

A.L. 97 ta' l-2005

**ATT DWAR IS-SERVIZZI VETERINARJI  
(KAP. 437)**

**Regoli ta' l-2005 dwar Metodi ta' Tehid ta' Kampjuni u Metodi  
ta' Analizi għall-Kontroll Uffiċjali tal-Livelli ta' ċertu  
Kontaminanti fl-Għalf**

BIS-SAHHA tas-setgħa mogħtija bl-artikolu 25 ta' l-Att dwar is-Servizzi Veterinarji, il-Ministru ta' l-Affarijiet Rurali u l-Ambjent għamel dawn ir-regoli li ġejjin:-

**1.** (1) It-titlu ta' dawn ir-regoli huwa Regoli ta' l-2005 dwar Metodi ta' Tehid ta' Kampjuni u Metodi ta' Analizi għall-Kontroll Uffiċjali tal-Livelli ta' ċertu Kontaminanti fl-Għalf. Titlu u skop.

(2) L-iskop ta' dawn ir-regoli hu l-implimentazzjoni tar-regoli mnizzla taht id-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 98/53/KE dwar metodi ta' tehid ta' kampjuni u metodi ta' analizi għall-kontroll uffiċjali tal-livelli ta' ċertu kontaminanti fl-għalf.

**2.** Għall-ghan ta' dawn ir-regoli -

Tifsir.

“l-awtorità kompetenti” tfisser is-Servizzi Veterinarji f'Malta kif pprovdut taht l-artikolu 2 ta' l-Att dwar is-Servizzi Veterinarji, jew kull awtorità oħra meta dik ir-responsabbiltà tkun hiet delegata lilha mis-Servizzi Veterinarji;

**3.** L-awtorità kompetenti għandha tiehu l-mizuri neċessarji biex tiżgura illi t-tehid ta' kampjuni għall-kontroll uffiċjali tal-livelli ta' aflatoxins fl-għalf huwa magħmul skond il-metodi mnizzla fi Skeda I li tinsab ma' dawn ir-regoli.

Mizuri neċessarji biex jihi żgurat it-tehid ta' kampjuni għall-kontroll uffiċjali tal-livelli ta' aflatoxins fl-għalf.

**4.** L-awtorità kompetenti għandha tiehu l-mizuri neċessarji biex tiżgura illi preparazzjoni ta' kampjuni u metodi ta' analizi użati għall-kontroll uffiċjali tal-livelli ta' aflatoxins fl-għalf huma konformi mal-kriterji mnizzla fi Skeda II li tinsab ma' dawn ir-regoli.

Mizuri neċessarji biex tihi żgurata preparazzjoni ta' kampjuni u metodi ta' analizi għall-kontroll uffiċjali tal-livelli ta' aflatoxins fl-għalf.

*SKEDA I*

**Metodi ta' tehid ta' kampjuni għall-kontroll uffiċjali tal-livelli ta' *aflatoxins* f'ċertu għalf**

**1. Għan u Skop**

Kampjuni mahsuba għall-kontroll uffiċjali tal-livelli ta' kontenut ta' *aflatoxin* fl-għalf għandhom jittieħdu skond il-metodi deskritti hawn taht. Is-somma kollha ta' kampjuni hekk miksuba għandhom jiġu kkunsidrati bħala rappreżentattivi tal-lottijiet. Konformità mal-livelli massimi mniżżla fir-Regoli tal-Kummissjoni Ewropea 98/1525/KE għandha tkun stabbilita fuq il-bażi tal-livelli determinati fil-kampjuni tal-laboratorju.

**2. Definizzjonijiet**

*Lott:* kwantità identifikabbli ta' komodità ta' ikel li jasal f'hin wiehed u determinat mill-ufficjal bħala li għandu karatteristiċi komuni, bħal oriġini, varjetà, tip ta' pakkettjar, min jippakkettja, konsenjatur jew marki.

*Sublott:* parti desinjata minn lott akbar sabiex japplika l-metodu ta' tehid ta' kampjuni fuq dik il-parti desinjata. Kull sublott għandu jkun fiżikament separat u identifikabbli.

*Kampjun inkriminali:* kwantità ta' materjal mehud minn minn post wiehed fil-lott jew sublott.

*Kampjun aggregat:* it-total kombinat tal-kampjuni kollha inkriminali mehuda mil-lott jew sublott.

*Kampjun tal-laboratorju:* kampjun mahsub għall-laboratorju (= subkampjun).

### **3. Disposizzjonijiet ġenerali**

#### **3.1. *Persunal***

Tehid ta' kampjuni għandu jsir minn persuna awtorizzata kif speċifikat mill-awtorità kompetenti.

#### **3.2. *Materjal li minnu għandu jittiehed kampjun***

Kull lott li għandu jkun eżaminat għandu jittiehed kampjun minnu separatament. Skond id-disposizzjonijiet speċifiċi f'punt 5 ta' din l-Iskeda, lottijiet kbar għandhom ikunu subdiviżi f'sublottijiet biex minnhom jittiehed kampjun separatament.

#### **3.3. *Prekawzjonijiet li għandhom jittiehdu***

Matul it-tehid ta' kampjuni u preparazzjoni ta' kampjuni tal-laboratorju għandhom jittiehdu prekawzjonijiet biex ikun evitat kull tibdil li jista' jolqot il-kontenut ta' l-*aflatoxin*, li jista' jolqot hażin id-determinazzjoni analitika jew li jista' jagħmel s-somma kollha tal-kampjuni waħda mhux rappreżentattiva.

#### **3.4. *Kampjuni inkriminali***

Sa fejn hu possibli kampjuni inkriminali għandhom jittiehdu f'postijiet varji distribwiti matul il-lott jew sublott. Tluq minn din il-proċedura għandha tkun reġistrata fir-reġistru mnizzel fi 3.8.

#### **3.5. *Preparazzjoni tas-somma kollha ta' kampjuni u tal-kampjuni tal-laboratorju (subkampjuni)***

Is-somma kollha ta' kampjuni hija magħmula billi tghaqqad u thallat suffiċjentement il-kampjuni inkriminali. Wara t-tahlit, is-somma kollha ta' kampjuni għandha tkun diviża f'ammonti ndaqs ta' subkampjuni skond id-disposizzjonijiet speċifiċi ta' punt 5 ta' din l-Iskeda.

It-tahlit huwa mehtieġ biex ikun żgurat illi kull subkampjun ikollu porzjonijiet tal-lott kollu jew sublott.

3.6. *Kampjuni replikati*

Il-kampjuni replikati għall-infurzar, kummerċ (difiża) u għall-iskop ta' *referee* għandhom jittiehdu mill-kampjun omoġeniku tal-laboratorju, kemm il-darba dan ikun f'konflitt mar-regoli fuq it-tehid ta' kampjuni ta' l-Istati Membri.

3.7. *Pakkettar u trasmissjoni ta' kampjuni tal-laboratorju*

Kull kampjun tal-laboratorju għandu jitqiegħed f'kontenitur nadif u inert li joffri protezzjoni adegwata minn kontaminazzjoni u kontra hsara meta jkun fit-transitu. Għandhom jittiehdu l-prekawzjonijiet kollha neċessarji biex ikun evitat tibdil fil-kompożizzjoni fil-kampjun tal-laboratorju li jista' jinqala matul it-trasport jew il-ħażna.

3.8. *Sigillar u tikettar tal-kampjuni tal-laboratorju*

Kull kampjun meħud għall-użu uffiċjali għandu jkun issiġillat fil-post ta' tehid ta' kampjuni u identifikat skond ir-regoli ta' l-Istati Membri. Għandu jinżamm *record* ta' kull tehid ta' kampjuni, li jippermetti kull lott ikun identifikat mingħajr ambigwià u jagħti d-data u l-post ta' tehid ta' kampjuni flimkien ma kull informazzjoni addizzjonali li x'aktarx tkun ta' assistenza għall-analista.

#### 4. Disposizzjonijiet ta' spjegazzjoni

##### 4.1. *Tipi differenti ta' lottijiet*

Kommoditajiet ta' l-ikel jistghu jitpoġġew fil-kummerċ bl-ingrossa, kontenituri, jew ippakkjar individwali (xkejjer, basktijiet, ippakkjar bl-imnut, eċċ.). Il-proċedura ta' tehid ta' kampjuni tista' tkun applikata għall-forom kollha differenti li fihom il-kommoditajiet ikunu mpoġġija fis-suq.

Minghajr preġudizzju għad-disposizzjonijiet speċifiċi mnizzla f'punt 5 ta' din l-Iskeda, il-formula li ġejja tista' tintuża bħala gwida għat-tehid ta' kampjuni tal-lottijiet fil-kummerċ f'ippakkjar individwali (xkejjer, basktijiet, ippakkjar bl-imnut, eċċ.):

$$\text{Frekwenza ta' tehid ta' kampjuni (SF)} = \frac{\text{Piż tal-lott x piż tal-kampjun inkrimentali}}{\text{Piż tas-somma kollha tal-kampjuni x piż ta' ippakkjar individwali}}$$

— Piż: f' kilogrammi

Frekwenza ta' tehid ta' kampjuni (SF): kull *nth* xkora jew basket minn fejn il-kampjun inkrimentali għandu jittiehed (figuri deċimali għandhom jittellgħu jew jitnizzlu għan-numru shiħ l-iktar viċin).

##### 4.2. *Piż tal-kampjun inkrimentali*

Il-piż tal-kampjun inkrimentali għandu jkun ta' bejn wiehded u ieħor 300 gramma sakemm mhux definit mod ieħor f'punt 5 ta' din l-Iskeda u bl-eċċezzjoni ta' hwawar f'liema każ il-piż tal-kampjun inkrimentali huwa bejn wiehded u ieħor 100 gramma. Fil-każ ta' ippakkjar bl-imnut, il-piż tal-kampjun inkrimentali jiddependi fuq il-piż ta' l-ippakkjar bl-imnut.

4.3. *Numru ta' kampjuni inkriminali għal-lottijiet ta' anqas minn 15-il tunellata*

In-numru ta' kampjuni inkriminali li għandhom jittiehdu jiddependi fuq il-piż tal-lott, b'minimu ta' 10 u massimu ta' 100, sakemm mhux definit mod ieħor f'punt 5 ta' din l-Iskeda. Il-figuri fit-tabella li ġejja jistgħu jintużaw biex ikun determinat in-numru ta' kampjuni inkriminali li għandhom jittiehdu.

**Tabella 1:** *L-ghadd ta' kampjuni inkriminali li għandhom jittiehdu jiddependi fuq il-piż tal-lott*

Piż tal-lott (tunellati)	Numru ta' kampjuni inkriminali
$\leq 0,1$	10
$> 0,1 - \leq 0,2$	15
$> 0,2 - \leq 0,5$	20
$> 0,5 - \leq 1,0$	30
$> 1,0 - \leq 2,0$	40
$> 2,0 - \leq 5,0$	60
$> 5,0 - \leq 10,0$	80
$> 10,0 - \leq 15,0$	100

**5. Disposizzjonijiet speċifiċi**

5.1. *Stharriġ generali tal-proċedura ta' teħid ta' kampjuni għall-ġewż ta' l-art, ġewż, frott niexef, ħwawar u ċereali*

**Table 2:** *Subdivisjoni tal-lottijiet f' sublottijiet jiddependi fuq il-prodott u l-piż tal-lott*

Kommodità	Piż tal-lott (tunellati)	Piż jew numru ta' sublottijiet	Numru ta' kampjuni inkrimentali	Is-somma kollha ta' kampjuni Piż (kg)
Tin niexef u frott niexef ieħor	$\geq 15$	15-30 tunellata	100	30
	$< 15$	—	10-100 <sup>(1)</sup>	$\leq 30$
Ġewż ta' l-art, pistakki, Ġewż tal-Brazil u ġewż oħra	$\geq 500$	100 tunellata	100	30
	$> 125$ u $< 500$	5 sublottijiet	100	30
	$\geq 15$ u $\leq 125$	25 tunellata	100	30
	$< 15$	—	10-100 <sup>(1)</sup>	$\leq 30$
Ċereali	$\geq 1\,500$	500 tunellata	100	30
	$> 300$ u $< 1\,500$	3 sublottijiet	100	30
	$\geq 50$ u $\leq 300$	100 tunellata	100	30
	$< 50$	—	10-100 <sup>(1)</sup>	1-10
Hwawar	$\geq 15$	25 tunellata	100	10
	$< 15$	—	10-100 <sup>(1)</sup>	1-10
<sup>(1)</sup> Dipendenti fuq il-piż tal-lott — ara punt 4.3 jew 5.3 ta' din l-Iskeda.				

5.2. *Ġewż ta' l-art, pistakki u ġewż tal-Brazil**Tin niexef**Ċereali (lottijiet  $\geq 50$  tunellati)**Hwawar*

## 5.2.1. Proċedura ta' teħid ta' kampjuni

- Bil-kondizzjoni illi s-sublottijiet jistgħu ikunu separati fiżikament, kull lott għandu jkun subdiviż f' sublottijiet skond Tabella 2 f'punt 5.1. Meta tqis illi l-piż

tal-lott m'huwiex dejjem multiplu eżatt tal-piż tas-sublottijiet, il-piż tas-sublott ma jistax jeċċedi il-piż imsemmi b'massimu ta' 20 %,

- għandu jittiehed kampjun minn kull sublott separatament,
- għadd ta' kampjuni inkriminali: 100. Fil-każ ta' lottijiet taht il-15 tunellata, l-għadd ta' kampjuni inkriminali li għandhom jittiehdu jiddependi fuq il-piż tal-lott, b'minimu ta' 10 u massimu ta' 100 (ara punt 4.3),
- piż tas-somma kollha tal-kampjun = 30 kg li għandu jkun imħallat u diviż fi tlett subkampjuni ugwali ta' 10 kg qabel jitfarrak (din id-diviżjoni fi tliet subkampjuni m'hijiex neċessarja fil-każ ta' lewż mithun, lewż, frott niexef u qamħ maħsub biex jitqiegħed f'ordni iktar il-quddiem jew trattament fiżiku ieħor, b'danakollu, dan jiddependi fuq id-disposizzjoni ta' l-apparat li hu kapaċi jomogeneizza kampjun ta' 30 kg). Fil-każijiet fejn is-somma kollha tal-piż tal-kampjun huma inqas minn 10 kg, is-somma kollha tal-kampjun ma tistax tkun diviża fi tliet subkampjuni. Fil-każ ta' hwawar is-somma kollha tal-kampjun tiżen mhux aktar minn 10 kg u għalhekk l-ebda diviżjoni fis-subkampjuni mhi neċessarja,
- kampjun tal-laboratorju: subkampjun ta' 10 kg (kull subkampjun għandu jkun imfarrak fin separatament u mħallat sewwa biex jikseb omoġeneizzazzjoni kompluta, skond id-disposizzjonijiet mniżżla fi Skeda II),
- jekk mhux possibli li jsir il-metodu ta' teħid ta' kampjuni deskritt hawn qabel minhabba fil-konsegwenzi kummerċjali li jirriżultaw mill-ħsara tal-lott (minhabba l-forom tal-pakkettjar, mezzi ta' trasport, eċċ.) metodu alternattiv ta'



tehid ta' kampjuni jista' jkun applikat sakemm dak il-metodu huwa rappreżentattiv kemm jista' jkun u jkunu deskritt kollu u dokumentat.

#### 5.2.2. Aċċettazzjoni ta' lott jew sublott

- Għal-lewż mithun, lewż, frott niexef u qamħ soġġetti għall-issortjar jew trattament fiżiku ieħor u hwawar:
  - aċċettazzjoni jekk is-somma kollha tal-kampjun jew il-medja tas-subkampjuni huma konformi mal-limitu massimu, meta tqis il-miżura ta' inċertezza u korrezzjoni għall-irkupru,
  - skartar jekk is-somma kollha tal-kampjun jew il-medja tas-subkampjuni teċċedi l-limitu massimu mingħajr ebda dubju raġonevoli meta tqis il-miżura ta' inċertezza u korrezzjoni għall-irkupru,
- għal-lewż mithun, lewż, frott niexef u ċereali maħsuba għall-konsum dirett tal-bniedem u ċereali, bl-eċċezzjoni ta' qamħ, li għandhom ikunu soġġetti għall-issortjar jew trattament fiżiku ieħor:
  - aċċettazzjoni jekk l-ebda wiehed mis-subkampjuni jeċċedi l-limitu massimu, meta tqis il-miżura ta' inċertezza u korrezzjoni għall-irkupru,
  - skartar jekk wiehed jew aktar mis-subkampjuni jeċċedi l-limitu massimu mingħajr ebda dubju raġonevoli meta tqies il-miżura ta' inċertezza u korrezzjoni għall-irkupru,
  - fejn is-somma kollha tal-kampjun hija iżgħar minn 10 kg:
    - aċċettazzjoni jekk is-somma kollha tal-kampjun hija konformi mal-limitu massimu, meta tqis il-miżura ta' inċertezza u korrezzjoni għall-irkupru,

— skartar jekk wiehed jew aktar mis-subkampjuni jeċċedi l-limitu massimu minghajr ebda dubju raġonevoli meta tqies l-inċertezza analitika u korrezzjoni għall-irkupru.

### 5.3. *Lewż barra lewż mithun, pistakki u Brazil nuts*

*Frott niexef li mhux tin*

*Ċereali (lottijiet taht 50 tunellata)*

#### 5.3.1. Proċedura ta' tehid ta' kampjuni

Għal dawn il-prodotti, il-proċedura ta' tehid ta' kampjuni mnizzla f'punt 5.2.1 tista' tkun applikata. Madankollu, meta tqies l-inċidenza baxxa ta' kontaminazzjoni għal dawn il-prodotti u /jew il-forom ġodda ta' pakkettjar f'liema il-prodotti jistgħu jitqiegħdu fil-kummerċ, metodi ta' tehid ta' kampjuni iktar sempliċi jistgħu japplikaw. Għal-lottijiet ta' ċereali taht il-50 tunellata, pjan ta' tehid ta' kampjuni li jikkonsisti minn, u jiddependi mill-piż tal-lott, 10 sa 100 kampjuni inkrimentali kull wiehed ta' 100 gramma, li jirriżultaw fis-somma kollha ta' kampjun ta' 1 sa 10 kg jistgħu jintużaw. Il-figuri fit-tabella li ġejja jistgħu jintużaw biex ikun determinat l-għadd ta' kampjuni inkrimentali li għandhom jittieħdu.

**Tabella 3:** *Għadd ta' kampjuni inkrimentali li għandhom jittieħdu dipendenti fuq il-piż tal-lott ta' ċereali*

Piż tal-lott (tunellati)	Numru ta' kampjuni inkrimentali
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$\leq 1$	10
$> 1 - \leq 3$	20
$> 3 - \leq 10$	40
$> 10 - \leq 20$	60
$> 20 - \leq 50$	100

### 5.3.2. Aċċettazzjoni ta' lott jew sublott

Ara punt 5.2.2.

## 5.4. *Halib*

### 5.4.1. Proċedura ta' tehid ta' kampjuni

Tehid ta' kampjuni skond id-Deċiżjoni tal-Kummissjoni Ewropea 91/180/KEE tal-14 ta' Frar 1991 li tniżżel ċertu metodi ta' analiżi u testijiet ta' halib mhux maħdum u halib trattat bis-shana:

- għadd ta' kampjuni inkriminali: minimu ta' 5,
- piż tas-somma kollha tal-kampjun: minimu ta' 0,5 kg jew litri.

### 5.4.2. Aċċettazzjoni ta' lott jew sublott

- Aċċettazzjoni jekk is-somma kollha tal-kampjun hija konformi mal-limitu massimu, meta tqies il-miżura ta' inċertezza u korrezzjoni għall-irkupru,
- rifjut jekk is-somma tal-kampjun teċċedi l-limitu massimu mingħajr ebda dubju meta tqies il-miżura ta' inċertezza u korrezzjoni għall-irkupru.

## 5.5. *Prodotti derivati u ikel kompost*

### 5.5.1. Prodotti tal-halib

#### 5.5.1.1. Proċedura ta' tehid ta' kampjuni

Tehid ta' kampjuni skond id-Direttiva tal-Kummissjoni ta' l-Unjoni Ewropea 87/524/KEE tas-6 ta' Ottubru, 1987 li tnizzel il-metodi ta' tehid ta' kampjuni għall-analiżi kemikali għall-kontroll ta' prodotti tal-ħalib preservati fil-Komunità Ewropea.

Għadd ta' kampjuni inkrimentali: minimum 5.

Għall-prodotti tal-ħalib oħra metodu ekwivalenti ta' tehid ta' kampjuni huwa użat.

5.5.1.2. Aċċettazzjoni ta' lott jew sublott

- Aċċettazzjoni jekk is-somma kollha tal-kampjun hija konformi mal-limitu massimu, meta tqies il-miżura ta' inċertezza u korrezzjoni għall-irkupru,
- rifjut jekk is-somma tal-kampjun teċċedi l-limitu massimu mingħajr ebda dubju meta tqies il-miżura ta' inċertezza u korrezzjoni għall-irkupru.

5.5.2. Prodotti derivati oħra bil-piż tal-partiċella żgħir hafna, i.e. dqiq, pasta tat-tin, butir tal-karawett (distribuzzjoni omogenika ta' kontaminazzjoni ta' *aflatoxin*).

5.5.2.1. Proċedura ta' tehid ta' kampjuni

- Għadd ta' kampjuni inkrimentali: 100. Għal-lottijiet taht il-50 tunellata in-numru ta' kampjuni inkrimentali għandu jkun ta' 10 sa 100, jiddependi fuq il-piż tal-lott (ara Tabella 3 f'punt 5.3.1 ta' din l-Iskeda),
- il-piż tal-kampjun inkrimentali għandu jkun bejn wiehded u ieħor 100 gramma. Fil-każ ta' lottijiet f'pakkettar bl-imnut, il-piż tal-kampjun inkrimentali jiddependi fuq il-piż tal-pakkettar bl-imnut,
- piż tas-somma kollha tal-kampjun = 1-10 kg imħallta suffiċjentement.

5.5.2.2. Għadd ta' kampjuni li għandhom jittiehdu

- Is-somma kollha tal-kampjuni li għandhom jittiehdu tiddependi fuq il-piż tal-lott. Id-diviżjoni ta' lottijiet kbar f'sublottijiet għandu jsir kif definit għaċ-ċereali f'Tabella 2 taħt punt 5.1,
- Għandu jittiehed kampjun kull sublott separatament.

#### 5.5.2.3 Aċċettazzjoni ta' lott jew sublott

- Aċċettazzjoni jekk is-somma kollha tal-kampjun hija konformi mal-limitu massimu, meta tqies il-miżura ta' inċertezza u korrezzjoni għall-irkupru,
- rifjut jekk is-somma tal-kampjun teċċedi l-limitu massimu mingħajr ebda dubju meta tqis il-miżura ta' inċertezza u korrezzjoni għall-irkupru.

#### 5.6. *Prodotti derivati oħra b'qies tal-particelli relattivament kbir (distribuzzjoni etroġenja għall-kontaminazzjoni ta' aflatoxin)*

Proċedura ta' teħid ta' kampjuni u aċċettazzjoni kif definit f'punti 5.2 u 5.3 ta' din l-Iskeda għall-prodott agrikolu mhux maħdum.

#### 5.7. *Ikel intiż għat-tfal u tfal żgħar*

##### 5.7.1. Proċedura ta' teħid ta' kampjuni

Il-proċedura ta' teħid ta' kampjuni kif imnizzla għall-ħalib u prodotti derivati kif ukoll għall-ikel kompost f'punti 5.4, 5.5 u 5.6 japplikaw.

##### 5.7.2. Aċċettazzjoni ta' lott

- Aċċettazzjoni jekk is-somma kollha tal-kampjun hija konformi mal-limitu massimu, meta tqies il-miżura ta' inċertezza u korrezzjoni għall-irkupru,
- rifjut jekk is-somma tal-kampjun teċċedi l-limitu massimu mingħajr ebda dubju meta tqies il-miżura ta' inċertezza u korrezzjoni għall-irkupru.

**6. Tehid ta' kampjuni fl-istadju ta' l-imnut**

Tehid ta' kampjuni ta' l-ghalf fl-istadju ta' l-imnut ghandu jsir, fejn possibli, skond id-disposizzjonijiet ta' tehid ta' kampjuni imsemmija hawn fuq. Fejn dan mhux possibli, proceduri effettivi ohra ta' tehid ta' kampjuni fl-istadju ta' l-imnut jistghu jintużaw sakemm jiżguraw rappreżentattivi suffiċenti ghal-lott li minnu jittiehed kampjun.

## SKEDA II

**Preparazzjoni tal-kampjun u kriterji għall-metodi ta' analiżi użati fil-kontroll  
uffiċjali tal-livelli ta' aflatoxins f'ċertu għalf**

**1. Introduzzjoni**

**1.1. Prekawzjonijiet**

Għandu jkun evitat kemm jista' jkun id-dawl tax-xemx matul il-proċedura, minhabba li l-*aflatoxin* jinqasam gradwalment taħt l-influwenza tad-dawl ta' ultravjolett. Minhabba li d-distribuzzjoni ta' *aflatoxin* hija estremament mhux omoġeneika, kampjuni għandhom ikunu preparati — u speċjalment omoġeneizzati — b'kura estrema.

Il-materjal kollha irċevut mil-laboratorju għandu jintuża għall-preparazzjoni tal-materjal għat-test.

**1.2. Kalkulazzjoni tal-proporzjon ta' qoxra/għadma tal-lewż *shih***

Il-limiti ffissati għall-*aflatoxins* fir-Regoli tal-Kummissjoni ta' l-Unjoni Ewropea (EC) Nru 1525/98 japplikaw għall-parti li tittiekel.

Il-livell ta' *aflatoxins* fil-parti li tittiekel jista' jkun determinat kif ġej:

- kampjuni tal-qoxra ta' lewż 'fil-qoxra' u l-livell ta' *aflatoxins* huma direttament determinati fil-parti li tittiekel,
- omoġenizza l-lewż 'fil-qoxra' billi tgħaddihom mill-proċedura ta' preparazzjoni tal-kampjun. It-tehid ta' kampjuni u l-proċedura analitika għandha tagħmel estimu tal-piż ta' l-għadma tal-lewża fis-somma kollha tal-kampjun. Il-piż ta' l-

ghadma tal-lewża fis-somma kollha tal-kampjun hija stmata wara li jkun stabbilit fattur adattat għall-proporzjon tal-qoxra tal-lewża sal-qoxra tal-lewża fil-lewż kollu. Dan il-proporzjon huwa użat biex ikun aċċertat l-ammont ta' għadam fil-biċċa l-kbira tal-kampjun mehud mill-preparazzjoni tal-kampjun u proċedura ta' analiżi. Daqs mitt lewża shiħa huma mehuda każwalment separatament mil-lott jew għandhom jitpoġġew apparti mis-somma kollha tal-kampjun. Għal kull kampjun tal-laboratorju, ir-rata tista' tkun miksuba billi jintiżen il-lewż kollu, jitqaxxar u jerga' jintiżen il-proporzjon tal-qoxra u ta' l-għadam. Madankollu, il-proporzjon tal-qoxra għall-għadam jista' jkun stabbilit mill-laboratorju minn għadd ta' kampjuni u għalhekk jistgħu ikunu hekk użati għal xogħol futur analitiku. Imma jekk kampjun tal-laboratorju partikolari huwa misjub li jkun f'kontravvenzjoni ma' xi limitu, il-proporzjon għal dak il-kampjun għandu jkun determinat bl-użu ta' daqs mitt lewża li kienu gew imħollija apparti.

## **2. Trattament tal-kampjun kif riċevut fil-laboratorju**

Kisser fin u hawwad sewwa kull kampjun tal-laboratorju bl-użu ta' proċess illi gie dimostrat li jwassal għall-omoġeneità kompluta. Fil-każ li l-livell massimu japplika għall-materja niexfa, il-kontenut tal-materja niexfa għandu jkun determinat fuq parti tal-kampjun omoġeneizzat, bl-użu ta' proċedura illi tkun ġiet muriġja li tiddetermina b'mod preċiż il-kontenut tal-materja niexfa.

## **3. Subdiviżjoni ta' kampjuni għall-infurzar u skopijiet ta' difiża**



Il-kampjuni replikati għall-infurzar, kummerċ (difiza) u skopijiet ta' riferenza għandhom jittiehdu minn materjal omoġeneizzat sakemm ma jmurx kontra r-regoli fuq tehid ta' kampjuni ta' l-Istati Membri.

#### 4. **Metodu ta' analiżi li għandu jintuża mill-laboratorju u rekwiżiti għall-kontroll tal-laboratorju**

##### 4.1. *Tifsiriet*

Għadd ta' l-aktar tifsiriet komuni li l-laboratorju jkun mehtieg li juża huma mnizzla hawn taht:

Il-parametri ta' preċiżjoni l-aktar komuni kwotati huma repetizzjoni u riproducibilità.

$r$  = repetizzjoni, il-valur taht xhiex id-differenza assoluta bejn żewġ testijiet singolari miksuba taht kondizzjonijiet ta' repetizzjoni (i.e. l-istess kampjun, l-istess operatur, l-istess apparat, l-istess laboratorju, u l-hin qasir ta' l-intervall) jistghu ikunu pretiżi li qegħdin fi probabbiltà speċifika (tipikament 95 %) u għalhekk  $r = 2,8 \times s_r$

$s_r$  = Devjazzjoni *standard*, kalkolata mir-riżultati ġenerati taht il-kondizzjonijiet ta' repetizzjoni

$RSD_r$  = devjazzjoni relattiva *standard*, kalkolata mir-riżultati ġenerati taht kondizzjonijiet ta' repetizzjoni  $[(S_r/x) \times 100]$ , fejn  $x$  hija l-medja tar-riżultati mil-laboratorji kollha u kampjuni

$R$  = riproducibilità, il-valur taht xhiex id-differenza assoluta bejn żewġ testijiet singolari miksub taht kondizzjonijiet ta' riproducibilità (i.e. fuq

materjal identiku ottenut minn operatori f'laboratorji differenti, bl-użu tat-test standardizzat) għandu jkun pretiż li jkun f'ċertu probabbiltà (tipikament 95 %);  $R = 2,8 s_R$

$s_R$  = devjazzjoni *standard*, kalkolata mir-riżultati taht il-kondizzjonijiet ta' riproduċibilità

$RSD_R$  = devjazzjoni relattiva *standard* mir-riżultati generati taht il-kondizzjonijiet ta' riproduċibilità  $[(S R/x) \times 100]$

#### 4.2. *Rekwiziti ġenerali*

Metodi għall-analiżi użati għall-iskop ta' kontroll ta' l-ikel għandhom ikunu konformi, fejn possibli, mad-disposizzjonijiet ta' punti 1 u 2 ta' l-Anness tad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 85/591/KEE.

#### 4.3. *Rekwiziti speċifiċi*

Fejn ma hemmx metodi speċifiċi għad-determinazzjoni tal-livelli ta' *aflatoxin* fl-għalf preskritti fil-livell tal-Komunità Ewropea, il-laboratorji jistghu jagħżlu kull metodu sakemm il-metodu magħżul jilhaq il-kriterji li ġejjin:

Kriterju	Sensiela ta' konċentrazzjonijiet	Valur rakommandat	Valur massimu permess
Vojta	Kollha	Negligibli	
Rkupru — Aflatoxin M <sub>1</sub>	0,01-0,05 µg/kg >0,05 µg/kg	60 sa 120 % 70 sa 110 %	
Rkupru — Aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> , G <sub>2</sub>	< 1,0 µg/kg 1-10 µg/kg >10 µg/kg	50 sa 120 % 70 sa 110 % 80 to 110 %	
Preċiżjoni $RSD_R$	Kollha	Kif derivat mill-	2 × valur derivat

		ekwazzjoni Horwitz	mill-ekwazzjoni Horwitz
Preċiżjini $RSD_r$ tista' tkun kalkolata bħala 0,66 darbiet tal-preċiżjoni $RSD_R$ fil-konċentrazzjoni ta' interess.			

*Noti:*

- Valuri għandhom japplikaw kemm għal  $B_1$  u s-somma ta'  $B_1 + B_2 + G_1 + G_2$ ,
- jekk is-somma individwali ta' *aflatoxins*  $B_1 + B_2 + G_1 + G_2$  għandhom ikunu rapportati, ir-rispons ta' kull sistema analitika għandha jew tkun magħrufa jew ekwivalenti,
- il-limiti ta' detenzjoni użati m'humiex imniżżla bħala l-valuri ta' preċiżjoni huma mogħtija fil-konċentrazzjonijiet ta' interess,
- il-valuri ta' preċiżjoni huma kalkolati mill-ekwazzjoni Horwitz, i. e.:  $RSD_R = 2^{(1-0,5 \log C)}$  fejn:
  - $RSD_R$  hija d-devjazzjoni *standard* relattiva kalkolata mir-riżultati generati taħt il-kondizzjonijiet ta' riproducibilità  $[(S_R/x) \times 100]$
  - $C$  hija r-rata ta' konċentrazzjoni (i.e.  $1 = 100 \text{ g}/100 \text{ g}$ ,  $0,001 = 1 \text{ 000 mg/kg}$ ).

Din hija ekwazzjoni ġenerali ta' preċiżjoni illi għet misjuba bħala indipendenti mill-analit u l-matriċi iżda dipenedenti biss fuq konċentrazzjoni għall-metodi ta' analiżi l-aktar ta' rutina.

#### 4.4. *Kalkulazzjoni ta' rkupru u rappurtar tar-riżultati*

Ir-riżultat analitiku għandu jkun rrapportat korrettament jew mhux korrettament għall-irkupru. Il-mod ta' rapurtagġ u l-livell ta' rkupru għandhom ikunu rapportati. Ir-riżultat

analitiku għall-irkupru kkoreġut huwa użat għall-konformità ta' l-iċċekjar (ara Skeda I, punti 5.2.2, 5.3.2, 5.4.2, 5.5.1.2 u 5.5.2.3).

Ir-riżultat analitiku għandu jkun rapportat bħala  $x \pm U$  fejn  $x$  huwa r-riżultat analitiku u  $U$  hija l-miżura ta' inċertezza estiża, bl-użu ta' fattur ta' kopertura ta' 2 li tagħti livell ta' aċċertament ta' approssimazzjoni ta' 95 %.

#### 4.5. Standards *ta' kwalita' tal-laboratorji*

Il-laboratorji għandhom ikunu konformi mad-Direttiva tal-Kunsill ta' l-Unjoni Ewropea 93/99/KEE.

**L.N. 97 of 2005**

**VETERINARY SERVICES ACT  
(CAP. 437)**

**Sampling Methods and Methods of Analysis for the Official  
Control of the Levels for Certain Contaminants in  
Foodstuffs Rules, 2005**

IN exercise of the powers conferred by article 25 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has made the following rules:-

**1.** (1) The title to these rules is the Sampling Methods and Methods of Analysis for the Official Control of the Levels for Certain Contaminants in Foodstuffs Rules, 2005. Title and scope.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 98/53/EC establishing methods of analysis for the official control of feedingstuffs.

**2.** For the purposes of these rules - Definitions.

“the competent authority” means the Veterinary Services within Malta as provided under article 2 of the Veterinary Services Act, or any other authority to which such responsibility has been delegated by the Veterinary Services.

**3.** The competent authority shall take all measures necessary to ensure that the sampling for the official control of the levels of aflatoxins in foodstuffs is carried out in accordance with the methods described in Schedule I to these rules. Necessary measures to ensure sampling for the official control of the levels of aflatoxins in foodstuffs.

**4.** The competent authority shall take all measures necessary to ensure that sample preparation and methods of analyses used for the official control of the levels of aflatoxins in foodstuffs comply with the criteria described in Schedule II to these rules. Necessary measures to ensure sample preparation and methods of analyses used for the official control of the levels of aflatoxins in foodstuffs.

## *SCHEDULE I*

### **Methods of sampling for official checking control of the levels of aflatoxins in certain foodstuffs**

#### **1. Purpose and scope**

Samples intended for official checking of the levels of aflatoxin content in foodstuffs shall be taken according to the methods described below. Aggregate samples thus obtained shall be considered as representative of the lots. Compliance with maximum limits laid down in European Commission Regulation 98/1525/EC shall be established on the basis of the levels determined in the laboratory samples.

#### **2. Definitions**

*Lot:* an identifiable quantity of a food commodity delivered at one time and determined by the official to have common characteristics, such as origin, variety, type of packing, packer, consignor or markings.

*Sublot:* designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.

*Incremental sample:* a quantity of material taken from a single place in the lot or sublot.

*Aggregate sample:* the combined total of all the incremental samples taken from the lot or sublot.

*Laboratory sample:* sample intended for the laboratory (= subsample).

#### **3. General provisions**

##### **3.1. Personnel**

Sampling shall be performed by an authorised person as specified by the competent authority.

3.2. *Material to be sampled*

Each lot which is to be examined must be sampled separately. In accordance with the specific provisions in point 5 of this Schedule, large lots should be subdivided into sublots to be sampled separately.

3.3. *Precautions to be taken*

In the course of sampling and preparation of the laboratory samples, precautions must be taken to avoid any changes which would affect the aflatoxin content, adversely affect the analytical determination or make the aggregate samples unrepresentative.

3.4. *Incremental samples*

As far as possible incremental samples should be taken at various places distributed throughout the lot or subplot. Departure from this procedure must be recorded in the record provided for in 3.8.

3.5. *Preparation of the aggregate sample and the laboratory samples (subsamples)*

The aggregate sample is made up by uniting and sufficiently mixing the incremental samples. After mixing, the aggregate sample must be divided into equal subsamples in accordance with the specific provisions of point 5 of this Schedule.

The mixing is necessary to ensure that each subsample contains Portions of the whole lot or subplot.

3.6. *Replicate samples*

The replicate samples for enforcement, trade (defence) and referee purposes are to be taken from the homogenised laboratory sample, unless this conflicts with Member States' rules on sampling.

3.7. *Packaging and transmission of laboratory samples*

Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination and against damage in transit. All necessary precautions shall be taken to avoid any change in composition of the laboratory sample which might arise during transportation or storage.

3.8. *Sealing and labelling of laboratory samples*

Each sample taken for official use shall be sealed at the place of sampling and identified following the Member State's regulations. A record must be kept of each sampling, permitting each lot to be identified unambiguously and giving the date and place of sampling together with any additional information likely to be of assistance to the analyst.

#### **4. Explanatory provisions**

##### **4.1. *Different types of lots***

Food commodities may be traded in bulk, containers, or individual packings (sacks, bags, retail packings, etc.). The sampling procedure can be applied to all the different forms in which the commodities are put on the market.

Without prejudice to the specific provisions as laid down in point 5 of this Schedule, the following formula can be used as a guide for the sampling of lots traded in individual packings (sacks, bags, retail packings, etc.):

$$\text{Sampling frequency (SF)} = \frac{\text{Weight of the lot} \times \text{weight of the incremental sample}}{\text{Weight of the aggregate sample} \times \text{weight of individual packing}}$$

— Weight: in kg

Sampling frequency (SF): every *n*th sack or bag from which an incremental sample must be taken (decimal figures should be rounded to the nearest whole number).

##### **4.2. *Weight of the incremental sample***

The weight of the incremental sample should be about 300 grams unless otherwise defined in point 5 of this Schedule and with the exception of spices in which case the weight of the incremental sample is about 100 grams. In the case of retail packings, the weight of the incremental sample depends on the weight of the retail packing.

##### **4.3. *Number of incremental samples for lots of less than 15 tonnes***

The number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100, unless otherwise defined in



point 5 of this Schedule. The figures in the following table may be used to determine the number of incremental samples to be taken.

**Table 1:** *Number of incremental samples to be taken depending on the weight of the lot*

Lot weight (tonnes)	No of incremental samples
$\leq 0,1$	10
$> 0,1 - \leq 0,2$	15
$> 0,2 - \leq 0,5$	20
$> 0,5 - \leq 1,0$	30
$> 1,0 - \leq 2,0$	40
$> 2,0 - \leq 5,0$	60
$> 5,0 - \leq 10,0$	80
$> 10,0 - \leq 15,0$	100

## 5. Specific provisions

### 5.1. *General survey of the sampling procedure for groundnuts, nuts, dried fruit, spices and cereals*

**Table 2:** *Subdivision of lots into sublots depending on product and lot weight*

Commodity	Lot weight (tonnes)	Weight or number of sublots	Number of incremental samples	Aggregate sample Weight (kg)
Dried figs and other dried fruit	$\geq 15$	15-30 tonnes	100	30
	$< 15$	—	10-100 ( <sup>1</sup> )	$\leq 30$
Groundnuts, pistachios, Brazil nuts and other	$\geq 500$	100 tonnes	100	30
	$> 125$ and $< 500$	5 sublots	100	30
	$\geq 15$ and $\leq 125$	25 tonnes	100	30

nuts	< 15	—	10-100 <sup>(1)</sup>	≤ 30
Cereals	≥ 1 500	500 tonnes	100	30
	> 300 and < 1 500	3 sublots	100	30
	≥ 50 and ≤ 300	100 tonnes	100	30
	< 50	—	10-100 <sup>(1)</sup>	1-10
Spices	≥ 15	25 tonnes	100	10
	< 15	—	10-100 <sup>(1)</sup>	1-10
<sup>(1)</sup> Depending on the lot weight — see point 4.3 or 5.3 of this Schedule.				

## 5.2. *Groundnuts, pistachios and Brazil nuts*

### *Dried figs*

### *Cereals* (lots ≥ 50 tonnes)

### *Spices*

#### 5.2.1. Sampling procedure

- On condition that the subplot can be separated physically, each lot must be subdivided into sublots following Table 2 at point 5.1. Taking into account that the weight of the lot is not always an exact multiple of the weight of the sublots, the weight of the subplot may exceed the mentioned weight by a maximum of 20 %,
- each subplot must be sampled separately,
- number of incremental samples: 100. In the case of lots under 15 tonnes, the number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100 (see point 4.3),
- weight of the aggregate sample = 30 kg which has to be mixed and to be divided into three equal subsamples of 10 kg before grinding (this division into three subsamples is not necessary in the case of groundnuts, nuts, dried fruit and maize intended for further sorting or other physical treatment, however, this will depend upon the availability of equipment which is able to homogenise a 30 kg sample). In cases where the aggregate sample weights are under 10 kg, the aggregate sample must not be divided into three subsamples. In the case of spices the aggregate sample weighs not more than 10 kg and therefore no division in subsamples is necessary,

- laboratory sample: a subsample of 10 kg (each subsample must be separately ground finely and mixed thoroughly to achieve complete homogenisation, in accordance with the provisions laid down in Schedule II),
- if it is not possible to carry out the method of sampling described above because of the commercial consequences resulting from damage to the lot (because of packaging forms, means of transport, etc.) an alternative method of sampling may be applied provided that it is as representative as possible and is fully described and documented.

#### 5.2.2. Acceptance of a lot or subplot

- For groundnuts, nuts, dried fruit and maize subjected to a sorting or other physical treatment and spices:
  - acceptance if the aggregate sample or the average of the subsamples conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,
  - rejection if the aggregate sample or the average of the subsamples exceeds the maximum limit beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery,
- for groundnuts, nuts, dried fruit and cereals intended for direct human consumption and cereals, with the exception of maize, to be subjected to a sorting or other physical treatment:
  - acceptance if none of the subsamples exceeds the maximum limit, taking into account the measurement uncertainty and correction for recovery,
  - rejection if one or more of the subsamples exceeds the maximum limit beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery,
  - where the aggregate sample is under 10 kg:
    - acceptance if the aggregate sample conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,

- rejection if the aggregate sample exceeds the maximum limit beyond reasonable doubt taking into account analytical uncertainty and correction for recovery.

5.3. *Nuts other than groundnuts, pistachios and Brazil nuts*

*Dried fruit other than figs*

*Cereals* (lots under 50 tonnes)

5.3.1. Sampling procedure

For these products, the sampling procedure laid down in point 5.2.1 may be applied. However, taking into account the low incidence of contamination for these products and/or the newer forms of packaging in which products can be traded, simpler sampling methods may be applied.

For cereal lots under 50 tonnes, a sampling plan consisting of, depending on the lot weight, 10 to 100 incremental samples each of 100 grams, resulting in an aggregate sample of 1 to 10 kg may be used. The figures in the following table can be used to determine the number of incremental samples to be taken.

**Table 3:** *Number of incremental samples to be taken depending on the weight of the lot of cereals*

Lot weight (tonnes)	Number of incremental samples
$\leq 1$	10
$> 1 - \leq 3$	20
$> 3 - \leq 10$	40
$> 10 - \leq 20$	60
$> 20 - \leq 50$	100

5.3.2. Acceptance of a lot or subplot

See point 5.2.2.

5.4. *Milk*

5.4.1. Sampling procedure

Sampling in accordance with European Union Commission Decision 91/180/EEC of 14 February 1991 laying down certain methods of analysis and testing of raw milk and heat-treated milk:

- number of incremental samples: minimum 5,
- weight of aggregate sample: minimum 0,5 kg or litres.

5.4.2. Acceptance of a lot or subplot

- Acceptance if the aggregate sample conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,
- rejection if the aggregate sample exceeds the maximum limit beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery.

5.5. *Derived products and compound foods*

5.5.1. Milk products

5.5.1.1. Sampling procedure

Sampling in accordance with European Union Commission Directive 87/524/EEC of 6 October 1987 laying down European Community methods of sampling for chemical analysis for the monitoring of preserved milk products.

Number of incremental samples: minimum 5.

For the other milk products an equivalent method of sampling is used.

5.5.1.2. Acceptance of a lot or subplot

- Acceptance if the aggregate sample conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,
- rejection if the aggregate sample exceeds the maximum limit beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery.

5.5.2. Other derived products with very small particle weight, i.e. flour, fig paste, peanut butter (homogeneous distribution of aflatoxin contamination).

5.5.2.1. Sampling procedure

- Number of incremental samples: 100. For lots of under 50 tonnes the number of incremental samples should be 10 to 100, depending on the lot weight (see Table 3 at point 5.3.1 of this Schedule),
- the weight of the incremental sample should be about 100 grams. In the case of lots in retail packing, the weight of the incremental sample depends on the weight of the retail packing,
- weight of aggregate sample = 1-10 kg sufficiently mixed.

5.5.2.2. Number of samples to be taken

- The number of aggregate samples to be taken depends on the lot weight. The division of large lots into sublots must be done as defined for cereals in Table 2 under point 5.1,
- each sublot must be sampled separately.

5.5.2.3 Acceptance of a lot or sublot

- Acceptance if the aggregate sample conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,
- rejection if the aggregate sample exceeds the maximum limit beyond reasonable doubt taking into account the measurement uncertainty and correction for recovery.

5.6. *Other derived products with a relatively large particle size (heterogeneous distribution of aflatoxin contamination)*

Sampling procedure and acceptance as defined at points 5.2 and 5.3 of This Schedule for the raw agricultural product.

5.7. *Foods intended for infants and young children*

5.7.1. Sampling procedure

The sampling procedure as mentioned for milk and derived products as well as for compound food in points 5.4, 5.5 and 5.6 applies.

5.7.2. Acceptance of a lot

- Acceptance if the aggregate sample conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,

- Rejection if the aggregate sample exceeds the maximum limit beyond reasonable doubt, taking into account the measurement uncertainty and correction for recovery.

**6. Sampling at retail stage**

Sampling of foodstuffs at the retail stage should be done where possible in accordance with the above sampling provisions. Where this is not possible, other effective sampling procedures at retail stage can be used provided that they ensure sufficient representativeness for the sampled lot.

*SCHEDULE II*

**Sample preparation and criteria for methods of analysis used in official  
checking of the levels of aflatoxins in certain foodstuffs**

**1. Introduction**

**1.1. *Precautions***

Daylight should be excluded as much as possible during the procedure, since aflatoxin gradually breaks down under the influence of ultra-violet light. As the distribution of aflatoxin is extremely non-homogeneous, samples should be prepared — and especially homogenised — with extreme care.

All the material received by the laboratory is to be used for the preparation of test material.

**1.2. *Calculation of proportion of shell/kernel of whole nuts***

The limits fixed for aflatoxins in European Union Commission Regulation (EC) No 1525/98 apply to the edible part.

The level of aflatoxins in the edible part can be determined by:

- shelling samples of nuts ‘in shell’ and the level of aflatoxins is directly determined in the edible part,
- homogenise the nuts ‘in shell’ by taking them through the sample preparation procedure. The sampling and analytical procedure must estimate the weight of nut kernel in the aggregate sample. The weight of nut kernel in the aggregate sample is estimated after establishing a suitable factor for the proportion of nut shell to nut kernel in whole nuts. This proportion is used to ascertain the amount of kernel in the bulk sample taken through the sample preparation and analysis procedure. Approximately 100 whole nuts are taken at random separately from the lot or are to be put aside from each aggregate sample. The ratio may, for each laboratory sample, be obtained by weighing the whole nuts, shelling and re-weighing the shell and kernel portions. However, the proportion of shell to kernel may be established by the laboratory from a number of samples



and so can be assumed for future analytical work. But if a particular laboratory sample is found to be in contravention of any limit, the proportion should be determined for that sample using the approximately 100 nuts that have been set aside.

**2. Treatment of the sample as received in the laboratory**

Finely grind and thoroughly mix each laboratory sample using a process that has been demonstrated to achieve complete homogenisation. In case the maximum level applies to the dry matter, the dry matter content shall be determined on a part of the homogenised sample, using a procedure that has been demonstrated to determine accurately the dry matter content.

**3. Subdivision of samples for enforcement and defence purposes**

The replicate samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised material unless this conflicts with Member States' rules on sampling.

**4. Method of analysis to be used by the laboratory and laboratory control requirements**

**4.1. Definitions**

A number of the most commonly used definitions that the laboratory will be required to use are given below:

The most commonly quoted precision parameters are repeatability and reproducibility.

$r$  = repeatability, the value below which the absolute difference between two single test results obtained under repeatability conditions (i. e. same sample, same operator, same apparatus, same laboratory, and short interval of time) may be expected to lie within a specific probability (typically 95 %) and hence  $r = 2,8 \times s_r$

$s_r$  = Standard deviation, calculated from results generated under repeatability conditions

- $RSD_r$  = relative standard deviation, calculated from results generated under repeatability conditions  $[(S_r/x) \times 100]$ , where  $x$  is the average of results over all laboratories and samples
- $R$  = reproducibility, the value below which the absolute difference between single test results obtained under reproducibility conditions (i. e. on identical material obtained by operators in different laboratories, using the standardised test method) may be expected to lie within a certain probability (typically 95 %);  $R = 2,8 s_R$
- $s_R$  = standard deviation, calculated from results under reproducibility conditions
- $RSD_R$  = relative standard deviation calculated from results generated under reproducibility conditions  $[(S_R/x) \times 100]$

#### 4.2. General requirements

Methods of analysis used for food control purposes must comply whenever possible with the provisions of points 1 and 2 of the Annex to European Union Council Directive 85/591/EEC.

#### 4.3. Specific requirements

Where no specific methods for the determination of aflatoxin levels in foodstuffs are prescribed at European Community level, laboratories may select any method provided the selected method meets the following criteria:

Criterion	Concentration range	Recommended value	Maximum permitted value
Blanks	All	Negligible	
Recovery — Aflatoxin M1	0,01-0,05 µg/kg >0,05 µg/kg	60 to 120 % 70 to 110 %	
Recovery — Aflatoxins B <sub>1</sub> , B <sub>2</sub> , G <sub>1</sub> , G <sub>2</sub>	< 1,0 µg/kg 1-10 µg/kg >10 µg/kg	50 to 120 % 70 to 110 % 80 to 110 %	
Precision $RSD_R$	All	As derived from Horwitz equation	$2 \times$ value derived from Horwitz equation

Precision  $RSD_r$  may be calculated as 0,66 times precision  $RSD_R$  at the concentration of interest.

*Notes:*

- Values to apply to both  $B_1$  and sum of  $B_1 + B_2 + G_1 + G_2$ ,
- if sum of individual aflatoxins  $B_1 + B_2 + G_1 + G_2$  are to be reported, then response of each to the analytical system must be either known or equivalent,
- the detection limits of the methods used are not stated as the precision values are given at the concentrations of interest,
- the precision values are calculated from the Horwitz equation, i. e.:  $RSD_R = 2^{(1-0,5 \log C)}$  where:
  - $RSD_R$  is the relative standard deviation calculated from results generated under reproducibility conditions  $[(S_R/x) \times 100]$
  - $C$  is the concentration ratio (i. e.  $1 = 100 \text{ g}/100 \text{ g}$ ,  $0,001 = 1 \text{ 000 mg/kg}$ ).

This is a generalised precision equation which has been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

#### 4.4. *Recovery calculation and reporting of results*

The analytical result is to be reported corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported. The analytical result corrected for recovery is used for checking compliance (see Schedule I, points 5.2.2, 5.3.2, 5.4.2, 5.5.1.2 and 5.5.2.3).

The analytical result has to be reported as  $x \pm U$  whereby  $x$  is the analytical result and  $U$  is the expanded measurement uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.

#### 4.5. *Laboratory quality standards*

Laboratories must comply with European Council Directive 93/99/EEC.

