these residues showed that no single organosoluble fraction exceeded < 0.01 mg/kg and aqueous or unextractable fractions represented < 0.05 mg/kg.

Residues in egg whites reached a plateau of only 0.008–0.011 mg/kg after 3–4 days of dosing. In egg yolks, the residues plateaued at 0.040–0.14 mg/kg after 6–8 days of the dosing. The Meeting noted that it typically takes up to ten days for an egg to form, therefore the egg yolk values can be used as representative of what is happening in the whole egg.

Azoxystrobin (< 0.001-0.006 mg/kg, 0.3-12% TRR) and 4-(2-cyanophenoxy)-6hydroxypyrimidine (0.002-0.004 mg/kg of azoxystrobin equivalents and 1.8-8.4% TRR), were identified in egg yolk. A significant portion of the radioactivity (0.018 mg/kg and 15% TRR) in egg yolk from the hens dosed with [pyrimidinyl-¹⁴C]azoxystrobin was due to the breakdown of azoxystrobin into small components, which were then incorporated through biosynthetic pathways into fatty acids.

Based on the results of the submitted studies, the Meeting concluded that, in goats and hens, azoxystrobin was rapidly metabolized and excreted in faeces and urine, with minimal retention of the parent and its metabolites in the tissues.

Plant metabolism

The Meeting received information on azoxystrobin metabolism, studied in wheat, grapes, peanuts, rice, and cotton.

<u>Wheat</u> was treated with radiolabelled azoxystrobin (labelled separately in each of the three rings) formulated as a suspension concentrate (250 g ai/L) and applied as a foliar spray twice (at BBCH 30–31 and 59–61) at a nominal rate of 0.5 kg ai/ha. The treated plants were harvested either as forage (a PHI of 13 days) or mature crop (a PHI of 61–62 days). The metabolic profile of azoxystrobin in wheat was very complex with at least 23 metabolites detected. Residues were mainly in the forage (TRR of 1.0–2.8 mg/kg) and straw (TRR of 3.1–9.4 mg/kg). The total radioactive residues in the grain were low (0.075–0.077 mg/kg).

In wheat grain, the only significant residue was the parent, azoxystrobin, (17–22% TRR and 0.013–0.017 mg/kg). No other discrete metabolite (12 compounds identified) was present at greater than 3.3% TRR (0.002 mg/kg). Naturally incorporated glucose comprised 9.7–21% TRR.

In the wheat straw and forage, 14 and 12 metabolites were identified, respectively. The major residue was azoxystrobin, representing 22–43% TRR (0.67–4.1 mg/kg) and 55–65% TRR (0.56–1.8 mg/kg) in the straw and forage, respectively.

Other significant components included:

- 4-(2-cyanophenoxy)-6-hydroxypyrimidine (a product of the cleavage of the ether linkage between the phenyacrylate ring and the pyrimidinyl ring), for which sum of free, conjugated and bound forms accounted for 8.2–10% TRR and 3.2–3.7% TRR in the straw and forage, respectively
- the Z-isomer of azoxystrobin (2.1–3.5% TRR in straw, 1.9–2.9% TRR in forage), which is the photo-isomerisation product of azoxystrobin
- (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid (3.0–3.4% TRR in straw, 0.7–0.8% in forage), which can be formed from azoxystrobin either by hydrolysis of the ester group or by oxidative de-alkylation.

The Meeting noted that the metabolic profile of the extractable residue of azoxystrobin in wheat was essentially the same in each analysed sample and very similar in each radiolabel, with the parent as the major residue accounting for 19–26%, 24–47%, and 59–68% of the extractable residue in grain, straw, and forage, respectively.

In an additional study, winter wheat was treated with [pyrimidinyl-¹⁴C]azoxystrobin applied once as a 250 SC formulation at 250 g ai/ha as a late season treatment at BBCH 71 (a PHI of 28 days). The total radioactive residues in grain and straw were 0.066 and 2.5 mg/kg, respectively. The only relevant radioactive residue was the parent, azoxystrobin, which accounted for 31% TRR (0.020 mg/kg) in grain and 51% TRR (1.3 mg/kg) in straw. Other significant metabolites, including 4-(2-cyanophenoxy)-6-hydroxypyrimidine or the Z-isomer of azoxystrobin, did not account for more than 3.4% TRR each. The Meeting noted that the results of this study were consistent with those from the previous wheat metabolism study. In both studies, azoxystrobin was the major component of the residue in grain and straw, representing 44% and 60% of the extractable residue, respectively.

Grapes were treated with radiolabelled azoxystrobin (labelled separately in each of the three rings), which was applied as a 250 SC formulation to three grape vines (one vine for each radiolabel) as a foliar spray four times with application rates of 0.25, 1.0, 1.0, and 0.25 kg ai/ha. Grapes and leaves were harvested 21 days after the final application. The TRR in grapes were 0.38–1.4 mg/kg of azoxystrobin equivalents. The major residue for each radiolabel was the parent, azoxystrobin (35-65% TRR and 0.13–0.92 mg/kg). A total of nine metabolites were identified and the most significant were 2-hydroxybenzonitrile (5.7% TRR), 4-(2-cyanophenoxy)-6-hydroxypyrimidine (2.6-5.2% of azoxystrobin (1.9–4.0%) TRR), the Z-isomer TRR), and methyl 2-{2-[6-(2cyanophenoxy)pyrimidin-4-yloxy]phenyl}-glycolate (2.5–3.9% TRR). Incorporation of radioactivity into naturally occurring sugars (glucose, fructose, and sucrose) indicated mineralization of [¹⁴C]azoxystrobin in soil, with subsequent assimilation of ¹⁴CO₂ and the formation of ¹⁴C-sugars via photosynthesis.

<u>Peanuts</u> were treated with radiolabelled azoxystrobin (labelled separately in each of the three rings), which was formulated as a 250 g ai/L suspension concentrate and applied three times as a foliar spray to peanut vines at 0.85, 0.85, and 0.3 kg ai/ha. Ten days after the last application, a portion of the vines was stored fresh and the remaining vines and pods (nut and hull intact) were dried. The radioactive residues were mainly in the hay (dried vine containing 39–47 mg/kg of azoxystrobin equivalent) and vine (16–21 mg/kg). Nuts and hulls contained only 0.24–0.65 mg/kg and 0.67–0.90 mg/kg, respectively. The most significant residues identified in the nutmeat were the fatty acids, oleic and linoleic, accounting for 28–32% TRR (0.074–0.21 mg/kg) and 11–16% (0.27–0.11 mg/kg), respectively. Natural incorporation of radioactivity into sugars sucrose (1.7–5.6% TRR), glucose (1.5–1.9% TRR), and fructose (1.4–2.2% TRR) indicated mineralization of [¹⁴C]azoxystrobin in soil with subsequent assimilation of ¹⁴CO₂. Parent azoxystrobin was not detected in the nutmeat and no individual metabolite was present at a level greater than 1.0% TRR. In hay and hulls, the

major component of the radioactive residue was the parent, azoxystrobin, accounting for 33–44% TRR (13–20 mg/kg) and 13–14% TRR (0.088–0.11 mg/kg), respectively. A total of 10 and 11 metabolites were identified in hay and hull, respectively (residues in the vine were qualitatively similar to those in the hay), the most significant of which were 4-(2-cyanophenoxy)-6-hydroxypyrimidine (3.9% TRR in hay and 2.5–2.6% TRR in hulls) and its glucose conjugate (2.9–5.6% TRR in hay and 1.2-1.9% TRR in hulls).

<u>Rice</u> was treated with radiolabelled azoxystrobin (labelled separately in each of the three rings) in two separate experiments, one with a single foliar spray and the other with two granular paddy applications. For the foliar treatment, azoxystrobin was applied formulated as a suspension concentrate just after heading, at rates equivalent to a total field application of 0.36–0.55 kg ai/ha. For the paddy application, the compound was formulated as a granular product and applied twice to the paddy water to give a total seasonal application rate of 1.73–1.92 kg ai/ha. Crops were harvested at maturity after a PHI of 75–95 days for the foliar-treated plants and a PHI of 95–98 days after the second application for the granular treated rice plants.

The TRR (expressed as azoxystrobin) were 0.32-0.74 mg/kg and 5.7-11 mg/kg in grain and straw, respectively. In rice grain, the only significant residues from the granular application were radiolabelled sugars (43–58% TRR) and the parent compound (3.4–5.3% TRR). Similarly, the foliar application resulted mainly in the residues of the parent (36–72% TRR) and radiolabelled sugars (4.9–17% TRR). In rice straw, the major components from the granular application were the parent (3.3–5.6% TRR), isomers of methyl-2-{2-[6-(2-cyano-4-hydroxyphenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy acrylate (5.1–8.1%TRR), and (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid (3.6–6.7% TRR). In foliar application, the parent, azoxystrobin, was the single most abundant component (38–46% TRR), followed by 4-(2-cyanophenoxy)-6-hydroxypyrimidine (5.2–8.5% TRR). Similarly to rice grain, a portion of the radioactivity (up to 3.9% TRR) was identified as radiolabelled sugars.

<u>Cotton</u> grown in the USA was treated with [pyrimidinyl-¹⁴C]azoxystrobin formulated as a suspension concentrate and applied at planting, as an in-furrow application, at a rate of 18 g ai/km (0.19 oz ai/1000 ft row), which was close to the US GAP for in-furrow application to cotton (19 g ai/km). The cotton was harvested both immature (forage) and mature (separated into seed, lint, and gin trash). Characterization of the residues was not carried out in seed, lint, and gin trash, in which the TRR were < 0.01 mg/kg. The TRR in forage was 0.085 mg/kg. The most significant residue in the forage was the parent, representing 15% TRR (0.013 mg/kg). At least eight unknowns were detected; not one representing > 0.01 mg/kg of parent equivalent. None of the unknowns co-chromatographed with any of the applied reference substances.

Based on the results of the submitted studies on wheat, grapes, peanut and cotton, the Meeting concluded that qualitatively similar metabolism occurred among these crops, with the parent, azoxystrobin, being the major component of the residue. In peanut meat, fatty acids (oleic and linoleic) accounted for most of the TRR. In cotton, no significant residues were detected in cottonseed after the in-furrow application at planting.

The Meeting noted that, in most of the studies, a significant portion of the radioactivity was identified as radiolabelled natural products such as sugars, starch, fatty acids, and amino acids. The presence of radioactivity in these natural products is believed to result from the mineralization of azoxystrobin in soil and subsequent incorporation of ¹⁴CO₂ via photosynthesis.

Environmental fate

The Meeting received information on aerobic and anaerobic degradation of azoxystrobin in <u>soil</u>; photolysis on soil surface; mobility in soil; field dissipation studies and azoxystrobin residues in rotational crops.

The aerobic and anaerobic degradation of radiolabelled azoxystrobin was studied in the dark at 20 °C in three soils (silt loam, sandy clay loam, and sandy loam) incubated for 120 days and one soil (sandy loam) incubated for 360 days.

Under aerobic conditions, azoxystrobin degraded with DT_{50} values between 56 and 279 days, depending on the amount of microbial biomass in this soil. No significant degradation was observed in sterile treatments, suggesting that the aerobic degradation was due to microbial activity. The major residue was azoxystrobin (31–55% and 33% of the applied radioactivity after 120 and 360 days, respectively). The only significant metabolite was (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid, accounting for 10–15% and 18% of the radioactivity after 120 and 360 days, respectively.

Under anaerobic conditions, the degradation was more rapid with DT_{50} of 49–181 days. Azoxystrobin accounted for 19–21% and 28% of the applied radioactivity after 120 and 360 days of incubation, respectively. (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid represented 57–59% and 49% of the radioactivity after 120 and 360 days, respectively.

Mineralization to CO_2 was significant with up to 27% detected after 120 days under aerobic conditions (only up to 5% under anaerobic conditions). The acid metabolite and other identified metabolites were also finally mineralized into CO_2 .

Photodegradation of radiolabelled azoxystrobin was studied on the surface of sandy loam soil irradiated under conditions equivalent of up to 30 days Florida summer sunlight. Azoxystrobin underwent rapid degradation with a mean DT_{50} of 11 days Florida summer sunlight, which is equivalent to 11.5 days summer sunlight at 50 °North. A total of nine photolysis products were identified, of which the Z-isomer of azoxystrobin, 2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]benzoic acid, and 4-(2-cyanophenoxy)-6-hydroxypyrimidine accounted for up to 9%, 7.5%, and 5.7% of applied radioactivity, respectively. The only significant photodegradation product was ¹⁴CO₂, reaching up to 29% of the applied radioactivity.

The Meeting concluded that both photolytic and microbial degradation are important routes of degradation under field conditions, with both routes ultimately leading to formation of CO_2 .

Mobility in soil was evaluated through adsorption/desorption and leaching studies, showing low to medium potential mobility of azoxystrobin in the tested soils.

Field dissipation studies on bare soil were performed in Northern and Southern Europe. The results showed a rapid degradation of azoxystrobin under field conditions (DT_{50} 3–39 days, DT_{90} 87–433 days). No measurable residues of azoxystrobin or its metabolites were determined below 10 cm. No measurable residues of the Z-isomer of azoxystrobin or (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxy-acrylic acid were determined in any samples from any trials, with the exception of detection of the acid metabolite in one trial in Northern Europe (0.03 mg/kg) in the 0–10 cm horizon. Residues of 4-(2-cyanophenoxy)-6-hydroxypyrimidine and 2-[6-(2-cyanophenoxy) pyrimidin-4-yloxy] benzoic acid ranged between < 0.01–0.03 and < 0.01–0.05 mg/kg, respectively, in the 0–10 cm horizon and declined to < 0.01 mg/kg by 28–195 days after application.

Residues in Rotational Crops

The Meeting received results of three greenhouse confined rotation studies conducted in the USA. In each study, radiolabelled azoxystrobin (different radiolabel each time) was applied directly to sandy loam soil at 2.2 kg ai/ha, which corresponds to the maximum seasonal application rate for azoxystrobin in the USA (maximum of six applications of a single rate of 0.37 kg ai/ha or maximum of eight applications of a single rate of 0.28 kg ai/ha), thus simulates a worst case scenario. Rotational crops (radish, lettuce, and wheat) were planted 30, 200, and 365 days after the treatment. Radish and lettuce were harvested at maturity while wheat was harvested at an immature stage (forage) and at maturity (grain and straw).

The TRR in the soil declined on average from 0.74-1.0 mg/kg at treatment to 88, 56, and 13% at 30, 200, and 365 days after treatment, respectively. The metabolism of azoxystrobin in rotational crops was complex with a large number of conjugated metabolites formed (mostly glucose or amino acid conjugates of the corresponding primary crop metabolites). The residues declined significantly at longer plant back intervals. Radioactive residues in the 365-day crops were generally in concentrations below 0.01 mg/kg. As in the primary crops, parent azoxystrobin represented the major residue detected in all rotational crops (up to 17-44% TRR); with very low actual residue levels in the tested crops (< 0.01–0.08 mg/kg at 30 days and < 0.01–0.01 mg/kg at 200 days). In wheat forage and wheat straw at 30 days, TRRs were 0.15–0.34 and 1.4–1.9 mg/kg, respectively, which declined significantly at the longer plant back intervals of 200 days (to 0.02–0.05 and 0.06–0.12 mg/kg, respectively) and 365 days (to < 0.01 mg/kg). Azoxystrobin residues in wheat grain were < 0.01 mg/kg even in wheat planted 30 days after the treatment.

In the absence of field rotational studies, it was difficult to assess the uptake of rotational crops (such as cereals), from soil under realistic conditions. The Meeting noted that the greenhouse confined studies were conducted at an exaggerated application rate: the TRR in the soil declined rapidly, and the azoxystrobin residues resulting from direct applications on the rotational crops were significantly higher than those found (even at the shortest plantback interval of 30 days) in the confined rotational studies resulting from the uptake from the treated soil.

Water-sediment systems

The hydrolysis rate of $[{}^{14}C]$ azoxystrobin was determined at 25 °C and 50 °C in buffered aqueous solutions at pH 5, 7 and 9 under sterile conditions in the dark for up to 31 days. At 25 °C, there was no significant hydrolysis (< 10%) at any pH. At 50 °C, there was no significant hydrolysis at pH 5 or 7. At 50 °C and pH 9, analysis showed significant hydrolysis (DT₅₀=12.56 days). The Meeting concluded that no significant hydrolysis of azoxystrobin is likely under realistic environmental conditions.

The aqueous photolysis of $[{}^{14}C]$ azoxystrobin was studied at 25 °C in buffered aqueous solutions at pH 7 under sterile conditions over a period of approximately 30 days using an artificial light source. The half-life was calculated to be in the range of 11 and 17 days Florida summer sunlight (12–18 days summer sunlight at 50 °North). Azoxystrobin was the major component in all samples, accounting for up to 26% of the applied radioactivity at the final sampling interval. Only one photoproduct, the Z-isomer, was present at levels greater than 10% of the applied radioactivity during the study.

Degradation in the sediment/water systems was studied in two natural systems under laboratory conditions in the dark at 20 °C over 152 days. Throughout the incubation period, the majority of the radioactivity (44–75% of applied radioactivity) was found in the sediment layer. In water, azoxystrobin was rapidly dissipated with a half-life of less than seven days. After 152 days of incubation, the parent compound azoxystrobin represented 47–61% of the applied radioactivity in the water-sediment systems. (*E*)-2-{2-[6-(2-cyano-phenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylic acid was the major metabolite, present at up to 20% of the applied activity 152 days after incubation, while up to 6% of the applied radioactivity had been mineralized to CO₂. Azoxystrobin reaching water would be quickly adsorbed onto sediment and subsequently degraded, thus unlikely to cause residues in crops.

Methods of analysis

The Meeting received descriptions and validation data for analytical methods for azoxystrobin in samples of plant and animal origin.

The described methods are mostly based on extraction with an organic solvent (usually acetonitrile or acetone); followed by a partition step, gel permeation chromatography (GPC) clean-up, and often also a silica, C18, alumina or Florisil solid-phase extraction (SPE) clean-up. The

determination step employs either capillary GC with nitrogen-phosphorus (GC-NPD) or mass spectrometric (GC-MS) detection or liquid chromatography with tandem MS detection (LC-MS/MS). The typical LOQ is 0.01 mg/kg for most plant and animal matrices, with mean recoveries typically ranging between 70–120%. Multiresidue methods, such as the German DFG S19, are available for azoxystrobin analysis in plant and animal matrices.

Adequate multi- and single-residue methods exist for both gathering data in supervised trials and other studies and for monitoring and enforcing azoxystrobin MRLs in samples of plant and animal origin.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of azoxystrobin in samples of plant and animal commodities freezer-stored at ≤ -18 °C. Fortified samples, typically at 0.1 mg/kg, of plant commodities (apples, orange oil, juice and pulp, peaches, grapes, wine, bananas, tomatoes, cucumbers, carrot root, lettuce leaf, oilseed rape, soya bean meal, corn grits, wheat straw, grain, and forage, peanuts, and pecans) were stored for up to 24 months. Fortified samples of processed commodities (peanut oil and meal, wheat bran and tomato juice and paste) were stored up to 12 months. Fortified samples of animal origin (beef muscle, liver, kidney, fat, milk and eggs) were stored up to ten months, which adequately covers the sample storage intervals in the livestock feeding studies.

No significant degradation of azoxystrobin was observed in the samples tested over the reported storage intervals. The uncorrected recoveries of azoxystrobin were > 70% during the storage intervals, except for one sample of orange pulp (56% recovery), for which the concurrent recovery was also low (69%).

Azoxystrobin is stable when stored frozen (≤ -18 °C) over the periods for which crop and animal tissue samples were stored, prior to the analysis in supervised trials, animal feeding and processing studies.

Residue definition

Azoxystrobin is extensively metabolized in animals and plants. Results of plant metabolism studies on wheat, rice, grapes, peanuts, and cottonseed indicate that azoxystrobin is rapidly metabolized and that portions of the molecule becomes associated with sugars and other natural plant constituents. The main residue remaining in the edible plant tissues at harvest is the parent compound, azoxystrobin. Although a number of metabolites were identified, all were at levels below 10% of the total recovered radioactive residue.

In ruminants (goats) and poultry (hen), azoxystrobin was rapidly metabolized with the majority of the administered dose excreted in the faeces and urine. The metabolism was quantitatively similar to rats. The total radioactive residues in goat milk, muscle, and fat were very low and characterization showed that the residues were unlikely to be attributed to any individual compound at a significant level. The residues were higher in kidney and liver, reflecting the role of these organs in metabolism and excretion. The major metabolites in the liver were not detected or found only at low levels in the kidney and vice versa. The parent, azoxystrobin, was present at low levels in both the kidney and liver. The hen metabolism showed very low transfer of radioactivity into tissues and eggs. The parent, azoxystrobin, was identified in the egg yolk (up to 12% TRR).

Based on the above, the Meeting agreed:

Definition of the residue in plant and animal commodities for estimation of dietary intake and for compliance with MRLs: *azoxystrobin*.

The log K_{ow} of azoxystrobin is 2.5 (at 20 °C, pH 7). In the cattle feeding study, azoxystrobin accumulated in cream when milk was processed to skimmed milk and cream (6.7 to 40-fold higher

azoxystrobin concentration in cream vs. skimmed milk), corresponding to 5–7.5 concentration factor for cream vs. whole milk. Also, even at the highest dosing level of 250 ppm, no measurable azoxystrobin residues (< 0.01 mg/kg) were found in cattle muscle, whereas azoxystrobin residues of 0.01-0.03 mg/kg were determined in fat. The Meeting noted that azoxystrobin represents a borderline case of fat solubility and concluded that the azoxystrobin residue is fat-soluble for the purpose of the residue definition.

Results of supervised residue trials on crops

The Meeting received supervised trials data for azoxystrobin on citrus fruits (post-harvest and foliar treatments), stone fruits (cherry, peach and plum), berries and small fruit (blackberry, blueberry, cranberry, grapes, raspberry and strawberry), tropical fruits with inedible peel (banana, mango and papaya), bulb vegetables (bulb onion, spring onion and leeks), brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower and kohlrabi), fruiting vegetables (cucumber, gherkin, melon, summer squash, pepper and tomato), lettuce, legume vegetables (beans and peas), pulses (soya beans), root and tuber vegetables (beetroot, carrot, chicory, potato, radish and sugar beet), stalk and stem vegetables (artichokes, asparagus, celery, witlof and chicory), cereal grains (barley, oat, rye, triticale, wheat, maize and rice), tree nuts (almonds, pecans and pistachios), oil seeds (cottonseed, peanuts and sunflower), herbs (basil, chives, parsley and mint), peanut hay, soya bean forage and hay, straw, fodder and forages of cereal grains (barley, oat, rye, triticale, wheat, maize and rice), sugar beet tops, dried herbs (basil, chives, parsley and hops), and almond hulls.

Citrus fruit

The Meeting received results from supervised trials with azoxystrobin used as post-harvest and foliar treatments on citrus fruits (grapefruit, orange, lemon, tangerine and mandarin) in the USA.

For the post-harvest treatment on citrus fruits, the GAP of the USA specifies a maximum of two treatments (for maximum decay control, once before storage and once after storage, just prior to marketing) that can be performed as a dip application with 0.12 kg ai/hL or a spray, drench, or flood application with 4 kg ai/ton fruit.

Ten trials were performed according to the GAP using two dip treatments (one with and one without a storage wax) at 0.12 kg ai/hL. Azoxystrobin residues in whole fruit were: 2.7 and 2.9 mg/kg for grapefruit, 2.1 and 2.2 mg/kg for orange, 2.6 and 4.2 mg/kg for tangerine, 3.4 and 6.2 mg/kg for mandarin, and 5.5 and 8.8 mg/kg for lemon. Three trials at the GAP using two spray treatments at 4 kg ai/ton fruit resulted in significantly lower azoxystrobin residues: 0.86 (grapefruit), 0.58 (orange) and 0.88 (lemon) mg/kg.

Eighteen other trials were performed at the GAP rate but only with a single application. Among these trials, the dip treatment with a storage wax resulted in the highest azoxystrobin residues (as compared to dip without wax or spray with or without wax), which were: 2.1 and 5.3 mg/kg for grapefruit, 1.6 and 4.0 mg/kg for orange, and 3.5 and 6.6 mg/kg for lemon.

In one post-harvest orange trial, involving a single dip without a storage wax, azoxystrobin residues in the whole fruit, pulp, and peel were analysed. Azoxystrobin residues were: 2.0 mg/kg in the whole fruit, 0.72 mg/kg in pulp, and 5.4 mg/kg in orange peel.

For the foliar treatment on citrus fruits, the GAP of the USA specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 7–21 day intervals) and a PHI of 0 days. Twenty-two trials were conducted at the GAP, with azoxystrobin residues in grapefruit (n = 6): 0.19, 0.20, 0.21, 0.25, 0.27, and 0.41 mg/kg; in orange (n = 11): 0.23, 0.26, 0.28, 0.30, 0.31, 0.32, 0.34, 0.37, 0.40, 0.41, and 0.53 mg/kg for orange; and for lemon (n = 5): 0.31, 0.52, 0.60, 0.65, and 0.74 mg/kg.

The Meeting noted that azoxystrobin residues from the foliar application were significantly lower as compared to the residues obtained in the post-harvest dip trials. The Meeting agreed to use

the post-harvest dip results with one and two applications on the smaller citrus fruits (lemon, tangerine, and mandarin) to support a "citrus fruit" maximum residue level. Azoxystrobin residues in whole citrus fruit, in ranked order, were (n = 8): 2.6, 3.4, 3.5, <u>4.2</u>, <u>5.5</u>, 6.2, 6.6 and 8.8 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in whole citrus fruit of 15 mg/kg and an STMR value of 4.9 mg/kg.

Stone fruit

The Meeting received results from supervised trials with azoxystrobin used as a foliar treatment on stone fruits (cherry, peach, and plum) in the USA.

The GAP of the USA for stone fruit specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 7–14 day intervals) and a PHI of 0 days.

Seven trials on sweet cherry were conducted at the GAP rate with eight applications. Azoxystrobin residues in cherry, in ranked order, were (n = 7): 0.20, 0.42 (2), 0.45, 0.50, 0.98, and 1.0 mg/kg.

Fourteen trials on peach were conducted at the GAP rate with eight applications. Azoxystrobin residues in peach, in ranked order, were (n = 14): 0.28, 0.38, 0.41, 0.60, 0.64, 0.72 (2), 0.73, 0.74, 0.83, 0.84, 0.86, 0.89, 0.94, and 1.4 mg/kg.

Eight trials on plum were conducted at the GAP rate with eight applications. Azoxystrobin residues in plum, in ranked order, were (8): 0.02, 0.09, 0.24 (2), 0.25, 0.30, 0.37, and 0.42 mg/kg.

The Meeting agreed that the data on cherry, peach, and plum complying with the US GAP for stone fruit could be used to support a commodity group maximum residue level. Based on the residues obtained on peach, the Meeting estimated a maximum residue level for azoxystrobin in stone fruit of 2 mg/kg and an STMR value of 0.74 mg/kg.

Berries and other small fruits

The Meeting received results from supervised trials from the USA where azoxystrobin was used as a foliar treatment on berries and other small fruits, i.e., blackberry, blueberry, cranberry, raspberry, grape, and strawberry.

Blackberry, raspberry and blueberry

The GAP of the USA for cane berries (including blackberry and raspberry) specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 7–14 day intervals) and a PHI of 0 days. One trial on blackberry was at the GAP rate with eight applications. Azoxystrobin residue was 3.6 mg/kg. Two trials on raspberry were according to the GAP (six or seven applications). Azoxystrobin residues were 0.71 and 2.4 mg/kg.

The GAP of the USA for bush berries (including blueberries) specifies a rate of 0.28 kg ai/ha with a seasonal total of 0.84 kg ai/ha (three applications at 7–14 day intervals) and a PHI of 0 days. Seven trials on blueberries were conducted at the GAP rate with six applications. Azoxystrobin residues, in ranked order, were (n = 7): 0.52, 0.79, 0.86, 0.95, 1.1 (2), and 1.4 mg/kg.

The Meeting decided to use the data on blackberry, raspberry, and blueberry to support a "Berries and other small fruits, except cranberry, grapes, and strawberry" commodity group maximum residue level. Azoxystrobin residues, in ranked order (n = 10): 0.52, 0.71, 0.79, 0.86, <u>0.95</u>, <u>1.1</u> (2), 1.4, 2.4, and 3.6 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in Berries and other small fruits, except cranberry, grapes, and strawberry of 5 mg/kg and an STMR value of 1.0 mg/kg.

Cranberry

The GAP of the USA for cranberry specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 7–14 day intervals) and a PHI of three days. Four trials were conducted according to the GAP. Azoxystrobin residues, in ranked order, were: 0.15, 0.19, 0.26, and 0.31 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in cranberry of 0.5 mg/kg and an STMR value of 0.23 mg/kg.

Grapes

The GAP of the USA for grapes specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications at 10–14 day intervals) and a PHI of 14 days. Fifteen trials on grapes were conducted according to the GAP with a PHI of 13–14 days. Azoxystrobin residues in grapes, in ranked order, were (n = 15): 0.11, 0.16, 0.24, 0.30, 0.33, 0.47 (2), 0.53 (3), 0.60, 0.62, 0.73, 0.76, and 0.80 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in grapes of 2 mg/kg and an STMR value of 0.53 mg/kg.

Strawberry

The GAP of the USA for strawberry specifies a rate of 0.28 kg ai/ha with a maximum seasonal total of 1.1 kg ai/ha (four applications at 7–10 day intervals) and a PHI of 0 days. Seven trials were conducted at the GAP rate with 6–7 applications. Azoxystrobin residues in strawberry in ranked order were (n = 7): 0.26, 0.28, 0.65, <u>1.3</u> (2), 4.3, and 4.5 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in strawberry of 10 mg/kg and an STMR value of 1.3 mg/kg.

Tropical fruits- inedible peel

Bananas

The Meeting received results from supervised trials with azoxystrobin used as a foliar treatment on bananas in the USA and as a post-harvest treatment in Central America (Costa Rica, Guatemala, and Mexico). The post-harvest trials were carried out according to the GAP of the USA.

For the foliar treatment on bananas and plantains, the GAP of the USA specifies a rate of 0.15 kg ai/ha with a maximum seasonal total of 1.2 kg ai/ha (eight applications at 12–14 day intervals) and a PHI of 0 days. Six trials were conducted according to the GAP. Azoxystrobin residues in whole fruit from bagged bunches were (n = 6): 0.01, 0.02 (2), 0.05 (2), and 0.15 mg/kg. Azoxystrobin residues in whole fruit from unbagged bunches were (n = 6): 0.10, 0.11, 0.17, 0.18, and 0.26 (2) mg/kg. Azoxystrobin residues in banana pulp were < 0.01 (4) and 0.01 (2) mg/kg for bagged bananas and < 0.01 (3), 0.02 (2), and 0.03 mg/kg for unbagged bananas.

For the post-harvest treatment on bananas and plantains, the GAP of the USA specifies a maximum of one application made as a spray, dip, or paint using 0.04 kg ai/hL. Six post-harvest trials on banana were conducted according to the GAP. Azoxystrobin residues in the whole fruit, in ranked order, were (n = 6): 0.58, 0.71, 0.82, 0.85, 0.98, and 1.1 mg/kg. Azoxystrobin residues in the pulp, in ranked order, were (n = 6): < 0.02, 0.02, 0.03 (2), 0.05, and 0.07 mg/kg.

The Meeting noted that the post-harvest trials resulted in higher residues, thus considered only the post-harvest results for maximum residue level and STMR estimations. Also, the Meeting agreed to extrapolate the results from bananas to plantains (the same GAP as bananas).

The Meeting estimated a maximum residue level for azoxystrobin in banana and plantain (whole fruit) of 2 mg/kg. Based on the pulp data, the Meeting estimated an STMR value of 0.03 mg/kg for banana and plantain pulp.

Mango

The Meeting received results from supervised trials on mango in Brazil, South Africa, and the USA.

In Brazil azoxystrobin is approved for use on mangoes at a spray rate of 0.008 kg ai/hL (0.06 kg ai/ha), with a maximum of six applications and a PHI of 2 days. From six trials in Brazil, at the GAP rate with six or eight applications residues of azoxystrobin, in whole fruit, were (n = 6): 0.03, 0.06 (2), 0.07, 0.08, and 0.13 mg/kg.

The GAP of South Africa specifies an application rate of 0.01 kg ai/hL, a maximum of two applications and a PHI of 21 days. Four trials complied with the GAP of South Africa, azoxystrobin residues, in whole fruit (n = 4), were: 0.02, 0.03, and 0.06 (2) mg/kg. The residues in flesh were < 0.01 mg/kg even at 200% GAP or in cases where fruit was harvested within the PHI of 21 days. In two trials at 100 and 200% of the GAP rate and a PHI of 0 days, azoxystrobin residues in flesh were 0.01 and 0.03 mg/kg and in whole fruit were 0.05 and 0.20 mg/kg, respectively, giving an average whole fruit/flesh residue concentration factor of 5.8.

The GAP of the USA (for tropical fruit) specifies a rate of 0.28 kg ai/ha with a maximum of six application (1.7 kg ai/ha seasonal total) and a PHI of 0 days. In three US trials, conducted according to the US GAP, residues of azoxystrobin in mango halves (stone removed) were: 0.09, 0.31, and 0.48 mg/kg. Using the stone/whole fruit weight factors of 0.10 and 0.09, based on the information provided in the South African trials for mango varieties Kent and Tommy Atkins, respectively, calculated residues of azoxystrobin in whole fruit were: (n = 3): 0.08, <u>0.28</u>, and 0.44 mg/kg.

Based on the results from the US trials, the Meeting estimated a maximum residue level for azoxystrobin in mango (whole fruit) of 0.7 mg/kg. Based on the whole fruit/flesh residue concentration factor of 5.8 and the median value in whole fruit of 0.28 mg/kg, the Meeting estimated an STMR value of 0.05 mg/kg for mango flesh.

Papaya

The Meeting received results from supervised trials with azoxystrobin used as a foliar treatment on papaya in Brazil and Malaysia.

The GAP of Brazil specifies a spray concentration 0.008 kg ai/hL (0.064 kg ai/ha), with a maximum of four applications and a PHI of 3 days. Four trials on papaya in Brazil involved six applications at 125% GAP rate. Azoxystrobin residues in the whole fruit were: 0.06, 0.09, 0.11, and 0.12 mg/kg. In two trials, papaya flesh was analysed, with azoxystrobin residues in flesh being 0.01 and 0.02 mg/kg at a PHI of three days. The whole fruit/flesh distribution data were also obtained for two trials at 250% GAP rate (PHIs of 0–14 days). The average whole fruit/flesh residue concentration factor was 5.8 (n = 18).

The GAP of Malaysia specifies a spray concentration 0.011 kg ai/hL (0.11 kg ai/ha), a maximum of two applications and a PHI of one day. Three trials on papaya in Malaysia were conducted according to the GAP. Azoxystrobin residues in the whole fruit were (n = 3): < 0.05 (2) and 0.15 mg/kg.

The Meeting decided to combine results obtained from supervised trials on papaya in Brazil and Malaysia for mutual support. Azoxystrobin residues in the whole fruit, in ranked order, were (n = 7): < 0.05 (2), 0.06, 0.09, 0.11, 0.12 and 0.15 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in papaya (whole fruit) of 0.3 mg/kg. Based on the whole fruit/flesh residue concentration factor of 5.8 and the median value in whole fruit of 0.09 mg/kg, the Meeting estimated an STMR value of 0.02 mg/kg for papaya flesh.

Bulb vegetables

Leeks

The Meeting received results from supervised trials with azoxystrobin on leeks in France (Southern and Northern), Germany, Switzerland, and the UK.

The GAP of France specifies a rate of 0.25 kg ai/ha, with a maximum of three applications and a PHI of 50 days. The GAP of Germany specifies a rate of 0.25 kg ai/ha, a maximum of two applications and a PHI of 42 days. No trials were conducted according the GAP of France or Germany.

The GAP of the UK specifies a rate of 0.25 kg ai/ha, a maximum of four applications and a PHI of 21 days. The GAP of Switzerland specifies a rate of 0.25 kg ai/ha, a maximum of two applications (14-day interval), and a PHI of 14 days. The GAP of Italy specifies a rate of 0.25 kg ai/ha, a maximum of two applications (7–14 day interval) and a PHI of 15 days. Twelve trials in France (Southern and Northern), Germany, Switzerland, and UK were conducted according to the GAP of Switzerland or Italy. Azoxystrobin residues found were (n = 12): 0.06, 0.07, 0.10, 0.11, 0.13, 0.14 (2), 0.17, 0.19, 0.34, 0.64, and 1.2 mg/kg.

Onion bulb, dry

The Meeting received results from supervised trials with azoxystrobin used on bulb onions in the USA. The GAP of the USA (for bulb vegetables) specifies a rate of 0.28 kg ai/ha, a maximum of 6 applications (total seasonal rate of 1.7 kg ai/ha) and a PHI of 0 days.

Eight trials were conducted according to the GAP. Azoxystrobin residues, in ranked order, were (n = 8): < 0.01, 0.07, 0.15, 0.21, 0.31, 0.36, 0.51, and 0.66 mg/kg.

Spring onion

The Meeting received results from supervised trials with azoxystrobin on spring onions in the USA. The GAP of the USA (for bulb vegetables) specifies a rate of 0.28 kg ai/ha, a maximum of 6 applications (total seasonal application rate of 1.7 kg ai/ha) and a PHI of 0 days.

Six trials were conducted according to the GAP with six applications. It was also decided to include one trial that involved 11 applications as the Meeting considered that the last application was more likely to contribute the majority to the residue of azoxystrobin. Also, the resulting residue of 3.3 mg/kg falls within the population of residues from the trials with six applications. Azoxystrobin residues, in ranked order, were (n = 7): 0.67, 1.3, 1.4, 2.2, 2.6, 2.7, 3.3, and 6.3 mg/kg.

The Meeting decided that the data on leeks, onion bulb and spring onion could be used to support a "bulb vegetables" commodity group maximum residue level. Based on the results on spring onions obtained according to the US GAP for bulb vegetables, the Meeting estimated a maximum residue level for azoxystrobin in bulb vegetables of 10 mg/kg and an STMR value of 2.2 mg/kg.

Brassica vegetables

Broccoli

The Meeting received results from supervised trials with azoxystrobin on broccoli in Europe (Germany, the Netherlands, and Spain), Canada and the USA.

In Europe, the GAPs of France, Germany, the Netherlands, and the UK specify a rate of 0.25 kg ai/ha, a maximum of two applications with a PHI of 14 days. Eight trials in Europe were conducted according to GAP. Azoxystrobin residues were (n = 8): < 0.01 (2), 0.01, 0.04 (3), 0.11, and 0.58 mg/kg.

The GAP of the USA (for brassica vegetables, head and stem subgroup) specifies a rate of 0.28 kg ai/ha with a maximum of 6 applications (total seasonal application rate of 1.7 kg ai/ha) and a PHI of 0 days. Two trials in Canada and two trials in the USA were conducted according to the US GAP. Azoxystrobin residues were (n = 4): 0.25, 0.93, 1.5, and 2.3 mg/kg.

The Meeting noted that azoxystrobin residues in broccoli obtained in the trials in the USA and Canada were significantly higher than those obtained in the European trials.

Brussels sprouts

The Meeting received results from supervised trials with azoxystrobin on Brussels sprouts in Europe (Austria, Germany, France, the Netherlands, Spain, and the UK).

In Europe, the GAPs of France, Germany, Italy, the Netherlands, and the UK for Brussels sprouts specifies a rate of 0.25 kg ai/ha, a maximum of two applications (8 to14-day interval) with a PHI of 14 days.

Twelve trials in Europe were conducted according to GAP with either two or four applications. Azoxystrobin residues, in ranked order were, were (n = 12): 0.03, 0.04 (3), 0.05 (3), 0.06, 0.08, 0.14, and 0.18 (2) mg/kg.

Cabbage, head

The Meeting received results from supervised trials with azoxystrobin on cabbage in Europe (Austria, Germany, Italy, the Netherlands, and Spain), Canada and the USA.

In Europe, the GAPs of France, Germany, Italy, the Netherlands, and the UK, for Brussels sprouts, specify a rate of 0.25 kg ai/ha, a maximum of two applications (8 to14-day interval), with a 14 day PHI. Twelve trials in Europe were conducted according to GAP with either two or four applications. Azoxystrobin residues, in ranked order were, were (n = 12): < 0.01 (7), 0.01 (2), 0.07, 0.09, and 0.18 mg/kg.

The GAP of the USA (for brassica vegetables, head and stem subgroup) specifies a maximum of six applications at 0.28 kg ai/ha (seasonal total rate of 1.7 kg ai/ha) with a PHI of 0 days. Two trials in Canada and two trials in the USA were conducted according to the US GAP. Azoxystrobin residues were (n = 4): 0.32, 0.90, 1.8 and 2.0 mg/kg.

The Meeting noted that azoxystrobin residues in cabbage obtained in the trials in the USA and Canada were significantly higher than those obtained in the European trials.

Cauliflower

The Meeting received results from supervised trials with azoxystrobin on cauliflower in Europe (Austria, Germany, Spain, and the UK).

The GAP of Germany specifies a maximum of two applications at 0.25 kg ai/ha, (8 to12-day interval) with a PHI of 10 days. Eight trials in Germany, Austria, and the UK were conducted according to the German GAP with either two or four applications. Azoxystrobin residues were (n = 8): < 0.01 (2), 0.04 (2), 0.07, 0.17, 0.42, and 0.46 mg/kg.

The GAP of France and Italy for cauliflower specify a maximum of two applications (12 to14-day interval) at 0.25 kg ai/ha, and a PHI of 14 days. Four trials in Spain were conducted according to the GAP with either two or four applications. Azoxystrobin residues were (n = 4): < 0.01 (2), 0.03, and 0.44 mg/kg.

Kohlrabi

The Meeting received results from supervised trials with azoxystrobin used on kohlrabi in Germany. The GAP of Germany for kohlrabi specifies a maximum of two applications (8 to12-day interval) at 0.25 kg ai/ha, and a PHI of 14 days. Six trials were conducted according to the GAP. Azoxystrobin residues, in ranked order, were (n = 6): < 0.02, 0.03, 0.04, 0.05, 0.06, and 0.09 mg/kg.

The Meeting agreed that the data on broccoli, Brussels sprouts, cabbages (head), cauliflower and kohlrabi could be used to support a "Brassica vegetables" commodity group maximum residue level. The Meeting noted that azoxystrobin residues obtained on broccoli and head cabbage according to the same US GAP for brassica vegetables appear to be from similar populations and decided to combine them. Combined azoxystrobin residues, in ranked order median underlined, were (n = 8): 0.25, 0.32, 0.90, <u>0.93</u>, <u>1.5</u>, 1.8, 2.0, and 2.3 mg/kg.

Based on the data on broccoli and head cabbage, the Meeting estimated a maximum residue level for azoxystrobin in brassica vegetables of 5 mg/kg, an STMR value of 1.2 mg/kg and a highest residue value of 2.3 mg/kg.

Fruiting vegetables, Cucurbits

Cucumber

The Meeting received results from supervised trials with azoxystrobin on cucumber both indoors (glasshouse) in Europe (France, Germany, Greece, and the UK) and in the field in Europe (France, Italy, and Spain) and the USA.

The indoor and field trials in France, Germany, Greece, and the UK were conducted using a spray concentration of 0.02 kg ai/hL with 4–8 applications and a PHI of three days. The rate and PHI corresponds to the GAP of France (0.02 kg ai/hL, three applications, a PHI of three days), which can cover both southern and northern parts of Europe. The GAPs of Italy and Switzerland specify a maximum of 3 applications at 0.025 kg ai/hL with a PHI of three days, i.e., the trials were conducted at 80% of the GAP rate in these countries. Azoxystrobin residues from the indoor trials were (n = 6), 0.03, 0.13 (2), 0.20, 0.49, and 0.75 mg/kg. Azoxystrobin residues from the outdoors trials in Europe were (n = 5): 0.02, 0.04, 0.06, 0.07, and 0.12 mg/kg.

Only two indoor trials in Germany (listed above with residues of 0.13 and 0.13 mg/kg at a PHI of three days) matched the GAP of the Netherlands, which specifies 0.02 kg ai/hL, 3 applications, and a PHI of one day for indoor use. Azoxystrobin residues were (n = 2): 0.19 and 0.23 mg/kg.

The GAP of the USA for cucurbits specifies a maximum of six applications at 0.28 kg ai/ha (with a total seasonal rate of 1.7 kg ai/ha) and a PHI of one day. Nine trials were conducted outdoors in the USA according to US GAP. Azoxystrobin residues were (n = 9): 0.04, 0.05, 0.06 (2), 0.07, 0.09, 0.11, 0.35, and 0.40 mg/kg.

Gherkin

The Meeting received results from supervised trials with azoxystrobin on gherkins in Germany. The GAP of Germany for cucumber specifies a maximum of two applications at 0.25 kg ai/ha, (8 to12-day interval) and a PHI of three days. Four trials in Germany on gherkins were conducted at the GAP rate with four or six applications. Azoxystrobin residues were (n = 4): 0.04, 0.05, 0.06, and 0.15 mg/kg.

Melons

The Meeting received results from supervised trials with azoxystrobin on indoor melons, i.e., in a glasshouse or a poly-tunnel, in Europe (France, Greece, Italy, the Netherlands, and Spain) and in the field in Europe (France, Greece, Italy, and Spain) and the USA.

Most of the indoor and field trials in Europe were conducted using a spray concentration of 0.02 kg ai/hL with 5–8 applications and a PHI of three days. The rate and PHI corresponds to the GAP of the Netherlands for indoor use (0.02 kg ai/hL, three applications, a PHI of three days) and 80% GAP rate for indoor/field application in Italy and Switzerland (0.025 kg ai/hL, three applications, a PHI of three days). Azoxystrobin residues from the indoor trials were (n = 8): 0.03 (2), 0.08, 0.16, 0.17, 0.18, 0.29, and 0.40 mg/kg. Azoxystrobin residues from the field trials in Europe were (n = 8): 0.01, 0.04 (3), 0.06, 0.07, 0.08, and 0.38 mg/kg.

Two field trials on melons in southern France were conducted at 0.20 kg ai/ha, eight applications, and a PHI of three days, which corresponds to the GAPs of France, Italy and Spain for field treatment (0.20 kg ai/ha, three applications, a PHI of three days). Azoxystrobin residues were: 0.06 and 0.09 mg/kg.

In six of the European trials, melon pulp and skin were analysed, azoxystrobin residues found in pulp (n = 6) were: < 0.01, 0.01 (2), 0.02, 0.05, and 0.06 mg/kg.

The GAP of the USA for cucurbits specifies a maximum of six applications (7–14 day intervals) at 0.28 kg ai/ha (total seasonal rate of 1.7 kg ai/ha) and a PHI of one day. Seven field trials were conducted in the USA according to GAP. Azoxystrobin residues were (n = 7): 0.10 (2), 0.16, 0.17 (2), 0.20, and 0.26 mg/kg.

Summer squash

The Meeting received results from supervised trials with azoxystrobin used on summer squash in the USA.

The GAP of the USA for cucurbits specifies a maximum of six applications at 0.28 kg ai/ha (total seasonal rate of 1.7 kg ai/ha) and a PHI of one day. Five trials on summer squash in the USA were conducted according to the GAP. Azoxystrobin residues, in ranked order, were (n = 5): 0.06, 0.07, 0.09, 0.11, and 0.16 mg/kg.

The Meeting agreed that the results obtained on cucumber, gherkins, melons, and summer squash could be used to support a "Fruiting vegetables, Cucurbits" commodity group maximum residue level. The Meeting noted that the results from indoor trials on cucumber and melon in Europe according to the same GAP gave highest residues. The Meeting also noted that these data sets appear to be from similar populations and decided to combine them. Azoxystrobin residues, in ranked order, were (n = 14): 0.03 (3), 0.08, 0.13 (2), 0.16, 0.17, 0.18, 0.20, 0.29, 0.40, 0.49, and 0.75 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in fruiting vegetables, cucurbits of 1 mg/kg and an STMR value of 0.17 mg/kg. Based on the pulp data for melon, the Meeting estimated an STMR value of 0.02 mg/kg for cucurbits with inedible peel.

Fruiting vegetables, other than cucurbits

Peppers, sweet

The Meeting received results from supervised trials with azoxystrobin on sweet pepper grown in an indoor environment, i.e., in a glasshouse or a poly-tunnel, in Europe (France, Italy, and the Netherlands) and in the field (outdoor) in southern Europe (France, Italy, and Spain).

Seven field trials in southern Europe were conducted using a spray concentration of 0.025 kg ai/hL with six applications and a PHI of three days. The rate and PHI corresponds to the GAP of Italy for indoor/field application (0.025 kg ai/hL, three applications and a PHI of three days) and 125% GAP of Spain (0.020 kg ai/h, three applications and a PHI of three days). Azoxystrobin residues from the field trials were (n = 7), 0.04, 0.17, 0.18, 0.44, 0.45, 0.61, and 0.85 mg/kg.

Five indoor trials were conducted using a spray concentration of 0.025 kg ai/hL with six applications and a PHI of three days. These trials were conducted at the GAP rate of Italy. Azoxystrobin residues were (n = 5): 0.27, 0.35 (2), 0.62, and 1.4 mg/kg.

Two indoor trials in France were conducted at 0.25 kg ai/ha with six applications and a PHI of three days. These trials were conducted at the GAP rate of France (0.25 kg ai/ha, three applications and a PHI of 3 days). Azoxystrobin residues were (n = 2): 0.25 and 0.58 mg/kg.

Tomato

The Meeting received results from supervised trials with azoxystrobin on indoor grown tomatoes (in a glasshouse) in Europe (France, Italy, the Netherlands, and Spain) and in the field in southern Europe (France, Greece, Italy, and Spain).

The indoor and field trials on tomatoes were conducted using a rate of 0.23–0.26 kg ai/ha or a spray concentration of 0.025 kg ai/hL with six applications and a PHI of six days. The rate and PHI correspond to the GAP of France for indoor/field use (0.25 kg ai/ha, three applications and a PHI of three days) or the GAP of Italy for indoor/field use (0.025 kg ai/hL, three applications and a PHI of three days) and the GAP of Switzerland for indoor application (0.025 kg ai/hL, three applications and a PHI of three days).

Six field trials on tomatoes were conducted using a spray concentration of 0.025 kg ai/hL with six applications and a PHI of three days. Azoxystrobin residues were (n = 8): 0.08, 0.15, 0.16, 0.19, 0.39, and 0.41 mg/kg.

Two field trials on tomatoes were conducted using a rate of 0.23-0.26 kg ai/ha with six applications and a PHI of three days. Azoxystrobin residues were (n = 2): 0.31 and 0.40 mg/kg.

Six indoor trials on tomatoes were conducted using or a spray concentration of 0.025 kg ai/hL with six applications and a PHI of six days. Azoxystrobin residues were (n = 6): 0.08, 0.20, 0.29, 0.33, 0.54, and 0.86 mg/kg.

Five field trials on tomatoes were conducted using 0.24–0.26 kg ai/ha with six applications and a PHI of three days. Azoxystrobin residues were (n = 5): 0.14, 0.20, 0.49, 0.54, and 0.69 mg/kg.

The Meeting agreed that the data on sweet pepper and tomato could be used to support a "Fruiting vegetables, other than Cucurbits, except fungi and sweet corn" commodity group maximum residue level. The Meeting noted that indoor trials on sweet pepper and tomato (conducted according to the same GAP with a spray concentration of 0.025 kg ai/hL) gave the highest residues (as compared to the indoor trials at 0.25 kg ai/ha or the field trials). The Meeting also noted that the data on sweet peppers and tomatoes from these trials appear to be from a similar population and decided to combine them. Azoxystrobin residues, in ranked order, were (n = 11): 0.08, 0.20, 0.27, 0.29, 0.33, 0.35 (2), 0.54, 0.62, 0.86, and 1.4 mg/kg

The Meeting estimated a maximum residue level for fruiting vegetables, other than cucurbits, except fungi and sweet corn of 3 mg/kg and an STMR value of 0.35 mg/kg.

Using a default concentration factor of 10 for extrapolation from sweet peppers to dried chilli peppers, the Meeting estimated a maximum residue level for azoxystrobin in dried chilli pepper of 30 mg/kg and an STMR value of 3.5 mg/kg.

Lettuce

The Meeting received results from supervised trials with azoxystrobin on lettuce in France, Spain and the UK.

The GAPs of France, Germany, and the Netherlands for lettuce specifies a rate of 0.25 kg ai/ha, a maximum of three applications (two applications in Germany), and a PHI of 14 days. The GAP of Italy specifies 0.25 kg ai/ha, a maximum of three applications, and a PHI of seven days.

Twelve trials in northern Europe (northern France and the UK) were conducted at the GAP of France, Germany, or the Netherlands. Azoxystrobin residues from these trials were (n = 12): < 0.01 (5), 0.24, 0.25, 0.39, 0.49, 0.56, 1.2, and 1.6 mg/kg.

Eight trials in southern Europe (southern France and Spain) were conducted at the GAP of Italy. Azoxystrobin residues from these trials were (n = 8): 0.12 (2), 0.14, 0.31, 0.44, 0.85, 1.1, and 1.4 mg/kg.

The Meeting noted that the residues in lettuce from the trials in northern and southern Europe appear to be from a similar population (based on the Mann-Whitney U-test). Combined azoxystrobin residues in lettuce, in ranked order median underlined, were (n = 20): < 0.01 (5), 0.12 (2), 0.14, 0.24, 0.25, 0.31, 0.39, 0.44, 0.49, 0.56, 0.85, 1.1, 1.2, 1.4, and 1.6 mg/kg.

The Meeting estimated a maximum residue level for lettuce (head) and lettuce (leaf) of 3 mg/kg and an STMR value of 0.28 mg/kg.

Legume vegetables

The Meeting received results from supervised trials with azoxystrobin on succulent beans and peas in the USA. The GAP of the USA for legume vegetables specify a maximum of six applications at 0.28 kg ai/ha with total seasonal rate of 1.7 kg ai/ha and a PHI of 0 days.

Beans

Six trials in the USA were conducted on succulent beans according to GAP with 7–8 applications. In three trials, the beans were collected without the pods. Azoxystrobin residues in beans without pods were: 0.02, 0.07, and 0.08 mg/kg. In three trials where beans were collected and analysed with the edible pods, azoxystrobin residues were: 0.11, 0.48, and 1.5 mg/kg.

Peas

Six trials in the USA were conducted on succulent peas according to the GAP of the USA with seven applications. In three trials, the peas were collected without the pods. Azoxystrobin residues in peas without pods were: 0.03, 0.08, and 0.17 mg/kg. In three trials where the peas were collected and analysed with the edible pods azoxystrobin residues were: 0.87, 1.2, and 1.5 mg/kg.

The Meeting agreed that the data on beans and peas obtained from trials according to the same GAP for legume vegetables could be used to estimate a "legume vegetables" commodity group maximum residue level. The Meeting decided to use the higher residues found on beans and peas with pods, for the estimation. Azoxystrobin residues in beans and peas with pods, in ranked order median underlined, were (n = 6): 0.11, 0.48, 0.87, 1.2, and 1.5 (2) mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in legume vegetables of 3 mg/kg and an STMR value of 1.0 mg/kg.

Soya beans, dry

The Meeting received results from supervised trials with azoxystrobin on soya beans in the USA.

The GAP of the USA for soya beans (seeds) specifies a maximum of 6 applications at 0.28 kg ai/ha with a total sanctioned seasonal total rate of 1.7 kg ai/ha and a PHI of 14 days. Nineteen trials on soya beans in the USA were conducted at the US GAP rate with 5–7 applications and a PHI of 12–16 days. Azoxystrobin residues, in ranked order median underlined, were (n = 19): < 0.01, 0.02 (5), 0.03, 0.05, <u>0.06</u> (3), 0.07, 0.09, 0.12, 0.15, 0.18, 0.23, 0.24, and 0.33 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in soya beans, dry of 0.5 mg/kg and an STMR value of 0.06 mg/kg.

Root and tuber vegetables

The Meeting received results from supervised trials with azoxystrobin on beetroot, carrot, radish, and sugar beet in the USA, on chicory root in France and on potato in Europe.

The GAP of the USA for root vegetables specifies a maximum of six applications at 0.37 kg ai/ha with a total seasonal rate of 2.2 kg ai/ha (six applications) and a PHI of 0 days.

Beetroot

Four trials on beetroot (garden beet) were conducted in the USA using 0.28 kg ai/ha (76% US GAP rate) with a total seasonal application of 2.2 kg ai/ha (six applications) and a PHI of 0 days. Azoxystrobin residues in beetroot, in ranked order, were (n = 4): 0.18, 0.23, 0.32, and 0.34 mg/kg.

Carrot

Six trials on carrot were conducted in the USA according to the US GAP for root vegetables (one trial with eight applications). Azoxystrobin residues in carrot, in ranked order, were (n = 6): 0.03, 0.13, 0.14, 0.17, 0.26, and 0.30 mg/kg.

Chicory root

Five supervised trials with azoxystrobin used on chicory (endive) in France (see chicory and endive leaves for trial details) were conducted according to the GAP of France, which specifies a PHI of 21 days, maximum of three applications at 2.5 kg ai/ha for chicons (the edible part) production (treatment of plants) and 0.25 kg ai/ha for root production (treatment of parts).

Azoxystrobin residues in chicory roots (harvest of chicory leaves and roots at a PHI of 21 days), were (n = 5) 0.06, 0.07, 0.11, 0.25, and 0.46 mg/kg.

Potato

The Meeting received results from supervised trials with azoxystrobin used on potato as soil treatment (whole field or in-furrow) in France, Italy, the Netherlands, Spain, and the UK or as a foliar treatment in Spain and the UK.

For the pre or at planting soil treatment, the GAP of the Netherlands and the UK specify a single application at 1.5 kg ai/ha as an overall or incorporated treatment or a single application at 0.75 kg ai/ha as an in-furrow treatment. The resulting application rates at the actual planting sites of potatoes are comparable (about 1.5 kg ai/ha) because of the reduced field area sprayed in the in-furrow application, i.e., applied as a 50% 'band' treatment.

Six trials in the Netherlands and two trials in the UK were performed using 1.5-1.6 kg ai/ha as a single application. Azoxystrobin residues in potatoes from these trials were (n = 8): < 0.01 (4) and 0.01 (4) mg/kg. Twelve trials were conducted using the same rate (1.5-1.6 kg ai/ha) in Southern Europe (southern France, Italy, and Spain), with azoxystrobin residues being (n = 12): < 0.01 (6), 0.02 (2), 0.03 (3), and 0.07 mg/kg. No GAP was available for potatoes in the southern Europe.

Six trials in the Netherlands were conducted using 0.77–0.8 kg ai/ha as a single in-furrow treatment at planting. Azoxystrobin residues in potato from these trials were (n = 6): < 0.01 (3), 0.02 and 0.03 (2) mg/kg. Four trials in southern France were conducted using 0.37–0.39 kg ai/ha (about 50% GAP rate) as a single in-furrow treatment at planting, resulting in azoxystrobin residues of (n = 4): 0.02 and 0.03 (3) mg/kg.

For the foliar application, the GAP of Germany specifies 0.13 kg ai/ha, a maximum three applications, and a PHI of seven days. The GAP of the Netherlands specifies 0.063 kg ai/ha, a maximum of two applications, and a PHI of seven days. Two trials in the UK, two trials in the Netherlands, and four trials in Spain were conducted according to the GAP of Germany. In addition,

two trials in the UK and four trials in Spain were conducted at 200% GAP rate and two trials in the Netherlands were conducted at 50% of German GAP (100% of the GAP of the Netherlands). Azoxystrobin residues in potato in all these trials were < 0.01 (16) mg/kg.

Radish

Five trials on radish were conducted in the USA according to the US GAP for root vegetables. Azoxystrobin residues in radish, in ranked order, were (n = 5): 0.13, 0.16, 0.29, 0.38, and 0.45 mg/kg.

Sugar beet

Nine trials on sugar beet were conducted in the USA according to the US GAP for root vegetables. Azoxystrobin residues in sugar beet, in ranked order, were (n = 9): 0.04, 0.05, 0.06 (2), 0.09 (2), 0.10, 0.11, and 0.24 mg/kg.

The Meeting decided to use the data on beetroot, carrot, and radish according to the same US GAP to estimate a "root and tuber vegetables" commodity group maximum residue level. The Meeting noted that the results on beetroot, carrot, and radish appear to be from a similar population and decided to combine them. Azoxystrobin residues, in ranked order median underlined were (n = 5): 0.03, 0.13 (2), 0.14, 0.16, 0.17, 0.18, 0.23, 0.26, 0.29, 0.30, 0.32, 0.34, 0.38, and 0.45 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in root and tuber vegetables of 1 mg/kg, an STMR value of 0.23 mg/kg, and a highest residue value of 0.45 mg/kg.

Stalk and stem vegetables

Artichoke, globe

The Meeting received results from supervised trials with azoxystrobin on artichokes in France, Spain, and the USA.

The GAP of France and Spain specify 0.25 kg ai/ha, a maximum three applications, and a PHI of seven days. Five trials in France and one trial in Spain were conducted according to the GAP of France and Spain. Azoxystrobin residues were (n = 6): 0.16, 0.24, 0.30, 0.42, 0.48, and 0.61 mg/kg.

The GAP of the USA for artichokes specifies a maximum of six applications at 0.28 kg ai/ha with total seasonal rate of 1.7 kg ai/ha and a PHI of 0 days. Three trials on artichokes in the USA were conducted according to the US GAP. Azoxystrobin residues were (n = 3): 1.6, <u>1.8</u>, and 2.4 mg/kg.

The Meeting noted that azoxystrobin residues from the US trials according to the US GAP were significantly higher that those from the European trials that were conducted at French GAP, which specifies a lower application rate and a longer PHI. The Meeting considered three trials acceptable for estimation of a maximum residue level for this minor crop.

The Meeting estimated a maximum residue level for azoxystrobin in artichoke, globe of 5 mg/kg and an STMR value of 1.8 mg/kg.

Asparagus

The Meeting received results from supervised trials with azoxystrobin on asparagus in France and the USA.

The GAP of France for asparagus specifies 0.25 kg ai/ha with a maximum of three applications (a PHI is not required). Four trials on asparagus in France were conducted according to

the GAP of France with four applications (PHI of 215–259 days). Azoxystrobin residues from these trials were < 0.01 (4) mg/kg.

The GAP of the USA for asparagus specifies six applications at 0.28 kg ai/ha with total seasonal rate of 1.7 kg ai/ha and a PHI of 100 days. Two trials on asparagus in the USA were conducted according to the US GAP with a PHI of 93 or 104 days. Azoxystrobin residues from both these trials were < 0.02 (2) mg/kg.

The Meeting estimated a maximum residue level for asparagus of 0.01 (*) mg/kg and an STMR value of 0.01 mg/kg.

Celery

The Meeting received results from supervised trials with azoxystrobin used on celery in Italy and the UK. Azoxystrobin residues were determined in trimmed and untrimmed celery.

The GAP of Italy for celery specifies a maximum of three applications at 0.25 kg ai/ha, and a PHI of seven days. Six trials in Italy were conducted at the GAP rate of Italy, with four applications and a PHI of 6–7 days. Azoxystrobin residues in trimmed celery were (n = 6): 0.12, 0.16, 0.19, 0.33, 0.41, and 0.73 mg/kg. Azoxystrobin residues in untrimmed celery were (n = 6): 0.19, 1.0, 1.4, 1.8, 2.0, and 2.5 mg/kg.

Eight trials on celery in the UK were conducted according to the GAP of Germany (0.25 kg ai/ha, two applications, a PHI of 14 days) with 4–7 applications. Azoxystrobin residues in trimmed celery were (n = 8): 0.05, 0.08, 0.09, 0.10, 0.11, 0.23, 0.26, and 0.33 mg/kg. Azoxystrobin residues in untrimmed celery were (n = 7): 0.23, 0.25, 0.28, <u>0.43</u>, 0.96, 2.9 and 3.2 mg/kg.

Based on the data on untrimmed celery in the UK, the Meeting estimated a maximum residue level for azoxystrobin in celery of 5 mg/kg and an STMR value of 0.43 mg/kg.

Witloof chicory (sprouts)

The Meeting received results from supervised trials with azoxystrobin used on witloof chicory in France. The GAP of France specifies a PHI of 21 days, maximum of three applications at 2.5 kg ai/ha for chicons (the edible part) production (treatment of plants) and 0.25 kg ai/ha for root production (treatment of parts).

In five trials, plants were treated twice at the rate of 0.25 kg ai/ha (at intervals of 20-22 days). Fourteen days after the second application mature plants were harvested, the leaves removed, and the roots stored in a climate controlled room.

After 14 days the roots were separated into two batches: the first set of roots were dipped in a solution containing 0.01 kg ai/hL and the second set were sprayed once at a rate of 2.5 kg ai/ha. Following the treatments, hydroponic forcing was performed on both sets of roots in dark climate-controlled rooms. Azoxystrobin residues in chicons from the second set (treatment according to the GAP of France), in ranked order, were (n = 5) 0.03 (2), 0.05, 0.10, and 0.11 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in witloof chicory (sprouts) of 0.3 mg/kg and an STMR value of 0.05 mg/kg.

Cereal grains

The Meeting received results from supervised trials with azoxystrobin used on barley, oat, rye, triticale and wheat in Europe and on maize and rice in the USA.

Barley

The Meeting received results in barley grain from supervised trials with azoxystrobin in France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland, and the UK.

The GAP of France for barley specifies a maximum of two applications at 0.25 kg ai/ha, with a 42-day PHI. The GAP of Spain for barley specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 36 days. The GAPs of Germany, Italy and the Netherlands specify a maximum of two applications at 0.25 kg ai/ha, and a PHI of 35 days. The Meeting decided to consider all trials on barley in continental Europe that were conducted at the GAP rate (\pm 30%) of 0.25 kg ai/ha, 2–3 applications, and a PHI of 35–42 days.

Nineteen trials in France conducted at 72–104% GAP rate, with 2–3 applications and a PHI of 35–42 days (both the highest and lowest residues were obtained at a PHI of 42 days). Azoxystrobin residues, in ranked order, were (n = 19): 0.01 (3), 0.02 (2), 0.03 (2), 0.04 (2), 0.05, 0.08, 0.09, 0.11 (2), 0.12, 0.13 (3), and 0.19 mg/kg.

Two trials in Germany conducted at 100% GAP rate, with three applications, and a PHI of 35 days, resulted in azoxystrobin residues of 0.10 and 0.11 mg/kg. One trial in Germany carried out at 80% GAP rate, with two applications, and a PHI of 37 days resulted in an azoxystrobin residue of 0.02 mg/kg.

Two trials in Italy conducted at 100–104% GAP rate, with two applications, and a PHI of 36 days resulted in azoxystrobin residues of 0.08 and 0.10 mg/kg.

One trial in Netherlands conducted at 100% GAP rate, with two applications, and a PHI of 37 days resulted in azoxystrobin residues of 0.08 mg/kg.

Two trials in Spain conducted at 100% GAP rate, with two applications, and a PHI of 35 days resulted in azoxystrobin residues of 0.03 and 0.11 mg/kg. One trial in Spain carried out at 104% GAP, with two applications, and a PHI of 38 days resulted in an azoxystrobin residue of 0.28 mg/kg.

One trial in Sweden carried out 100% GAP rate, with two applications, and a PHI of 42 days resulted in an azoxystrobin residue of 0.20 mg/kg.

Two trials in Switzerland conducted at 104% GAP rate, with two applications, and a PHI of 36 days resulted in azoxystrobin residues of 0.02 and 0.04 mg/kg. Four trials in Switzerland carried out at 80% GAP, with two applications, and a PHI of 35 days resulted in azoxystrobin residues of 0.01, 0.02 (2) and 0.03 mg/kg.

The GAP of the UK for barley specifies 0.25 kg ai/ha, a maximum two applications, and the latest time of application up to and including watery ripe stage (BBCH growth stage 71). Three trials in the UK were conducted at 100% GAP rate, with three applications, and the last application including growth stage 71 (PHIs at harvest were 38–54 days). Azoxystrobin residues in barley grain were 0.13, 0.14, and 0.23 mg/kg.

Combined azoxystrobin residues in barley grain from the trials in Europe (n = 38), in ranked order median underlined, were: 0.01 (4), 0.02 (6), 0.03 (4), 0.04 (3), 0.05, 0.08 (3), 0.09, 0.10 (2), 0.11 (4), 0.12, 0.13 (4), 0.14, 0.19, 0.20, 0.23, and 0.28 mg/kg.

Oat, rye, and triticale

The Meeting received results in oat, rye, and triticale grain from supervised trials with azoxystrobin in Germany. The GAP of Germany for oat, rye, and triticale specifies a maximum two applications at 0.25 kg ai/ha, and a PHI of 35 days.

Two trials on oat in Germany conducted at 100% GAP rate, with three applications, and a PHI of 35 or 36 days. Azoxystrobin residues were 0.01 and 0.06 mg/kg.

Two trials on rye in Germany conducted at 100% GAP rate, with three applications, and a PHI of 35 days. Azoxystrobin residues were 0.02 and 0.04 mg/kg.

Two trials on triticale in Germany conducted at 100% GAP rate, with three applications, and a PHI of 36 days. Azoxystrobin residues were < 0.01 and 0.02 mg/kg.

Wheat

The Meeting received results in wheat grain from supervised trials with azoxystrobin on wheat in France, Germany, Italy, Spain, Switzerland, and the UK.

The GAP of France for wheat specifies a maximum of two applications at 0.25 kg ai/ha, with a PHI of 42 days. The GAP of Spain for wheat specifies a maximum two applications at 0.25 kg ai/ha, and a PHI of 36 days. The GAPs of Germany, Italy and the Netherlands for barley specify 0.25 kg ai/ha, a maximum two applications, and a PHI of 35 days. The Meeting decided to consider all trials on wheat in continental Europe that were conducted at the GAP rate (\pm 30%) of 0.25 kg ai/ha, 2–3 applications, and a PHI of 35–42 days.

Fourteen trials on wheat in France were conducted at 80-104% GAP rate, with 2–3 applications and a PHI of 35–42 days (the highest and lowest residues were obtained at a PHI of 38 and 35–42 days, respectively). Azoxystrobin residues, in ranked order, were: < 0.01 (5), 0.01 (4), 0.02, 0.03 (3), and 0.14 mg/kg.

Four trials in Germany were conducted at 80-100% GAP rate, with 2–3 applications, and a PHI of 35-42 days (both the highest and lowest residues were obtained at a PHI of 35 days). Azoxystrobin residues, in ranked order, were: < 0.01, 0.01, 0.02 and 0.04 mg/kg.

Two trials in Italy were conducted at 100-104% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues were: < 0.01 and 0.02 mg/kg.

Three trials in Spain were conducted at 100% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues, in ranked order, were: < 0.01, 0.01, and 0.04 mg/kg.

Five trials in Switzerland were conducted at 80-108% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues were: < 0.01 (5) mg/kg.

The GAP of the UK for wheat specifies 0.25 kg ai/ha, a maximum two applications, and the latest time of application up to and including watery ripe stage (BBCH growth stage 71). Three trials in the UK were conducted at 100% GAP rate, with three applications, and the last application including growth stage 71 (PHIs at harvest were 40–59 days). Azoxystrobin residues in wheat grain were: 0.01, 0.02, and 0.03 mg/kg.

Combined azoxystrobin residues in wheat grain from the trials in Europe (n = 31), in ranked order median underlined, were: < 0.01 (13), <u>0.01</u> (7), 0.02 (4), 0.03 (4), 0.04 (2) and 0.14 mg/kg.

The Meeting decided to use the data on barley grain to extrapolate to oat and data on wheat grain to extrapolate to rye and triticale.

The Meeting estimated a maximum residue level for azoxystrobin in barley and oat grain of 0.50 mg/kg and an STMR value of 0.08 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in wheat, rye and triticale grain of 0.20 mg/kg and an STMR value of 0.01 mg/kg.

Maize

The Meeting received results in maize grain from supervised trials with azoxystrobin in the USA.

The GAP of the USA for maize specifies a maximum of eight applications at 0.28 kg ai/ha with a total seasonal application of 2.2 kg ai/ha and a PHI of seven days. Twenty trials in the USA

were conducted on maize according to the US GAP with a PHI of 6–7 days. Azoxystrobin residues in maize grains in these trials were (n = 20): < 0.01 (17), <u>0.01</u> (2), and 0.02 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in maize grain of 0.02 mg/kg and an STMR value of 0.01 mg/kg.

Rice

The Meeting received results in rice grain from supervised trials with azoxystrobin used on rice in the USA.

The GAP of the USA for rice specifies a rate of 0.34 kg ai/ha with a total seasonal rate of 0.78 kg ai/ha and a PHI of 28 days. Sixteen trials were conducted in the USA on rice, in accordance with the US GAP with a maximal seasonal application of 0.78 kg ai/ha (2×0.22 and 1×0.34 kg ai/ha) and a PHI of 26–28 days. Azoxystrobin residues in rice grain, in ranked order median underlined, were (n = 16): 0.07, 0.19, 0.29, 0.30 (2), 0.41, 0.43, <u>0.62</u>, <u>0.74</u>, 0.81, 0.89, 1.6, 2.3, 2.8, 3.0 and 3.3 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in rice grain of 5 mg/kg and an STMR value of 0.68 mg/kg.

Tree nuts

The Meeting received results from supervised trials with azoxystrobin used on almonds, pecans, and pistachios in the USA.

Almonds

The GAP of the USA for almonds specifies a maximum of six applications at 0.28 kg ai/ha with a total authorized seasonal rate of 1.7 kg ai/ha and a PHI of 28 days. Five trials in the USA were conducted on almonds according to the US GAP with a PHI of 28–29 days. Azoxystrobin residues in almonds were (n = 5): < 0.01 (4) and 0.01 mg/kg.

Pecans

The GAP of the USA for pecans specifies 0.22 kg ai/ha with total seasonal application of 1.3 kg ai/ha (six applications) and a PHI of 45 days. Six trials in the USA were conducted on pecans at the US GAP rate with six applications. In four trials with a PHI shorter than 45 days (24–42 days), azoxystrobin residues were < 0.01 (4) mg/kg. In two trials with a PHI of 20–25 days, azoxystrobin residues were 0.01 and 0.02 mg/kg.

Based on the data on almonds and pecans, the Meeting estimated a maximum residue level for azoxystrobin in tree nuts, except pistachios of 0.01 mg/kg and an STMR value of 0.01 mg/kg.

Pistachios

The GAP of the USA for pistachios specifies a rate of 0.28 kg ai/ha with a total seasonal rate of 1.7 kg ai/ha (six applications) and a PHI of seven days. Three trials in the USA were conducted on pistachios according to the US GAP. Azoxystrobin residues were 0.25, <u>0.44</u>, and 0.48 mg/kg. The Meeting considered three trials acceptable for estimation of a maximum residue level for this minor crop.

The Meeting estimated a maximum residue level for azoxystrobin in pistachios of 1 mg/kg and an STMR value of 0.44 mg/kg.

Oilseeds

Cotton seed

The Meeting received results from supervised trials with azoxystrobin used on cotton as in-furrow and foliar treatments in the USA.

For in-furrow treatment, the GAP of the USA specifies 0.019 kg ai/km of row (0.20 oz ai/1000 row feet), which corresponds to the maximum of 0.34 kg ai/ha (for 22-inch rows). Twelve trials were conducted in the USA according to the US GAP for in-furrow treatment immediately before planting. In all these trials, azoxystrobin residues in cottonseed, taken at normal harvest, (PHI of 121–186 days) were < 0.01 (12) mg/kg.

For foliar application, the GAP of the USA for cotton specifies 0.17 kg ai/ha with total seasonal application rate of 0.5 kg ai/ha (three applications) as a foliar spray and a PHI of 45 days. Twelve trials in the USA were conducted with a combined in-furrow application at the planting (0.17 kg ai/ha) and three foliar applications at 0.17 kg ai/ha with a PHI of 45 days. Azoxystrobin residues from these trials, in ranked order, were (n = 12): < 0.01 (5), <u>0.01</u> (2), 0.02, 0.03 (3), and 0.54 mg/kg.

Based on the trials with combined foliar and in-furrow (at-planting) application, the Meeting estimated a maximum residue level for azoxystrobin in cotton seed of 0.7 mg/kg and an STMR value of 0.01 mg/kg.

Peanuts

The Meeting received results from supervised trials with azoxystrobin used on peanuts in the USA.

The GAP of the USA for peanuts specifies a rate of 0.45 kg ai/ha with a seasonal total of 0.9 kg ai/ha (two applications) with a PHI of 14 days. Eleven trials on peanuts in the USA were conducted according to the US GAP with a PHI of 13–14 days. Azoxystrobin residues, in ranked order, were (n = 11): < 0.01 (5), 0.01 (4), 0.06, and 0.13 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in peanut of 0.2 mg/kg and an STMR value of 0.01 mg/kg.

Sunflower seed

The Meeting received results from supervised trials with azoxystrobin used on sunflower in the USA.

The GAP of the USA for sunflower specifies a rate of 0.28 kg ai/ha with a seasonal total of 0.5 kg ai/ha and a PHI of 30 days. Six trials on sunflower in the USA were conducted according to the US GAP with a seasonal application of 0.5 kg ai/ha (three applications of 0.12, 0.26, and 0.12 kg ai/ha) and a PHI of 28–30 days. Azoxystrobin residues, in ranked order, were (n = 6): 0.01, 0.03 (2), 0.05, 0.08, and 0.24 mg/kg.

The Meeting estimated a maximum residue level for sunflower seed of 0.5 mg/kg and an STMR value of 0.04 mg/kg.

Herbs

The Meeting received results from supervised trials with azoxystrobin used on basil, chives, mint, and parsley in the USA.

The GAP of the USA for herbs (including basil, chives, parsley) specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications) and a PHI of 0 days.

Three trials on <u>basil</u> were conducted according to the GAP of the USA for herbs with 5–6 applications. Azoxystrobin residues in fresh basil were: 23, 25, and 48 mg/kg. Four trials on <u>chives</u>

were conducted according to the US GAP. Azoxystrobin residues in fresh chives were 1.1, 2.7, 4.2, and 7.3 mg/kg. Two trials on <u>parsley</u> were conducted according to the US GAP with five or six applications. Azoxystrobin residues in fresh parsley were 17 and 20 mg/kg.

The GAP of the USA for <u>mint</u> specifies 0.28 kg ai/ha with maximal seasonal application of 1.7 kg ai/ha (six applications) and a PHI of 0 days for fresh mint and a PHI of seven days for mint intended for processing. Two trials in the USA were conducted on fresh mint according to the US GAP with a PHI of 0 days. Azoxystrobin residues in fresh mint were 21 and 25 mg/kg. Five trials were conducted on mint intended for processing according to the US GAP with a PHI of seven days (one trial with a PHI of six days). Azoxystrobin residues in the trials with a PHI of seven days were 4.8, 5.48, 8.0, and 12 mg/kg. Azoxystrobin residue from the trial with a PHI of six days was 17 mg/kg.

The Meeting noted that significantly higher residues were obtained in basil, parsley, and mint (with a critical PHI of 0 days) as compared to chives. Also, the residues in basil, mint, and parsley appear to be from a similar population, were obtained using the same US GAP rate and PHI, and could be used to support an "herbs, fresh" commodity maximum residue level. Azoxystrobin residues in fresh herbs, in ranked order, were (n = 7): 17, 20, 21, 23, 25 (2), and 48 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in herbs, (fresh) of 70 mg/kg and an STMR value of 23 mg/kg.

Legume animal feeds

Peanut fodder

The Meeting received results in peanut hay from supervised trials with azoxystrobin on peanuts in the USA.

The GAP of the USA for peanuts specifies an application rate of 0.45 kg ai/ha with a seasonal total of 0.9 kg ai/ha (two applications) and a PHI of 14 days. Eleven trials on peanuts in the USA were conducted according to the US GAP with a PHI of 13–14 days. Azoxystrobin residues, in ranked order, were (n = 11): 1.5, 3.0, 3.1, 3.3, 4.0, <u>4.3</u>, 4.7, 8.3, 8.9, 9.3, and 13 mg/kg. On dry-weight basis (DM=85%), azoxystrobin residues in peanut hay, in ranked order, were (n = 11): 1.8, 3.5, 3.6, 3.9, 4.7, <u>5.1</u>, 5.5, 9.8, 10, 11, and 15 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in peanut fodder of 30 mg/kg, an STMR value of 5.1 mg/kg and a highest residue value of 15 mg/kg.

Soya bean fodder and forage

The Meeting received results in soya bean forage and hay from supervised trials with azoxystrobin used on soya beans in the USA.

The GAP of the USA for soya bean forage and hay specifies 0.28 kg ai/ha, one application and a PHI of 0 days. Nineteen trials on soya beans forage were conducted according to the US GAP. A portion of forage was dried for hay.

Azoxystrobin residues in soya bean forage (n = 19), in ranked order, were: 4.6, 6.8, 7.1, 7.2, 7.4, 7.6, 7.7, 8.3, 8.5, <u>9.4</u>, 9.5, 9.9, 10, 11, 12 (2), 18, 20, and 23 mg/kg.

Azoxystrobin residues in soya bean hay, in ranked order, were (n = 19): 6.8, 16 (2), 22 (2), 24, 27 (2), 28, 31, 33 (2), 34, 37, 38 (2), 43, 51 and 53 mg/kg. On dry-weight basis (DM=85%), azoxystrobin residues in soya bean hay were (n = 19): 8.0, 19 (2), 26 (2), 28, 32 (2), 33, 36, 39 (2), 40, 44, 45 (2), 51, 60, and 62 mg/kg.

The Meeting estimated an STMR value of 9.4 mg/kg and a highest residue value of 23 mg/kg for azoxystrobin in soya bean forage and a maximum residue level for azoxystrobin in soya bean

fodder (dry-weight basis) of 100 mg/kg, an STMR value of 36 mg/kg, and a highest residue value of 62 mg/kg.

Straw and fodder (dry) of cereal grains

The Meeting received results in cereal straw from supervised trials with azoxystrobin used on barley, oat, rye, triticale and wheat in Europe and rice in the USA. The Meeting also received results in maize fodder from supervised trials with azoxystrobin used on maize in the USA.

Barley straw

The Meeting received results in barley straw from supervised trials with azoxystrobin used on barley in France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland, and the UK.

The GAP of France for barley specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 42 days. The GAP of Spain for barley specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 36 days. The GAPs of Germany, Italy and the Netherlands for barley specify 0.25 kg ai/ha, a maximum two applications, and a PHI of 35 days. For barley straw, the Meeting decided to consider all trials on barley in continental Europe that were conducted at the GAP rate $(\pm 30\%)$ of 0.25 kg ai/ha, 2–3 applications, and a PHI of 35–42 days.

Seventeen trials in France were conducted at 72–100% GAP rate, with 2–3 applications and a PHI of 35–42 days (both the highest and lowest residues were obtained at a PHI of 42 days). Azoxystrobin residues, in ranked order, were: 0.53, 0.65, 0.67, 0.72, 0.82, 0.84, 0.91 (2), 1.2, 1.3 (3), 1.6 (2), 2.9, 3.6 and 3.7 mg/kg.

Two trials in Germany were conducted at the GAP rate, with three applications, and a PHI of 35 days, resulting in azoxystrobin residues of 2.2 and 2.9 mg/kg. One trial in Germany was carried out at 80% GAP rate, with two applications, and a PHI of 37 days. Azoxystrobin residue was 0.58 mg/kg.

Two trials in Italy were conducted at 100–104% GAP rate, with two applications, and a PHI of 36 days. Azoxystrobin residues were 2.3 (2) mg/kg.

One trial in Netherlands was conducted at the GAP rate, with two applications, and a PHI of 37 days. Azoxystrobin residue was 1.5 mg/kg.

One trial in Spain was conducted at the GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residue was 1.2 mg/kg. One trial in Spain was carried out at 104% GAP, with two applications, and a PHI of 38 days. Azoxystrobin residue was 5.5 mg/kg.

One trial in Sweden was carried out the GAP rate, with two applications, and a PHI of 42 days. Azoxystrobin residue was 5.3 mg/kg.

Two trials in Switzerland were conducted at 104% GAP rate, with two applications, and a PHI of 36 days. Azoxystrobin residues were 0.39 and 0.48 mg/kg. Four trials in Switzerland were carried out at 80% GAP, with two applications, and a PHI of 35 days. Azoxystrobin residues were 0.50, 0.61, 0.71, and 0.94 mg/kg.

The GAP of the UK for barley specifies 0.25 kg ai/ha, a maximum two applications, and the latest time of application up to and including watery ripe stage (growth stage 71). Three trials in the UK were conducted at the GAP rate, with three applications, and the last application including growth stage 71 (PHIs at harvest were 38–54 days). Azoxystrobin residues in barley straw were 1.6, 3.4, and 4.5 mg/kg.

Combined azoxystrobin residues in barley straw from the trials in Europe (n = 35), in ranked order, were: 0.39, 0.48, 0.50, 0.53, 0.58, 0.61, 0.65, 0.67, 0.71, 0.72, 0.82, 0.84, 0.91 (2), 0.94, 1.2 (2), 1.3 (3), 1.5, 1.6 (3), 2.2, 2.3 (2), 2.9 (2), 3.4, 3.6, 3.7, 4.5, 5.3, and 5.5 mg/kg.

On dry-weight basis (DM=89%), azoxystrobin residues in barley straw were (*n* = 35): 0.44, 0.54, 0.56, 0.60, 0.65, 0.69, 0.73, 0.75, 0.80, 0.81, 0.92, 0.94, 1.0 (2), 1.1, 1.3 (2), 1.5 (3), 1.7, 1.8 (3), 2.5, 2.6 (2), 3.3 (2), 3.8, 4.0, 4.2, 5.1, 6.0, and 6.2 mg/kg.

Maize fodder

The Meeting received results in maize fodder from supervised trials with azoxystrobin used on maize in the USA.

The GAP of the USA for maize specifies 0.28 kg ai/ha with maximal seasonal application of 2.2 kg ai/ha (eight applications) and a PHI of seven days. Twenty trials in the USA were conducted on maize according to the US GAP with a PHI of 6–7 days. Azoxystrobin residues in maize fodder, in ranked order, were (n = 20), 0.88, 1.1, 2.5, 2.6 (2), 2.9, 3.1, 3.2, 3.5, 4.0, 4.4, 4.7, 5.2, 5.3, 7.8, 8.7 (2), 9.3, 16, and 21 mg/kg.

On dry-weight basis (DM=83%), azoxystrobin residues in maize fodder were (n = 20), 1.1, 1.3, 3.0, 3.1 (2), 3.5, 3.7, 3.9, 4.2, <u>4.8</u>, <u>5.3</u>, 5.7, 6.3, 6.4, 9.4, 10 (2), 11, 19, and 25 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in maize fodder (dryweight basis) of 40 mg/kg, an STMR value of 5.0 mg/kg, and a highest residue value of 25 mg/kg.

Oat, rye and triticale straw

The Meeting received results in oat, rye, and triticale straw from supervised trials with azoxystrobin in Germany. The GAP of Germany for oat, rye, and triticale specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 35 days.

Two trials on oat in Germany were conducted at the GAP rate, with three applications, and a PHI of 35 or 36 days. Azoxystrobin residues were 1.0 and 1.5 mg/kg. On dry-weight basis (DM=90%), azoxystrobin residues in oat straw were (n = 2), 1.1 and 1.6 mg/kg.

Two trials on rye in Germany were conducted at the GAP rate, with three applications, and a PHI of 35 days (higher residues were obtained at 42 and 44-day PHIs). Azoxystrobin residues were 2.0 and 2.7 mg/kg. On dry-weight basis (DM=88%), azoxystrobin residues in rye straw were (n = 2) 2.3 and 3.1 mg/kg.

Two trials on triticale in Germany were conducted at the GAP rate, with three applications, and a PHI of 36 days. Azoxystrobin residues were 1.4 and 1.5 mg/kg. On dry-weight basis (DM=90%), azoxystrobin residues in triticale straw were (n = 2), 1.6 and 1.7 mg/kg.

Rice straw

The Meeting received results in rice straw from supervised trials with azoxystrobin used on rice in the USA.

The GAP of the USA for rice specifies 0.34 kg ai/ha with maximal seasonal application of 0.78 kg ai/ha and a PHI of 28 days. Sixteen trials in the USA were conducted on rice according to the US GAP with a maximal seasonal application of 0.78 kg ai/ha (2×0.22 and 1×0.34 kg ai/ha) and a PHI of 26–28 days. Azoxystrobin residues in rice straw (n = 16), in ranked order, were: 0.59, 0.62, 0.78, 0.84, 0.91, 1.9, 2.6, 2.7, 3.2, 4.1, 4.2 (2), 5.0, 6.4, 6.9, and 10 mg/kg.

On dry-weight basis (DM=90%), azoxystrobin residues in rice straw were (n = 16): 0.66, 0.69, 0.87, 0.93, 1.0, 2.1, 2.9, 3.0, 3.6, 4.6, 4.7 (2), 5.6, 7.1, 7.7, and 11 mg/kg.

Wheat straw

The Meeting received results in wheat straw from supervised trials with azoxystrobin used on wheat in France, Germany, Italy, Spain, Switzerland, and the UK.

The GAP of France for wheat specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 42 days. The GAP of Spain for wheat specifies 0.25 kg ai/ha, a maximum two applications, and a PHI of 36 days. The GAPs of Germany, Italy and the Netherlands for barley specify 0.25 kg ai/ha, a maximum two applications, and a PHI of 35 days. The Meeting decided to consider all trials on wheat in continental Europe that were conducted at the GAP rate (\pm 30%) of 0.25 kg ai/ha, 2–3 applications, and a PHI of 35–42 days.

Thirteen trials on wheat in France were conducted at 80–104% GAP rate, with 2–3 applications and a PHI of 35–42 days. Azoxystrobin residues in wheat straw, in ranked order, were: 0.36, 0.73, 0.75, 0.81, 0.83, 1.7, 1.8, 2.3, 2.4, 2.5, 3.2, 3.5, and 6.2 mg/kg.

Four trials in Germany were conducted at 80–100% GAP rate, with 2–3 applications, and a PHI of 35–42 days (both the highest and lowest residues were obtained at a PHI of 35 days). Azoxystrobin residues, in ranked order, were: 0.36, 0.50, 1.2, and 1.7 mg/kg.

Two trials in Italy were conducted at 100–104% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues were 1.6 and 3.8 mg/kg.

Three trials in Spain were conducted at the GAP rate, with two applications, and a PHI of 35 and 41 days (the 41-day PHI gave the highest residue). Azoxystrobin residues, in ranked order, were: 1.2, 1.9, and 3.5 mg/kg.

Five trials in Switzerland were conducted at 80–108% GAP rate, with two applications, and a PHI of 35 days. Azoxystrobin residues were: 0.22, 0.41 (2), 0.46, and 0.58 mg/kg.

The GAP of the UK for wheat specifies 0.25 kg ai/ha, a maximum two applications, and the latest time of application up to and including watery ripe stage (BBCH growth stage 71). Three trials in the UK were conducted at the GAP rate, with three applications, and the last application including growth stage 71 (PHIs at harvest were 40–59 days). Azoxystrobin residues in wheat straw were 1.6, 2.3, and 5.7 mg/kg.

Combined azoxystrobin residues in wheat straw from the trials in Europe (n = 30), in ranked order, were: 0.22, 0.36 (2), 0.41 (2), 0.46, 0.50, 0.58, 0.73, 0.75, 0.81, 0.83, 1.2 (2), 1.6 (2), 1.7 (2), 1.8, 1.9, 2.3 (2), 2.4, 2.5, 3.2, 3.5 (2), 3.8, 5.7, and 6.2 mg/kg.

On dry-weight basis (DM=88%), azoxystrobin residues in wheat straw were (n = 30): 0.25, 0.41 (2), 0.47 (2), 0.52, 0.57, 0.66, 0.83, 0.85, 0.92, 0.94, 1.4 (2), 1.8 (2), 1.9 (2), 2.0, 2.2, 2.6 (2), 2.7, 2.8, 3.6, 4.0 (2), 4.3, 6.5, and 7.0 mg/kg.

The Meeting agreed that the data on barley, oat, rice, rye, triticale, and wheat straw appear to be from a similar population and could be combined to estimate a "Straw and fodder (dry) of cereal grains, except maize" commodity group maximum residue level. On dry-weight basis, azoxystrobin residues, in ranked order median underlined, were (n = 87): 0.25, 0.41 (2), 0.44, 0.47 (2), 0.52, 0.54, 0.56, 0.57, 0.60, 0.65, 0.66 (2), 0.69 (2), 0.73, 0.75, 0.80, 0.81, 0.83, 0.85, 0.87, 0.92 (2), 0.93, 0.94 (2), 1.0 (3), 1.1 (2), 1.3 (2), 1.4 (2), 1.5 (3), 1.6, <u>1.7</u> (3), 1.8 (5), 1.9 (2), 2.0, 2.1, 2.2, 2.3, 2.5, 2.6 (4), 2.7, 2.8, 2.9, 3.0, 3.1, 3.3 (2), 3.6 (2), 3.8, 4.0 (3), 4.2, 4.3, 4.6, 4.7 (2), 5.1, 5.6, 6.0 6.2, 6.5, 7.0, 7.1, 7.7, and 11 mg/kg.

On dry-weight basis, the Meeting estimated a maximum residue level for straw and fodder (dry) of cereal grains, except maize of 15 mg/kg, an STMR value of 1.7 mg/kg, and a highest residue value of 11 mg/kg.

Forage of cereal grains

The Meeting received results in cereal forages from supervised trials with azoxystrobin used on barley, oat, rye, triticale and wheat in Europe and on maize in the USA.

Barley, oat, rye, triticale and wheat forage

The Meeting received results in barley and wheat forage from supervised trials with azoxystrobin applied to barley and wheat in France, Germany, Italy, the Netherlands (barley only), Spain, Switzerland, and the UK. The Meeting also received results in oat, rye, and triticale forage from supervised trials in Germany.

The GAPs in Europe do not specify a PHI for cereal forage. In the case of livestock grazing, it is assumed that animals are unlikely to be foraging within seven days of the application of the fungicide. Therefore, the Meeting decided to consider all trials conducted at \pm 30% of the GAP rate available in Europe (0.25 kg ai/ha), with 2–3 applications and with forage data obtained at a PHI of seven days.

Azoxystrobin residues in <u>barley forage</u> (n = 10), in ranked order, were: 0.54, 0.73, 0.75, 1.1, <u>1.6, 1.8, 1.9, 3.8, 3.9</u>, and 4.0 mg/kg.

Azoxystrobin residues in wheat forage (n = 10), in ranked order, were: 0.61, 1.4, 1.6 (2), 1.8, 1.9, 2.9, 3.2, 4.0, and 5.4 mg/kg.

For oat, rye, and triticale, the Meeting received residue data in forage for days 0 and 20–23 from seven trials.

The Meeting decided to use the data on barley forage to extrapolate to oat forage and data on wheat forage to extrapolate to rye and triticale forage. The Meeting estimated an STMR value of 1.7 mg/kg and a highest value of 4.0 mg/kg for azoxystrobin in barley and oat forage. The Meeting estimated an STMR value of 1.9 mg/kg and a highest residue value of 5.4 mg/kg for azoxystrobin in wheat, rye and triticale forage.

Maize forage

The Meeting received results in maize forage from supervised trials of azoxystrobin applied to maize in the USA.

In the 20 maize trials, harvested for grain and fodder, in the USA (conducted according to the US GAP of 0.28 kg ai/ha with a seasonal total rate of 2.2 kg ai/ha), forage was harvested at the milk stage, 6–7 days after the sixth application (out of eight applications for fodder and grain) of azoxystrobin. Azoxystrobin residues in maize forage (n = 20), in ranked order, were: 0.49, 0.58, 0.65, 0.83, 0.94, 1.0, 1.1, 1.2 (2), 1.5, 1.7, 2.4, 2.7, 2.8 (3), 2.9, 3.6, 3.8, and 7.2 mg/kg.

The Meeting estimated an STMR value of 1.6 mg/kg and a highest residue value of 7.2 mg/kg for azoxystrobin in maize forage.

Sugar beet leaves and tops

The Meeting received results in sugar beet tops from supervised trials with azoxystrobin in the USA. The GAP of the USA for root vegetables (both for leaves and root) specifies a rate of 0.37 kg ai/ha with a seasonal total of 2.2 kg ai/ha (six applications) and a PHI of 0 days.

Nine trials on sugar beet were conducted in the USA according to the US GAP for root vegetables. Azoxystrobin residues in sugar beet tops, in ranked order, were: 5.8, 8.7, 9.5, 11, $\underline{16}$ (2), 22, 25, and 44 mg/kg.

The Meeting estimated an STMR value of 16 mg/kg and a highest residue value of 44 mg/kg for azoxystrobin in sugar beet tops.

Dried herbs

The Meeting received results in dried herbs from supervised trials with azoxystrobin used on basil, chives, and parsley in the USA and on hops in Germany and the UK.

Basil, chives and parsley, dry

The GAP of the USA for herbs (including basil, chives, parsley) specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications) and a PHI of 0 days.

Two trials on basil were conducted in the USA according to the US GAP. Azoxystrobin residues in dried basil were 139 and 235 mg/kg.

Three trials on chives were conducted in the USA according to the US GAP. Azoxystrobin residues in dried chives were 27, 31, and 45 mg/kg.

Two trials on parsley were conducted in the USA according to the US GAP with five or six applications. Azoxystrobin residues in dried parsley were 135 and 165 mg/kg.

The Meeting decided to use the results on dried basil and parsley for the estimation of a maximum residue level for dried herbs, except dry hops. Azoxystrobin residues were (n = 4), 135, 139, 165, and 235 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in dried herbs, except dry hops of 300 mg/kg and an STMR value of 152 mg/kg.

Hops, dry

The GAP of Germany for hops specifies a rate of 0.19 kg ai/ha up to BBCH 37, 0.25 kg ai/ha up to BBCH 55, and 0.4 kg ai/ha above BBCH 55, with a total seasonal rate of 0.8 kg ai/ha and a PHI of 28 days.

Four trials on hops in the UK were carried out using six applications of 0.4 kg ai/ha and a PHI of 28 days or two applications at 0.20 kg ai/ha, followed by two applications at 0.30 kg ai/ha and two applications at 0.40 kg ai/ha, with a PHI of 27–28 days. Azoxystrobin residues were (n = 4) 0.83, 1.1, 1.3, and 2.2 mg/kg.

Four trials on hops in Germany were carried out using two applications at 0.23–0.25 kg ai/ha, followed by two applications at 0.30–0.36 kg ai/ha and two applications at 0.40–0.46 kg ai/ha, with a PHI of 26–28 days. Azoxystrobin residues were (n = 4): 5.7, <u>11</u> (2), and 12 mg/kg.

Based on the data from the German trials, the Meeting estimated a maximum residue level for azoxystrobin in hops, dry of 30 mg/kg and an STMR value of 11 mg/kg.

Almond hulls

The Meeting received results in almond hulls from supervised trials with azoxystrobin on almonds in the USA.

The GAP of the USA for almonds specifies a rate of 0.28 kg ai/ha with a seasonal total of 1.7 kg ai/ha (six applications) and a PHI of 28 days. Five trials in the USA were conducted on almonds according to the US GAP. Almonds were harvested slightly immature (PHI of 28–29 days) and mature (PHI of 43–44 days). In each trial, azoxystrobin residues in hulls of the mature almonds were higher than those in slightly immature almonds (a PHI specified in the US GAP). Azoxystrobin residues in hulls of mature almonds, in ranked order, were (n = 5): 0.69, 1.5, <u>1.9</u>, 2.1, and 3.0 mg/kg.

On dry-weight basis (DM=90%), azoxystrobin residues in almond hulls, in ranked order, were (n = 5): 0.77, 1.7, 2.1, 2.3, and 3.3 mg/kg.

On dry-weigh basis, the Meeting estimated a maximum residue level for azoxystrobin almond hulls of 7 mg/kg and an STMR value of 2.1 mg/kg.

Fate of residues during processing

The Meeting received information on the fate of azoxystrobin residues during processing of oranges, grapes, plums, tomato, barley, corn, rice, wheat, soya beans, sunflower, and peanuts and on azoxystrobin fate under hydrolysis conditions simulating commercial food processing.

In a high-temperature hydrolysis study, 97-101% of radiolabelled azoxystrobin remained under conditions simulating industrial processing (temperatures ranging from 90-120 °C; pH 4–6). Therefore, azoxystrobin can be considered stable to simulated pasteurization, baking, brewing, boiling and sterilization.

The processing factors obtained in the processing studies and estimated STMR-P values are summarized in the table below.

Raw agricultural commodity		Processed c	Processed commodity				
N	STMR	CON	N	Processing	STMR-P		
Name	(mg/kg)	CCN	Name	factor ^a	(mg/kg)		
Orange ^b	4.9	JF 0004	Orange juice	< 0.08	0.39		
			Orange oil, cold-pressed	4.8	24		
		AB 0001	Citrus pulp, dry	1.9	9.3		
Grapes	0.53		Distillate	< 0.04	0.02		
		DF 0269	Dried grapes (raisins)	0.45	0.24		
		JF 0269	Grape juice	0.36	0.19		
			Grape must	0.52	0.28		
		AB 0269	Grape pomace, dry	5.0	2.7		
			Grape pomace, wet	3.1	1.6		
			Pasteurized wine	0.54	0.29		
			Spirit	< 0.04	0.02		
			Wine	0.67	0.36		
Plum ^c	0.74	DF 0014	Prunes	0.19	0.14		
Tomato ^d	0.44		Tomato conserve	< 0.12	0.05		
		JF 0448	Tomato juice	0.36	0.16		
			Tomato ketchup	0.47	0.21		
		VW 0448	Tomato paste	2.6	1.1		
			Tomato pomace, dry	24	11		
			Tomato pomace, wet	9.2	4.0		
			Tomato puree	0.8	0.35		
Barley	0.08		Barley malt	0.10	0.01		
			Barley roots	0.45	0.04		
			Barley spent grain	0.15	0.01		
			Beer	0.03	0.002		
Maize	0.01	CF 1255	Maize flour	0.73	0.01		
			Maize grits	0.27	0.003		
		CF 0645	Maize meal	0.55	0.01		
		OP 0645	Maize oil, refined	0.64	0.01		
		01 0043	(dry milling)				
		OP 0645	Maize oil, refined	6.1	0.06		
		UK 0043	(wet milling)				

Raw agricultural commodity		Processed c	Processed commodity				
NT	STMR	CON	NT	Processing	STMR-P		
Name	(mg/kg)	CCN	Name	factor ^a	(mg/kg)		
			Maize starch	< 0.09	0.001		
Rice	0.68	CF 0649	Rice bran, processed	1.2	0.82		
		CM 1205	Rice grain, polished	0.09	0.06		
		CM 1207	Rice hulls	4.8	3.3		
Wheat	0.01	CF 0654	Wheat bran	0.38	0.004		
		CP 1211	Wheat bread, white	0.13	0.001		
		CP 1212	Wheat bread, wholemeal	< 0.13	0.001		
		CF 1210	Wheat flour, low grade	0.25	0.003		
		CF 1210	Wheat flour, patent	0.25	0.003		
		CF 1212	Wheat flour, wholemeal	0.25	0.003		
			Wheat shorts	0.13	0.001		
Soya beans	0.06	AB 0541	Soya bean hulls	2.2	0.13		
		AB 1265	Soya bean meal	0.09	0.01		
		OR 0541	Soya bean oil, refined	0.77	0.05		
Sunflower	0.04		Sunflower meal	< 0.08	0.003		
		OR 0702	Sunflower oil, refined	0.15	0.01		
Peanuts	0.01		Peanut meal	1.0	0.01		
		OC 0697	Peanut oil, crude	4.0	0.04		
		OR 0697	Peanut oil, refined	3.0	0.03		

^a Processing factors were mostly obtained in a single study on each crop, except for grapes (4 studies, but a single study for raisins) and tomato (3 studies), in which case a median processing factor was calculated.

^b STMR and HR values for citrus fruit commodity group.

^c STMR and HR values for stone fruit commodity group.

^d STMR and HR values for fruiting vegetables, other that cucurbits, except fungi and sweet corn commodity group.

Based on the STRM-P value of 0.06 mg/kg, the Meeting estimated a maximum residue level of 0.1 mg/kg for azoxystrobin in maize oil, refined.

Farm animal dietary burden

The Meeting estimated the dietary burden of azoxystrobin in farm animals on the basis of the diets listed in Annex 6 of the 2006 JMPR Report (OECD Feedstuffs Derived from Field Crops). Calculation from the highest residue, STMR (some bulk commodities) and STMR-P values provides the levels in feed suitable for estimating maximum residue levels, while calculation from STMR and STMR-P values for feed is suitable for estimating STMR values for animal commodities.

The table below shows estimated maximum and mean dietary burdens for beef cattle, dairy cattle, broilers, and laying poultry based on the animal diets from the United States/Canada, the European Union, and Australia. The calculations are provided in Annex 6.

		Azoxystrobin, Animal dietary burden (ppm of dry matter diet)				
		US-Canada	EU	Australia		
Beef cattle	Maximum	34	55	58		
	Mean	15	19	32 ^a		
Dairy cattle	Maximum	33	72 ^b	39		
	Mean	16	27 °	20		
Poultry - broiler	Maximum	0.44	0.62	0.59		
	Mean	0.44	0.40	0.59		
Poultry - layer	Maximum	0.44	23 ^d	0.59		
	Mean	0.44	9.1 ^e	0.59		

^a Highest mean beef cattle dietary burden suitable for STMR estimates for mammalian meat.

^b Highest maximum cattle dietary burden suitable for MRL estimates for milk and mammalian meat.

^c Highest mean dairy cattle dietary burden suitable for STMR estimates for milk.

^d Highest maximum poultry dietary burden suitable for MRL estimates for poultry meat and eggs.

^e Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs.

Farm animal feeding studies

The Meeting received information on lactating dairy cow and laying hen feeding studies.

Fifteen lactating cows were randomly assigned among five dosing groups of three animals each: one control group and four groups dosed at one of three azoxystrobin feeding levels each (5, 25, 75 and 250 ppm based on measured feed intake). All groups were fed for 30 consecutive days. Milk samples were taken twice a day and the daily production bulked into one single sample per cow. Samples of milk collected on days 21–23 were processed into cream and skimmed milk. Average fat contents in the whole milk and cream were 3.7% and 55%, respectively.

Azoxystrobin residues in whole milk, skimmed milk, milk cream and tissues obtained at the 5, 25, 75 and 250 ppm dosing levels in the diet are summarized in the table below.

Matrix	Dose (ppm)	Highest residue, mg/kg	Mean residue, mg/kg
Whole milk	5	0.003	0.002
	25	0.006	0.002
	75	0.004	0.002
	250	0.009	0.004
Skimmed milk	5	< 0.001	< 0.001
	25	< 0.001	< 0.001
	75	0.001	0.001
	250	0.003	0.002
Milk cream	5	< 0.01	< 0.01
	25	< 0.01	< 0.01
	75	0.02	0.01
	250	0.04	0.03
Muscle	5	< 0.01	< 0.01
	25	< 0.01	< 0.01
	75	< 0.01	< 0.01
	250	< 0.01	< 0.01
Liver	5	< 0.01	< 0.01
	25	0.01	0.01
	75	0.05	0.03
	250	0.07	0.05
Kidney	5	< 0.01	< 0.01
-	25	< 0.01	< 0.01

Matrix	Dose (ppm)	Highest residue, mg/kg	Mean residue, mg/kg
	75	0.01	0.01
	250	0.02	0.02
Fat ^a	5	< 0.01	< 0.01
	25	< 0.01	< 0.01
	75	0.03	0.02
	250	0.03	0.02

^a Residues in peritoneal fat, which were higher than residues obtained in subcutaneous fat.

The azoxystrobin residues in muscle were lower than in fat. Also, azoxystrobin accumulated in the cream when whole milk was processed to skimmed milk and cream.

In a hen feeding study, forty eight laying hens were divided into four groups and each group was divided into three pens holding four birds each. Each group was fed for 28 consecutive days with a nominal dose rate of 0, 6, 18, or 60 ppm of azoxystrobin in the diet. Eggs were collected twice daily and the total daily production for each group bulked. On day 21, the eggs were separated into egg yolk and egg white.

At the 60 ppm dosing level in the diet, azoxystrobin residues in eggs (whole egg, egg white, egg yolk) and tissues (muscle, liver, and fat) were < 0.01 mg/kg in all analysed samples. No analyses were carried out on the samples from the lower dose rate groups.

Animal commodity maximum residue levels

The dietary burdens for the estimation of maximum residue levels for azoxystrobin in animal commodities are 72 ppm for cattle and 22 ppm for poultry. The dietary burdens for the estimation of STMR values for animal commodities are 32 ppm for beef cattle, 27 ppm for dairy cattle and 9.1 ppm for poultry.

In the table below, dietary burdens for cattle are shown in round brackets (), feeding levels and resulting residue concentrations in square brackets [], and estimated azoxystrobin concentration related to the dietary burdens are shown without brackets.

Dietary burden (ppm) Feeding level [mg/kg]	Milk	Cream	Muscle	Liver	Kidney	Fat
MRL Cattle	Mean	Mean	Highest	Highest	Highest	Highest
(72)	0.002	0.01	< 0.01	0.048	0.01	0.029
[25, 75]	[0.002,	[< 0.01,	[< 0.01,< 0.0		[< 0.01,	[< 0.01,
	0.002]	0.01]	1]	[0.01, 0.05]	0.01]	0.03]
STMR Beef Cattle			Mean	Mean	Mean	Mean
(32)			< 0.01	0.013	0.01	0.01
[25, 75]			[< 0.01,	[0.01, 0.03]	[< 0.01,	[< 0.01,
			< 0.01]		0.01]	0.02]
STMR Dairy Cattle	Mean	Mean				
(27)	0.002	0.01				
[25, 75]	[0.002,	[< 0.01,				
	0.002]	0.01]				

Maximum dietary burden of 72 ppm for cattle is very close to the 75 ppm dosing level in the cattle feeding study. The residues in muscle were significantly lower (all < 0.01 mg/kg even at the dosing level of 250 ppm) than in fat. Based on the highest residues at the dosing levels of 25 and 75

Based on the mean residues for the dosing levels of 25 and 75 ppm, the interpolated (estimated) mean residues for the beef cattle dietary burden of 32 ppm were 0.013 mg/kg in liver, < 0.01 mg/kg in kidney, and 0.01 mg/kg in fat.

On the fat basis, the Meeting estimated a maximum residue level of 0.05 mg/kg for meat (fat) from mammals (other than marine mammals) and an STMR value of 0.01 mg/kg. Based on the liver results, the Meeting estimated a maximum residue level of 0.07 mg/kg for mammalian edible offal and an STMR value of 0.01 mg/kg.

Based on the mean residues for the dosing levels of 25 and 75 ppm, the interpolated (estimated) mean residues for the dairy cattle dietary burdens of 72 ppm and 27 ppm were in both cases 0.002 mg/kg in milk and 0.01 mg/kg in cream. Based on the average fat content in the cream (55 in the feeding study), the calculated mean residue in milk fats would be 0.018 mg/kg.

The Meeting estimated a maximum residue level for azoxystrobin in whole milk of 0.01 mg/kg and an STMR value of 0.01 mg/kg. The Meeting estimated a maximum residue level for azoxystrobin in milk fats of 0.03 mg/kg and an STMR value of 0.03 mg/kg.

For poultry, the maximum dietary burden of 22 ppm is lower that the dose level of 60 ppm in the hen feeding study, which resulted in azoxystrobin residues < 0.01 mg/kg in eggs and tissues. The Meeting estimated maximum residue levels of 0.01 (*) mg/kg and STMR value of 0 mg/kg for poultry meat (fat), poultry edible offal, and eggs.

DIETARY RISK ASSESSMENT

Long-term intake

The International Estimated Daily Intakes (IEDIs) of azoxystrobin based on STMR and STMR-P values estimated for 82 commodities or commodity groups for the thirteen GEMS/Food regional diets were 2-10% of the maximum ADI (0.2 mg/kg bw). The results are shown in Annex 3 of the Report. The Meeting concluded that the long-term dietary intake of azoxystrobin residues is unlikely to present a public health concern.

Short-term intake

The 2008 Meeting decided that an ARfD for azoxystrobin is unnecessary and concluded that the short-term dietary intake of azoxystrobin is unlikely to present a public health concern.