A.L. 98 ta' l-2005

ATT DWAR IS-SERVIZZI VETERINARJI (KAP. 437)

Regoli tal-2005 dwar Metodi għat-Teħid ta' Kampjuni u metodi ta' analiżi għall-kontroll uffiċjali tal-livelli taċ-ċomb, kadmju, merkurju u 3-MCPD fl-Għalf

BIS-SAĦĦA tad-disposizjonijiet ta' l-artiklu 25 tal-Att dwar is-Servizzi Veterinarji, il-Ministru ta' l-Affarijiet Rurali u l-Ambjent bi ftehim mal-Ministeru tas-Saħħa, l-Anzjani u Kura fil-Komuità għamel dawn ir-regoli li ġejjin:-

Titolu u skop.

1. (1) It-titlu ta' dawn ir-regoli hu Regoli ta' l-2005 dwar Metodi għat-Teħid ta' Kampjuni u metodi ta' analiżi għall-kontroll uffiċjali tal-livelli taċ-ċomb, kadmju, merkurju u 3-MCPD fl-għalf.

(2) L-iskop ta' dawn ir-regoli huwa l-implimentazzjoni tar-regoli li jinsabu taħt id-Direttiv tal-Kunsill tal-Unjoni Ewropea 2001/22/KE dwar il-metodi għat-teħid ta' kampjuni u l-metodi ta' analiżi għall-kontroll uffiċjali tal-livelli taċ-ċomb, kadmju, merkurju u 3-MCPD fl-għalf.

Tifsiriet.

2. Għall-iskop ta' dawn ir-regoli, u sakemm il-kuntest ma' jirrikjedix mod ieħor:

"l-awtorità kompetenti" tfisser is-Servizzi Veterinarji ta' Malta skond kif provdut taħt l-artikolu 2 ta' l-Att dwar is-Servizzi Veterinarji;

"l-ammont tal-kampjun" tfisser it-total kombinat tal-kampjuni inkrimentali kollha meħudin mill-lot jew mis-sublott;

"kampjun inkrimentali" tfisser il-kwantità tal-materjal meħud minn post wieħed mill-lott jew mis-sublott;

"kampjun mil-laboratorju" tfisser il-kampjun intiż għall-laboratorju;

"Il-komunità" tfisser il-Komunità Ewropea skond kif stabbilita taħt it-Trattat li jwaqqaf il-Komunità Ewropea;

"il-Kummissjoni" tfisser il-Kummissjoni Ewropea;

"lott" tfisser kwantità identifikabbli ta' ikel ikkonsenjat mill-veterinarju uffiċjali li għandu jkollu karatteristiċi komuni, bħal l-oriġini, il-varjetà, it-tip ta' pakkettjar, min jippakkja, minn jikkonsenja jew il-marki. Fil-każ tal-ħut, anki d-daqs tal-ħut għandu jiġi mqabbel;

"pajjiż terz" tfisser Stat li ma huwiex membru tal-Komunità Ewropea;

"is-Servizzi Veterinarji" tfisser l-awtorità kompetenti f'Malta skond l-artiklu 2 ta' Att dwar is-Servizzi Veterinarji;

"Stat Membru'' tfisser Stat li huwa Membru tal-Komunità Ewropea;

"sublott" tfisser il-parti speċifika minn lott akbar sabiex jiġi applikat il-metodu tat-teħid tal-kampjuni fuq dik il-parti magħzula. Kull sublott għandu jkun fisikament separat u identifikat.

Teħid ta' kampjuni għal kontrolli uffiċjali.

3. Malta għandha tieħu l-miżuri neċessarji kollha sabiex jiġi żgurat li t-teħid tal-kampjuni għall-kontroll uffiċjali tal-livelli taċ-ċomb, kadmju, merkurju u 3-MCPD fl-għalf għandhom isiru skond il-metodi deskritti fl-Iskeda I li tinsab ma' dawn r-regoli.

Preparazzjoni ta' kampjuni u metodi ta' analiżi.

4. Malta għandha tieħu l-miżuri kollha neċessarji sabiex jiżgura illi l-preparazzjoni ta' kampjuni u l-metodi għall-analiżi użati għall-kontroll uffiċjali tal-livelli taċ-ċomb, kadmju, merkurju u 3- MCPD fl-għalf huma konformi mal-kriterji deskritti fl-Iskeda II li tinstab ma' dawn ir-regoli.

Procedura ta' referenza u applikabilità.

5. Meta Malta tadotta dawn id-disposizzjonijiet, id-disposizzjonijiet għandu jkun fihom referenza għal dawn ir-regoli jew għandu jkollhom referenza bħal dik fil-waqt tal-publikazzjoni uffiċjali tagħhom. Il-proċedura għal dik ir-referenza għandha tkun dik li tkun tapplika f'Malta.

SKEDA I

METODI GĦAT-TEĦID TA' KAMPJUNI GĦALL-KONTROLL UFFIĊJALI TAL-LIVELLI TAĊ-ĊOMB, KADMJU, MERKURJU U 3-MCPD f'ĊERTU GĦALF

1. GĦAN U SKOP

Il-kampjuni li huma intenzjonati għall-kontrolli uffiċjali tal-livelli taċ-ċomb, kadmju, merkurju u 3-MCPD kontenuti f'għalf għandhom jittieġdu skond il-metodu deskritt hawn taħt. Il-kampjuni totali miksuba b'dan il-mod għandhom jitqiesu bħala rappreżentattivi tal-lottijiet jew sublottijiet minn fejn jittieħdu. Tħaris mall-livelli massimi indikati fir-Regolament (KE) Nru 466/2001 għandu jiġi stabbilit a bażi tal-livelli determinati fil-kampjuni tal-laboratorju.

2. DISPOSIZZJONIJIET ĠENERALI

2.1. **Persunal**

It-teħid tal-kampjuni għandu jsir minn persuna awtorizzata kwalifikata skond kif speċifikat minn Malta.

2.2. **Materjal li għandhom jittieħdu kampjuni minnu**

Il-kampjuni minn kull lot li għandu jiġi eżaminat għandhom jittieħdu separatament.

2.3. **Prekawzjonijiet li għandhom jittieħdu**

Fil-kors tat-teħid tal-kampjuni u tal-preparazzjoni tal-kampjuni għal laboratorju, għandhom jittieħdu prekawzjonijiet sabiex jiġu evitati tibdiliet li jistgħu jolqtu l-kontentut taċ-ċomb, kamdju, merkurju u 3-MCPD, sal-punt li jistgħu jolqtu d-determinazzjoni analitika jew il-kampjuni totali ma' jkollomx rappreżentanza.

2.4. Kampjuni inkrimentali

Safejn huwa possibbli l-kampjuni inkrimentali għandhom jittieħdu f'diversi postijiet u għandhom jiġu distribwiti tul il-lott jew sublott kollu. Divergenza minn din il-proċeduria għandha tiġi reġistrata f'*record* ipprovdut taħt 2.8.

2.5. **Preparazzjoni tal-kampjun totali**

Il-kampjun totali huwa magħmul billi jiġu magħquda il-kampjuni inkrimentali kollha. Dan għandu jkun mill-inqas kilogramma waħda sakemm dan ma' jkunx pratikabbli, eż. meta' ittieħed kampjun minn pakett wieħed waħdu.

2.6. **Subdiviżjoni tal-kampjun totali fil-kampjuni tal-laboratorju, għall-skopijiet ta' infurzar, difiża u kontroll**

Il-kampjuni tal-laboratorju għall-iskopijiet ta' infurzar, kummerċ (difiża) u kontroll għandu jittieħed minn kampjuni totali omoġeneiżżati sakemm dan ma' jmurx kontra ir-regolamenti tas-Servizzi Veterinarji dwar it-teħid tal-kampjuni. Id-daqs tal-kampjuni tal-laboratorju għall-infurzar għandhom ikunu suffiċjenti sabiex jippermettu mill-inqas analiżi doppja.

2.7. **Ippakettjar u trasmissjoni tal-kampjuni totali u għall-laboratorju**

Kull kampjun totali u għall-laboratorju għandu jittqiehed f'kontenitur nadif, li joffri protezzjoni xierqa mill-kontaminazzjoni, mit-telf ta' analiti minħabba assorbiment fil-ħitan interni tal-kontenitur u kontra danni waqt il-vjaġġ/trasferiment. Kull prekawzjoni neċessarja għandha tittieħed sabiex jiġu evitat it-tibdil fil-kompożizzjoni tal-kampjuni totali u għall-laboratorju li jista' jseħħ waqt it-trasportazzjoni jew il-ħażna.

2.8. **Siġillar u ttimbrar tal-kampjuni totali u għal-laboratorju**

Kull kampjun meħud għal użu uffiċjali għandu jiġi siġillat fil-post tat-teħid tal-kampjuni u identifikat skond ir-Regolamenti tas-Servizzi Veterinarji. Għandu jinżamm *record* ta' kull teħid ta' kampjuni, sabiex kull lot ikun jista' jiġi identifikat b'mod mhux ambigwu u għandu jindika d-data u l-post tat-teħid tal-kampjuni flimkien ma' kull informazzjoni oħra li jista' jkun ta' għajuna għall-analista.

3. PJANIJIET GĦAT-TEĦID TAL-KAMPJUNI

It-teħid tal-kampjuni għandu idealment isir fejn dik il-kommodita' tidħol fil-katina tal-ikel u jiġi identifikat lot li ma' jidirx. Il-metodu użat għat-teħid tal-kampjuni għandu jiżgura li l-kampjuni totali jirrapreżentaw l-lot li għandu jiġi kontrolat.

3.1. **Għadd ta' kampjuni inkrimentali**

Fil-kaz ta' prodotti likwidi fejn distribuzzjoni omoġenea ta' kontaminant jista' jiġi pretiż ġewwa lott partikolari, ikun suffiċjenti li jittieħed kampjun inkrimentali wieħed ta' kull lott li jifforma parti tal-kampjun totali. Għandha tingħata referenza lin-numru tal-lott. Prodotti likwidi li jikkonsistu minn proteini veġetali idzolizati (HPV) jew sugu tas-soja likwida għandhom jitħaltu sew, jew jiġu omoġeneizzati b'mezzi oħra xierqa, qabel ma jittieħed il-kampjun inkrimentali.

Fir-rigward ta' prodotti oħra, l-inqas għadd ta' kampjuni inkrimentali li jittieħdu mil-lott, għandhom jingħataw kif jidher f'Tabella 1. Il-kampjuni inkrimentali għandhom ikunu ta' l-istess piż. Diverġenza minn din il-proċedura għandha tiġi reġistrata fir-reġistru provdut taħt 2.8.

Table 1: L-inqas għadd ta' kampjuni inkrimentali li għandhom jittieħdu mill-lott

Piz tal-lott (kg)	L-inqas għadd tal-kampjuni inkrimentali li għandhom jittieħdu
< 50 50 to 500 > 500	3 5 10

Jekk il-lott jikkonsisti f' paketti individwali, l-għadd tal-pakketti li għandom jittieħdu fil-forma ta' kampjuni totali huwa muri fit-Tabella 2.

Tabella 2: Għadd tal-paketti (kampjuni inkrimentali) li għandu jittieħed fil-forma ta' kampjuni totali jekk il-lott jikkonsisti minn paketti individwali

Għadd ta' paketti jew unitajiet fil-lott	Għadd ta' paketti jew unitajiet li għandhom jittieħdu
1 sa 25 26 sa 100 > 100	pakkett wieħed jew unita Madwar 5 %, mill-inqas 2 paketti jew unitajiet Madwar 5 %,bil-massimu ta' 10 paketti jew unitajiet

4. ĦARSIEN TAL-LOTT JEW SUBLOTT MA' L-ISPEĊIFIKAZZJONIJIET

Il-laboratorju ta' kontroll għandu janalizza il-kampjun tal-laboratorju għal infurzar ta' mill-inqas żewġ analiżi indipendenti, u għandu jikkalkula l-medja tar-reżultati. Il-lott ma' għandux jiġi aċċettat jekk il-mezz huwa konformi mal-livelli massimi rispettivi kif indikati fir-Regolamenti (KE) Nru 466/2001. Għandu jiġi riġettat jekk il-medja tkun teċċedi il-livell massimu rispettiv.

SKEDA II

PREPARAZZJONI TAL-KAMPJUNI U L-KRITERJI GĦALL-METODI GĦALL-ANALIŻI UŻATI FIL-KONTROLL UFFIĊJALI TAL-LIVELLI TAĊ-ĊOMB, MERKURJU U 3-MCPD F'ĊERTI GĦALF

1. INTRODUZZJONI

Ir-rekwizit basiku huwa li jiġi ottjenut kampjun mill-laboratorju raprezentant u omoġenEu mingħajr l-introduzzjoni sekondarja tal-kontaminazzjoni.

2. IL-PROĊEDURA SPEĊIFIKA TAL-PREPARAZZJONI TAL-KAMPJUNI GĦAĊ-ĊOMB, KADMJU U MERKURJU

Hemm ħafna proċeduri sodisfaċenti għall-preparazzjoni ta' kampjuni speċifiċi li jistgħu jintużaw għall-prodotti in konsiderazzjoni. Dawk deskritti fl-abboz CEN Standard *'Foodstuffs — Determination of trace elements — Performance criteria and general consideration'* instabu li huma sodisfaċenti iżda oħrajn huma validi bl-istess mod.

Għandhom jiġu innotati il-punti segwenti għal kull proċedura li tista tintuża:

— molluski b'żewġ valvi, krostaċeji u ħut żgħir: fejn dawn normalment jittieklu sħaħ, il-vixxera għandha tiġi inkluża mal-materjal għall-analiżi,

— ħaxix: il-parti li tittiekel biss għandha tiġi eżaminata, filwaqt li jinżamm amment tar-rekwiżiti tar-Regolament (KE) Nru 466/2001.

3. METODU TA' ANALIŻI LI GĦANDU JINTUŻA MIL-LABORATORJU U R-REKWIŻITI GĦALL-KONTROLL TAL-LABORATORJU

3.1. **Tifsiriet**

Għadd ta' tifsiriet użati l-iktar komunement u li l-laboratorju jinħtieġ li juża huma mogħtija hawn taħt:

r = ripetizzjoni (repeatability), il-valur inqas li d-differenza assoluta bejn ir-riżultati ta' zewġ testijiet singoli u miksubin taħt kundizzjonijiet ta' ripetuzzjoni (jiġifieri, l-istess kampjun, operator, apparat, laboratorju u intervall ta' qasir żmien) jista' jkun pretiż li jinstab ġewwa probbabilta speċifika (tipikament 95%) u b'hekk r = 2,8 × sr.

sr = devjazzjoni *standard*, ikkalukulata minn riżultati ġenerati taħt kundizzjonijiet ta' ripettizzjoni.

RSDr = devjazzjoni relattiva *standard*, kalkulata mir-riżultati ġenerati taħt kundizzjonijiet ta' ripetizzjoni [(sr / x-) × 100], fejn x – huwa l-medja tar-riżultati fuq kampjuni tal-laboratorji kollha.

R = riproduzzjoni, il-valur inqas li d-differenza assoluta fejn ir-riżultati ta' test waħdu magħmul taħt kundizzjonijiet ta' riproduzzjoni (jiġifieri, fuq materjal identiku miksub minn operaturi minn laboratorji differenti, bl-użu ta' metodi ta' ezami *standard*), jista' jiġi pretiż li jaqa f'ċerta probabbilta` (tipikament 95 %); R = 2,8 × sR.

sR = devjazzjoni *standard*, kalkulata mir-riżultati taħt kundizzjonijiet ta' riproduzzjoni.

RSDR = devjazzjoni relattiva *standard* ikkalkulata minn riżultati ġenerati taħt kundizzjonijiet ta' riproduzttivi [(sR / x-) x 100]

HORRATr = l-RSDr osservat diviż mill-valur tal-RSDr stimat mis-somma (*equation*) Horwitz bl-użu ta' assunsjoni r = 0,66R

HORRATR = l-valur tal-RSDR osservat diviż mill-valur tal-RSDR ikkalkulat mis-somma (*equation*) Horwitz

.

3.2. **Rekwiżiti ġenerali**

Metodi għall-analizi għall-użu għall-iskop tal-kontroll tal-ikel għandu jkun jikkonforma fejn possibbli mad-dispozizzjonijiet tal-paragrafu 1 u 2 tal-Anness mad-Direttiva 85/591/KE.

Għall-analizi taċ-ċomb fl-inbid, Ir-Regolament tal-Kummissjoni (KE) Nru 2676/90(1) li jiddetermina il-metodi Komunitarji għall-analiżi tal-inbejed jindikat il-metodu li għandu jintuża fil-Kapitolu 35 tal-Aness tagħha.

3.3. **Rekwiżiti speċifici**

3.3.1. *Analiżi ta`ċomb, kadmju u merkurju*

Il-metodi speċifiċi għad-determinazzjoni tal-kontenut taċ-ċomb, kadmju u merkurju mhumiex preskritti. Il-laboratorji għandhom jużaw metodu konfermat li jissodisfa l-kriterji ta` għemil indikati fit-Tabella 3. Fejn ikun possibbli, il-konferma għandha tinkludi referenza ċertifikata fil-materjali ċertifikati użati għat-testijiet ta` prova.

Tabella 3: Kriterji għall-għemil tal-metodi għall-analiżi taċ-ċomb, kadmju u merkurju.

Parametru	Valur/kumment
Applikabilita`	L-ikel speċifikat fir-Regolament (KE) Nru 466/2001
Limitu ta` sejbien	Mhux iktar minn wieħed f'kull għaxra tal-valur tal-ispeċifikazzjoni fir-Regolament (KE) Nru 466/2001, ħlief jekk il-valur tal-ispeċifikazzjoni għaċ-ċomb huwa inqas minn 0,1mg/kg. Fil-każ ta` l-aħħar, mhux iktar minn wieħed f'ħamsa tal-valur tal-ispeċifikazzjoni
Limitu tal-kwantifikazzjoni	Mhux iktar minn wieħed f'ħamsa tal-valur tal-ispeċifikazzjoni fir-Regolament (KE) Nru 466/2001, ħlief jekk il-valur tal-ispeċifikazzjoni għaċ-ċomb ikun inqas minn 0,1 mg/kg. Fl-aħħar każ, mhux iktar minn tnejn f'kull ħamsa tal-valur tal-ispeċifikazzjoni
Preċiżjoni	Valuri ta' HORRATr jew HORRATR ta' inqas min 1,5 fil-konferma tat-test kollaborattiv
Rikoveru	80-120 % (kif indikat fl-eżami kollaborattiv)
Speċifiċita'	Ħieles minn interferenzi matriċi jew spettrali

3.3.2. *Analiżi 3-MCPD*

Il-metodi speċifiċi għad-determinazzjoni tal-kontenut tal-3-MCPD mhumiex prekritti. Il-laboratorji għandhom jużaw metodu validat li jissodisfa l-kriterju tal-għemil kif indikat fit-Tabella 4. Meta' jkun possibbli, il-validazzjoni għandha tinkludi referenza certifikata fil-materjali certifikati uzati ghat-testijiet ta` prova. Metodu speċifiku ġie validat permezz ta' testijiet kollaborattivi u intwera li jilħaq il-rekwiziti taħt Tabella 4.

Tabella 4: Kriterja għal-għemil tal-metodi għall-analizi tal-3MCPD

Kriterji	Valur Rakommandat	Konċentrazzjoni
Spazzji fil-kamp (Field blanks)	Inqas mill-limitu tas-sejba	—
Rikoveru	75-110 %	Kollha
Limitu ta' kwantifikazzjoni	10 (jew inqas) ìg/kg fuq bażi ta' materja niexfa	—
Devjazzjoni *standard* tas-sinjal indikattiv ta' spazji fil-kamp	Inqas minn 4 ìg/kg	—

Stimi preċiżi *in-house* —	< 4 ìg/kg	20 ìg/kg
devjazzjoni *standard* tal-kejl	< 6 ìg/kg	30 ìg/kg
għar-replikazzjoni	< 7 ìg/kg	40 ìg/kg
f'konċentrazzjonijiet differenti	< 8 ìg/kg	50 ìg/kg
	< 15 ìg/kg	100 ìg/kg

3.4. **Stima tal-kalkulazzjonijiet analitiċi veritieri u ta' rikoveru**

Fejn huwa possibbli l-verita` tal-analizi għandu jiġi stimat bl-inkluzjoni ta' materjali ċertifikati ta' referenża xierqa tul l-analiżi.

Fil-*'Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement'* sviluppat taħt l-awspiċi ta' IUPAC/ISO/AOAC għandu jittieħed in konsiderazzjoni.

Ir-riżultati analitiċi għandu jiġi rapurtat korretement jew le. Il-maniera tar-raportaġġ u l-livell tar-rikoveru għandhom jiġu rappurtati.

3.5. **Livelli ta' kwalita` tal-laboratorju**

Il-laboratorji għandhom jimxu skond id-Direttiva 93/99/KE.

3.6. **Expressjoni ta' riżultati**

Ir-riżultati għandhom jiġu espressi fl-istess unitajiet bħala l-livell massimu indikat fir-Regolament (KE) Nru 466/2001.

L.N. 98 of 2005

VETERINARY SERVICES ACT
(CAP. 437)

Sampling Methods and the methods of analysis for the official control of thelevels of lead, cadmium, mercury and 3-MCPD in Foodstuffs Rules, 2005

IN exercise of the powers conferred under article 25 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment, in agreement with the Minister of Health, the Elderly and Community Care, has made the following rules:-

Title and scope.

1. (1) The title of these rules is the Sampling Methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in Foodstuffs Rules, 2005.

(2) The scope of these rules is to implement the rules found under European Union Council Directive 2001/22/EC on the sampling methods and the methods of analysis for the official control of the levels of lead, cadmium, mercury and 3-MCPD in foodstuffs.

Definitions.

2. For the purposes of these rules, and unless context otherwise requires -

"aggregate sample" means the combined total of all the incremental samples taken from the lot or sublot;

"the Commission" means the European Commission;

"the Community" means the European Community as established under the Treaty establishing the European Community;

"the competent authority" means the Veterinary Services within Malta as provided under article 2 of the Veterinary Services Act;

"incremental sample" means a quantity of material taken from a single place in the lot or sublot;

"laboratory sample" means the sample intended for the laboratory;

"lot" means an identifiable quantity of food delivered at one time and determined by the veterinary official to have common

characteristics, such as origin, variety, type of packing, packer, consignor or markings. In the case of fish, also the size of fish shall be comparable;

"Member State" means a State which is a Member within the European Community;

"sublot" means a designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separated and identifiable;

"third country" means a State which is not a Member within the European Community;

"Veterinary Services" means the competent authority within the territory of Malta as established under article 2 of the Veterinary Services Act.

Sampling for official controls.

3. Malta shall take all measures necessary to ensure that the sampling for the official controls of the levels of lead, cadium, mercury and 3-MCPD in foodstuffs is carried out in accordance with the methods described in Schedule I to these rules.

Sample preparation and methods of analyses.

4. Malta shall take all measures necessary to ensure that sample preparation and methods of analyses used for the official control of the levels of lead, cadmium, mercury and 3- MCPD in foodstuffs comply with the criteria described in Schedule II to these rules.

Reference of procedure and applicability.

5. When Malta adopts these provisions, the provisions shall contain a reference to these rules or shall be accompanied by such reference at the time of their official publication. The procedure for such reference shall be that applicable in Malta.

SCHEDULE I

METHODS OF SAMPLING FOR OFFICAL CONTROL OF THE LEVELS OF LEAD, CADMIUM, MERCURY AND 3-MCPD IN CERTAIN FOODSTUFFS

1. PURPOSE AND SCOPE

Samples intended for the official control of the levels of lead, cadmium, mercury and 3-MCPD contents in foodstuffs shall be taken according to the methods described below. Aggregate samples thus obtained shall be considered as representative of the lots or sublots from which they are taken. Compliance with maximum levels laid down in Regulation (EC) No 466/2001 shall be established on the basis of the levels determined in the laboratory samples.

2. GENERAL PROVISIONS

2.1. **Personnel**

Sampling shall be performed by an authorised qualified person as specified by Malta.

2.2. **Material to be sampled**

Each lot which is to be examined must be sampled separately.

2.3. **Precautions to be taken**

In the course of sampling and preparation of laboratory samples precautions must be taken to avoid any changes which would affect the lead, cadmium, mercury and 3-MCPD contents, adversely affect the analytical determination or make the aggregate samples unrepresentative.

2.4. **Incremental samples**

As far as possible incremental samples shall be taken at various places distributed throughout the lot or sublot. Departure from this procedure must be recorded in the record provided for under 2.8.

2.5. **Preparation of the aggregate sample**

The aggregate sample is made up by uniting all incremental samples. It shall be at least 1 kg unless not practical, e.g. when a single package has been sampled.

2.6. **Subdivision of aggregate sample in laboratory samples for enforcement, defence and referee purposes**

The laboratory samples for enforcement, trade (defence) and referee purposes shall be taken from the homogenised aggregate sample unless this conflicts with Veterinary Services' regulations on sampling. The size of the laboratory samples for enforcement shall be sufficient to allow at least for duplicate analyses.

2.7. **Packaging and transmission of aggregate and laboratory samples**

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

2.8. **Sealing and labelling of aggregate and laboratory samples**

Each sample taken for official use shall be sealed at the place of sampling and identified following the Veterinary Services' 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.

3. SAMPLING PLANS

Sampling should ideally take place at the point where the commodity enters the food chain and a discrete lot becomes identifiable. The sampling method applied shall ensure that the aggregate sample is representative for the lot that is to be controlled.

3.1. **Number of incremental samples**

In the case of liquid products for which a homogeneous distribution of the contaminant in question can be assumed within a given lot, it is sufficient to take one incremental sample per lot which forms the aggregate sample. Reference to the lot number shall be given. Liquid products containing hydrolysed vegetable protein (HVP) or liquid soya sauce shall be shaken well, or homogenised by other suitable means, before the incremental sample is taken.

For other products, the minimum number of incremental samples to be taken from the lot shall be as given in Table 1. The incremental samples shall be of similar weight. Departure from this procedure must be recorded in the record provided for under 2.8.

Table 1: Minimum number of incremental samples to be taken from the lot

Weight of lot (kg)	Minimum number of incremental samples to be taken
< 50	3
50 to 500	5
> 500	10

If the lot consists of individual packages, then the number of packages which shall be taken to form the aggregate sample is given in Table 2.

Table 2: Number of packages (incremental samples) which shall be taken to form the aggregate sample if the lot consists of individual packages

Number of packages or units in the lot	Number of packages or units to be taken
1 to 25	1 package or unit
26 to 100	About 5 %, at least 2 packages or units
> 100	About 5 %, at maximum 10 packages or units

4. COMPLIANCE OF THE LOT OR SUBLOT WITH THE SPECIFICATION

The control laboratory shall analyse the laboratory sample for enforcement at least in two independent analyses, and calculate the mean of the results. The lot is accepted if the mean conforms to the respective

maximum level as laid down in Regulation (EC) No 466/2001. It is rejected if the mean exceeds the respective maximum level.

SCHEDULE II

SAMPLE PREPARATION AND CRITERIA FOR METHODS OF ANALYSIS USED IN OFFICAL CONTROL OF THE LEVELS OF LEAD, CADMIUM, MERCURY AND 3-MCPD IN CERTAIN FOODSTUFFS

1. INTRODUCTION

The basic requirement is to obtain a representative and homogeneous laboratory sample without introducing secondary contamination.

2. SPECIFIC SAMPLE PREPARATION PROCEDURES FOR LEAD, CADMIUM AND MERCURY

There are many satisfactory specific sample preparation procedures which may be used for the products under consideration. Those described in the draft CEN Standard 'Foodstuffs — Determination of trace elements — Performance criteria and general consideration' have been found to be satisfactory (a) but others may be equally valid.

The following points must be noted for any procedure used:

— bivalve molluscs, crustaceans and small fish: where these are normally eaten whole, the viscera are to be included in the material to be analysed,

— vegetables: only the edible portion of is to be tested, with note to be taken of the requirements of the Regulation (EC) No 466/2001.

3. METHOD OF ANALYSIS TO BE USED BY THE LABORATORY AND LABORATORY CONTROL REQUIREMENTS

3.1. **Definitions**

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

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 × sr.

sr = standard deviation, calculated from results generated under repeatability conditions.

RSDr = relative standard deviation, calculated from results generated under repeatability conditions [(sr / x-) × 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 × sR.

sR = standard deviation, calculated from results under reproducibility conditions.

RSDR = relative standard deviation calculated from results generated under reproducibility conditions [(sR / x-) x 100]

HORRATr = the observed RSDr divided by the RSDr value estimated from the Horwitz equation using the assumption r = 0,66R

HORRATR = the observed RSDR value divided by the RSDR value calculated from the Horwitz equation (b).

3.2. **General requirements**

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

For the analysis of lead in wine, Commission Regulation (EEC) No 2676/90(1) determining Community methods for the analysis of wines lays down the method to be used in Chapter 35 of its Annex.

3.3. **Specific requirements**

3.3.1. *Lead, cadmium and mercury analyses*

Specific methods for the determination of lead, cadmium and mercury contents are not prescribed. Laboratories shall use a validated method that fulfils the performance criteria indicated in Table 3. Where possible, the validation shall include a certified reference material in the collaborative trial test materials.

Table 3: Performance criteria of methods for lead, cadmium and mercury analyses

Parameter	Value/comment
Applicability	Foods specified in Regulation (EC) No 466/2001
Detection limit	No more than one tenth of the value of the specification in Regulation (EC) No 466/2001, except if the value of the specification for lead is less than 0,1mg/kg. For the latter, no more than one fifth of the value of the specification
Limit of quantification	No more than one fifth of the value of the specification in Regulation (EC) No 466/2001, except if the value of the specification for lead is less than 0,1 mg/kg. For the latter, no more than two fifths of the value of the specification
Precision	HORRATr or HORRATR values of less than 1,5 in the validation collaborative trial
Recovery	80-120 % (as indicated in the collaborative trial)
Specificity	Free from matrix or spectral interferences

3.3.2. *3-MCPD analysis*

Specific methods for the determination of 3-MCPD contents are not prescribed. Laboratories shall use a validated method that fulfils the performance criteria indicated in Table 4. Where possible, the validation shall include a certified reference material in the collaborative trial test materials. A specific method has been validated by collaborative trial and has been shown to meet the requirements of Table 4 (c).

Table 4: Performance criteria of methods for 3-MCPD analysis

Criterion	Recommended value	Concentration
Field blanks	Less than the detection limit	—

Recovery	75-110 %	All
Limit of quantification	10 (or less) ìg/kg on a dry matter basis	—
Standard deviation of the field blank signal	Less than 4 ìg/kg	—
In-house precision estimates — standard deviation of replicate measurements at different concentrations	< 4 ìg/kg < 6 ìg/kg < 7 ìg/kg < 8 ìg/kg < 15 ìg/kg	20 ìg/kg 30 ìg/kg 40 ìg/kg 50 ìg/kg 100 ìg/kg

3.4. **Estimation of the analytical trueness and recovery calculations**

Wherever possible the trueness of the analysis shall be estimated by including suitable certified reference materials in the analytical run.

The 'Harmonised Guidelines for the Use of Recovery Information in Analytical Measurement' (d) developed under the auspices of IUPAC/ISO/AOAC shall be taken into account.

The analytical result shall be reported corrected or uncorrected. The manner of reporting and the level of recovery must be reported.

3.5. **Laboratory quality standards**

Laboratories must comply with Directive 93/99/EEC.

3.6. **Expression of results**

The results shall be expressed in the same units as the maximum levels laid down in Regulation (EC) No 466/2001.

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