平成２３年１２月２２日

薬事・食品衛生審議会　食品衛生分科会

放射性物質対策部会

参考資料

参考資料１：「放射能汚染された食品の取り扱いについて」
（厚生労働省食品安全部長通知）

参考資料２：「放射性物質に関する緊急とりまめ」のポイント
（内閣府食品安全委員会公表資料）

参考資料３：評価書　食品中に含まれる放射性物質（抜粋）
（内閣府食品安全委員会公表資料）

参考資料４：食品安全委員会委員長談話
～食品に含まれる放射性物質の食品健康影響評価について～
（内閣府食品安全委員会公表資料）

参考資料５：　WHO飲料水水質ガイドライン（抜粋）

参考資料６：CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CODEX STAN 193-1995)

参考資料７：福島第一原子力発電所から20-30km圏内の土壌試料のPu、Uの分析結果　（文部科学省公表資料）

参考資料８：福島第一原子力発電所 土壌中のU測定結果　（東京電力公表資料）

参考資料１

別紙

食安発０３１７第３号
平成２３年３月１７日

各（都道府県知事／保健所設置市長／特別区長）殿

厚生労働省医薬食品局食品安全部長

放射能汚染された食品の取り扱いについて

平成２３年３月１１日、東京電力株式会社福島第一原子力発電所事故に係る内閣総理大臣による原子力緊急事態宣言が発出されたところである。

このため、飲食に起因する衛生上の危害の発生を防止し、もって国民の健康の保護を図ることを目的とする食品衛生法の観点から、当分の間、別添の原子力安全委員会により示された指標値を暫定規制値とし、これを上回る食品については、食品衛生法第６条第２号に当たるものとして食用に供されることがないよう販売その他について十分処置されたい。

なお、検査に当たっては、平成１４年５月９日付け事務連絡「緊急時における食品の放射能測定マニュアルの送付について」を参照し、実施すること。

核　種	食品衛生法（昭和 22 年法律第 233 号）の規定に基づく食品中の放射性物質に関する暫定規制値（Bq/kg）	
放射性ヨウ素（混合核種の代表核種：^{131}I）	飲料水	300
	牛乳・乳製品　注）	
	野菜類（根菜、芋類を除く。）	2,000
	魚介類※	
放射性セシウム	飲料水	200
	牛乳・乳製品	
	野菜類	500
	穀類	
	肉・卵・魚・その他	
ウラン	乳幼児用食品	20
	飲料水	
	牛乳・乳製品	
	野菜類	100
	穀類	
	肉・卵・魚・その他	
プルトニウム及び超ウラン元素のアルファ核種（^{238}Pu, ^{239}Pu, ^{240}Pu, ^{242}Pu, ^{241}Am, ^{242}Cm, ^{243}Cm, ^{244}Cm 放射能濃度の合計）	乳幼児用食品	1
	飲料水	
	牛乳・乳製品	
	野菜類	10
	穀類	
	肉・卵・魚・その他	

注）100 Bq/kg を超えるものは、乳児用調製粉乳及び直接飲用に供する乳に使用しないよう指導すること。

※（平成２３年４月５日一部改正）

（食品安全委員会公表資料）

参考資料２

平成２３年３月２９日
食品安全委員会事務局

「放射性物質に関する緊急とりまとめ」のポイント

1. 基本的考え方

食品安全委員会としては、今回の緊急とりまとめに当たり、国民の健康保護が最も重要であるという基本的認識の下、国際放射線防護委員会（ICRP）から出されている情報を中心に、世界保健機関（WHO）等から出されている情報等も含め、可能な限り科学的知見に関する情報を収集・分析して検討を行った。

食品中の放射性物質は、本来、可能な限り低減されるべきものであり、特に、妊産婦若しくは妊娠している可能性のある女性、乳児・幼児等に関しては、十分留意されるべきものであると考える。

現時点で収集できた情報等に基づき、極めて短期間のうちに緊急時の対応として検討結果をとりまとめたものである。

2. 緊急とりまとめ

（１）放射性ヨウ素

放射性ヨウ素について、年間５０mSv とする甲状腺等価線量（実効線量として２mSv に相当）は、食品由来の放射線曝露を防ぐ上で相当な安全性を見込んだものと考えられた。

←１９８８年に、WHO は、５mSv の介入水準が実効線量として設定されると、甲状腺のみが被ばくしたと仮定して甲状腺等価線量は１６７mSv となるが、甲状腺照射後の非致死性がんの発生や、ヨウ素１３１が潜在的に甲状腺だけに照射する能力にかんがみると、この線量は過大と考え、甲状腺等価線量として５０mSv という制限値をとることとしたとの見解を示しているが、食品安全委員会としては、現在までにこの WHO の見解を否定する根拠を見いだせていない。

←５０mSv の甲状腺等価線量（実効線量として２mSv に相当）に基づいて規制を行うことについても、健康影響の観点から不適当といえる根拠も現在までに見いだせていない。

（２）放射性セシウム

自然環境下においても 10mSv 程度の曝露が認められている地域が存在すること、10～20mSv までなら特段の健康への影響は考えられないとの専門委員及び専門参考人の意見があったこと等も踏まえると、ICRP の実効線量として年間 10mSv という値について、緊急時にこれに基づきリスク管理を行うことが不適切とまで言える根拠も見いだせていない。これらのことから、少なくとも放射性セシウムに関し実効線量として年間５mSv は、食品由来の放射線曝露を防ぐ上でかなり安全側に立ったものであると考えられた。

←多くの人口集団が、およそ１０mSv/年程度で何年もの間生活（ICRP）

←自然からの放射線は１～１３mSv（平均２．４mSv）であり、かなりの人口集団が１０～２０mSv の放射線を受けていること（UNSCEAR）
←インドや中国の高自然放射線地域に住む住民では、がんの罹患率や死亡率に増加が認められていないこと（UNSCEAR）
←数１０mGy の線量では致死的影響は極めて稀（ICRP）
←約１０mGy の胎児線量でのがん自然発生率に対する相対リスクは１．４程度かこれより低く、小児がんの自然発生率が約０．２～０．３％と極めて低いことから、子宮内被ばく後における個人レベルでの小児がんの発生確率は約０．３～０．４％と極めて小さいとされていること（ICRP）
←約１００mGy までの吸収線量では、どの組織も臨床的に意味のある機能障害を示すとは判断されないこと（ICRP）
←約１００mSv を下回る低線量域では、がん又は遺伝性影響の発生率が関係する臓器及び組織の等価線量の増加に正比例して増加するであろうと仮定するのが科学的にもっともらしい（ICRP）
←飲食物への対策がほとんどすべての場合正当化される介入レベルとして、１種類の食品に対して１年間に実効線量で１０mSv を勧告（ICRP）
←専門参考人からは以下のような意見が出された。
・１０～２０mSv までなら特段の健康への影響は考えられない。
・ICRP における介入基準（１０ mSv）を代用できるのではないか。
・仮に１０ mSv とした場合、妊産婦若しくは妊娠している可能性のある女性、乳児・幼児等に対し、長期曝露の影響はないものと考えられる。

（３）放射性ヨウ素及び放射性セシウムに共通する事項

今回は既に定められている暫定規制値の妥当性について検討したものではなく、今後、リスク管理側において、必要に応じた適切な検討がなされるべきである。

３．今後の課題

今回は、緊急的なとりまとめを行ったものであり、今後、諮問を受けた内容範囲について継続して食品健康影響評価を行う必要がある。

放射性物質は、遺伝毒性発がん性を示すと考えられ、発がん性に関する詳細な検討及び胎児への影響等について詳細な検討が本来必要であり、今回の検討では、発がん性のリスクについての詳細な検討は行えていない等、さまざまな検討課題が残っている。

さらに、ウラン並びにプルトニウム及び超ウラン元素のアルファ核種についての評価、放射性ヨウ素及びセシウムも含めて遺伝毒性発がん物質としての詳細な評価、各核種の体内動態等に関する検討も必要である。

（食品安全委員会公表資料）

参考資料３

評価書

食品中に含まれる放射性物質

（抜粋）

２０１１年１０月

食品安全委員会

要　約

2011年3月11日に、東日本大震災に伴い東京電力福島第一原子力発電所において事故が発生し、周辺環境から通常よりも高い程度の放射能が検出されたことを受けて、厚生労働省は、当面の間、原子力安全委員会により示された「飲食物摂取制限に関する指標」を暫定規制値とした。この暫定規制値は、緊急を要するために食品健康影響評価を受けずに定めたものであることから、厚生労働大臣は、2011年3月20日、食品安全基本法第24条第3項に基づき、食品安全委員会に食品健康影響評価を要請した。

今回、食品健康影響評価を行うに当たっては、原子放射線に関する国連科学委員会（UNSCEAR）及び米国毒性物質疾病登録機関（ATSDR）の放射性物質に関する報告書に引用されている文献、国際放射線防護委員会（ICRP）、世界保健機関（WHO）が公表している資料に加え、その他放射性物質に関連する文献等を幅広く検討の対象とした。なお、経口摂取による放射性物質の健康影響に関する文献は限られていることから、経口摂取による内部被ばくの報告に限らず、また、化学物質としての毒性に関する報告も含め、広く知見を収集した。

個別の核種としては、厚生労働省により暫定規制値が定められている放射性ヨウ素、放射性セシウム、ウラン、並びにプルトニウム及び超ウラン元素のアルファ核種（アメリシウム、キュリウム）、さらに放射性ストロンチウムについて検討を行ったが、検討を行った各核種について、経口摂取による健康影響に関するデータは乏しかった。

放射線による影響よりも化学物質としての毒性がより鋭敏に出ると判断されたウランについては、耐容一日摂取量（TDI）を設定することとした。

ウラン以外の核種については、甲状腺への影響が大きく、甲状腺がんが懸念される放射性ヨウ素、及び食品中からの放射性物質の検出状況等を勘案すると、現状では、食品からの放射性物質の摂取に関して最も重要な核種と考えられた放射性セシウムも含め、個別に評価結果を示すに足る情報は得られなかった。

以上のことを踏まえ、低線量放射線の健康影響に関する検討を疫学データを中心に行い、その結果をとりまとめた。ただし、ウランについてはTDIを設定した。

疫学データには種々の制約が存在するが、そうした制約を十分認識した上で、食品安全委員会においては、入手し得た文献について検討を重ね、研究デザインや対象集団の妥当性、統計学的有意差の有無、推定曝露量の適切性、交絡因子の影響、著者による不確実性の言及等の様々な観点から、本評価において参考にし得る文献か否かについて整理した。

その結果、成人に関して、低線量での健康への影響がみられた、あるいは高線量での健康への影響がみられなかったと報告している大規模な疫学データに基づく次のような文献があった。

① インドの高線量地域での累積吸収線量500 mGy強において発がんリスクの増加がみられなかったことを報告している文献（Nair et al. 2009）

② 広島・長崎の被爆者における固形がんによる死亡の過剰相対リスクについて、被ばく線量0～125 mSvの範囲で線量反応関係においての有意な直線性が認められたが、被ばく線量 0～100 mSv の範囲では有意な相関が認められなかったことを報告している文献（Preston et al. 2003）

③ 広島・長崎の被爆者における白血病による死亡の推定相対リスクについて、対照（0 Gy）群と比較した場合、臓器吸収線量0.2 Gy以上で統計学的に有意に上昇したが、0.2 Gy未満では有意差はなかったことを報告している文献（Shimizu et al. 1988）

以上から、食品健康影響評価として食品安全委員会が検討した範囲においては、放射線による影響が見いだされているのは、通常の一般生活において受ける放射線量を除いた生涯における累積の実効線量として、おおよそ100 mSv以上と判断した。

そのうち、小児の期間については、感受性が成人より高い可能性（甲状腺がんや白血病）があると考えられた。

100 mSv未満の線量における放射線の健康影響については、疫学研究で健康影響がみられたとの報告はあるが、信頼のおけるデータと判断することは困難であった。種々の要因により、低線量の放射線による健康影響を疫学調査で検証し得ていない可能性を否定することもできず、追加の累積線量として100 mSv未満の健康影響について言及することは現在得られている知見からは困難であった。

ウランについては、ラットの91日間飲水投与試験における全投与群で認められた腎尿細管の変化（雌雄に尿細管上皮核の小嚢状の変形、雄では、近位尿細管の拡張、尿細管基底部の核の管腔側への変位、及び細胞質の空胞変性）より、LOAELはウランとして0.06 mg/kg体重/日であった。この試験では離乳期のラット（雌雄、各投与群15匹）が用いられ、病理組織学的検査を含め幅広い検査が行われており、この試験におけるLOAELに不確実係数を適用してTDIを算出することが適切であると考えられた。この試験における腎臓に対する影響及び体内動態においては、排泄が速く、定常状態にあると判断されることから、91日間の亜慢性試験による追加の不確実係数は不要と考えられた。ウランは腎臓から速やかに排泄されることを考慮して、不確実係数は300（種差10、個体差10、LOAELからNOAELへの外挿3）を適用することが適当と判断した。したがってウランのLOAELを0.06 mg/kg体重/日とし、不確実係数300を適用したところ、ウランのTDIは0.2 μg/kg体重/日となった。

「食品中に含まれる放射性物質の食品健康影響評価」の概要

○ 食品健康影響評価として、生涯における追加(※1)の累積の実効線量がおおよそ100mSv以上で放射線による健康影響の可能性(※2)

※1)自然放射線(日本平均約1.5mSv／年)や、医療被ばくなど通常の一般生活において受ける放射線量を除いた分

※2)健康影響が見いだされる値についての疫学データは錯綜していたが、食品分野のリスク分析の考え方(科学的知見の確実性や、健康影響が出る可能性のある指標のうち最も厳しいものの重視等)に基づいておおよそ100mSvと判断したもの

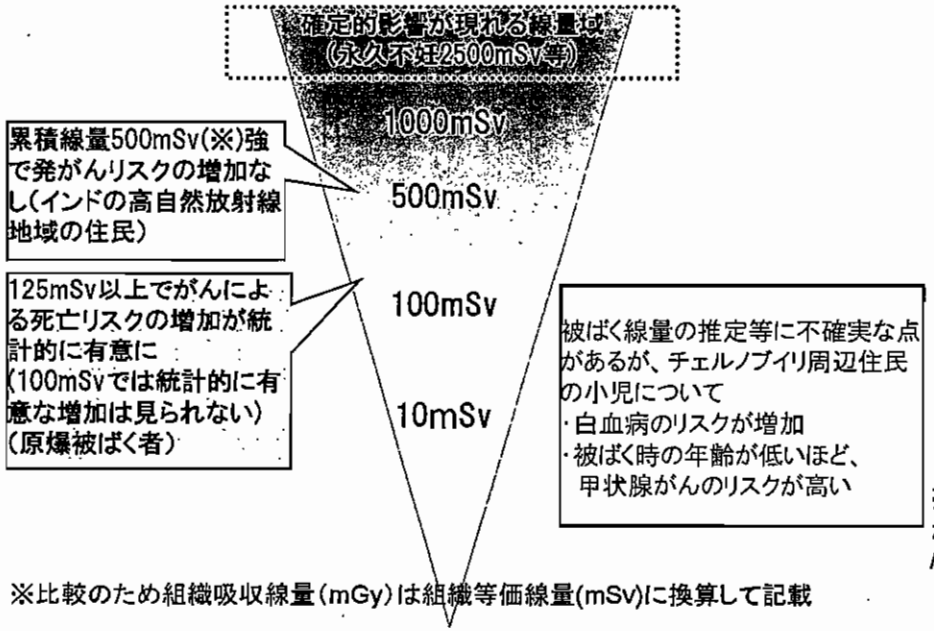
○ そのうち、小児の期間については、感受性が成人より高い可能性(甲状腺がんや白血病)(※3)

※3)被ばく線量の推定等に不確実な点があるが、チェルノブイリ原発事故の際、周辺住民の小児について、白血病のリスクが増加した、被ばく時の年齢が低いほど甲状腺がんのリスクが高い等の疫学データ有り。

○ 100mSv未満の健康影響について言及することは現在得られている知見からは困難

⇒ 今後のリスク管理(食品の規制値の設定等)は、評価結果が生涯における追加の累積線量で示されていることを考慮し、食品からの放射性物質の検出状況、日本人の食品摂取の実態等を踏まえて行うべき

主な疫学データによる放射線の健康影響



※比較のため組織吸収線量(mGy)は組織等価線量(mSv)に換算して記載

「放射性物質に関する緊急とりまとめ」(3月29日)と「食品中に含まれる放射性物質の食品健康影響評価」(10月27日)との比較

	緊急とりまとめ (3月29日)	評価 (10月27日)
期間	緊急時(年間線量)	緊急時・平常時を通じた生涯の追加の累積線量
対象核種・線量	ヨウ素(甲状腺等価線量50mSv(実効線量2mSv相当)) セシウム(実効線量5mSv)	食品健康影響評価として、放射性物質合計の実効線量でおおよそ100mSv以上 (※)
主要な論拠	国際機関(ICRP等)の緊急時対応に関する見解	放射線による健康影響の疫学データ (※食品由来限定の疫学データが極めて少なかったため、外部被ばくも含めたデータも使用)

※ ウランは放射線による健康影響より、化学物質(重金属)としての毒性の方がより低用量で現れることから、他の核種とは別に、耐容一日摂取量を0.2μg/Kg体重/日と設定。

（食品安全委員会公表資料）　　参考資料４

平成２３年１０月２７日

食品安全委員会委員長談話

～食品に含まれる放射性物質の食品健康影響評価について～

１　厚生労働大臣から要請があった放射性物質の食品健康影響評価について、食品安全委員会として、専門家による国内外の数多くの知見の調査審議、国民の皆様からの御意見・情報の募集を経て、本日、評価結果をとりまとめました。

２　今回の食品健康影響評価は、食品安全委員会として、現時点の科学的知見に基づき、客観的かつ中立公正に評価を行ったものです。「食品に関して年間何mSvまでは安全」といった明確な線を引いたものにはなりませんでしたが、現在の科学においてわかっていることとわかっていないことについて、可能な限りの評価を示したものです。評価に当たっての基本的な考え方、評価の概要、判断根拠等の概略は別紙のとおりです。

３　今後、本評価を踏まえ、食品からの放射性物質の検出状況、日本人の食品摂取の実態等を勘案しながら、リスク管理機関において適切な管理措置がとられることを期待しています。

４　３０００通を超える御意見や情報が寄せられましたが、これはこの問題に対する国民の皆様の強い関心や不安の表れと受け止めています。食品安全委員会としては、頂いた御意見等を真摯に受け止め、国民の皆様の判断の一助となるよう、引き続き、できる限りの科学的な情報を提供していくとともに、リスク管理機関とともに丁寧なリスクコミュニケーションに努めてまいります。

（別紙）

1　今回の評価の経緯

福島第一原子力発電所の事故に伴う食品の放射性物質による汚染に関し、平成２３年３月１７日から厚生労働省で食品衛生法上の暫定規制値を設定し、管理が行われている。この暫定規制値は、緊急を要するために食品安全委員会の食品健康影響評価を受けずに定めたものであったことから、３月２０日の厚生労働大臣からの諮問を受け、食品安全委員会では３月２９日に緊急とりまとめをまとめた。その後、残された課題について、４月２１日から放射性物質の専門家等を含めた「放射性物質の食品健康影響評価に関するワーキンググループ」において緻密で詳細な審議が行われた。国内外の放射線影響に関する非常に多くの文献にあたりながら、９回のワーキンググループ会合を重ねて食品健康影響評価書案がとりまとめられた。７月２９日から８月２７日まで御意見・情報を募集し、国民の皆様から３０００通を超える御意見・情報が寄せられた。その中には文献とともに寄せられたものもあり、それについてはその文献にあたり精査した。その結果、評価結果自体に影響を及ぼすような御意見・情報は確認できなかったため、１０月２７日の食品安全委員会において、最終的に評価書をとりまとめた。

2　食品健康影響評価の基本的考え方

食品安全委員会の食品健康影響評価を行うに当たっての基本的考え方は次のとおりである。

（１）　食品健康影響評価は、食品の摂取に伴うヒトの健康へ及ぼす影響について評価を行うものであって、緊急時であるか、平時であるかによって、科学的な評価の基準などが変わる性格のものではない。

（２）食品健康影響評価は、食品分野のリスク分析の考え方（リスクの評価と管理の分離、科学的知見の確実性や健康影響が出る可能性のある指標のうち最も厳しいものの重視等）に基づき安全側に立って実施するものである。

3　今回の評価の概要

食品の健康影響評価として、現在の科学的知見に基づき、食品からの追加的な被ばくについて検討した結果、放射線による健康への影響が見いだされるのは、通常の一般生活において受ける放射線量を除いた生涯における追加の累積線量として、おおよそ 100mSv 以上と判断した。そのうち、小児の期間については、甲状腺がんや白血病といった点で感受性が成人より高い可能性があるとした。また、100mSv 未満の健康影響について言及することは困難と判断した。

前述のとおり、この値はあくまで食品のみから追加的な被ばくを受けたことを前提としているが、この根拠となった科学的知見については、収集された文献に内部被ばくのデータが極めて少なく評価を行うには十分でなかったため、食品健康影響評価に採用し得るものとして、外部被ばくを含んだデータも用いて検討した。しかしながら、これは外部被ばく自体の評価をしたものではない。今回の評価は、食品安全委員会が、国の健康影響評価機関として、「内部と外部とを合計して生涯 100mSv でリスクがある」と評価したわけではなく、外部被ばくなどの食品以外からの被ばくについては、しかるべき機関において適切な措置を講ずべきものと考えている。また、食品安全委員会として、ＩＣＲＰ勧告等を受けて我が国で講じられてきた外部被ばくへの対応の変更や見直しを提起しているものではない。

4　今回の評価に当たっての判断根拠等について

（1）日常自然に浴びる放射線を超えた追加的な被ばくにより健康上の影響が見いだされる数値的データは錯綜していたが、食品については、食品分野のリスク分析の考え方に基づき評価するというのが食品健康影響評価の基本的考え方である。このため、科学的には瞬間的な被ばくをした場合に比較して、慢性的・低線量の被ばくをした場合は、影響が小さいとする知見の存在も承知しているが、様々な知見が存在している中、食品健康影響評価に採用し得る知見がなかったことから、今回はその点を考慮せずに評価を行った。また、インドにおける慢性的・低線量被ばく（累積吸収線量が 500mGy に相当）に関する研究結果は疫学データとして信頼に足るものであったが、食品分野のリスク分析の考え方に基づき、広島・長崎の被ばくデータを援用し、「生涯における追加の累積線量としておおよそ 100mSv 以上」を食品に関する健康影響評価として結論づけることが適当であるとの判断を行ったものである。

※ インドの高線量地域（低線量・低線量率被ばくによる累積吸収線量が 500mGy 相当に達する住民が存在）で発がんリスクの増加がみられなかったとする信頼に足る文献があったが、食品健康影響評価に採用し得るデータとして広島・長崎の疫学データを援用した。

※ 広島・長崎の被ばくにおける疫学調査を援用し、食品健康影響評価として、おおよそ 100mSv 以上の被ばくにおいて放射線による影響が見いだされると判断した。

※被ばく時間については、高線量率で短時間に照射することにより得られる影響と比べて、同じ種類の放射線を線量率を下げて時間をかけて照射した場合には影響が減弱するという知見の存在を食品安全委員会も認識しているが、食品健康影響評価に採用し得る定量的な知見が乏しかったため、その点を捨象した。

（2） 「おおよそ 100mSv」は、

① おおよその値である。また、閾値ではない。なお、100mSv 未満の健康影響については、放射線以外の様々な影響と明確に区別できない可能性や、根拠となる疫学データの対象集団の規模が小さいことや曝露量の推定の不正確さなどのために追加的な被ばくによる発がん等の健康影響を証明できないという限界があるため、疫学的知見からは健康に影響があるともないとも言えず、言及は困難と判断した。

つまり、おおよそ 100mSv とは、健康への影響が必ず生じるという数値ではなく、食品について、リスク管理機関が適切な管理を行うために考慮すべき値である。

② 食品については、緊急時や平時を問わない評価の値である。

③ その値は、食品からの被ばくを軽減するための行政上の規制値（介入線量レベル）ではなく、放射性物質を含む食品の摂取に関するモニタリングデータに基づく追加的な実際の被ばく量について適用されるものである。

5 リスク管理との関係について

（1）本年３月２９日にまとめた食品安全委員会の「緊急とりまとめ」は、緊急時における取扱いを示したものであり、累積線量で示した今回の考え方は、緊急時の対応と矛盾するものではない。

（2）リスク管理機関が、緊急時や平時の判断を行い、実行可能性や国際機関における対応その他の事情を勘案して、適切なリスク管理を行えば、生涯の累積線量としておおよそ 100mSv を超える措置を講じることも想定される。このようなリスク管理は、今回の評価結果と矛盾するものではないと考えられる。

（3）今後、本評価を踏まえ、食品からの放射性物質の検出状況、日本人の食品摂取の実態等を勘案しながら、リスク管理機関において適切な管理措置がとられることを期待している。

（4）食品安全委員会としては、国民の皆様の判断の一助となるよう、引き続き、できる限りの科学的な情報を提供していくとともに、リスク管理機関とともに丁寧なリスクコミュニケーションに努めていく。

参考資料５

WHO飲料水水質ガイドライン

Guidelines for drinking-water quality

第３版
（第１巻）

（抜粋）

WORLD HEALTH ORGANIZATION
Geneva 2004

社団法人　日本水道協会

第9章　放射線学的観点

本章の目的は、放射性核種に関する飲料水の安全性を評価するための基準を設定することである。本ガイドラインでは、自然由来の放射性核種と人工的な放射性核種を区別していない。

本ガイドラインの初版で勧告された飲料水中の放射能のガイドライン値は、放射線の線源からの被ばくリスクおよび放射線に被ばくした場合の健康影響に基づいている。本ガイドラインの第2版では、1990年の国際放射線防護委員会勧告（International Commission on Radiological Protection：ICRP）（ICRP, 1991）を取り入れている。この第3版では、長期被ばくおよび線量換算係数に関するICRPの報告を含めた最近の進展を取り入れている。

放射線による危害は、飲料水中の放射性物質（化学物質）から放出される電離放射線によりもたらされる。飲料水によるこのような危害が公衆衛生上重大となることはまれであるが、飲料水による放射線被ばくは、他の線源による被ばくと並行して評価されなければならない。

放射線による危害を制御するための本ガイドラインで取り上げられるアプローチは、以下の2段階である。

- 放射能濃度（Bq/Lの単位による）が、さらに対策を取る必要があるレベル以下であるかどうかを判断するための、全αおよび全β放射能の初期スクリーニング
- これらのスクリーニングレベルを超過しているなら、個々の放射性核種の濃度の調査、および、各種放射性核種濃度のガイダンスレベルとの比較

地下水に由来する飲料水中のラドンによるリスクは、全吸入ラドンによるリスクに比べて一般に低いが、溶存ガスの摂取と、放出されたラドンおよびその娘核種の吸入の双方により被ばくするので、そのリスクは明白である。最大の被ばくは、一般的な環境からの吸入と地殻に由来する線源からの吸入であり、ガスは特に地下室などの住居内にも侵入する。地下水に由来するラドンの全体に占める割合は通常小さいが、地下室へラドンを放射するその地域の堆積物の指標となるであろう。

スクリーニングレベルおよびガイダンスレベルは、既存のまたは新規の飲料水供給における日常の（「正常な」）運転条件に適用される。これらは、環境中に放射性核種が放出されているような、緊急時で汚染を受けている水供給に適用されるものではない。緊急時のガイダンスレベルと一般的な対策レベルについては、他の資料（IAEA, 1996, 1997, 1999, 2002）に示されている。

本ガイドラインは、以下のことに基づいている。

- 1年間の飲料水摂取による（1年間の飲料水摂取を通してあり得る全放射能汚染による）預託実効線量の勧告参照線量レベル（RDL）0.1mSv。これは、長期被ばく、すなわち、一般

大衆が飲料水を長期にわたり摂取するような状況(ICRP, 2000)に関して、主要商品(例えば、食品および飲料水など)に対してICRPが勧告している介入免除レベルの10%に相当する。RDL 0.1mSvは、ICRP(1991)並びに国際基礎安全基準(International Basic Safcty Standards: BSS)(IAEA, 1996)が勧告する一般住民の線量限界値の10%にも相当する。これらは、ほとんどのWHO加盟国、ヨーロッパ委員会、FAOおよびWHOにより受け入れられている。

－ ICRPにより示されている成人の線量換算係数

飲料水からの放射性核種の摂取に関する年間線量0.1mSvの被ばくによる付加的健康リスクは、以下の理由により低いと考えられる。

- 全集団に対する致命的ながん、非致命的ながんおよび重度の遺伝的影響を含めた、放射線によるものとして推計される健康影響の正規確率係数は、7.3×10^{-2}/Sv(ICRP, 1991)である。これに、飲料水による年間被ばく量0.1mSvのRDLを掛けることにより、推計学的健康影響の推定生涯リスク10^{-5}が得られ、この値は他の健康リスクに比べると低いと考えられる。このリスクレベルは、本ガイドラインの他の箇所で用いられている参照リスクレベルと同程度である。
- バックグラウンド放射線被ばくは地球上の地域によって大きく変化するが、その平均は約2.4mSv/年で、明らかな健康影響はないものの最高地域レベルはこの10倍にも達する。したがって、0.1mSvは、バックグラウンドレベルに比べてごくわずかの増加にしか過ぎない。
- 低レベルの放射線被ばくによるリスクの判定には不確実性があるが、放射線によるリスクは、飲料水中の微生物やある種の化学物質によるものに比べておそらく十分に低い。

9.1 放射線被ばくの線源と健康影響

環境中の放射線は、多くの自然由来および人工の線源によるものである。放射性物質(例えば、ウラン、トリウム、カリウム-40など)は環境中のどこにでも自然に存在する。放射線によるヒトの被ばくうち最も大きな部分は、自然線源からのものー宇宙線および地殻放射を含めた外部線源によるもの、並びに、放射性物質の吸入または摂取によるものーである(図9.1)。原子放射線の影響に関する国連科学委員会(United Nations Scientific Committee on the Effects of Atomic Radiation: UNSCEAR)(UNSCEAR, 2000)では、自然線源からのヒトの年間被ばく量の世界平均は2.4mSv/年であると推定している(表9.1)。一部の線源(例えば、ウランなど)は、鉱業およびその他の産業活動による抽出の過程で濃縮されることがある。

ヒトの放射線による被ばくは、海抜高度、土壌中の放射性核種の量と種類(地殻被ばく)、大気、食品および飲料水中の放射性核種の組成、並びに、吸入または摂取による体内への取り込み量

など、多くの要因により地域ごとに大きく変化する。世界には、インドのケララ州やブラジルのPocos del Caldas平原の一部など、バックグラウンド放射線レベルが比較的高い地域がある。これらの地域における一般集団の被ばくレベルは、表9.1に示した平均バックグラウンドレベル2.4mSvの10倍にも達することがある。この高い放射線被ばくによる健康への悪影響は検知されていない。

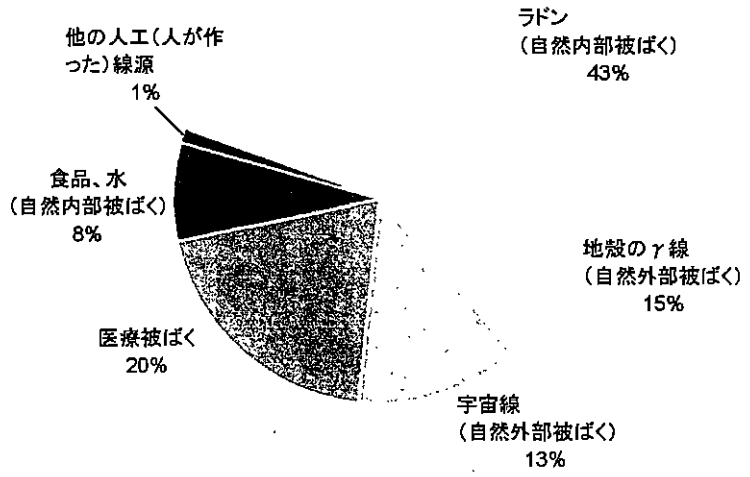


図 9-1　世界の人々への平均的な放射線被ばくの線源と分布

表 9-1　自然線源からの平均的な放射線量

線源	世界の平均年実効線量 (mSv)	代表的な範囲 (mSv)
外部被ばく		
宇宙線	0.4	0.3～1.0
地殻ガンマ線[a]	0.5	0.3～0.6
内部被ばく		
吸入（主にラドン）	1.2	0.2～10[b]
摂取（食物および飲料水）	0.3	0.2～0.8
総計	2.4	1～10

a　地殻による被ばくは、土壌および建材中の放射性核種による。
b　ラドンの吸入線量が 10 mSv/年を超える居住地域がある。
出典：UNSCEAR（2000）

いくつかの放射性化合物が、人の活動に伴って人工的な線源から（例えば、放射線源の医療または産業用の利用などから）、環境中、ひいては飲料水供給に放出されることがある。2000年の世界の健康診断における1人当たり実効線量は、0.4mSv/年であった（ヘルスケアレベルにより異なるが、通常の範囲は0.04～1.0mSv/年である）。原子力発電や核兵器実験による世界的な寄与

は極めてわずかである。2000年の世界の核兵器実験による一人当たり年間実効線量は0.005mSv、これに対して、チェルノブイリ事故によるものは0.002mSv、原子力発電によるものは0.0002mSvと推定されている(UNSCEAR, 2000)。

9.1.1 飲料水を通しての放射線被ばく

飲料水中の放射性成分は以下に由来する。

- 自然由来の放射性核種(例えば、トリウムおよびウランの放射性核種は、飲料水源においてそれぞれの系列にしたがって崩壊する)。特に、ラジウム-226/228およびその他いくつかのもの。
- 自然由来の放射性物質に関わる技術上のプロセス(例えば、鉱砂の採掘および加工、または、リン肥料の製造など)
- 核燃料サイクル施設から排出された放射性核種
- 製造された放射性核種(非密封型で製造されて使用されるもの)。特に、放射性物質の不適切な医療または産業用利用および廃棄処分の場合など、定期的な排出の結果として飲料水供給に混入するもの。これらは、本ガイドラインで視野に入れていない緊急時とは異なる。
- 放射性核種の飲料水源を含めた環境中への過去の放出

全被ばく量に対する飲料水の寄与は、一般に非常に小さく、ウランおよびトリウム系列の自然起因放射性核種に大きく依存する。しかし、核燃料サイクル、並びに、医療およびその他の用途における放射性物質の利用からの放射性核種が、飲料水供給に混入することがある。これらの線源による寄与は、通常、線源または業務の規制により制限されており、これらの線源が飲料水の汚染による懸念の原因となるような事態に際して防除措置が取られるのは、まさにこのような規制の仕組みを通してである。

9.1.2 飲料水を通しての放射線被ばくによる健康影響

低ないしは中線量の放射線被ばくが長期化するとがんの増加をもたらすことは、ヒトおよび動物による研究の証拠がある。特に動物実験では、放射線被ばくによる先天奇形発生率の増加が示唆されている。

放射性核種の濃度がガイダンスレベル以下(すなわち、預託実効線量0.1mSv/年以下)であれば、飲料水の摂取による放射線学的な健康への悪影響はあり得ないと考えられる。

血球数の減少や、非常に重篤な場合には死に至ることもあるような放射線の急性健康影響は、全身または身体の大部分が非常に高線量の被ばくを受けたときにもたらされる(IAEA, 1998)。飲料水供給で通常検出される放射性核種は低レベルであるため、飲料水供給において放射線によ

る急性の健康影響が重要な問題となることはない。

9.2 放射能と放射線量の単位

放射能のSI単位はベクレル(Bq)で、1Bq=1崩壊/秒である。飲料水についてのガイダンスレベルは、1L中の放射性核種による放射能、すなわち放射能濃度(Bq/L)と呼ばれる、として与えられている。放射性核種の摂取によりもたらされる被ばく線量は、多くの化学的および生物学的要因により左右される。これらは、摂取された放射性核種のうち消化管、器官または組織まで運ばれてそれから吸収される部分の割合および放射性核種が排泄されるまで器官または組織内にとどまっている時間などである。崩壊に伴い放射される放射線の特性および放射線に対する器官または組織の感受性も考慮されなければならない。

吸収線量は、どれだけ多くのエネルギーが放射線により物質に投与されたかを表す。吸収線量のSI単位はグレイ(Gy)で、1Gy=1J/kg(ジュール/キログラム)である。

等価線量は、吸収線量と特別な種類の放射線に関係する係数(電離能および密度に依存する)との積である。

ヒトが受ける放射線の実効線量は、簡単に言えば、「組織荷重係数」による荷重を掛けた、すべての組織または器官が受ける等価線量の和である。これらは、人体の異なる器官および組織の放射線に対する感受性の違いを反映している。等価線量および実効線量のSI単位はシーベルト(Sv)で、1Sv=1J/kgである。

一旦体内に取り込まれた放射性核種の残留性を反映させるため、ある放射性核種の摂取(内部被ばく)に伴い一生涯(70年)にわたって受ける全実効線量の尺度として、預託実効線量が用いられる。

「線量」という用語は、状況により、吸収線量(Gy)または実効線量(Sv)を意味する一般的な用語として使われる。監視の目的のため、与えられた物質の放射性核種の放射能濃度から線量が測定される。水の場合には、放射能濃度がBq/Lの単位で表される。この値は、線量換算係数(mSv/Bq)および水の年平均摂取量(L/年)を用いることにより、一年当たりの実効線量(mSv/年)と関連付けることができる。

特定の化学形態の放射性同位体の摂取による実効線量は、線量換算係数を用いて推定することができる。放射性核種の摂取に関する年齢と関連付けた線量換算係数のデータが、ICRPおよび国際原子力機関(International Atomic Energy Agency: IAEA)により公表されている。表9.2に、飲料水供給で検出される自然由来の放射性核種、または、人為活動に起因する放射性核種についての線量換算係数を示す(IAEA, 1996; ICRP, 1996)。

表 9-2 一般成人による放射性核種の摂取に関する線量換算係数

分類	放射性核種	線量換算係数(mSv/Bq)
天然ウラン系列	ウラン-238	4.5×10^{-5}
	ウラン-234	4.9×10^{-5}
	トリウム-230	2.1×10^{-4}
	ラジウム-226	2.8×10^{-4}
	鉛-210	6.9×10^{-4}
	ポロニウム-210	1.2×10^{-3}
天然トリウム系列	トリウム-232	2.3×10^{-4}
	ラジウム-228	6.9×10^{-4}
	トリウム-228	7.2×10^{-5}
核分裂生成物	セシウム－134	1.9×10^{-5}
	セシウム－137	1.3×10^{-5}
	ストロンチウム-90	2.8×10^{-5}
	ヨウ素-131	2.2×10^{-5}
他の放射性核種	トリチウム	1.8×10^{-8}
	炭素-14	5.8×10^{-7}
	プルトニウム-239	2.5×10^{-4}
	アメリシウム-241	2.0×10^{-4}

9.3 飲料水中の放射性核種のガイダンスレベル

天然線源に由来する放射性核種、または、現在もしくは過去における活動の結果として環境中に排出された放射性核種につき、飲料水中の放射性核種のガイダンスレベルを表9.3に示す。これらのレベルは、一年以上前の核事故で放出された放射性核種にも適用できる。表9.3の放射能濃度の値は、その年に摂取された飲料水中の濃度がこの値を超えなければ、各放射性核種につきRDL 0.1mSv/年に相当する。これによるリスクの推定値は本章の初めに記した。しかし、事故直後の1年間は、BSS(IAEA, 1996)並びにその他のWHOおよびIAEAの関連刊行物(WHO, 1988; IAEA, 1997, 1999)に記載されているように、食材に関しての一般的アクションレベルが適用される。

飲料水中の放射性核種のガイダンスレベルは、次式により計算された。

$$GL=1DC/(h_{ing}\cdot q)$$

ここに、

GL: 飲料水中の放射性核種のガイダンスレベル(Bq/L)

IDC: 個別線量基準、この計算では0.1mSv/年

h_{ing}: 成人による摂取の線量換算係数(mSv/Bq)

q: 飲料水の年摂取量、730L/年と仮定

小児について計算された年齢依存線量換算係数がより高い(より高い摂取量もしくは代謝速度を意味する)が、幼児または小児により摂取される飲料水量が平均的により少いために、線量が顕著により高くなるということはない。この結果、一年間の飲料水摂取による預託実効線量

0.1mSv/年の勧告RDLは、年齢に関係なく適用される。

表 9-3 飲料水中の放射性核種のガイダンスレベル

(1/2)

放射性核種	ガイダンスレベル(Bq/L)[a]	放射性核種	ガイダンスレベル(Bq/L)[a]	放射性核種	ガイダンスレベル(Bq/L)[a]
^{3}H	10,000	^{93}Mo	100	^{140}La	100
^{7}Be	10,000	^{99}Mo	100	^{139}Ce	1,000
^{14}C	100	^{96}Tc	100	^{141}Ce	100
^{22}Na	100	^{97}Tc	1,000	^{143}Ce	100
^{32}P	100	^{97m}Tc	100	^{144}Ce	10
^{33}P	1,000	^{99}Tc	100	^{143}Pr	100
^{35}S	100	^{97}Ru	1,000	^{147}Nd	100
^{36}Cl	100	^{103}Ru	100	^{147}Pm	1,000
^{45}Ca	100	^{106}Ru	10	^{149}Pm	100
^{47}Ca	100	^{105}Rh	1,000	^{151}Sm	1,000
^{46}Sc	100	^{103}Pd	1,000	^{153}Sm	100
^{47}Sc	100	^{105}Ag	100	^{152}Eu	100
^{48}Sc	100	^{110m}Ag	100	^{154}Eu	100
^{48}V	100	^{111}Ag	100	^{155}Eu	1,000
^{51}Cr	10,000	^{109}Cd	100	^{153}Gd	1,000
^{52}Mn	100	^{115}Cd	100	^{160}Tb	100
^{53}Mn	10,000	^{115m}Cd	100	^{169}Er	1,000
^{54}Mn	100	^{111}In	1,000	^{171}Tm	1,000
^{55}Fe	1,000	^{114m}In	100	^{175}Yb	1,000
^{59}Fe	100	^{113}Sn	100	^{182}Ta	100
^{56}Co	100	^{125}Sn	100	^{181}W	1,000
^{57}Co	1,000	^{122}Sb	100	^{185}W	1,000
^{58}Co	100	^{124}Sb	100	^{186}Re	100
^{60}Co	100	^{125}Sb	100	^{185}Os	100
^{59}Ni	1,000	^{123m}Te	100	^{191}Os	100
^{63}Ni	1,000	^{127}Te	1,000	^{193}Os	100
^{65}Zn	100	^{127m}Te	100	^{190}Ir	100
^{71}Ge	10,000	^{129}Te	1,000	^{192}Ir	100
^{73}As	1,000	^{129m}Te	100	^{191}Pt	1,000
^{74}As	100	^{131}Te	1,000	^{193m}Pt	1,000
^{76}As	100	^{131m}Te	100	^{198}Au	100
^{77}As	1,000	^{132}Te	100	^{199}Au	1,000
^{75}Se	100	^{125}I	10	^{197}Hg	1,000
^{82}Br	100	^{126}I	10	^{203}Hg	100
^{86}Rb	100	^{129}I	1,000	^{200}Ti	1,000
^{85}Sr	100	^{131}I	10	^{201}Ti	1,000
^{89}Sr	100	^{129}Cs	1,000	^{202}Ti	1,000
^{90}Sr	10	^{131}Cs	1,000	^{204}Ti	100
^{90}Y	100	^{132}Cs	100	^{203}Pb	1,000
^{91}Y	100	^{134}Cs	10	^{206}Bi	100
^{93}Zr	100	^{135}Cs	100	^{207}Bi	100
^{95}Zr	100	^{136}Cs	100	^{210}Bi[b]	100
^{93m}Nb	1,000	^{137}Cs	10	^{210}Pb[b]	0.1

表 9-3 飲料水中の放射性核種のガイダンスレベル

(2/2)

放射性核種	ガイダンスレベル(Bq/L)[a]	放射性核種	ガイダンスレベル(Bq/L)[a]	放射性核種	ガイダンスレベル(Bq/L)[a]
^{94}Nb	100	^{131}Ba	1,000	^{210}Po[b]	0.1
^{95}Nb	100	^{140}Ba	100	^{223}Ra[b]	1
^{224}Ra[b]	1	^{235}U[b]	1	^{242}Cm	10
^{225}Ra	1	^{236}U[b]	1	^{243}Cm	1
^{226}Ra[b]	1	^{237}U	100	^{244}Cm	1
^{228}Ra[b]	0.1	^{238}U[b,c]	10	^{245}Cm	1
^{227}Th[b]	10	^{237}Np	1	^{246}Cm	1
^{228}Th[b]	1	^{239}Np	100	^{247}Cm	1
^{229}Th	0.1	^{236}Pu	1	^{248}Cm	0.1
^{230}Th[b]	1	^{237}Pu	1,000	^{249}Bk	100
^{231}Th[b]	1,000	^{238}Pu	1	^{246}Cf	100
^{232}Th[b]	1	^{239}Pu	1	^{248}Cf	10
^{234}Th[b]	100	^{240}Pu	1	^{249}Cf	1
^{230}Pa	100	^{241}Pu	10	^{250}Cf	1
^{231}Pa[b]	0.1	^{242}Pu	1	^{251}Cf	1
^{233}Pa	100	^{244}Pu	1	^{252}Cf	1
^{230}U	1	^{241}Am	1	^{253}Cf	100
^{231}U	1,000	^{242}Am	1,000	^{254}Cf	1
^{232}U	1	^{242m}Am	1	^{253}Es	10
^{233}U	1	^{243}Am	1	^{254}Es	10
^{234}U[b]	10			^{254m}Es	100

a ガイダンスレベルは、対数の値の平均を丸めたものである（算定値が 3×10^{n} 以下および $3\times10^{n-1}$ 以上であれば 10nに）。

b 天然放射性核種

c 飲料水中のウランの暫定ガイドライン値は、腎臓に対する化学的な毒性に基づき 15 μg/L である。(8.5 参照)。

9.4 溶存放射性核種の監視と評価

9.4.1 飲料水供給のスクリーニング

個々の放射性核種を同定し、その濃度を測定するプロセスでは、高度で高価な分析が求められるが、このような分析は、ほとんどの状況においては放射性核種の濃度が非常に低いので、通常は正当化されるものではない。より実際的なアプローチは、特定の放射性核種を同定することは考えないで、アルファ(α)およびベータ(β)放射線の形で存在する全放射能をまず測定する、スクリーニング手順を用いることである。

それ以下であればさらに対策を取る必要がない飲料水のスクリーニングレベルは、全α放射能0.5Bq/Lおよび全β放射能1Bq/Lである。全β放射能のスクリーニングレベルは、本ガイドラインの第2版で公表されたもので、最悪(ラジウム-222)の場合にはガイダンスRDL 0.1mSv/年に近い線量となる。全α放射能のスクリーニングレベルは0.5Bq/L(以前の0.1Bq/Lに代えて)で、これは、この放射能濃度が、放射性核種ごとのガイダンスRDLにより近い値を反映しているからである。

9.4.2 飲料水の評価方法

もし前記いずれかのスクリーニングレベルを超えるようなことがあれば、この放射能を発生させている放射性核種を同定して、それらの個々の放射能濃度を測定するべきである。これらのデータから、個々の放射性核種の預託実効線量を推定して、これらの線量の合計値を決定するべきである。次式が満たされれば、さらに対策を取る必要はない。

$$\sum_i \frac{C_i}{GL_i} \leq 1$$

ここに、

C_i: 放射性核種iについて測定された放射能濃度

GL_i: 1 年間毎日 2Lずつ摂取した場合の預託実効線量が 0.1mSv/年となる放射性核種iのガイダンスレベル値(表 9.3参照)

単一試料についてこの合計が1を超えており、これらと同じ測定濃度の被ばくが丸1年間続いていた場合に限って、RDL 0.1mSvを超過していたと見なされる。したがって、このような試料は、それ自体で、その水が飲用不適であることを意味するわけではないが、追加して試料採取を行うなど、さらに調査する必要があることを示すものと見なすべきである。全βおよび全α放射能のスクリーニングを最初に繰り返して行うべきであり、続けて測定したこれらの値が、ここで勧告する実務上のスクリーニング値(それぞれ、1Bq/Lおよび0.5Bq/L)を超える場合に限って、個々の放射性核種についての分析を行うべきである。

このような勧告法の適用について図9.2に示す。

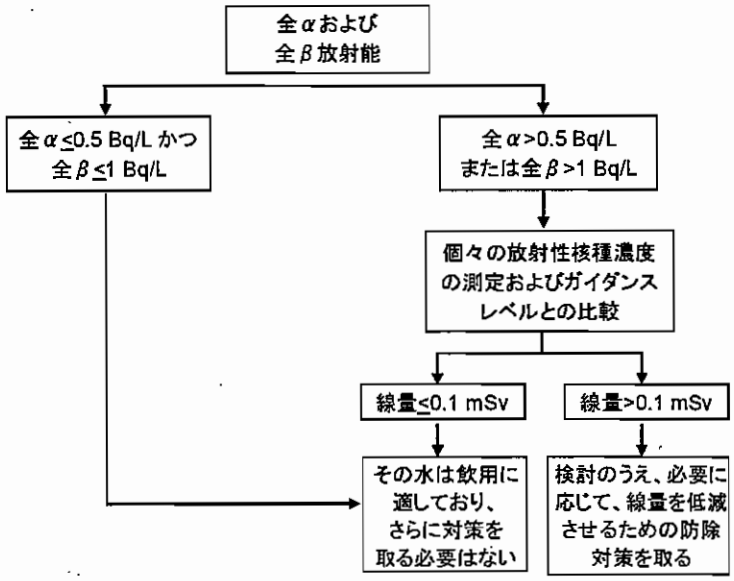


図 9-2 飲料水中の放射性核種へのスクリーニングレベルおよびガイダンスレベルの適用

全βの測定は、カリウムの安定同位体に対して一定比率で自然界に存在してβ線を放射する、カリウム-40による寄与を含む。カリウムはヒトの必須元素であり、主に食品として摂取して吸収される。カリウム-40は体内に蓄積されないが、摂取量とは関係なく一定のレベルが維持されている。したがって、カリウム-40のβ放射能に対する寄与は、全カリウムを別途測定したあとに差し引かれるべきである。カリウム-40の比放射能は30.7Bq/gカリウムである。しかし、カリウム-40からの放射能のすべてがβ放射能とは考えられない。カリウム-40のβ放射能は27.6Bq/g安定同位体カリウムであり、カリウム-40によるβ放射能の計算には、この係数を用いるべきである。

9.4.3 防除手段

総計としてRDL 0.1mSv/年を超える場合には、線量を低減させるために担当官署に与えられた選択肢が試されるべきである。防除手段につき考慮する場合、それがどのような方法であっても、まずその正当性を確認（それが正味の便益をもたらすことという意味において）してから、ICRP勧告（1989, 1991）にしたがって正味の便益を最大にするための最適化を図るべきである。

9.5 ラドン

9.5.1 空気中および水中のラドン

自然放射線被ばくのうち最大のものは、ラドン、すなわち、ウラン系列放射性核種の一部として岩石や土壌に含まれる、ラジウムの崩壊による放射性ガス（表9.1および図9.1参照）によるものである。一般のラドンという用語は、多くの場合、ラドン-222を意味する。ラドンは、文字どおり地球上のどこにでも存在しているが、特に陸上の空気や建築物内の空気に存在する。

天然ウランを含む地中の岩石は、それと接触する地下水中に絶えずラドンを放出し続けている。ラドンは表流水からは容易に放出されるので、通常、地下水中のラドンの濃度は表流水中のそれよりもずっと高い。ラドンの平均濃度は、通常、表流水を原水とする飲料水供給では0.4Bq/L以下、地下水を原水とするものでは約20Bq/Lである。しかし、井戸によっては、平均値の400倍もの高濃度が測定されており、まれに10kBq/Lを超えるものもある。

ラドンの摂取による線量を評価するためには、摂取に先立つ浄水技術を考慮に入れることが重要である。さらに、地下水を一般の家事用途に使用する際には、空気中のラドンレベルが上昇し、その結果、吸入線量も増加する。この線量は、水の利用形態と住居の構造に顕著に左右される（NCRP, 1989）。水の摂取量とその形態、家庭でのその他の水利用および家屋構造は世界中で大いに異なる。

UNSCEAR（2000）では、US NAS報告（1999）を参照し、空気中のラドンおよびその崩壊生成物からの吸入線量1.1mSv/年に対して、「飲料水中のラドンからの平均線量は、吸入によるものが0.025mSv/年、摂取によるものが0.002mSv/年といずれも低い値」であると算定している。

9.5.2 リスク

ある報告書では、アメリカ合衆国における肺がん死亡の12%は、室内空気中のラドン（ラドン-222およびその短寿命崩壊生成物）によるものであると推定している（US NAS, 1999）。これに従えば、主として喫煙による年間の全肺がん死亡者数約160,000人のうち約19,000人（15,000～22,000人の範囲）は、ラドンに起因している。

US NAS（1999）では、飲料水中のラドンによる被ばくのリスクは、上記の約100分の1（すなわち、年間死亡者数183人）であると報告している。室内空気中のラドンに起因する肺がん死亡者数19,000人に加えて、さらに160人が、家屋内で用いる水から放射されるラドンの吸入によるものと推定された。比較までに、年間肺がん死亡者数のうち約700人は、野外で自然レベルのラドンによる被ばくによるものとされている。

また、US NAS（1999）は、溶解性ラドンを含む飲料水に起因する胃がんのリスクは、アメリカ合衆国のその他の原因での胃がんによる年間死亡者数13,000人に比べて、推計値約20人と極めて小さく評価している。

9.5.3 飲料水供給におけるラドンについてのガイダンス

飲料水供給のラドン濃度が100Bq/Lを超える場合には制御するべきである。どのような新規の飲料水供給でも、供用開始前に試験を行うべきである。もしラドン濃度が100Bq/Lを超えていれば、ラドンレベルが100Bq/Lよりも十分に低くなるように浄水処理を行うべきである。水源の周辺にラドンを発生させる鉱物が大量に存在している場合には、例えば5年ごとなど、大規模飲料水供給であれば定期的にラドン濃度を検査することが適切であろう。

9.6 試料採取、分析および報告

9.6.1 全α、全β放射能濃度の測定

飲料水の全αおよび全β放射能（ラドンを除く）を分析するための最も一般的なアプローチは、既知量の試料水を蒸発乾固させ、残渣の放射能を測定する方法である。α放射線は薄層の固体に吸収されやすいので、TDS含有量の高い試料では、この全α測定法の信頼性と感度が低下するおそれがある。

全αおよび全β放射能濃度の測定には、可能な限り標準化された方法を用いるべきである。3つの分析法の手順を表9.4に示す。

蒸発法による全β放射能の測定では、カリウム-40の寄与が含まれる。したがって、全βスクリーニング値が超過する場合には、全カリウムにつき追加分析することが必要である。

共沈法（APHA, 1998）ではカリウム-40の寄与は排除されるので、全カリウムの測定は不要である。この方法は、セシウム-137など、特定の核分裂生成物を含む試料水の評価に用いることはで

きない。しかし、通常の状況のもとでは、飲料水供給における核分裂生成物の濃度は極めて低い。

表 9-4 飲料水中の全αおよび全β放射能の分析法

方法、参照文献	技術	検出限界	適用
国際標準化機関 ISO-9695（全β） ISO-9696（全α） (ISO, 1991a, 1991b)	蒸発	0.02～0.1 Bq/L	TDS 0.1 g/L 以上の地下水
米国公衆衛生協会 (APHA, 1998)	共沈	0.02 Bq/L	表流水および地下水（TDS は因子でない）

9.6.2 カリウム-40 の測定

試料水のカリウム-40濃度の測定には、ガンマ(γ)線分析の感度が低いこと、および水溶液から放射性核種を化学的に分離することが困難なことから、放射能測定法を用いることは実際的ではない。カリウム-40とその安定同位体の比率は一定なので、カリウムの化学分析が推奨される。カリウムの測定感度が1mg/Lであれば十分で、これを容易に達成し得る技術としては原子吸光光度法と特定イオン分析がある。カリウム-40によるβ放射能は、全カリウム1g当たり27.6Bqの係数を用いて計算することができる。

9.6.3 ラドンの測定

飲料水中のラドン-222による放射能濃度は、その取り扱いに際してラドンが水中から放出されやすいため、測定が困難である。撹拌や別の容器への水の移し換えにより、溶解性のラドンが遊離する。広く用いられているPylon法(Pylon, 1989, 2003)では、水脱気ユニットとLucasシンチレーション検出器を用いて、飲料水中のラドンを検出することができる。水を放置することによりラドンによる放射能が減少し、さらに、煮沸することによりラドンが完全に除去される。

9.6.4 試料採取

新規の飲料水源については、その設計および建設に先立って放射線学的水質特性を明らかにし、放射性核種濃度の季節変化を評価して、飲料水供給としての適正を判定するために、試料を採取(例えば、当初の12ヶ月間は3ヶ月ごとなど)するべきである。これには、ラドンおよびその娘核種の分析を含めるべきである。

飲料水供給として正常な範囲にあることが測定によって示されたあとは、試料採取頻度を例えば毎年または5年ごとなどにしても良い。しかし、放射性核種の汚染源(例えば、鉱山または原子炉など)が周辺に存在する場合には、試料採取をより頻繁に行うべきである。それほど重大でない表流水や地下水を水源とする場合には、試料採取頻度を低くして良い。

地下水を水源とする水供給でのラドンおよびその娘核種のレベルは、通常は長期間にわたり安定である。したがって、ラドンおよびその娘核種についての水の監視は、比較的低い頻度で良い。水源が高濃度のラドンおよびその娘核種を含んでいそうかどうかを判定するために、当該地域の地質情報を考慮するべきである。その他のリスク要因としては周辺における鉱山の存在が上げられ、このような場合には、より高い頻度の監視を行うことが適当であろう。

水質の評価、試料採取の方法と計画、並びに、試料の保存と取り扱いについての手引きは、オーストラリアおよびニュージーランド基準(Australian and New Zealand Standard)(AS, 1998)に記されている。

9.6.5 結果の報告

各試料についての分析結果には、以下の情報が含まれるべきである。

- 試料識別コードまたは情報
- 報告結果の参照日時(例えば、試料採取日など)
- 用いた標準分析法の特定、または、標準法でない場合にはその簡単な説明
- 測定した放射性核種または放射能の種類および全放射能の特定
- 各放射性核種につき適切なブランクを用いて計算した、測定に基づく濃度または放射能の値
- 計数上の不確実性および予測される全不確実性の推定値
- 放射性核種または分析パラメータごとの最小検出可能濃度

報告結果についての予測される全不確実性の推定値には、その分析法におけるすべてのパラメータによる寄与(すなわち、計数、並びに、その他のランダムおよび系統的な不確実性または誤差)を含めるべきである。

CODEX GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED

CODEX STAN 193-1995

1. PREAMBLE

1.1 SCOPE

This Standard contains the main principles which are recommended by the Codex Alimentarius in dealing with contaminants and toxins in food and feed, and lists the maximum levels and associated sampling plans of contaminants and natural toxicants in food and feed which are recommended by the CAC to be applied to commodities moving in international trade.

This standard includes only maximum levels of contaminants and natural toxicants in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health.

1.2 DEFINITION OF TERMS

1.2.1 General

The definitions for the purpose of the Codex Alimentarius, as mentioned in the Procedural Manual, are applicable to the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) and only the most important ones are repeated here. Some new definitions are introduced, where this seems warranted to obtain optimal clarity. When reference is made to foods, this also applies to animal feed, in those cases where this is appropriate.

1.2.2 Contaminant

Codex Alimentarius defines a contaminant as follows:

"Any substance not intentionally added to food, which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter".

This standard applies to any substance that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, except:

1) Contaminants having only food and feed quality significance (e.g. copper), but no public health significance, in the food(s) given that the standards elaborated within the Codex Committee on Contaminants in Foods (CCCF) has the objective to protect public health.

2) Pesticide residues, as defined by the Codex definition that are within the terms of reference of the Codex Committee on Pesticide Residues (CCPR).

3) Residues of veterinary drugs, as defined by the Codex definition, that are within the terms of reference of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the Codex Committee on Food Hygiene (CCFH).

5) Residues of processing aids that are within the terms of reference of the Codex Committee on Food Additives (CCFA)[1].

1.2.3 Natural toxins included in this standard

The Codex definition of a contaminant implicitly includes naturally occurring toxicants including toxic metabolites of certain microfungi that are not intentionally added to food and feed (mycotoxins).

Toxins that are produced by algae and that may be accumulated in edible aquatic organisms such as shellfish (phycotoxins) are also included in this standard. Mycotoxins and phycotoxins are both subclasses of contaminants.

[1] Processing aids are any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

Adopted 1995; Revised 1997, 2006, 2008, 2009; Amended 2009, 2010

Endogenous natural toxicants, such as e.g. solanine in potatoes, that are implicit constituents of food and feed resulting from a genus, species or strain ordinarily producing hazardous levels of a toxic metabolite(s), i.e. phytotoxins are not generally considered within the scope of this standard. They are, however, within the terms of reference of the CCCF and will be dealt with on a case by case basis.

1.2.4 Maximum level and related terms[2]

The ***Codex maximum level (ML)*** for a contaminant in a food or feed commodity is the maximum concentration of that substance recommended by the Codex Alimentarius Commission (CAC) to be legally permitted in that commodity.

1.3 PRINCIPLES REGARDING CONTAMINANTS IN FOOD AND FEED

1.3.1 General

Contamination of food and feed may pose a risk to human (and/or animal health). Moreover in some cases they may also have a negative impact on the quality of the food or feed. Food and feed can become contaminated by various causes and processes.

Contaminant levels in food and feed shall be as low as reasonably achievable through best practice such as Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP) following an appropriate risk assessment. The following actions may serve to prevent or to reduce contamination of feed and food[3]:

- preventing food and feed contamination at the source, e.g. by reducing environmental pollution.
- applying appropriate technology control measure(s) in food and feed production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding.
- applying measures aimed at decontamination of contaminated feed or food and measures to prevent contaminated feed or food to be marketed for consumption.

To ensure that adequate action is taken to reduce contamination of food and feed a Code of Practice shall be elaborated comprising source related measures and Good Manufacturing Practice as well as Good Agricultural Practice in relation to the specific contamination problem.

The degree of contamination of food and feed and the effect of actions to reduce contamination shall be assessed by monitoring, survey programs and more specialized research programs, where necessary.

When there are indications that health hazards may be involved with consumption of food that is contaminated, it is necessary that a risk assessment should be undertaken. When health concerns can be substantiated, a risk management measure must be applied, based on a thorough evaluation of the situation and consideration of a range of risk management options. Depending on the assessment of the problems and the possible solutions, it may be necessary to establish MLs or other measures to control the contamination of food and feed. In special cases, specific advice on dietary recommendations may also have to be considered to complement other regulatory measures, when the measures are not sufficiently adequate to protect public health and safety.

National measures regarding food and feed contamination should avoid the creation of unnecessary barriers to international trade in food and feed commodities. The purpose of the GSCTFF is to provide guidance about possible approaches to eliminate or reduce the contamination problem and to promote international harmonization through recommendations which in turn may prevent trade barriers and disputes.

For all contaminants, which may be present in more than one feed or food item, a broad approach shall be applied, taking into account all relevant information that is available, for the assessing of risks and for developing recommendations and control measures, including the setting of maximum levels.

1.3.2 Principles for establishing maximum levels in food and feed

MLs shall only be set for food in which the contaminant may be found in amounts that are significant for the total exposure of the consumer, taking into consideration the Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Section III of the Procedural Manual)

The maximum levels shall be set in such a way that the consumer is adequately protected. At the same time the other legitimate factors need to be considered. . This will be performed in accordance with the "Working principles for Risk Analysis for Food safety for Application by Governments".

The principles of Good Manufacturing Practice and Good Agricultural Practice as defined by Codex shall be used. Maximum levels shall be based on sound scientific principles leading to levels which are acceptable worldwide, so that there is no unjustified barrier to international trade. MLs shall be clearly defined with respect to status and intended use.

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2 For the contaminants methylmercury, radionuclides, acrylonitrile and vinylchloride monomer a **Codex guideline level (GL)** has been established. A ***Codex guideline level (GL)*** is the maximum level of a substance in a food or feed commodity which is recommended by the CAC to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction.
Because the CAC has decided that the preferred format of a Codex standard in food or feed is a maximum level, the present existing or proposed guideline levels shall be reviewed for their possible conversion to a maximum level after a risk assessment performed by JECFA, if appropriate.

3 In addition, reference is made to the Code of Practice for source Directed measures to reduce contamination of food with chemicals (CAC/RCP 49-2001) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004)

1.3.3 Specific criteria

The following criteria should (not preventing the use of other relevant criteria) be considered when developing MLs and/or other measures in connection with the Codex General Standard for Contaminants and Toxins in Food and Feed : (Further details about these criteria are given in Annex I).

Toxicological information

- identification of the toxic substance(s);
- metabolism by humans and animals, as appropriate;
- toxicokinetics and toxicodynamics including information on possible carry-over of the toxic substance from feed to edible animal tissue/products;
- information about acute and long term toxicity and other relevant toxicity data; and
- integrated toxicological expert advice regarding the acceptability and safety of intake levels of contaminants, including information on any population groups which are specially vulnerable.

Analytical data

- validated qualitative and quantitative data on representative samples; and
- appropriate sampling procedures.

Intake data

- presence in food of dietary significance for the contaminant;
- presence in food that are widely consumed;
- presence in feed and feed components
- food intake data for average and most exposed/high consumer groups;
- results from total diet studies;
- calculated contaminant intake data from food consumption models;
- data on intake by susceptible groups; and
- data on intake by food producing animals.

Technological considerations

- information about contamination processes, technological possibilities, production and manufacturing practices and economic aspects related to contaminant level management and control.

Risk assessment and risk management considerations (cf. "Working Principles for Risk Analysis for Food Safety for Application by Governments")

- risk management options and considerations;
- consideration of possible maximum levels in food and feed based on the criteria mentioned above; and
- consideration of alternative solutions.

1.4 Format of the General Standard for Contaminants in Food and Feed

The General Standard for Contaminants and Toxins in Food and Feed contains one type of presentation for the Standards: Schedule I in which the standards are listed per contaminant in the various food and feed categories.

In order to obtain maximum clarity, explanatory notes shall be added where appropriate. The format contains all elements necessary for full understanding of the meaning, background, application and scope of the standards and contains references to the relevant documents and reports on which the standard is based.

A full description of the format is provided in Annex II.

ANNEX I

CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOOD AND FEED

Introduction

In this Annex criteria are mentioned regarding information which is considered necessary for evaluating contaminant problems in food and feed and for the establishment of maximum levels. The criteria mentioned here are elaborated in more detail than in section 1.3.3. of the Preamble. Only those aspects that need further clarification are detailed; however, criteria or aspects that are not specifically detailed here should not be ruled out in the evaluation process.

Toxicological information

Integrated toxicological expert advice regarding a safe/tolerable intake level of a contaminant is essential when decisions about maximum levels in foods are considered. A recommendation from JECFA regarding the maximum allowable or tolerable intake, based on a full evaluation of an adequate toxicological data base, should be the main basis for decisions by Codex members. In urgent cases, it may be possible to rely on less developed evaluations from JECFA or on toxicological expert advice from other international or national bodies.

When toxicological information is presented in relation to proposals for maximum levels for contaminants in food and feed, information about the following aspects is desirable:

- identification of the toxic substance(s);
- metabolism in humans and animals, as appropriate;
- toxicokinetics and toxicodynamics including information on possible carry-over of the contaminant from feed to edible animal tissue/products;
- information about acute and long term toxicity in animals and humans, including epidemiological data on humans and other relevant toxicity data;
- conclusions and advice of toxicological expert(s) (groups), with references, including information on specially vulnerable population groups or animals.

Analytical data

Validated qualitative and quantitative analytical data on representative samples should be supplied. Information on the analytical and sampling methods used and on the validation of the results is desirable. A statement on the representativeness of the samples for the contamination of the product in general (e.g. on a national basis) should be added. The portion of the commodity that was analyzed and to which the contaminant content is related should be clearly stated and preferably should be equivalent to the definition of the commodity for this purpose or to existing related contaminant regulation.

Information on appropriate sampling procedures should be supplied. Special attention to this aspect is necessary in the case of contaminants that may not be homogeneously distributed in the product (e.g. mycotoxins in some commodities).

Intake data

It is desirable to have information about the contaminant concentrations in those foods or food groups that (together) are responsible for at least half and preferably 80% or more of the total dietary intake of the contaminant, both for consumers with average and high consumption patterns.

Information about the ***presence of the contaminant in foods that are widely consumed*** (staple foods) is desirable in order to be able to make a satisfactory assessment of the contaminant intake and of risks associated with food trade.

For the contaminants which can be present in food of animal origin as a consequence of the carry over from feed, information about the presence of the contaminant in the feed and feed components should be given. Furthermore the intake of contaminants by the different food producing animals and the resulting levels of the contaminant in the food of animal origin should be estimated.

Food consumption data for average, most exposed (high consumers) and susceptible consumer groups are desirable for evaluations of (potential) intake of contaminants. This problem, however, has to be addressed differently on a national and on an international scale. It is therefore important to have information about both average and high consumption patterns regarding a wide variety of foodstuffs, so that for every contaminant the most exposed consumer groups may be identified for every contaminant. Detailed information about high consumption patterns is desirable, both regarding group identification criteria (e.g. age or sex differences, vegetarian or regional dietary customs, etc.) and statistical aspects.

Dietary intake of contaminants: Reference is made to the Guidelines for the study of dietary intake of chemical contaminants (WHO, 1985 - http://whqlibdoc.who.int/offset/WHO_OFFSET_87.pdf). It is important to supply all relevant details, such as the type of study (duplicate diet, total diet or market basket study, selective study), and statistical details. Calculated contaminant intake data from food consumption models may also be useful. When results about food groups and about effects of preparation and cooking etc. are available, these should also be supplied:

Technological considerations

Information about the source of the contaminant and the way in which the food and feed is contaminated, possibly including information, if available, about contamination being present in parts only of the product, is essential for assessing the possibilities to control the contamination process and to be able to guarantee a desired product safety and quality. Where possible ***Source-related measures*** should be proposed. ***Good Manufacturing Practice (GMP)*** and/or ***Good Agricultural Practice (GAP)*** should also be adapted to control a contamination problem. When this is possible, maximum levels may be based on GMP or GAP considerations to establish at a level as low as reasonably achievable and necessary to protect the consumer. Considerations regarding the technological possibilities to control a contamination problem, e.g. by cleaning, should also be taken into account when a primary risk assessment model (theoretical maximum daily intake) shows possible intakes exceeding the toxicological reference value. In such a case the possibilities of lower contamination levels need further careful examination. Then a detailed study about all the aspects involved is necessary, so that decisions about maximum levels can be based on a thorough evaluation of both the public health arguments and the potential problem with complying with the proposed standard.

Risk assessment and risk management considerations

Risk assessment and risk management are conducted in accordance with the Working Principles for Risk Analysis for Food Safety Application by Governments.

Establishment of maximum levels

In case it is decided that, on the basis of the outcome of the risk assessment, there is no need to establish a maximum level to protect public health as the level of hazard/risk does not pose a public health problem, this should be communicated in a transparent and accessible manner (e.g. by using the full format as provided for Schedule I and to mention in the box of Maximum level "not necessary").

The ***establishment of maximum levels (MLs) of contaminants in food and feed*** involves several principles, some of which have already been mentioned in this Preamble. Briefly stated, the following criteria will help in maintaining a consistent policy in this matter:

- MLs should be set only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade.
- MLs should be set only for food that is significant for the total exposure of the consumer to the contaminant. When identifying the significance of certain foods in the total exposure to the contaminant, the criteria contained in para 11 of the Policy of the Codex Committee on contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (section III of the Codex Alimentarius Commission Procedural Manual) should be consulted.
- MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade. Where possible, MLs should be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable and necessary to protect the consumer. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless a higher ML can be shown to be acceptable from a public health point of view and significant economic aspects are at stake.
- Proposals for MLs in products should be based on data from various countries and sources, encompassing the main production areas/processes of those products, as far as they are engaged in international trade. When there is evidence that contamination patterns are sufficiently understood and will be comparable on a global scale, more limited data may be enough.
- MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group, or when there are other arguments that extrapolation is appropriate.
- Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs.
- MLs should apply to representative samples per lot. If necessary, appropriate methods of sampling should be specified.
- MLs should not be lower than a level which can be analyzed with methods of analysis that can readily be set up and applied in food and feed control laboratories, unless public health considerations necessitate a lower ML which can only be controlled by means of a more elaborate and sensitive method of analysis with an adequate lower detection limit. In all cases, a validated method of analysis should be available with which a ML can be controlled.
- The contaminant as it should be analyzed and to which the ML applies should be clearly defined. The definition may include important metabolites when this is appropriate from an analytical or toxicological point of view. It may also be aimed at indicator substances which are chosen from a group of related contaminants.

- The product as it should be analyzed and to which the ML applies, should be clearly defined. In general, MLs are set on primary products. MLs should in general preferably be expressed as a level of the contaminant related to the product as it is, on a fresh weight basis. In some cases, however, there may be valid arguments to prefer expression on a dry weight basis (this might be in particular the case for contaminants in feed) or on a fat weight basis (this might be in particular the case for fat soluble contaminants). Preferably the product should be defined as it moves in trade, with provisions where necessary for the removal of inedible parts that might interfere with the preparation and the analysis of the sample. The product definitions used by the CCPR and contained in the Classification of food and feed may serve as guidance on this subject; other product definitions should only be used for specified reasons. For contaminant purposes, however, analysis and consequently MLs should preferably be on the basis of the edible part of the product.

  For fat soluble contaminants which may accumulate in animal products, provisions should be applied regarding the application of the ML to products with various fat content (comparable to the provisions for fat soluble pesticides).

- Guidance is desirable regarding the possible application of MLs established for primary products to processed products and multi-ingredient products. When products are concentrated, dried or diluted, use of the concentration or dilution factor is generally appropriate in order to be able to obtain a primary judgement of the contaminant levels in these processed products. The maximum contaminant concentration in a multi-ingredient food and feed can likewise be calculated from the composition of the food and feed. Information regarding the behaviour of the contaminant during processing (e.g. washing, peeling, extraction, cooking, drying etc.) is however desirable to give more adequate guidance. When contaminant levels are consistently different in processed products related to the primary products from which they are derived, and sufficient information is available about the contamination pattern, it may be appropriate to establish separate maximum levels for these processed products. This also applies when contamination may occur during processing. In general however, MLs should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient food and feed by using appropriate conversion factors. When these factors are sufficiently known, they should be mentioned in the suffix to the maximum level following the format of list of MLs as defined in Annex II.

- MLs should preferably not be set higher than is acceptable in a primary (theoretical maximum intake and risk estimation) approach of their acceptability from a public health point of view. When this poses problems in relation to other criteria for establishing MLs, further evaluations are necessary regarding the possibilities to reduce the contaminant levels, e.g. by improving GAP and/or GMP conditions. When this does not bring a satisfactory solution, further refined risk assessment and contaminant risk management evaluations will have to be made in order to try to reach agreement about an acceptable ML.

Procedure for risk assessment in relation to (proposed) MLs

It is more difficult to control food and feed contamination problems than in the case of food additives and pesticide residues. Proposed MLs will inevitably be influenced by this situation. In order to promote acceptance of Codex contaminant MLs, it is therefore important that assessments of the impact of those MLs on dietary exposure are done in a consistent and realistic way. The procedure involves assessment of the dietary intake in relation to the proposed or existing MLs and the toxicological reference value.

In case a contaminant is carried over from feed to food of animal origin, the intake of a contaminant by the different food producing animal species and the resulting levels in the food of animal origin should be estimated.

The best estimate of dietary intake involves the national dietary pattern and corrections for concentration changes during transport, storage, food preparation, for known levels in foods as consumed, etc. Caution is recommended when using other than average food consumption values, although it is considered appropriate to use relevant average food consumption data for identifiable subgroups of the population. Food consumption patterns with a higher intake of critical foods may be used in the intake calculations when this is part of an accepted national or international health protection and risk management policy. A harmonized approach using an appropriate intake estimation model that is as realistic as possible is recommended. (cf. the "Policy of the Codex Committee on contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups" -section III of the Codex Alimentarius Commission Procedural Manual). Calculated data should where possible always be compared with measured intake data. Proposals for MLs should be accompanied by intake calculations and risk assessment conclusions regarding their impact on dietary intake and use. The intake calculations should follow the methodology described in the CCCF Policy for Exposure Assessment and, if appropriate, be accompanied by the generation of distribution curves for the concentration in specific foods/food groups (see paras 5-8 and 12-14 of the Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods in the Codex Alimentarius Commission Procedural Manual). Statements from Governments about the non-acceptance of (proposed) Codex MLs should refer to specified intake calculations and risk management conclusions which support this position.

ANNEX II

FORMAT OF THE GSCTFF

Introduction

The format for Schedule shall contain the following elements:

- ***Name of the contaminant:*** symbols, synonyms, abbreviations, scientific descriptions shall be mentioned.
- ***Reference to JECFA meetings*** (in which the contaminant was discussed).
- ***PMTDI, PTWI or similar toxicological reference value:*** when the situation is complex a short statement and further references may be necessary here.
- ***Contaminant definition:*** definition of the contaminant as it shall be analyzed and to which the maximum level applies.
- ***Reference to a source***-directed measure or a code of practice for the contaminant, if appropriate.
- ***List of Codex maximum levels for that contaminant;*** this list shall be composed of the following elements, in columns:
  - Classification number of feed/food commodity or feed/food category;
  - Name of feed/food commodity/category;
  - Numerical value of maximum level;
  - Suffix accompanying a ML to specify the application of the ML;
  - References to documents, or adoption year;
  - References to standard criteria for methods of analysis and sampling;
  - Notes/remarks.

SCHEDULE I - MAXIMUM AND GUIDELINE LEVELS FOR CONTAMINANTS AND TOXINS IN FOODS

INDEX OF CONTAMINANTS

EXPLANATORY NOTES

Reference to JECFA:	References to JECFA meeting in which the contaminant was evaluated and the year of that meeting.
Toxicological guidance value:	Toxicological advice about the tolerable intake level of the contaminant for humans, expressed in milligrammes (mg) per kg body weight (bw). The year of recommendations and additional explanation are included.
Residue definition:	Definition of the contaminant in the form of which the ML applies or which may or should be analyzed in commodities.
Synonyms:	Symbols, synonyms abbreviations, scientific descriptions and identification codes used to define the contaminant.
Commodity code:	The code for food commodities is according to the food and feed categorization system as contained in Annex IV-A of the GSCTFF or the Codex Classification of foods and feeds. The food/feed categorization system also specifies the part of Commodity which should be analysed and to which the ML applies, unless a specific commodity definition is provided as an annex to the ML. For those maximum levels contained in Codex commodity standards, the relevant standard numbers are referred, if the code numbers are not readily available for these commodities.
Suffix:	A note accompanying an ML or GL, used to specify the application or the future revision of the ML, e.g., specific residue definitions can be mentioned by abbreviations here. See also "Qualification of MLs" below.
Type:	Indicates whether the value is Codex maximum level (ML) or Codex guideline level (GL). See also the definitions of these terms in the preamble of the GSCTFF.

Qualification of MLs

C:	In canned products only.

Definitions of some toxicological terms

PMTDI:	*(Provisional Maximum Tolerable Daily Intake)* The endpoint used for contaminants with no cumulative properties. Its value represents permissible human exposure as a result of the natural occurrence of the substance in food and in drinking-water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI.
PTWI:	*(Provisional Tolerable Weekly Intake)* An endpoint used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods.
PTMI:	*(Provisional Tolerable Monthly Intake)* An endpoint used for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods.

AFLATOXINS, TOTAL

Reference to JECFA: 31 (1987), 46 (1996), 49 (1997), 68 (2007)

Toxicological guidance: Carcinogenic potency estimates for aflatoxins B, G, M (1997, Intake should be reduced to levels as low as reasonably possible.)

Residue definition: Aflatoxins total (B1 +B2 + G1 + G2)

Synonyms: Abbreviations, AFB, AFG, with numbers, to designate specific compounds

Related Code of Practice: Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Peanuts (CAC/RCP 55-2004)
Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Tree Nuts (CAC/RCP 59-2005)
Code of Practice for the Reduction of Aflatoxin B1 in Raw Materials and Supplemental Feedingstuffs for Milk Producing Animals (CAC/RCP 45-1997)
Code of Practice for the Prevention and Reduction of Aflatoxin Contamination in Dried Figs (CAC/RCP 65-2008)

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks
SO 0697	Peanut	15		ML		The ML applies to peanuts intended for further processing. For sampling plan, see Annex 1 below.
TN 0660	Almonds	15		ML		The ML applies to almonds intended for further processing For sampling plan, see Annex 2 below
	Brazil nuts	10		ML		The ML applies to shelled ready-to-eat Brazil nuts For sampling plan, see Annex 2 below
	Brazil nuts	15		ML		The ML applies to shelled Brazil nuts destined for further processing
TN 0666	Hazelnuts	15		ML		The ML applies to hazelnuts intended for further processing For sampling plan, see Annex 2 below
TN 0675	Pistachios	15		ML		The ML applies to pistachios intended for further processing For sampling plan, see Annex 2 below
TN 0660	Almonds	10		ML		The ML applies to almonds "ready-to-eat". For sampling plan, see Annex 2
TN 0666	Hazelnuts	10		ML		The ML applies tohazelnuts "ready-to-eat". For sampling plan, see Annex 2.
TN 0675	Pistachios	10		ML		The ML applies to pistachios "ready-to-eat". For sampling plan, see Annex 2.

Aflatoxins are a group of highly toxic mycotoxins produced by fungi of the genus Aspergillus. The four main aflatoxins found in contaminated plant products are B1, B2, G1 and G2 and are a group of structurally related difuranocoumarin derivatives that usually occur together in varying ratios, AFB1 usually being the most important one. These compounds pose a substantial hazard to human and animal health. IARC (1992) classified aflatoxin B1 in Group 1 (human carcinogen) and AFM in Group 2B (probable human carcinogen). The liver is the primary target organ.

Annex 1

SAMPLING PLAN FOR TOTAL AFLATOXINS IN PEANUTS INTENDED FOR FURTHER PROCESSING

INTRODUCTION

1. The sampling plan calls for a single 20 kg laboratory sample of shelled peanuts (27 kg of unshelled peanuts) to be taken from a peanut lot (sub-lot) and tested against a maximum level of 15 micrograms per kilogram (µg/kg) total aflatoxins.

2. This sampling plan has been designed for enforcement and controls concerning total aflatoxins in bulk consignments of peanuts traded in the export market. To assist member countries in implementing the Codex sampling plan, sample selection methods, sample preparation methods and analytical methods required to quantify aflatoxin in bulk peanut lots are described in this document.

A. 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.

Sampling plan: is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the Codex maximum limit.

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

Aggregate sample: the combined total of all the incremental samples taken from the lot or sublot. The aggregate sample has to be at least as large as the 20 kg laboratory sample.

Laboratory sample: smallest quantity of peanuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than 20 kg, a 20 kg laboratory sample should be removed in a random manner from the aggregate sample. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenisation as possible.

Test portion: portion of the comminuted laboratory sample. The entire 20 kg laboratory sample should be comminuted in a mill. A portion of the comminuted 20 kg sample is randomly removed for the extraction of the aflatoxin for chemical analysis. Based upon grinder capacity, the 20 kg aggregate sample can be divided into several equal sized samples, if all results are averaged.

B. Sampling

Material to be Sampled

3. Each lot which is to be examined must be sampled separately. Large lots should be subdivided into sublots to be sampled separately. The subdivision can be done following provisions laid down in Table 1 below.

4. 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 sublot may exceed the mentioned weight by a maximum of 20 %.

Table 1: Subdivision of Large Lots into Sublots for Sampling

Commodity	Lot weight – tonne (T)	Weight or number of sublots	Number of incremental samples	Laboratory Sample Weight (kg)
Peanuts	≥ 500	100 tonnes	100	20
	>100 and <500	5 sublots	100	20
	≥ 25 and ≤ 100	25 tonnes	100	20
	>15 and <= 25	–1 sublot	100	20

Number of Incremental Samples for Lots of Less than 15 Tonnes

5. 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. The figures in the following Table 2 may be used to determine the number of incremental samples to be taken. It is necessary that the total sample weight of 20 kg is achieved.

Table 2: Number of Incremental Samples to be Taken Depending on the Weight of the Lot

Lot weight tonnes – (T)	N° of incremental samples
T≤ 1	10
1 <T ≤ 5	40
5< T ≤ 10	60
10<T < 15	80

Incremental Sample Selection

6. Procedures used to take incremental samples from a peanut lot are extremely important. Every individual peanut in the lot should have an equal chance of being chosen. Biases will be introduced by the sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

7. Since there is no way to know if the contaminated peanut kernels are uniformly dispersed through out the lot, it is essential that the aggregate sample be the accumulation of many small portions or increments of the product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

Static Lots

8. A static lot can be defined as a large mass of peanuts contained either in a single large container such as a wagon, truck, or railcar or in many small containers such as sacks or boxes and the peanuts are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because the container may not allow access to all peanuts.

9. Taking a aggregate sample from a static lot usually requires the use of probing devices to select product from the lot. The probing devices used should be specially designed for the type of container. The probe should (1) be long enough to reach all product, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small increments of product taken from many different locations throughout the lot.

10. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows :

Equation 1 : SF = (LT x IS)/(AS x IP). The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic Lots

11. True random sampling can be more nearly achieved when selecting an aggregate sample from a moving stream of peanuts as the lot is transferred, for example, by a conveyor belt from one location to another. When sampling from a moving stream, take small increments of product from the entire length of the moving stream; composite the peanuts to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample, then blend and subdivide the aggregate sample to obtain the desired size laboratory sample.

12. Automatic sampling equipment such as cross-cut samplers are commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic equipment is not available, a person can be assigned to manually pass a cup though the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, small increments of peanuts should be collected and composited at frequent and uniform intervals throughout the entire time peanuts flow past the sampling point.

13. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about three times the largest dimensions of the items in the lot.

14. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is :

Equation 2 : $S = (D \times LT) / (T \times V)$. D is the width of the diverter cup opening (in cm), LT is the lot size (in kg), T is interval or time between cup movement through the stream (in seconds), and V is cup velocity (in cm/sec).

15. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup is :

Equation 3 : $SF = (S \times V) / (D \times MR)$.

16. Equation 2 can also be used to compute other terms of interest such as the time between cuts (T). For example, the required time (T) between cuts of the diverter cup to obtain a 20 kg aggregate sample from a 30,000 kg lot where the diverter cup width is 5.08 cm (2 inches), and the cup velocity through the stream 30 cm/sec. Solving for T in Equation 2,

$T = (5.08 \text{ cm} \times 30{,}000 \text{ kg})/(20 \text{ kg} \times 30 \text{ cm/sec}) = 254 \text{ sec}$

17. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 60 minutes and only 14 cuts (14 incremental samples) will be made by the cup through the lot. This may be considered too infrequent, in that too much product passes through the sampler between the time the cup cuts through the stream.

Weight of the Incremental Sample

18. The weight of the incremental sample should be approximately 200 grams or greater, depending on the total number of increments, to obtain an aggregate sample of 20kg.

Packaging and transmission of samples

19. 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.

Sealing and labelling of samples

20. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. 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.

C. Sample Preparation

Precautions

21. Daylight should be excluded as much as possible during the procedure, since aflatoxin gradually breaks down under the influence of ultra-violet light.

Homogenisation – Grinding

22. As the distribution of aflatoxin is extremely non-homogeneous, samples should be prepared - and especially homogenised - with extreme care. All laboratory sample obtained from aggregate sample is to be used for the homogenisation/grinding of the sample.

23. The sample should be finely ground and mixed thoroughly using a process that approaches as complete a homogenisation as possible.

24. The use of a hammer mill with a #14 screen (3.1 mm diameter hole in the screen) has been proven to represent a compromise in terms of cost and precision. A better homogenisation (finer grind – slurry) can be obtained by more sophisticated equipment, resulting in a lower sample preparation variance.

Test portion

25. A minimum test portion size of 100 g taken from the laboratory sample.

D. Analytical Methods

Background

26. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specified method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation, reproducibility coefficient of variation, and the percent recovery necessary for various statutory limits. Utilising this approach, laboratories would be free to use the analytical method most appropriate for their facilities. Analytical methods that are accepted by chemists internationally (such as AOAC) may be used. These methods are regularly monitored and improved depending upon technology.

Performance Criteria for Methods of Analysis

Table 3: Specific Requirements with which Methods of Analysis Should Comply

Criterion	Concentration Range	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	-
Recovery-Aflatoxins Total	1 - 15 µg/kg	70 to 110 %	
	> 15 µg/kg	80 to 110 %	
Precision RSD_R	All	As derived from Horwitz Equation	2 x value derived from Horwitz Equation
Precision RSD_r may be calculated as 0.66 times Precision RSD_R at the concentration of interest			

- 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 $[(s_R / \bar{x}) \times 100]$
* C is the concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1,000 mg/kg)

27. 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.

SAMPLING PLANS FOR AFLATOXIN CONTAMINATION IN READY-TO-EAT TREENUTS AND TREENUTS DESTINED FOR FURTHER PROCESSING: ALMONDS, HAZELNUTS, PISTACHIOS AND SHELLED BRAZIL NUTS

DEFINITION

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 larger lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.

Sampling plan - is defined by an aflatoxin test procedure and an accept/reject limit. An aflatoxin test procedure consists of three steps: sample selection, sample preparation and aflatoxin quantification. The accept/reject limit is a tolerance usually equal to the Codex maximum level.

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

Aggregate sample - the combined total of all the incremental samples that is taken from the lot or sublot. The aggregate sample has to be at least as large as the laboratory sample or samples combined.

Laboratory sample – the smallest quantity of tree nuts comminuted in a mill. The laboratory sample may be a portion of or the entire aggregate sample. If the aggregate sample is larger than the laboratory sample(s), the laboratory sample(s) should be removed in a random manner from the aggregate sample.

Test portion – a portion of the comminuted laboratory sample. The entire laboratory sample should be comminuted in a mill. A portion of the comminuted laboratory sample is randomly removed for the extraction of the aflatoxin for chemical analysis.

Ready-to-eat treenuts – nuts, which are not intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins.

Treenuts destined for further processing – nuts, which are intended to undergo an additional processing/treatment that has proven to reduce levels of aflatoxins before being used as an ingredient in foodstuffs, otherwise processed or offered for human consumption. Processes that have proven to reduce levels of aflatoxins are shelling, blanching followed by color sorting, and sorting by specific gravity and color (damage). There is some evidence that roasting reduces aflatoxins in pistachios but for other nuts the evidence is still to be supplied

Operating Characteristic (OC) Curve – a plot of the probability of a accepting a lot versus lot concentration when using a specific sampling plan design. The OC curve provides an estimate of good lots rejected (exporter's risk) and bad lots accepted (importer's risk) by a specific aflatoxin sampling plan design.

SAMPLING PLAN DESIGN CONSIDERATIONS

1. Importers may commercially classify treenuts as either "ready-to-eat" (RTE) or "destined for further processing" (DFP). As a result, maximum levels and sampling plans are proposed for both commercial types of treenuts. Maximum levels need to be defined for treenuts destined for further processing and ready-to-eat treenuts before a final decision can be made about a sampling plan design.

2. Treenuts can be marketed either as inshell or shelled nuts. For example, pistachios are predominately marketed as inshell nuts while almonds are predominately marketed as shelled nuts.

3. Sampling statistics, shown in Annex I, are based upon the uncertainty and aflatoxin distribution among laboratory samples of shelled nuts. Because the shelled nut count per kg is different for each of the treenuts, the laboratory sample size is expressed in number of nuts for statistical purposes. However, the shelled nut count per kg for each treenut, shown in Annex I, can be used to convert laboratory sample size from number of nuts to mass and vice versa.

4. Uncertainty estimates associated with sampling, sample preparation, and analysis, shown in Annex I, and the negative binomial distribution[4],[2],[3] are used to calculate operating characteristic (OC) curves that describe the performance of the proposed aflatoxin-sampling plans (Annex II).

5. In Annex I, the analytical variance reflects a reproducibility relative standard deviation of 22%, which is suggested by Thompson and is based upon Food Analysis Performance Assessment Scheme (FAPAS) data[5]. A relative standard deviation of 22% is considered by FAPAS as an appropriate measure of the best agreement that can be reliably obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory variation measured in the sampling studies for the four treenuts. The within laboratory analytical uncertainty for almonds, hazelnuts and pistachios can be found at the website http://www5.bae.ncsu.edu/usda/www/ResearchActDocs/treenutwg.html and for Brazil nuts in the CONFORCAST[6].

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4 Whitaker, T., Dickens, J., Monroe, R., and Wiser, E. 1972. Comparison of the negative binomial distribution of aflatoxin in shelled peanuts to the negative binomial distribution. J. American Oil Chemists' Society, 49:590-593.

5 Thompson, M. 2000. Recent trends in inter-laboratory precision at ppb and sub-ppb concentrations in relation to fitness for purpose criteria in proficiency testing. J. Royal Society of Chemistry, 125:385-386.

6 CONFORCAST. Ferramentas Analiticas para Capacitação do Brasil na Garantia da Conformidade da Castanha-Do-Brasil (Bertholletia Excelsa) quanto ao Perigo aflatoxina. Projeto nº 1.265/05, Aprovado pela FINEP na Chamada Pública, "Ação Transversal - TIB - 06/2005 - Linha 1". MAPA. Ministerio da Agricultura, pecuária e do Abastecienio. Secretaria de Defesa Agropecuária - DAS, Departamento de Inspeção de Produtos de Origem Vegetal – DIPOV. Coordenação-Geral de Apoio Laboratorial – CGAL, Laboratório Nacional Agropecuário – LANAGRO/MG, United States Department of Agriculture (Thomas Whitaker and Andy Slate).

6. The issue of correcting the analytical test result for recovery is not addressed in this document. However, Table 2 specifies several performance criteria for analytical methods including suggestions for the range of acceptable recovery rates.

AFLATOXIN TEST PROCEDURE AND MAXIMUM LEVELS

7. An aflatoxin-sampling plan is defined by an aflatoxin test procedure and a maximum level. A value for the proposed maximum level and the aflatoxin test procedure are given below in this section.

8. The maximum levels for total aflatoxins in treenuts (almonds, hazelnuts, pistachios and shelled Brazil nuts) "ready-to-eat" and "destined for further processing" are 10 and 15 µg/kg, respectively.

9. Choice of the number and size of the laboratory sample is a compromise between minimizing risks (false positives and false negatives) and costs related to sampling and restricting trade. For simplicity, it is recommended that the proposed aflatoxin sampling plans use a 20 kg aggregate sample for all four treenuts.

10. The two sampling plans (RTE and DFP) have been designed for enforcement and controls concerning total aflatoxins in bulk consignments (lots) of treenuts traded in the export market.

Treenuts destined for further processing

Maximum level – 15 µg/kg total aflatoxins

Number of laboratory samples – 1

Laboratory sample size - 20 kg
Almonds – shelled nuts
Hazelnuts – shelled nuts
Pistachios – inshell nuts (equivalent to about 10kg shelled nuts that is calculated on the basis of the actual edible portion in the sample)
Brazil nuts – shelled nuts

Sample preparation – sample shall be finely ground and mixed thoroughly using a process, e.g., dry grind with a vertical cutter mixer type mill, that has been demonstrated to provide the lowest sample preparation variance. Preferably, Brazil nuts should be ground as slurry.

Analytical method – performance based (see Table 2)

Decision rule – If the aflatoxin test result is less than or equal to 15 µg/kg total aflatoxins, then accept the lot. Otherwise, reject the lot.

The operating characteristic curve describing the performance of the sampling plan for the three treenuts destined for further processing is shown in Annex II.

Ready-to-eat treenuts

Maximum level – 10 µg/kg total aflatoxins

Number of laboratory samples – 2

Laboratory sample size - 10 kg
Almonds – shelled nuts
Hazelnuts – shelled nuts
Pistachios – inshell nuts (equivalent to about 5 kg shelled nuts per test sample that is calculated on the basis of the actual edible portion in the sample)
Brazil nuts – shelled nuts

Sample preparation – sample shall be finely ground and mixed thoroughly using a process, e.g., dry grind with a vertical cutter mixer type mill, that has been demonstrated to provide the lowest sample preparation variance. Preferably, Brazil nuts should be ground as slurry.

Analytical method – performance based (see Table 2)

Decision rule – If the aflatoxin test result is less than or equal to 10 µg/kg total aflatoxin in both test samples, then accept the lot. Otherwise, reject the lot.

The operating characteristic curve describing the performance of the sampling plan for the four ready-to-eat treenuts is shown in Annex II.

11. To assist member countries implement these two Codex sampling plans, sample selection methods, sample preparation methods, and analytical methods required to quantify aflatoxin in laboratory samples taken from bulk treenut lots are described in the following sections.

SAMPLE SELECTION

Material to be sampled

12. Each lot, which is to be examined for aflatoxin, must be sampled separately. Lots larger than 25 tonnes should be subdivided into sublots to be sampled separately. If a lot is greater than 25 tonnes, the number of sublots is equal to the lot weight in tonnes divided by 25 tonnes. It is recommended that a lot or a sublot should not exceed 25 tonnes. The minimum lot weight should be 500 kg.

13. Taking into account that the weight of the lot is not always an exact multiple of 25 tonne sublots, the weight of the sublot may exceed the mentioned weight by a maximum of 25%.

14. Samples should be taken from the same lot, i.e. they should have the same batch code or at the very least the same best before date. Any changes which would affect the mycotoxin content, the analytical determination or make the aggregate samples collected unrepresentative should be avoided. For example do not open packaging in adverse weather conditions or expose samples to excessive moisture or sunlight. Avoid cross-contamination from other potentially contaminated consignments nearby.

15. In most cases any truck or container will have to be unloaded to allow representative sampling to be carried out.

Incremental Sample Selection

16. Procedures used to take incremental samples from a treenut lot are extremely important. Every individual nut in the lot should have an equal chance of being chosen. Biases will be introduced by sample selection methods if equipment and procedures used to select the incremental samples prohibit or reduce the chances of any item in the lot from being chosen.

17. Since there is no way to know if the contaminated treenut kernels are uniformly dispersed throughout the lot, it is essential that the aggregate sample be the accumulation of many small incremental samples of product selected from different locations throughout the lot. If the aggregate sample is larger than desired, it should be blended and subdivided until the desired laboratory sample size is achieved.

Number of Incremental Samples for Lots of varying weight

18. The number and size of the laboratory sample(s) will not vary with lot (sublot) size. However, the number and size of the incremental samples will vary with lot (sublot) size.

19. The number of incremental samples to be taken from a lot (sublot) depends on the weight of the lot. Table 1 shall be used to determine the number of incremental samples to be taken from lots or sublots of various sizes below 25 tonnes. The number of incremental samples varies from a minimum of 10 and to a maximum of 100.

Table 1. Number and size of incremental samples composited for an aggregate sample of 20 kg[a] as a function of lot (or sublot) weight.

a/ Minimum aggregate sample size = laboratory sample size of 20 kg

Lot or Sublot Weight[b] (T in Tonnes)	Minimum Number of Incremental Samples	Minimum Incremental Sample Size[c] (g)	Minimum Aggregate Sample Size (kg)
T<1	10	2000	20
1≤T<5	25	800	20
5≤T<10	50	400	20
10≤T<15	75	267	20
15≤T	100	200	20

b/ 1 Tonne = 1000 kg

c/ Minimum incremental sample size = laboratory sample size (20 kg)/minimum number of incremental samples, i.e.

for 0.5<T< 1 tonne, 2000 g = 20000/10

Weight of the Incremental Sample

20. The suggested minimum weight of the incremental sample should be approximately 200 grams for lots of 25 metric tonnes (25,000 kg). The number and/or size of incremental samples will have to be larger than that suggested in Table 1 for lots sizes below 25,000 kg in order to obtain an aggregate sample greater than or equal to the 20 kg laboratory sample.

Static Lots

21. A static lot can be defined as a large mass of treenuts contained either in a large single container such as a wagon, truck or railcar or in many small containers such as sacks or boxes and the nuts are stationary at the time a sample is selected. Selecting a truly random sample from a static lot can be difficult because all containers in the lot or sublot may not be accessible.

22. Taking incremental samples from a static lot usually requires the use of probing devices to select product from the lot. The probing devices should be specifically designed for the commodity and type of container. The probe should (1) be long enough to reach all products, (2) not restrict any item in the lot from being selected, and (3) not alter the items in the lot. As mentioned above, the aggregate sample should be a composite from many small incremental samples of product taken from many different locations throughout the lot.

23. For lots traded in individual packages, the sampling frequency (SF), or number of packages that incremental samples are taken from, is a function of the lot weight (LT), incremental sample weight (IS), aggregate sample weight (AS) and the individual packing weight (IP), as follows:

    Equation 1: SF=(LT x IS)/(AS x IP).

24. The sampling frequency (SF) is the number of packages sampled. All weights should be in the same mass units such as kg.

Dynamic Lots

25. Representative aggregate samples can be more easily produced when selecting incremental samples from a moving stream of treenuts as the lot is transferred from one location to another. When sampling from a moving stream, take small incremental samples of product from the entire length of the moving stream; composite the incremental samples to obtain an aggregate sample; if the aggregate sample is larger than the required laboratory sample(s), then blend and subdivide the aggregate sample to obtain the desired size laboratory sample(s).

26. Automatic sampling equipment such as a cross-cut sampler is commercially available with timers that automatically pass a diverter cup through the moving stream at predetermined and uniform intervals. When automatic sampling equipment is not available, a person can be assigned to manually pass a cup through the stream at periodic intervals to collect incremental samples. Whether using automatic or manual methods, incremental samples should be collected and composited at frequent and uniform intervals throughout the entire time the nuts flow past the sampling point.

27. Cross-cut samplers should be installed in the following manner: (1) the plane of the opening of the diverter cup should be perpendicular to the direction of the flow; (2) the diverter cup should pass through the entire cross sectional area of the stream; and (3) the opening of the diverter cup should be wide enough to accept all items of interest in the lot. As a general rule, the width of the diverter cup opening should be about two to three times the largest dimensions of items in the lot.

28. The size of the aggregate sample (S) in kg, taken from a lot by a cross cut sampler is:

    Equation 2: S=(D x LT) / (T x V),

    where D is the width of the diverter cup opening (cm), LT is the lot size (kg), T is interval or time between cup movement through the stream (seconds), and V is cup velocity (cm/sec).

29. If the mass flow rate of the moving stream, MR (kg/sec), is known, then the sampling frequency (SF), or number of cuts made by the automatic sampler cup can be computed from Equation 3 as a function of S, V, D, and MR.

    Equation 3: SF = (S x V) / (D x MR).

30. Equations 2 and 3 can also be used to compute other terms of interest such as the time between cuts (T). For example, the time (T) required between cuts of the diverter cup to obtain a 20 kg aggregate sample from a 20,000 kg lot where the diverter cup width is 5.0 cm and the cup velocity through the stream 30 cm/sec. Solving for T in Equation 2,

    T = (5.0 cm x 20,000 kg)/(20 kg x 20 cm/sec) = 250 sec.

31. If the lot is moving at 500 kg per minute, the entire lot will pass through the sampler in 40 minutes (2400 sec) and only 9.6 cuts (9 incremental samples) will be made by the cup through the lot (Equation 3). This may be considered too infrequent, in that too much product (2,083.3 kg) passes through the sampler between the time the cup cuts through the stream.

Packaging and Transportation of Samples

32. Each laboratory sample shall be placed in a clean, inert container offering adequate protection from contamination, sunlight, 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. Samples should be stored in a cool dark place.

Sealing and Labelling of Samples

33. Each laboratory sample taken for official use shall be sealed at the place of sampling and identified. 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.

SAMPLE PREPARATION

Precautions

34. Sunlight should be excluded as much as possible during sample preparation, since aflatoxin gradually breaks down under the influence of ultra-violet light. Also, environmental temperature and relative humidity should be controlled and not favor mold growth and aflatoxin formation.

Homogenization - Grinding

35. As the distribution of aflatoxin is extremely non-homogeneous, laboratory samples should be homogenized by grinding the entire laboratory sample received by the laboratory. Homogenization is a procedure that reduces particle size and disperses the contaminated particles evenly throughout the comminuted laboratory sample.

36. The laboratory sample should be finely ground and mixed thoroughly using a process that approaches as complete homogenization as possible. Complete homogenization implies that particle size is extremely small and the variability associated with sample preparation (Annex I) approaches zero. After grinding, the grinder should be cleaned to prevent aflatoxin cross-contamination.

37. The use of vertical cutter mixer type grinders that mix and comminute the laboratory sample into a paste represent a compromise in terms of cost and fineness of grind or particle size reduction[7]. A better homogenization (finer grind), such as a liquid slurry, can be obtained by more sophisticated equipment and should provide the lowest sample preparation variance[8].

Test portion

38. The suggested weight of the test portion taken from the comminuted laboratory sample should be approximately 50 grams. If the laboratory sample is prepared using a liquid slurry, the slurry should contain 50 g of nut mass.

39. Procedures for selecting the 50 g test portion from the comminuted laboratory sample should be a random process. If mixing occurred during or after the comminution process, the 50 g test portion can be selected from any location throughout the comminuted laboratory sample. Otherwise, the 50 g test portion should be the accumulation of several small portions selected throughout the laboratory sample.

40. It is suggested that three test portions be selected from each comminuted laboratory sample. The three test portions will be used for enforcement, appeal, and confirmation if needed.

ANALYTICAL METHODS

Background

41. A criteria-based approach, whereby a set of performance criteria is established with which the analytical method used should comply, is appropriate. The criteria-based approach has the advantage that, by avoiding setting down specific details of the method used, developments in methodology can be exploited without having to reconsider or modify the specific method. The performance criteria established for methods should include all the parameters that need to be addressed by each laboratory such as the detection limit, repeatability coefficient of variation (within lab), reproducibility coefficient of variation (among lab), and the percent recovery necessary for various statutory limits. Analytical methods that are accepted by chemists internationally (such as AOAC, ISO) may be used. These methods are regularly monitored and improved depending upon technology.

Performance Criteria for Methods of Analysis

42. A list of criteria and performance levels are shown in Table 2. Utilizing this approach, laboratories would be free to use the analytical method most appropriate for their facilities.

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7 Ozay, G., Seyhan, F., Yilmaz, A., Whitaker, T., Slate, A., and Giesbrecht, F. 2006. Sampling hazelnuts for aflatoxin: Uncertainty associated with sampling, sample preparation, and analysis. J. Association Official Analytical Chemists, Int., 89:1004-1011.

8 Spanjer, M., Scholtan, J., Kastrup, S., Jorissen, U., Schatzki, T., Toyofuku, N. 2006. Sample comminution for mycotoxin analysis: Dry milling or slurry mixing?, Food Additives and Contaminants, 23:73-83.

Table 2: Specific Requirements with which Methods of Analysis Should Comply

Criterion	Concentration Range (ng/g)	Recommended Value	Maximum Permitted Value
Blanks	All	Negligible	n/a
Recovery	1 to 15	70 to 110%	n/a
	>15	80 to 110%	n/a
Precision or Relative Standard Deviation RSD_R (Reproducibility)	1 to 120	Equation 4 by Thompson	2 x value derived from Equation 4
	>120	Equation 5 by Horwitz	2 x value derived from Equation 5
Precision or Relative Standard Deviation RSD_r (Repeatability)	1 to 120	Calculated as 0.66 times Precision RSD_R	n/a
	>120	Calculated as 0.66 times Precision RSD_r	n/a

n/a = not applicable

43. The detection limits of the methods used are not stated. Only the precision values are given at the concentrations of interest. The precision values are calculated from equations 4 and 5 developed by Thompson[2] and Horwitz and Albert[9], respectively.

Equation 4: $RSD_R = 22.0$ (for $C \leq 120$ µg/kg or $c \leq 120 \times 10^{-9}$)
Equation 5: $RSD_R = 2^{(1-0.5\log c)}$ (for $C > 120$ µg/kg or $c > 120 \times 10^{-9}$)
where:

- RSD_R = the relative standard deviation calculated from results generated under reproducibility conditions
- RSD_r = the relative standard deviation calculated from results generated under repeatability conditions = $0.66 RSD_R$
- c = the aflatoxin concentration ratio (i.e. 1 = 100g/100g, 0.001 = 1,000 mg/kg)
- C = aflatoxin concentration or mass of aflatoxin to mass of treenuts (i.e. µg/kg)

44. Equations 4 and 5 are generalized precision equations, which have been found to be independent of analyte and matrix but solely dependent on concentration for most routine methods of analysis.

45. Results should be reported on the edible portion of the sample.

[9] Horwitz, W. and Albert, R. 2006. The Horwitz ratio (HorRat): A useful index of method performance with respect to precision. J. Association of Official Analytical Chemists, Int., 89:1095-1109.

Annex I

Uncertainty, as measured by the variance, associated with sampling, sample preparation, and analytical steps of the aflatoxin test procedure used to estimate aflatoxin in almonds, hazelnuts, pistachios and shelled Brazil nuts.

Sampling data for almonds, hazelnuts, pistachios and shelled Brazil nuts were supplied by the United States, Turkey, Iran and Brazil, respectively.

Variance estimates and the negative binomial distribution[1] were used to compute operating characteristic curves for each treenut in Annex II. Sampling, sample preparation, and analytical variances associated with testing almonds, hazelnuts, pistachios and shelled Brazil nuts are shown in Table 1 below.

Because of the computational complexities associated with use of the negative binomial distribution to compute operational characteristic (OC) curves for various sampling plan designs, the effect of various laboratory sample sizes, various numbers of laboratory samples, and various maximum levels on the performance (OC curves) of sampling plan designs is provided at the website address http://www5.bae.ncsu.edu/usda/www/ResearchActDocs/treenutwg.html and for Brazil nuts in the CONFORCAST[3].

Table 1. Variances[a] associated with the aflatoxin test procedure for each treenut.

Test Procedure	Almonds	Hazelnuts	Pistachios	Shelled Brazil nuts
Sampling[b,c]	$S^2_s = (7{,}730/ns)5.759C^{1.561}$	$S^2_s = (10{,}000/ns)4.291C^{1.609}$	$S^2_s = 8{,}000/ns)7.913C^{1.475}$	$s_s^2 = (1850/ns)\ 4.8616C^{1.889}$
Sample Prep[d]	$S^2_{sp} = (100/nss)0.170C^{1.646}$	$S^2_{sp} = (50/nss)0.021C^{1.545}$	$S^2_{sp} = (25/nss)2.334C^{1.522}$	$s_{ss}^2 = (50/nss)0.0306C^{0.632}$
Analytical[e]	$S^2_a = (1/na)0.0484C^{2.0}$	$S^2_a = (1/na)0.0484C^{2.0}$	$S^2_a = (1/na)0.0484C^{2.0}$	experimental $s_a^2 = (1/n)\ 0.0164C^{1.117}$ or FAPAS $s_a^2 = (1/n)\ 0.0484C^{2.0}$
Total variance	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$	$S^2_s + S^2_{sp} + S^2_a$

a/ Variance = S^2 (s, sp, and a denote sampling, sample preparation, and analytical steps, respectively, of aflatoxin test procedure)

b/ ns = laboratory sample size in number of shelled nuts, nss =test portion size in grams, na = number of aliquots quantified by HPLC, and C = aflatoxin concentration in µg/kg total aflatoxin.

c/ Shelled nut count/kg for almonds, hazelnuts, pistachios and Brazil nuts is 773, 1000, 1600 and 185, respectively.

d/ Sample preparation for almonds, hazelnuts, and pistachios reflect Hobart, Robot Coupe, Marjaan Khatman and Turrax type mills, respectively. Laboratory samples were dry ground into a paste for each treenut except for Brazil nut that were prepared as a slurry Brazil nut/water 1/1 w/w.

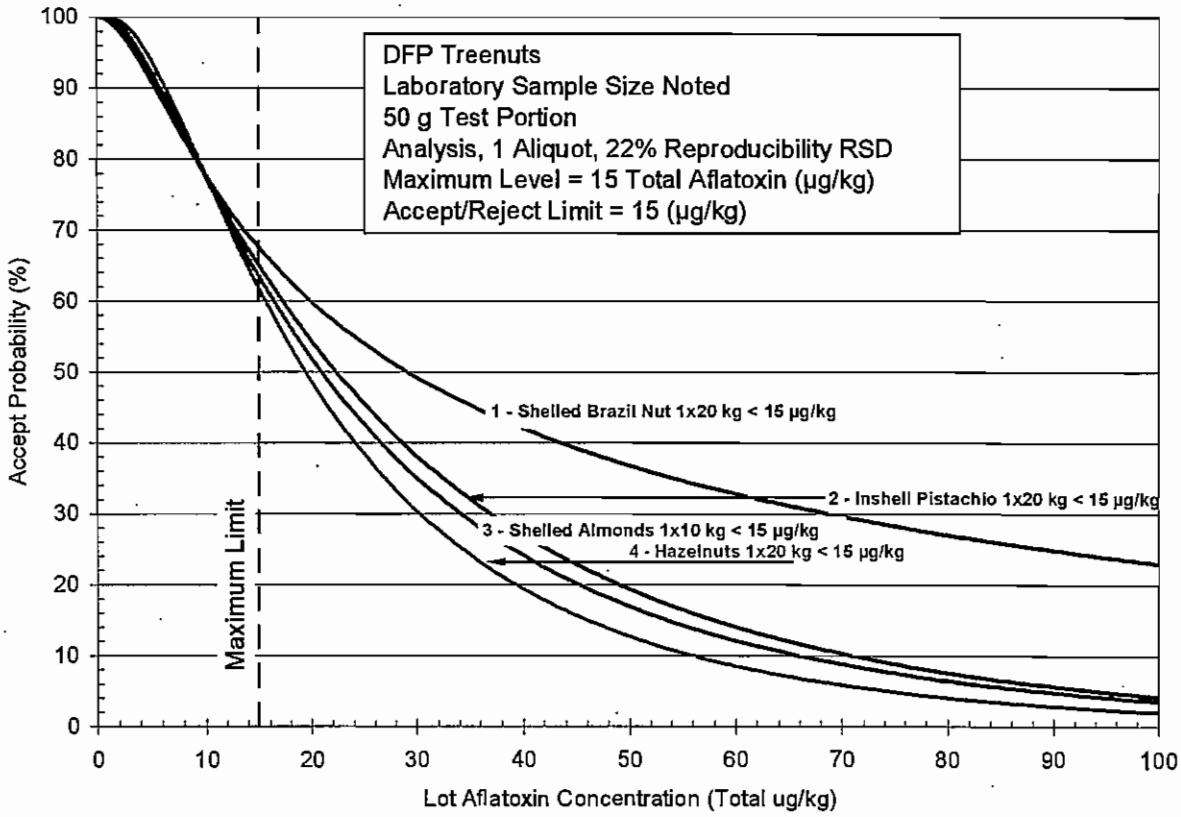
e/ Analytical variances reflect FAPAS recommendation for upper limit of analytical reproducibility uncertainty. A relative standard deviation of 22% is considered by Thompson[2] (based upon FAPAS data) as an appropriate measure of the best agreement that can be obtained between laboratories. An analytical uncertainty of 22% is larger than the within laboratory uncertainty measured in the sampling studies for the four treenuts.

Annex II

Operating Characteristic Curves describing the performance of aflatoxin sampling plans for almonds, hazelnuts, pistachios and shelled Brazil nuts.

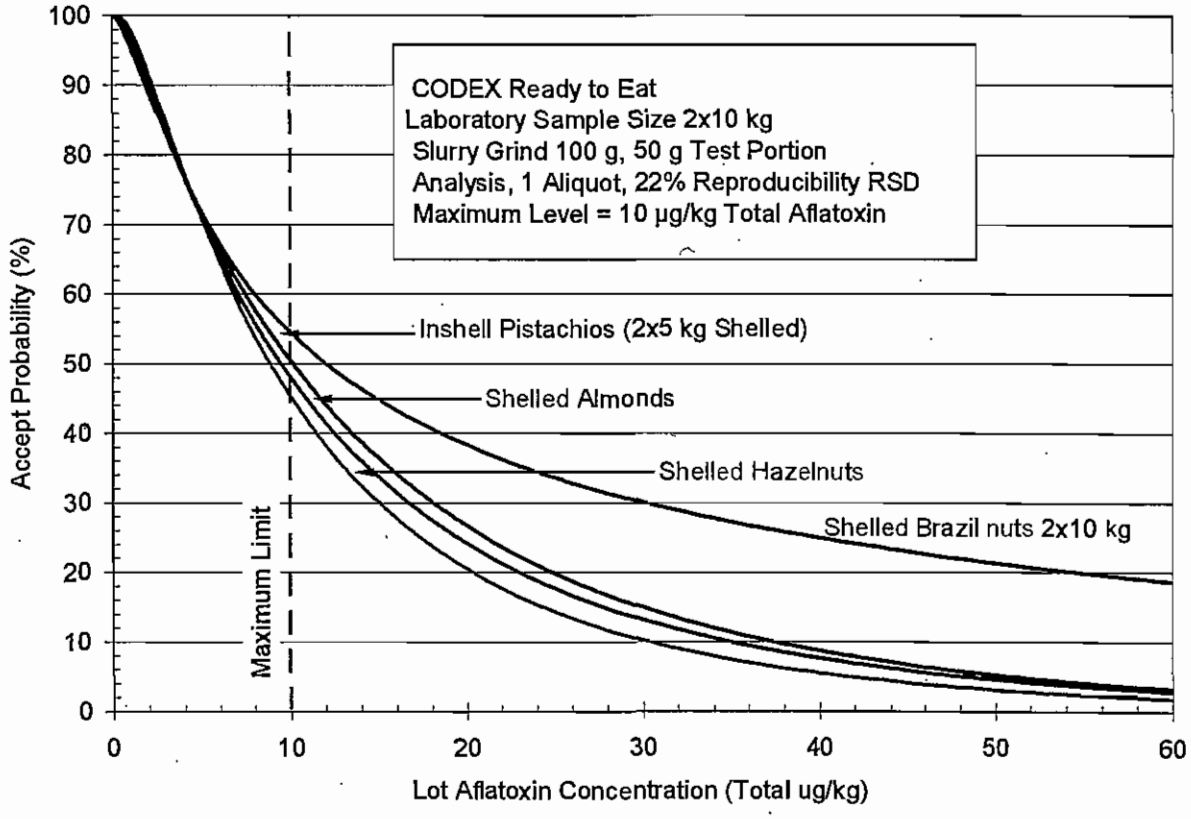
Treenuts Destined for Further Processing

Operating Characteristic curve describing the performance of the aflatoxin sampling plan for almonds, hazelnuts, pistachios and shelled Brazil nuts destined for further processing using a single laboratory sample of 20 kg and a maximum level of 15 µg/kg for total aflatoxins. The operating characteristic curve reflects uncertainty associated with a 20 kg laboratory sample of shelled nuts for almonds, hazelnuts and shelled Brazil nuts and a 20 kg laboratory sample of inshell nuts (about 10kg shelled nuts) for pistachios with dry grind with a vertical cutter mixer type mill almonds, hazelnuts and pistachios and slurry preparation for shelled Brazil nuts, 50 g test portion, and quantification of aflatoxin in the test portion by HPLC.



Ready-to-Eats Treenuts

Operating Characteristic curve describing the performance of the aflatoxin sampling plan for ready-to-eat almonds, hazelnuts, pistachios and shelled Brazil nuts using two laboratory samples of 10 kg each and a maximum level of 10 µg/kg for total aflatoxins, with dry grind with a vertical cutter mixer type mill almonds, hazelnuts and pistachios and slurry preparation for shelled Brazil nuts, 50 g test portion, and quantification of aflatoxin in the test portion by HPLC.



AFLATOXIN M1

Reference to JECFA: 56 (2001)

Toxicological guidance: Cancer potency estimates at specified residue levels (2001, Using worst-case assumptions, the additional risks for liver cancer predicted with use of proposed maximum levels of aflatoxin M1 of 0.05 and 0.5 µg/kg are very small. The potency of aflatoxin M1 appears to be so low in HBsAg- individuals that a carcinogenic effect of M1 intake in those who consume large quantities of milk and milk products in comparison with non-consumers of these products would be impossible to demonstrate. Hepatitis B virus carriers might benefit from a reduction in the aflatoxin concentration in their diet, and the reduction might also offer some protection in hepatitis C virus carriers.)

Residue definition: Aflatoxin M1

Synonyms: AFM1

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks
ML 0106	Milk	0.5		ML		

OCHRATOXIN A

Reference to JECFA: 37 (1990), 44 (1995), 56 (2001), 68 (2007)

Toxicological guidance: PTWI 0.0001 mg/kg bw (2001)

Residue definition: Ochratoxin A

Synonyms: (The term 'ochratoxins'includes a number of related mycotoxins (A, B, C and their esters and metabolites), the most important one being ochratoxin A)

Related Code of Practice: Code of Practice for the Prevention and Reduction of Mycotoxin Contamination in Cereals, including Annexes on Ochratoxin A, Zéaralenone, Fumonisins and Tricothecenes (CAC/RCP 51-2003)
Code of Practice for the Prevention and Reduction of Ochratoxin A Contamination in Wine (CAC/RCP 63-2007)

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks for Codex Alimentarius
GC 0654	Raw Wheat	5		ML		
GC 0640	Barley	5		ML		
GC 0650	Rye	5		ML		

PATULIN

Reference to JECFA: 35 (1989), 44 (1995)
Toxicological guidance: PMTDI 0.0004 mg/kg bw (1995)
Residue definition: patulin
Related Code of Practice: Code of Practice for the Prevention and Reduction of Patulin Contamination in Apple Juice and Apple Juice Ingredients in Other Beverages (CAC/RCP 50-2003)

Commodity/Product Code	Name	Level ug/kg	Suffix	Type	Reference	Notes/Remarks
JF 0226	Apple juice	50		ML		The ML also covers apple juice as ingredient in other beverages.

Patulin is a low molecular weight hemiacetal lactone mycotoxin produced by species of the genera Aspergillus, Penicillium and Byssochlamys.

ARSENIC

Reference to JECFA: 5 (1960), 10 (1967), 27 (1983), 33 (1988)
Toxicological guidance: PTWI 0.015 mg/kg bw (1988, For inorganic arsenic)
Residue definition: Arsenic: total (As-tot) when not otherwise mentioned; inorganic arsenic (As-in); or other specification
Synonyms: As
Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Edible fats and oils	0.1		ML	CS 19-1981	Edible fats and oils not covered by individual standards
	Margarine	0.1		ML	CS 32-1981	
	Minarine	0.1		ML	CS 135-1981	
	Named animal fats	0.1		ML	CS 211-1999	Lard, rendered pork fat, premier jus and edible tallow.
OR 0305	Olive oil, refined	0.1		ML	CS 33-1981	
OC 0305	Olive oil, virgin	0.1		ML	CS 33-1981	
OR 5330	Olive, residue oil	0.1		ML	CS 33-1981	Olive pomace oil
OC 0172	Vegetable oils, Crude	0.1		ML	CS 210-1999	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.
OR 0172	Vegetable oils, Edible	0.1		ML	CS 210-1999	Named vegeable oils from arachis, babassu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, safflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein.
	Natural mineral waters	0.01		ML	CS 108-1981	Expressed in total As mg/l
	Salt, food grade	0.5		ML	CS 150-1985	

Arsenic is a metalloid element which is normally occurring in mineral bound form in the earth's crust and which can become more easily available by natural sources such as volcanic activity and weathering of minerals, and by anthropogenic activity causing emissions in the environment, such as ore smelting, burning of coal and specific uses, such as arsenic-based wood preservatives, pesticides or veterinary or human medicinal drugs. As a result of naturally occurring metabolic processes in the biosphere arsenic occurs as a large number of organic or inorganic chemical forms in food (species). Especially in the marine environment arsenic is often found in high concentrations of organic forms, up to 50 mg/kg of arsenic on a wet weight basis in some seafood including seaweed, fish, shellfish and crustaceans. In fresh water and in the terrestrial environments arsenic is normally found in much lower levels (typically 0-20 ug/kg) in crop plants and in livestock. Higher levels may be found in rice, mushrooms and sometimes in poultry which is fed fish meal containing arsenic. The most toxic forms of arsenic are the inorganic arsenic (III) and (V) compounds; the inorganic arsenic trioxide is well known as a rat poison, which was also sometimes used for homicide. Methylated forms of arsenic have a low acute toxicity; arsenobetaine which is the principal arsenic form in fish and crustaceans is considered non-toxic. In shellfish, molluscs and seaweed dimethylarsinylriboside derivatives occur ("arsenosugars"), the possible toxicity of which is not known in detail. Only a few percent of the total arsenic in fish is present in inorganic form, which is the only form about which a PTWI has been developed by JECFA. The human epidemiological data used for this risk assessment is based on exposure to inorganic arsenic in drinking water. IARC has classified inorganic arsenic as a human carcinogen, and the estimated lifetime risk for arsenic-induced skin cancer which may be caused by drinking water at or in excess of the WHO guideline for arsenic in drinking water is estimated at 6x 10-4.

CADMIUM

Reference to JECFA: 16 (1972), 33 (1988), 41 (1993), 55 (2000), 61 (2003), 64 (2005)

Toxicological guidance: PTWI 0.007 mg/kg bw (1988 (maintained in 2000 & 2003), The 64th JECFA concluded that the effect of different MLs on overall intake of cadmium would be very small. At the proposed Codex MLs, mean intake of cadmium would be reduced by approximately 1% of the PTWI. The imposition of MLs one level lower would result in potential reductions in intake of cadmium of no more than 6% (wheat grain, potatoes) of the PTWI. At the proposed Codex MLs, no more than 9% of a commodity would be violative (oysters). MLs one level below those proposed would result in approximately 25% of molluscs, potatoes, and other vegetables being violative.)

Residue definition: Cadmium, total

Synonyms: Cd

Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
VB 0040	Brassica vegetables	0.05		ML		
VA 0035	Bulb vegetables	0.05		ML		
VC 0045	Fruiting vegetables, cucurbits	0.05		ML		
VO 0050	Fruiting vegetables, other than cucurbits	0.05		ML		Excluding tomatoes and edible fungi.
VL 0053	Leafy vegetables	0.2		ML		
VP 0060	Legume vegetables	0.1		ML		
VR 0589	Potato	0.1		ML		Peeled
VD 0070	Pulses	0.1		ML		Excluding soya bean (dry)
VR 0075	Root and tuber vegetables	0.1		ML		Excluding potato and celeriac
VS 0078	Stalk and stem vegetables	0.1		ML		
GC 0081	Cereal grains, except buckwheat, cañihua and quinoa	0.1		ML		Excluding wheat and rice; and bran and germ
CM 0649	Rice, polished	0.4		ML		
GC 0654	Wheat	0.2		ML		
IM 0151	Marine bivalve molluscs	2		ML		Excluding oysters and scallops
IM 0152	Cephalopods	2		ML		Without viscera
	Natural mineral waters	0.003		ML	CS 108-1981	Expressed in mg/l
	Salt, food grade	0.5		ML	CS 150-1985	

Cadmium is a relatively rare element, released to the air, land, and water by human activities. In general, the two major sources of contamination are the production and utilization of cadmium and the disposal of wastes containing cadmium. Increases in soil cadmium content will result in an increase in the uptake of cadmium by plants; the pathway of human exposure from agricultural crops is thus susceptible to increases in soil cadmium. The cadmium uptake by plants from soil is greater at low soil pH. Edible free-living food organisms such as shellfish, crustaceans, and fungi are natural accumulators of cadmium. Similar to humans, there are increased levels of cadmium in the liver and kidney of horses and some feral terrestrial animals. Regular consumption of these items can result in increased exposure. Tobacco is an important source of cadmium uptake in smokers. (Environmental health criteria for cadmium; International Programme on Chemical Safety (IPCS); 1992)

LEAD

Reference to JECFA: 10 (1966), 16 (1972), 22 (1978), 30 (1986), 41 (1993), 53 (1999)
Toxicological guidance: PTWI 0.025 mg/kg bw (1987 for infants and young children, extended to all age groups in 1993, maintained 1999)
Residue definition: Lead, total
Synonyms: Pb
Related Code of Practice: Code of Practice for the Prevention and Reduction of Lead Contamination in Foods (CAC/RCP 56-2004)
Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
FT 0026	Assorted (sub)tropical fruits, edible peel	0.1		ML		
FI 0030	Assorted (sub)tropical fruits, inedible peel	0.1		ML		
FB 0018	Berries and other small fruits	0.2		ML		
FC 0001	Citrus fruits	0.1		ML		
FP 0009	Pome fruits	0.1		ML		
FS 0012	Stone fruits	0.1		ML		
VB 0040	Brassica vegetables	0.3		ML		Excluding kale
VA 0035	Bulb vegetables	0.1		ML		
VC 0045	Fruiting vegetables, Cucurbits	0.1		ML		
VO 0050	Fruiting vegetables, other than Cucurbits	0.1		ML		Excluding mushrooms
VL 0053	Leafy vegetables	0.3		ML		Including Brassica leafy vegetables but excluding spinach.
VP 0060	Legume vegetables	0.2		ML		
VD 0070	Pulses	0.2		ML		
VR 0075	Root and tuber vegetables	0.1		ML		Including peeled potatoes
	Canned fruit cocktail	1		ML	CS 78-1981	
	Canned grapefruit	1		ML	CS 15-1981	
	Canned mandarin oranges	1		ML	CS 68-1981	
	Canned mangoes	1		ML	CS 159-1987	
	Canned pineapple	1		ML	CS 42-1981	
	Canned raspberries	1		ML	CS 60-1981	
	Canned strawberries	1		ML	CS 62-1981	
	Canned tropical fruit salad	1		ML	CS 99-1981	
	Jams (fruit preserves) and jellies	1		ML	CS 79-1981	
	Mango chutney	1		ML	CS 160-1987	
	Table olives	1		ML	CS 66-1981	
	Canned asparagus	1		ML	CS 56-1981	
	Canned carrots	1		ML	CS 116-1981	
	Canned green beans and canned wax beans	1		ML	CS 16-1981	
	Canned green peas	1		ML	CS 58-1981	

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Canned mature processed peas	1		ML	CS 81-1981	
	Canned mushrooms	1		ML	CS 55-1981	
	Canned palmito	1		ML	CS 144-1985	
	Canned sweet corn	1		ML	CS 18-1981	
	Canned tomatoes	1		ML	CS 13-1981	
	Pickled cucumbers (cucumber pickles)	1		ML	CS 115-1981	
	Processed tomato concentrates	1.5		ML	CS 57-1981	
JF 0175	Fruit juices	0.05		ML		Including nectars; Ready to drink
GC 0081	Cereal grains, except buckwheat, cañihua and quinoa	0.2		ML		
	Canned chestnuts and canned chestnuts puree	1		ML	CS 145-1985	
MM 0097	Meat of cattle, pigs and sheep	0.1		ML		Also applies to the fat from meat
PM 0110	Poultry meat	0.1		ML		
MO 0812	Cattle, Edible offal of	0.5		ML		
MO 0818	Pig, Edible offal of	0.5		ML		
PO 0111	Poultry, Edible offal of	0.5		ML		
	Edible fats and oils	0.1		ML	CS 19-1981	Edible fats and oils not covered by individual standards
	Fish	0.3		ML		
	Margarine	0.1		ML	CS 32-1981	
	Minarine	0.1		ML	CS 135-1981	
	Named animal fats	0.1		ML	CS 211-1999	Lard, rendered pork fat, premier jus and edible tallow.
OR 0305	Olive oil, refined	0.1		ML	CS 33-1981	
OC 0305	Olive oil, virgin	0.1		ML	CS 33-1981	
OR 5330	Olive, residue oil	0.1		ML	CS 33-1981	Olive pomace oil
PF 0111	Poultry fats	0.1		ML		
OC 0172	Vegetable oils; Crude	0.1		ML	CS 210-1999	Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, saflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter.
OR 0172	Vegetable oils, Edible	0.1		ML	CS 210-1999	Oils of arachis, babasu, coconut, cottonseed, grapeseed, maize, mustardseed, palm kernel, palm, rapeseed, saflowerseed, sesameseed, soya bean, and sunflowerseed, and palm olein, stearin and superolein and other oils but excluding cocoa butter.
ML 0106	Milks	0.02		ML		A concentration factor applies to partially or wholly dehydrated milks.
LS	Secondary milk products	0.02		ML		As consumed
	Natural mineral waters	0.01		ML	CS 108-1981	Expressed in mg/l

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Infant formula	0.02		ML		Ready to use
	Salt, food grade	2		ML	CS 150-1985	
	Wine	0.2		ML		

MERCURY

Reference to JECFA: 10 (1966), 14 (1970), 16 (1972), 22 (1978)
Toxicological guidance: PTWI 0.005 mg/kg bw (1978)
Residue definition: Mercury, Total
Synonyms: Hg
Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Natural mineral waters	0.001		ML	CS 108-1981	Expressed in mg/l
	Salt, food grade	0.1		ML	CS 150-1985	

Mercury is a naturally occurring metallic element which can be present in foodstuffs by natural causes; elevated levels can also occur due to e.g. environmental contamination by industrial or other uses of mercury. Methylmercury and also total mercury levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher methyl mercury levels in other animal products.

METHYLMERCURY

Reference to JECFA: 22 (1978), 33 (1988), 53 (1999), 61 (2003)
Toxicological guidance: PTWI 0.0016 mg/kg bw (2003)
Residue definition: Methylmercury
Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Fish	0.5		GL		Except predatory fish The Guideline levels are intended for methylmercury in fresh or processed fish and fish products moving in international trade.
	Predatory fish	1		GL		Predatory fish such as shark (WS 0131), swordfish, tuna (WS 0132), pike *(WF 0865) and others.* The Guideline level for methylmercury in fresh or processed fish and fish products moving in international trade.

Lots should be considered as being in compliance with the guideline levels if the level of methylmercury in the analytical sample, derived from the composite bulk sample, does not exceed the above levels. Where these Guideline levels are exceeded, governments should decide whether and under what circumstances, the food should be distributed within their territory or jurisdiction and what recommendations, if any, should be given as regards restrictions on consumption, especially by vulnerable groups such as pregnant women.
Methylmercury is the most toxic form of mercury and is formed in aquatic environments. Methylmercury therefore is found mainly in aquatic organisms. It can accumulate in the food chain; the levels in large predatory fish species are therefore higher than in other species and fish is the predominant source of human exposure to methylmercury. Methylmercury and also total mercury levels in terrestrial animals and plants are usually very low; the use of fish meal as animal feed can however also lead to higher methyl mercury levels in other animal products.

TIN

Reference to JECFA:	10 (1966), 14 (1970), 15 (1971), 19 (1975), 22 (1978), 26(1982), 33(1988), 55 (2000), 64 (2005)
Toxicological guidance:	PTWI 14 mg/kg bw (1988, Expressed as Sn; includes tin from food additive uses; maintained in 2000.)
Residue definition:	Tin, total (Sn-tot) when not otherwise mentioned; inorganic tin (Sn-in); or other specification
Synonyms:	Sn
Related Code of Practice:	Code of Practice for the Prevention and Reduction of Inorganic Tin Contamination in Canned Foods (CAC/RCP 60-2005) Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Canned foods (other than beverages)	250	C	ML		
	Canned beverages	150	C	ML		
	Canned citrus fruits	250	C	ML	CX STAN 254-2007	The scope of the Standard includes canned mandarin oranges, canned grapefruits, canned pummelos and canned sweet oranges offered for direct consumption, including for catering purposes or for repacking if required.
	Jams, jellies and marmalades	250	C	ML	CX STAN 296-2009	The scope of the Standard covers jams, jellies and marmalades made from all fruits and vegetables offered for direct consumption, including for catering purposes or for repacking if required excluding: a. products when indicated as being intended for further processing such as those intended for use in the manufacture of fine bakery wares, pastries or biscuits; b. products which are clearly intended or labelled as intended for special dietary uses; c. reduced sugar products or those with a very low sugar content; d. products where the foodstuffs with sweetening properties have been replaced wholly or partially by food additive sweeteners.
	Canned stone fruits	250		ML	CX STAN 242-2003	The scope of the Standard includes canned peaches, canned plums, canned apricots and canned cherries offered for direct consumption, including for catering purposes or for repacking if required.
	Canned vegetables	250	C	ML	CX STAN 297-2009	The scope of the Standard includes canned asparagus, canned carrots,

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
						canned green peas, canned green beans and wax beans, canned mature processed peas, canned palmito, canned sweet corn and canned baby corn offered for direct consumption, including for catering purposes or for repacking if required.
	Canned fruit cocktail	250	C	ML	CS 78-1981	
	Canned mangoes	250	C	ML	CS 159-1987	
	Canned pineapple	250	C	ML	CS 42-1981	
	Canned raspberries	250	C	ML	CS 60-1981	
	Canned strawberries	200	C	ML	CS 62-1981	
	Canned tropical fruit salad	250	C	ML	CS 99-1981	
	Mango chutney	250	C	ML	CS 160-1987	
	Table olives	250	C	ML	CS 66-1981	
	Canned mushrooms	250	C	ML	CS 55-1981	
	Canned tomatoes	250	C	ML	CS 13-1981	
	Pickled cucumber	250	C	ML	CS 115-1981	
	Processed tomato concentrates	250	C	ML	CS 57-1981	
	Canned chestnuts and chestnut purée	250	C	ML	CS 145-1985	
	Cooked cured chopped meat	200	C	ML	CS 98-1981	For products in tinplate containers
	Cooked cured chopped meat	50		ML	CS 98-1981	For products in other containers
	Cooked cured ham	50		ML	CS 96-1981	For products in other containers
	Cooked cured ham	200	C	ML	CS 96-1981	For products in tinplate containers
	Cooked cured pork shoulder	50		ML	CS 97-1981	For products in other containers
	Cooked cured pork shoulder	200	C	ML	CS 97-1981	For products in tinplate containers
	Corned beef	50		ML	CS 88-1981	For products in other containers
	Corned beef	200	C	ML	CS 88-1981	For products in tinplate containers
	Luncheon meat	200	C	ML	CS 89-1981	For products in tinplate containers
	Luncheon meat	50		ML	CS 89-1981	For products in other containers

Tin is mainly used in tinplated containers, but it is also extensively used in solders, in alloys including dental amalgams. Inorganic tin compounds, in which the element may be present in the oxidation states of +2 or +4, are used in a variety of industrial processes for the strengthening of glass, as a base for colours, as catalysts, as stabilizers in perfumes and soaps, and as dental anticariogenic agents. On the whole, contamination of the environment by tin is only slight. Food is the main source of tin for man. Small amounts are found in fresh meat, cereals, and vegetables. Larger amounts of tin may be found in foods stored in plain cans and, occasionally, in foods stored in lacquered cans. Some foods such as asparagus, tomatoes, fruits, and their juices tend to contain high concentrations of tin if stored in unlaquered cans (Environmental health criteria for tin; International Programme on Chemical Safety (IPCS); 1980). Inorganic tin is found in food in the +2 and +4 oxidation states; it may occur in a cationic form (stannous and stannic compounds) or as inorganic anions (stannites or stannates).

RADIONUCLIDES

Commodity Code	Product Name	Representative radionuclides	Dose per unit intake factor in Sv/Bq	Level in Bq/kg	Type	Reference	Notes/Remarks
	Infant foods*	^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Am		1	GL		
	Infant foods *	^{90}Sr, ^{106}Ru, ^{129}I, ^{131}I, ^{235}U		100	GL		
	Infant foods *	^{35}S**, ^{60}Co, ^{89}Sr, ^{103}Ru, ^{134}Cs, ^{137}Cs, ^{144}Ce, ^{192}Ir		**1000**	**GL**		
	Infant foods *	^{3}H***, ^{14}C, ^{99}Tc		**1000**	**GL**		
	Foods other than infant foods	^{238}Pu, ^{239}Pu, ^{240}Pu, ^{241}Am		**10**	**GL**		
	Foods other than infant foods	^{90}Sr, ^{106}Ru, ^{129}I, ^{131}I, ^{235}U		**100**	**GL**		
	Foods other than infant foods	^{35}S**, ^{60}Co, ^{89}Sr, ^{103}Ru, ^{134}Cs, ^{137}Cs, ^{144}Ce, ^{192}Ir		**1000**	**GL**		
	Foods other than infant foods	^{3}H***, ^{14}C, ^{99}Tc		10000	GL		

* When intended for use as such.
** This represents the value for organically bound sulphur.
*** This represents the value for organically bound tritium.

Scope: The Guideline Levels apply to radionuclides contained in foods destined for human consumption and traded internationally, which have been contaminated following a nuclear or radiological emergency[1]. These guideline levels apply to food after reconstitution or as prepared for consumption, i.e., not to dried or concentrated foods, and are based on an intervention exemption level of 1 mSv in a year.

Application: As far as generic radiological protection of food consumers is concerned, when radionuclide levels in food do not exceed the corresponding Guideline Levels, the food should be considered as safe for human consumption. When the Guideline Levels are exceeded, national governments shall decide whether and under what circumstances the food should be distributed within their territory or jurisdiction. National governments may wish to adopt different values for internal use within their own territories where the assumptions concerning food distribution that have been made to derive the Guideline Levels may not apply, e.g., in the case of wide-spread radioactive contamination. For foods that are consumed in small quantities, such as spices, that represent a small percentage of total diet and hence a small addition to the total dose, the Guideline Levels may be increased by a factor of 10.

1 For the purposes of this document, the term "emergency" includes both accidents and malevolent actions.

Radionuclides: The Guideline Levels do not include all radionuclides. Radionuclides included are those important for uptake into the food chain; are usually contained in nuclear installations or used as a radiation source in large enough quantities to be significant potential contributors to levels in foods, and; could be accidentally released into the environment from typical installations or might be employed in malevolent actions. Radionuclides of natural origin are generally excluded from consideration in this document.

In the Table, the radionuclides are grouped according to the guideline levels rounded logarithmically by orders of magnitude. Guideline levels are defined for two separate categories "infant foods" and "other foods". This is because, for a number of radionuclides, the sensitivity of infants could pose a problem. The guideline levels have been checked against age-dependent ingestion dose coefficients defined as committed effective doses per unit intake for each radionuclide, which are taken from the "International Basic Safety Standards" (IAEA, 1996)[2].

Multiple radionuclides in foods: The guideline levels have been developed with the understanding that there is no need to add contributions from radionuclides in different groups. Each group should be treated independently. However, the activity concentrations of each radionuclide within the same group should be added together[3].

Annex 1

SCIENTIFIC JUSTIFICATION FOR THE GUIDELINE LEVELS FOR RADIONUCLIDES IN FOODS CONTAMINATED FOLLOWING A NUCLEAR OR RADIOLOGICAL EMERGENCY

The Guideline Levels for Radionuclides in Foods and specifically the values presented in Table 1 above are based on the following general radiological considerations and experience of application of the existing international and national standards for control of radionuclides in food.

Significant improvements in the assessment of radiation doses resulting from the human intake of radioactive substances have become available since the Guideline Levels were issued by the Codex Alimentarius Commission in 1989[4] (CAC/GL 5-1989).

Infants and adults: The levels of human exposure resulting from consumption of foods containing radionuclides listed in Table 1 at the suggested guideline levels have been assessed both for infants and adults and checked for compliance with the appropriate dose criterion.

In order to assess public exposure and the associated health risks from intake of radionuclides in food, estimates of food consumption rates and ingestion dose coefficients are needed. According to Ref. (WHO, 1988) it is assumed that 550 kg of food is consumed by an adult in a year. The value of infant food and milk consumption during first year of life used for infant dose calculation equal to 200 kg is based on contemporary human habit assessments (F. Luykx, 1990[5]; US DoH, 1998[6]; NRPB, 2003[7]). The most conservative values of the radionuclide-specific and age-specific ingestion dose coefficients, i.e. relevant to the chemical forms of radionuclides which are most absorbed from the gastro-intestinal tract and retained in body tissues, are taken from the (IAEA, 1996).

Radiological criterion: The appropriate radiological criterion, which has been used for comparison with the dose assessment data below, is a generic intervention exemption level of around 1 mSv for individual annual dose from radionuclides in major commodities, e.g. food, recommended by the International Commission on Radiological Protection as safe for members of the public (ICRP, 1999)[8].

Naturally occurring radionuclides: Radionuclides of natural origin are ubiquitous and as a consequence are present in all foodstuffs to varying degrees. Radiation doses from the consumption of foodstuffs typically range from a few tens to a few hundreds of microsieverts in a year. In essence, the doses from these radionuclides when naturally present in the diet are unamenable to control; the resources that would be required to affect exposures would be out of proportion to the benefits achieved for health. These radionuclides are excluded from consideration in this document as they are not associated with emergencies.

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2 Food and Agriculture Organization of the United Nations, International Atomic Energy Agency, International Labour Office, OECD Nuclear Energy Agency, Pan American Health Organization, World Health Organization (1996) International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources, IAEA, Vienna.

3 For example, if ^{134}Cs and ^{137}Cs are contaminants in food, the guideline level of 1000 Bq/kg refers to the summed activity of both these radionuclides.

4 The Codex Alimentarius Commission at its 18th Session (Geneva 1989) adopted Guideline Levels for Radionuclides in Foods Following Accidental Nuclear Contamination for Use in International Trade (CAC/GL 5-1989) applicable for six radionuclides (^{90}Sr, ^{131}I, ^{137}Cs, ^{134}Cs, ^{239}Pu and ^{241}Am) during one year after the nuclear accident.

5 F. Luykx (1990) Response of the European Communities to environmental contamination following the Chernobyl accident. In: Environmental Contamination Following a Major Nuclear Accident, IAEA, Vienna, v.2, 269-287.

6 US DoHHS (1998) Accidental Radioactive Contamination of Human Food and Animal Feeds: Recommendations for State and Local Agencies. Food and Drug Administration, Rockville.

7 K. Smith and A. Jones (2003) Generalised Habit Data for Radiological Assessments. NRPB Report W41.

8 International Commission on Radiological Protection (1999). Principles for the Protection of the Public in Situations of Prolonged Exposure. ICRP Publication 82, Annals of the ICRP.

One-year exposure assessment: It is conservatively assumed that during the first year after major environmental radioactive contamination caused by a nuclear or radiological emergency it might be difficult to readily replace foods imported from contaminated regions with foods imported from unaffected areas. According to FAO statistical data the mean fraction of major foodstuff quantities imported by all the countries worldwide is 0.1. The values in Table 1 as regards foods consumed by infants and the general population have been derived to ensure that if a country continues to import major foods from areas contaminated with radionuclides, the mean annual internal dose of its inhabitants will not exceed around 1 mSv (see Annex 2). This conclusion might not apply for some radionuclides if the fraction of contaminated food is found to be higher than 0.1, as might be the case for infants who have a diet essentially based on milk with little variety.

Long-term exposure assessment: Beyond one year after the emergency the fraction of contaminated food placed on the market will generally decrease as a result of national restrictions (withdrawal from the market), changes to other produce, agricultural countermeasures and decay.

Experience has shown that in the long term the fraction of imported contaminated food will decrease by a factor of a hundred or more. Specific food categories, e.g. wild forest products, may show persistent or even increasing levels of contamination. Other categories of food may gradually be exempted from controls. Nevertheless, it must be anticipated that it may take many years before levels of individual exposure as a result of contaminated food could be qualified as negligible.

Annex 2

ASSESSMENT OF HUMAN INTERNAL EXPOSURE WHEN THE GUIDELINE LEVELS ARE APPLIED

For the purpose of assessment of the mean public exposure level in a country caused by the import of food products from foreign areas with residual radioactivity, in implementing the present guideline levels the following data should be used: annual food consumption rates for infants and adults, radionuclide- and age-dependent ingestion dose coefficients and the import/production factors. When assessing the mean internal dose in infants and adults it is suggested that due to monitoring and inspection the radionuclide concentration in imported foods does not exceed the present guideline levels. Using cautious assessment approach it is considered that all the foodstuffs imported from foreign areas with residual radioactivity are contaminated with radionuclides at the present guideline levels.

Then, the mean internal dose of the public, E (mSv), due to annual consumption of imported foods containing radionuclides can be estimated using the following formula:

$$E = GL(A) \cdot M(A) \cdot e_{ing}(A) \cdot IPF$$

where:

GL(A) is the Guideline Level (Bq/kg)

M(A) is the age-dependent mass of food consumed per year (kg)

e_{ing}***(A)*** is the age-dependent ingestion dose coefficient (mSv/Bq)

IPF is the import/production factor[9] (dimensionless).

Assessment results presented in Table 2 both for infants and adults demonstrate that for all the twenty radionuclides doses from consumption of imported foods during the 1st year after major radioactive contamination do not exceed 1 mSv. It should be noted that the doses were calculated on the basis of a value for the IPF equal to 0.1 and that this assumption may not always apply, in particular to infants who have a diet essentially based on milk with little variety.

It should be noted that for ^{239}Pu as well as for a number of other radionuclides the dose estimate is conservative. This is because elevated gastro-intestinal tract absorption factors and associated ingestion dose coefficients are applied for the whole first year of life whereas this is valid mainly during suckling period recently estimated by ICRP to be as average first six months of life (ICRP, 2005[10]). For the subsequent six months of the first year of life the gut absorption factors are much lower. This is not the case for ^{3}H, ^{14}C, ^{35}S, iodine and caesium isotopes.

As an example, dose assessment for ^{137}Cs in foods is presented below for the first year after the area contamination with this nuclide.

For adults: E = 1000 Bq/kg ·550 kg ·1.3·10^{-5} mSv/Bq ·0.1 = 0.7 mSv;

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9 The import/production factor (***IPF***) is defined as the ratio of the amount of foodstuffs imported per year from areas contaminated with radionuclides to the total amount produced and imported annually in the region or country under consideration.

10 International Commission on Radiological Protection (2005) Doses to Infants from Radionuclides Ingested in Mothers Milk. To be published.

For infants: E = 1000 Bq/kg ·200 kg ·$2.1 \cdot 10^{-5}$ mSv/Bq ·0.1 = 0.4 mSv

TABLE 2

ASSESSMENT OF EFFECTIVE DOSE FOR INFANTS AND ADULTS FROM INGESTION OF IMPORTED FOODS IN A YEAR

Radionuclide	Guideline Level (Bq/kg)		Effective dose (mSv)	
	Infant foods	Other foods	1st year after major contamination	
			Infants	Adults
^{238}Pu	1	10	0.08	0.1
^{239}Pu			0.08	0.1
^{240}Pu			0.08	0.1
^{241}Am			0.07	0.1
^{90}Sr	100	100	0.5	0.2
^{106}Ru			0.2	0.04
^{129}I			0.4	0.6
^{131}I			0.4	0.1
^{235}U			0.7	0.3
^{35}S*	1000	1000	0.2	0.04
^{60}Co			1	0.2
^{89}Sr			0.7	0.1
^{103}Ru			0.1	0.04
^{134}Cs			0.5	1
^{137}Cs			0.4	0.7
^{144}Ce			1	0.3
^{192}Ir			0.3	0.08
^{3}H**	1000	10000	0.002	0.02
^{14}C			0.03	0.3
^{99}Tc			0.2	0.4

* This represents the value for organically bound sulphur.
** This represents the value for organically bound tritium.
See for "Scientific justification for the Guideline Levels" (Annex 1) and the "Assessment of human internal exposure when the Guideline Levels are applied" (Annex 2)

ACRYLONITRILE

Reference to JECFA:	28 (1984)
Toxicological guidance:	Provisional Acceptance (1984, the use of food-contact materials from which acrylonitrile may migrate is provisionally accepted on condition that the amount of the substance migrating into food is reduced to the lowest level technologically attainable.)
Residue definition:	acrylonitrile (monomer)
Synonyms:	2-Propenenitrile; vinyl cyanide (VCN); cyanoethylene; abbreviations, AN, CAN.
Related Code of Practice:	Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Food	0.02		GL		

Acrylonitrile monomer is the starting substance for the manufacture of polymers which are used as fibres, resins, rubbers and also as packaging material for o.a. foods. Acrylonitrile is not known to occur as a natural product. Acrylonitrile is classified by IARC as possibly carcinogenic to humans (Group 2B). Polymers derived from acrylonitrile may still contain small amounts of free monomer.

CHLOROPROPANOLS

Reference to JECFA:	41 (1993; for 1,3-dichloro-2-propanol only), 57 (2001), 67 (2006)
Toxicological guidance:	PMTDI 0.002 mg/kg bw (2001, for 3-chloro-1,2-propanediol); maintained in 2006. Establishment of tolerable intake was considered to be inappropriate for 1,3-dichloro-2-propanol because of the nature of the toxicity (tumorogenic in various organs in rats and the contaminant can interact with chromosomes and/or DNA). BMDL 10 cancer, 3.3 mg/kg bw/day (for 1,3-dichloro-2-propanol); MOE, 65000 (general population), 2400 (high level intake, including young children)
Residue definition:	3-MCPD
Synonyms:	Two substances are the most important members of this group: 3-monochloropropane-1,2-diol (3-MCPD, also referred to as 3-monochloro-1,2-propanediol) and 1,3-dichloro-2-propanol (1,3-DCP)
Related Code of Practice:	Code of Practice for the Reduction of 3-Monochloropropane-1,2-diol (3-MCPD) during the production of Acid-Hydrolyzed Vegetable Proteins (Acid-HVPs) and Products that Contain Acid-HVPs (CAC/RCP 64 – 2008)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Liquid condiments containing acid-hydrolyzed vegetable proteins (excluding naturally fermented soy sauce)	0.4		ML		

MELAMINE

Reference to JECFA: FAO/WHO Expert Meeting, 2008
Toxicological guidance: TDI 0.2 mg/kg bw

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Food (other than infant formula)	2.5		ML		The ML applies to food other than infant formula
	Feed	2.5		ML		Note 1 The maximum level applies to levels of melamine resulting from its non-intentional and unavoidable presence in feed and food. The maximum level does not apply to feed and food for which it can be proven that the level of melamine higher than 2.5 mg/kg is the consequence of - authorised use of cyromazine as insecticide. The melamine level shall not exceed the level of cyromazine. - migration from food contact materials taking account of any nationally authorised migration limit. Note 2 The maximum level does not apply to melamine that could be present in the following feed ingredients / addtives: guanidino acetic acid (GAA), urea and biuret; as a result of normal proceduction processes
	Powdered Infant formula	1		ML		

VINYL CHLORIDE MONOMER

Reference to JECFA: 28 (1984)
Toxicological guidance: Provisional Acceptance (1984, the use of food-contact materials from which vinyl chloride may migrate is provisionally accepted, on condition that the amount of the substance migrating into food is reduced to the lowest level technologically
Residue definition: Vinylchloride monomer
Synonyms: Monochloroethene, chloroethylene; abbreviation VC or VCM
Related Code of Practice: Code of Practice for Source Directed Measures to Reduce Contamination of Foods with Chemicals (CAC/RCP 49-2001)

Commodity/Product Code	Name	Level mg/kg	Suffix	Type	Reference	Notes/Remarks
	Food	0.01		GL		The GL in food packaging material is 1.0 mg/kg.

Vinylchloride monomer is the main starting substance for the manufacture of polymers which are used as resins, as packaging material for foods. Vinyl chloride is not known to occur as a natural product. Residues of VCM may be still present in the polymer. Vinyl chloride is considered by IARC to be a human carcinogen (as has been shown in occupational exposure situations).

（文部科学省公表資料）

参考資料７

平成 23 年 4 月 1 日

福島第一原子力発電所から 20-30km 圏内の土壌試料の Pu、U の分析結果

1．結果概要

走行サーベイで空間放射線量率の高かった 3 箇所で、土壌試料を採取し、Pu-238、Pu-239+240 濃度及び U-235/U-238 を求めた。

その結果、Pu-238 及び Pu-239+240 は検出されておらず、U-235/U-238 は自然の存在比であった。

2．測定結果

採取場所	採取日時	空間放射線量率 [μSv/h]	Pu-238	Pu-239+240	U-235/U-238
葛尾村小出谷付近	3 月 23 日 10:20 頃	43.5	検出されず (0.1 Bq/kg 以下)	検出されず (0.1 Bq/kg 以下)	0.00731
浪江町昼曽根トンネル東側	3 月 23 日 10:40 頃	46.5	検出されず (0.1 Bq/kg 以下)	検出されず (0.1 Bq/kg 以下)	0.00726
浪江町赤宇木	3 月 22 日 11:30 頃	50.1	検出されず (0.1 Bq/kg 以下)	検出されず (0.1 Bq/kg 以下)	0.00723

*自然の U-235/U-238　0.00725

以上

（東京電力公表資料）

参考資料８

（別紙３）

福島第一原子力発電所　土壌中のＵ測定結果

1. 測定結果

（単位：Bq/kg･乾土）

採取場所 （）は1,2号機スタックからの距離	採取日 分析機関	U-234	U-235	U-238
①グランド(西北西約500m)	3月28日 日本分析センター	12±0.6	0.50±0.086	12±0.6
③産廃処分場近傍(南南西約500m)		4.4±0.27	0.23±0.057	4.3±0.27
天然ウラン比放射能(Bq/g)		1.2×10^{4}	5.7×10^{2}	1.2×10^{4}
天然ウラン存在比(wt%)		0.0054	0.72	99.3

2. 評価

今回検出されたウランは以下により、天然に存在するものと同じレベルと評価する。

- 自然界のウランは放射平衡（U-234とU-238の放射能濃度が同じ）になっているが試料番号①、③ともにU-234とU-238の放射能濃度が同じである
- 天然のU-235の存在比U-235/U-238＝0.0073とほぼ同じであること

試料番号①のU-235:6.2×10^{-6}g(0.5Bq/kg乾土)

試料番号①のU-238:9.6×10^{-4}g(12Bq/kg乾土)

U-235/U-238=0.0064≒0.0073

試料番号③のU-235:2.9×10^{-6}g(0.23Bq/kg乾土)

試料番号③のU-238:3.5×10^{-4}g(4.3Bq/kg乾土)

U-235/U-238=0.0084≒0.0072

以　上