

A.L. 304 ta' l-2007

**ATT DWAR IS-SIGURTÀ FL-IKEL
 (KAP. 449)**

Regolamenti ta' l-2007 dwar Formuli għat-Trabi u Formuli ta' Prosegwiment

BIS-SAHHA tas-setgħat mogħtija bl-artikolu 10 ta' l-Att dwar is-Sigurtà fl-Ikel, il-Ministru tas-Sahħa, l-Anzjani u Kura fil-Kommunità għamel ir-regolamenti li ġejjin:-

1. It-titolu ta' dawn ir-regolamenti hu **Regolamenti ta' l-2007** Titolu.
 dwar Formuli għat-Trabi u Formuli ta' Prosegwiment.

2. (1) Dawn ir-regolamenti jimplimentaw il-provvedimenti tad-Direttiva tal-Kummissjoni 2006/141/KE tat-22 ta' Diċembru, 2006, u għandhom jidhlu fis-seħħ fil-31 ta' Diċembru, 2007. Bidu fis-seħħ u skop.

(2) Dawn il-provvedimenti għandhom japplikaw b'tali mod li:

(a) jhallu l-bejgħ ta' prodotti li ma jikkonformawx ma' dawn ir-regolamenti sa mhux aktar tard mill-1 ta' Jannar, 2008,

(b) mingħajr preġudizzju għall-paragrafu 13, jipprojbixxu, mill-31 ta' Diċembru, 2009 bejgħ ta' prodotti li ma jikkonformawx ma' dawn ir-regolamenti.

3. Dawn ir-regolamenti għandhom x'jaqsmu ma' htigiet ta' kompożizzjoni u twaħħil ta' tikketti għal formuli għat-trabi u formuli ta' prosegwiment maħsubin biex jintużaw minn trabi f'saħħithom. Applikabilità ta' dawn ir-Regolamenti.

4. (1) Għal l-iskop ta' dawn ir-regolamenti, għandhom japplikaw it-tifsiriet 'stqarrija', 'stqarrijiet dwar in-nutrizzjoni', 'stqarrijiet dwar is-sahħa' u 'stqarrijiet dwar tnaqqis fir-riskju ta' mard' fl-Artiklu 2(2)(1), (4), (5) u (6) tar-Regolament (KE) Numru 1924/2006. Tifsir.

(2) Dawn it-tifsiriet li ġejjin għandhom japplikaw ukoll:

(a) "trabi" tfisser tfal taħt it-12-il xahar;

(b) “tfal żgħar” tfisser tfal bejn is-sena u t-tliet snin;

(ċ) “formuli għal trabi” tfisser oġġetti ta’ l-ikel mahsubin għal użu nutrittiv partikolari minn trabi tul l-ewwel xhur tal-hajja u li wahedhom jissodisfaw il-htigiet nutrittivi ta’ dawn it-trabi sakemm jibdew jingħataw ikel addatt li jikkumplimenta d-dieta tagħhom.

(d) “formuli ta’ prosegwiment” tfisser oġġetti ta’ l-ikel mahsubin għal użu nutrittiv partikolari minn trabi meta jiġu mogħtija ikel addatt li jikkumplimenta d-dieta tagħhom u jikkostitwixxu l-element likwidu prinċipali f’dieta progressivament diversifikata ta’ dawn it-trabi;

(e) “fdalijiet ta’ pesticidi” tfisser il-fdalijiet f’formuli għat-trabi u formuli ta’ prosegwiment ta’ prodott li jintuza fil-protezzjoni ta’ impjant kif definit f’punt 1 ta’ l-artikolu 2 tad-Direttiva tal-Kunsill 91/414/EEC, inklużi l-metaboliti tagħhom u prodotti li jirriżultaw mid-degradazzjoni jew reazzjoni tagħhom.

Bejgħ ta’ formuli għal trabi u formuli ta’ prosegwiment.

5. (1) Ebda persuna ma tista’ tqiegħed fis-suq xi formula għat-trabi jew formula ta’ prosegwiment li ma tikkonformax mal-htigiet ta’ dawn ir-regolamenti.

(2) Ebda prodott hlief formula għal trabi ma jista’ jitqiegħed fis-suq jew ikun ipprezentat b’xi mod ieħor bhala adatt biex wahdu jissodisfa l-htigiet nutrittivi ta’ trabi normalment b’saħħithom tul l-ewwel xhur tal-hajja sakemm jibdew jingħataw ikel adatt li jikkumplimenta d-dieta tagħhom.

Manifattura ta’ formuli għal trabi u formuli ta’ prosegwiment.

6. (1) Il-formuli għal trabi għandhom ikunu manifatturati minn sorsi ta’ proteini definiti f’punt 2 ta’ l-Ewwel Skeda u ingredjenti ta’ l-ikel ohrajn, skond il-każ, li l-idoneità tagħhom għal użu nutrittiv partikolari minn trabi sa mit-twelid kien stabbilit minn informazzjoni xjentifika aċċettata b’mod ġenerali.

(2) Il-formuli ta’ prosegwiment għandhom ikunu manifatturati minn sorsi ta’ proteini definiti f’punt 2 tat-Tieni Skeda u ingredjenti ta’ l-ikel ohrajn, skond il-każ, li l-idoneità tagħhom għal użu nutrittiv partikolari minn trabi minn sitt xhur ’il fuq kienet stabbilita minn informazzjoni xjentifika aċċettata b’mod ġenerali.

(3) Din l-idoneità, kif imsemmija f’paragrafi 6(1) u 6(2), għanda tiġi murija permezz ta’ revizjoni sistematika ta’ informazzjoni li tkun aċċessibli li għanda x’taqsam ma’ benefiċċji li jkunu mistennija u ma’ kunsiderazzjonijiet ta’ sigurtà kif ukoll, fejn ikun hemm bżonn,

studju kif suppost, magħmul fuq gwida esperta, li ġeneralment tkun aċċettata, fuq id-disinn u kif dan it-tip ta' studju għandu jiġi magħmul.

(4) Il-projbizzjonijiet u l-limitazzjonijiet fl-użu ta' ingredjenti ta' ikel imnizzlin fl-Ewwel u t-Tieni Skedi, għandhom ikunu osservati.

7. (1) Il-formuli għal trabi għandhom jikkonformaw mal-kriterji ta' kompożizzjoni kif hemm speċifikat fl-Ewwel Skeda u kif ukoll ma' l-ispeċifikazzjonijiet li hemm fil-Hames Skeda. Kriterji ta' kompożizzjoni.

Fil-każ ta' formuli għal trabi manifatturati minn proteini tal-halib tal-baqra definit f'punt 2.1 ta' l-Ewwel Skeda b'kwantità ta' proteini bejn il-minimu u 0,5 g/100 kJ (2 g/100 kcal), l-idonietà ta' formuli għat-trabi għall-użijiet nutrittivi partikolari minn trabi għanda tiġi murija permezz ta' studji kif suppost, magħmulin fuq gwida esperta, li ġeneralment tkun aċċettata, fuq id-disinn u kif dan it-tip ta' studju għandu jiġi magħmul.

Fil-każ ta' formuli għal trabi manifatturati minn idrolisati ta' proteini definit f'punt 2.2 ta' l-Ewwel Skeda b'kwantità ta' proteini bejn il-minimu u 0,56 g/100 kJ (2,25 g/100 kcal), l-idonietà ta' formuli għal trabi għall-użijiet nutrittivi partikolari minn trabi għanda tiġi murija permezz ta' studji kif suppost, magħmulin fuq gwida esperta, li ġeneralment tkun aċċettata, fuq id-disinn u kif dan it-tip ta' studju għandu jiġi magħmul u għandha taqbel ma' l-ispeċifikazzjonijiet li hemm fis-Sitt Skeda.

(2) Il-formuli ta' prosegwiment għandhom jikkonformaw mal-kriterji ta' kompożizzjoni speċifikati fit-Tieni Skeda u kif ukoll ma' l-ispeċifikazzjonijiet li hemm fil-Hames Skeda.

(3) Biex formuli għal trabi u formuli ta' prosegwiment ikunu lesti biex jintużaw, m'għandu jinhtieg xejn aktar, skond il-każ, hlief li jiżdidilhom l-ilma.

(4) Is-sustanzi biss li hemm elenkati fit-Tielet Skeda jistghu jintużaw fil-manifattura ta' formuli għal trabi u formuli ta' prosegwiment biex jissodisfaw il-htigiet dwar:

- (a) sustanzi minerali,
- (b) vitamini,
- (c) aċidi aminiċi u komposti tan-nitroġenu ohra,

(d) sustanzi ohra li ghandhom skop nutrittiv partikolari.

(5) Formuli ghal trabi u formuli ta' prosegwiment m'ghandux ikollhom xi sustanza fi kwantità tali li tista' tqieghed fil-periklu s-sahha tat-trabi u ta' tfal zghar.

(6) Il-Kriterji tal-purità ghall-sustanzi, li jikkoncernaw is-sustanzi imnizzlin fit-Tielet Skeda, fil-manifattura ta' oġġetti ta' l-ikel ghall-skopijiet iktar minn dawk li jaqaw taht dawn ir-Regolamenti, ghandom japplikaw.

(7) Ghal dawk is-sustanzi li ma ġewx provduti bi kriterji tal-purità mill-leġislazzjoni tal-Komunità, ġeneralment kriterji tal-purità aċċettati jiġu rakkomandati minn korpi internazzjonali; dan ghandu japplika sakemm dawn il-kriterji jiġu adottati fil-livell tal-Komunità. Madanakollu, liġijiet nazzjonali li jpoġġu kriterji tal-purità iktar stretti minn dawk li jiġu rakkomandati minn korpi internazzjonali jistgħu jinżammu.

(8) Formuli ghal trabi u formuli ta' prosegwiment m'ghandux ikollhom residwi ta' pesticidi individwali f'livelli li jaqbzu 0.01 mg/kg tal-prodott kif propost lest ghall-konsum jew kif rikostitwit skond l-istruzzjonijiet tal-manifattur. Metodi analitiċi biex jiddeterminaw il-livelli ta' fdalijiet ta' pesticidi ghandhom ikunu metodi standardizzati aċċettati b'mod ġenerali.

(9) Dawk il-pesticidi elenkati fit-Tmien Skeda ma ghandhomx jintużaw fi prodotti agrikoli intiżi ghall-produzzjoni ta' formuli għat-trabi u formuli ta' prosegwiment.

Madanakollu, għall-iskop ta' kontroll:

(a) pesticidi elenkati fl-Ewwel Tabella tat-Tmien Skeda jitqiesu bhala li ma ntużawx jekk ir-residwi tagħhom ma jaqbzux livell ta' 0.003 mg/kg. Dan il-livell, li huwa kkunsidrat bhala limitu ta' kwantifikazzjoni tal-metodi analitiċi, għandu jibqa taht revizjoni regolari fid-dawl tal-progress tekniku.

(b) pesticidi elenkati fit-Tieni Tabella tat-Disa' Skeda jitqiesu bhala li ma ntużawx jekk ir-residwi tagħhom ma jaqbzux livell ta' 0.003 mg/kg. Dan il-livell, li huwa kkunsidrat bhala limitu ta' kwantifikazzjoni tal-metodi analitiċi, għandu jibqa taht revizjoni regolari fid-dawl tal-progress tekniku.

(10) B'derogazzjoni minn paragrafu 7(8), għall-pestiċidi mnizzla fid-Disa' Skeda, il-livelli massimi tar-residwi speċifikati fiha għandom japplikaw.

(11) Il-livelli b'referenza għal paragrafi 7(9) u 7(10) għandom jiġu applikati għall-prodotti kif propost lest għall-konsum jew kif rikostitwit skond l-istruzzjonijiet tal-manifattur.

8. (1) Biex jiġi faċilitat uffiċjalment il-kontroll effiċjenti ta' formuli għal trabi, meta operatur kummerċjali ta' l-ikel ipoġġi għall-bejgħ formuli għal trabi għandu bżonn jagħmel notifika mall-Kummissjoni tas-Sigurtà ta' l-Ikel billi jibgħat it-tiketta użata għall-prodott.

Kontroll ta' formuli għal trabi.

(2) L-awtoritajiet kompetenti għall-iskopijiet ta' dan il-paragrafu huma dawk imsemmija f'paragrafi 19(13) sa 19(18) ta' Regolamenti ta' l-2004 dwar Twahhil ta' Tikketti, Prezentazzjoni u Riklamar ta' Ogġetti ta' l-Ikel.

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9. (1) (a) B'eċċezzjoni ta' kif ġie provdut f'paragrafu 9(2), l-isem li bih il-formuli għal trabi u l-formuli ta' prosegwiment jinbiegħu għandhom ikunu, rispettivament:

Twahhil ta' tikketti u prezentazzjoni ta' formuli għal trabi u formuli ta' prosegwiment.

(i) *bl-Ingliż*: 'infant formula' u 'follow-on formula'

(ii) *bil-Malti*: 'formula tat-trabi' u 'formula tal-prosegwiment'

(b) L-isem li bih il-prodotti koperti bir-regolament 4(2) (ċ) u (d) jinbiegħu għandhu jkun, rispettivament:

“formula għat-trabi” u “formula ta' prosegwiment”.

Iżda, l-isem ta' prodotti maniffatturati għalkollox minn proteini ġejjin mill-halib tal-baqra, għandu rispettivament ikun:

“halib tat-trabi” u “halib ta' prosegwiment”.

(ċ) Bla hsara għal paragrafu (b) ta' hawn fuq, il-lista provduta fl-Għaxar Skeda tispeċifika l-ismijiet li bihom il-prodotti koperti bir-regolament 4(2) (ċ) u (d) jinbiegħu f'kull lingwa tal-Komunità Ewropea.

(2) L-Isem ta' prodotti maniffatturati għal kollox minn proteini tal-halib tal-baqra, għandu rispettivament ikun:

(i) *bl-Ingliż*: ‘infant milk’ u ‘follow-on milk’

(ii) *bil-Malti*: ‘halib tat-trabi’ u ‘halib tal-prosegwiment’

(3) It-tikketti għandu jkollhom fuqhom, minbarra dawk li hemm provduti dwarhom f’paragrafu 5(1) fir-Regolamenti dwar it-Twahhil ta’ Tikketti u Preżentazzjoni ta’ Oġġetti ta’ l-Ikel, il-partikolaritajiet mandatarji li ġejjin bil-Malti u, jew bl-Ingliż:

(a) fil-każ ta’ formuli għal trabi, dikjarazzjoni li tghid li l-prodott ikun adatt għal użu nutritiv partikolari minn trabi mit-twelid meta ma jitreddghux;

(b) fil-każ ta’ formuli ta’ prosegwiment, dikjarazzjoni li tkun tghid li, l-prodott huwa addatt biss għal użu nutritiv partikolari li jinghata lil trabi ’l fuq minn sitt xhur, li għandu jifforma biss parti minn dieta diversifikata u li m’għandux jintuża bhala sostitut għall-halib tas-sider tul l-ewwel sitt xhur tal-hajja u li d-deċiżjoni biex jiġi introdott l-ikel addatt li jikkumplementa il-formuli ta’ prosegwiment, li jinkludi kull tip ta’ eċċezzjoni sa l-età ta’ sitt xhur, irid jiġi wżat biss fuq avviz minn persuni indipendenti li għandom kwalifiki fil-mediċina, nutriment jew fil-farmaċija, jew nies professjonali oħra responsabbli għall-kura ta’ l-ommijiet u tat-tfal, ibbażati fuq il-bżonnijiet tat-tarbija biex tkun tista’ tikber u tiżviluppa.

(ċ) fil-każ ta’ formuli għal trabi u formuli ta’ prosegwiment, il-valur ta’ enerġija li disponibbli, espress f’kJ u kcal, u l-kontenut ta’ proteini, karboidrati u lipidi, espressi f’forma numerika, għal kull 100 ml tal-prodott lest biex jintuża;

(d) fil-każ ta’ formuli għal trabi u formuli ta’ prosegwiment, il-kwantità medja ta’ kull sustanza minerali u ta’ kull vitamina msemmin fl-Ewwel u t-Tieni Skedi rispettivament, u fejn dan japplika, ta’ kolina, inositol u karnitina, espressi f’forma numerika, kull 100 ml tal-prodott lest biex jintuża;

(e) fil-każ ta’ formuli għal trabi u formuli ta’ prosegwiment, struzzjonijiet kif suppost għall-preparazzjoni, għall-ħżin u għar-rimi tal-prodott u twissija kontra l-perikli għas-saħha jekk ma jkunx hemm preparazzjoni u ħżin kif suppost.

(4) It-tikketta tista’ ġġib fuqha:

(a) għall-formuli għal trabi u formuli ta’ prosegwiment il-kwantità medja ta’ nutrienti msemminja fit-Tielet Skeda meta din

id-dikjarazzjoni ma tkunx koperta mid-disposizzjonijiet tal-paragrafu (3)(d) ta' dan ir-regolament, espressi f'forma numerika, kull 100 ml tal-prodott lest biex jintuża;

(b) fil-każ ta' formuli ta' prosegwiment, minbarra informazzjoni numerika, informazzjoni fuq vitamini u minerali inklużi fis-Seba' Skeda, espressi bhala perċentwali tal-valuri ta' referenza mogħtija hemmhekk, għal kull 100 ml tal-prodott lest biex jintuża.

(5) It-tikketti fuq formuli għal trabi u formuli ta' prosegwiment għandhom ikunu ddisinjati biex jagħtu l-informazzjoni meħtieġa fuq l-użu kif suppost tal-prodotti u biex ma jiskoraġġux it-treddeiegh. L-użu ta' frażijiet “umanizzat”, “maternalizzat”, “adattat”, jew termini simili hu pprojbit.

(6) It-tikketti fuq formuli għal trabi għandu jkollhom fuqhom ukoll il-partikolaritajiet mandatorji li ġejjin, li qabilhom ikun hemm il-kliem “Nota Importanti” jew l-ekwivalenti tagħhom:

(a) dikjarazzjoni dwar kemm hu ahjar it-treddeiegh;

(b) dikjarazzjoni li tirrakkomanda li l-prodott jintuża biss fuq parir ta' persuni indipendenti li jkollhom kwalifika fil-medicina, nutriment jew fil-farmaċija, jew nies professjonali oħra responsabbli għall-kura ta' l-ommijiet u tat-tfal.

(7) It-tikketti fuq formuli għat-trabi m'għandux ikollhom fuqhom stampi ta' trabi, lanqas ma jistgħu jinkludu stampi oħra jew kitba li jistgħu jidealizzaw l-użu tal-prodott. Jista' madankollu jkollhom rappreżentazzjonijiet grafiċi biex il-prodott ikun identifikat faċilment u biex jintwerew il-metodi ta' preparazzjoni.

(8) It-tikketti jista' jkollhom fuqhom stqarrijiet dwar in-nutrizzjoni u dwar is-saħħa fil-każijiet biss li huma elenkati fir-Raba' Skeda u skond il-kondizzjonijiet imniżżlin hemmhekk.

(9) It-tikketti ta' formuli għat-trabi u formuli ta' prosegwiment għandom jiġu magħmula b'tali mod li l-konsumatur ikun jista' jagħmel distinzjoni ara bejn dawn il-prodotti halli jevita r-riskju ta' konfużjoni bejn formuli għal trabi u formuli ta' prosegwiment.

(10) Il-htigiet, projbizzjonijiet u restrizzjonijiet li hemm imsemmija f'paragrafi 10(5) sa 10(9) għandhom japplikaw ukoll:

(a) għall-prezentazzjoni tal-prodotti inkwistjoni, b'mod partikolari l-forma, d-dehra jew l-ippakkjar tagħhom, il-materjal użat għall-ippakkjar, il-mod kif inhuma rranġati u l-ambjent kif jiġu esposti għall-pubbliku;

(b) għar-riklamar.

Riklamar għal formuli għat-trabi.

10. (1) Riklamar ta' formuli għal trabi għandu jiġi ristrett għal publikazzjonijiet li jispeċjalizzaw f'kura ta' trabi u publikazzjonijiet xjentifiċi. Dan it-tip ta' riklamar għal formuli għal trabi għandu jkun soġġett għal kundizzjonijiet imniżżla f'paragrafi 9(5) sa 9(9) u paragrafu 9(10)(b) u jkollu informazzjoni biss fuq natura xjentifika u fattwali. Din it-tip ta' informazzjoni m'għandhiex tfisser jew tohloq twemmien li l-halib tal-bott huwa ekwivalenti jew aqwa mill-halib tas-sider.

(2) M'għandux ikun hemm riklamar għall-bejgħ permezz ta' distribuzzjoni ta' kampjuni jew kwalunkwe tip ta' meżzi promozzjonali li jwasslu għall-bejgħ ta' formuli għal trabi direttament lill-konsumatur f'livell ta' imnut, bħal wirja speċjali, biljetti li joffru roħs fil-prezzijiet, *premiums*, bejgħ speċjali, bejgħ ta' prodotti b'roħs fil-prezzijiet li jirriżulta f'bejgħ b'aktar profitt u bejgħ ta' prodotti li jkun assoċjat ma riklamar ta' prodotti oħra.

(3) Il-Manifattur u d-distributtur ta' formuli għal trabi m'għandhomx jipprovdu, lill-pubbliku ġenerali jew lin-nisa tqala, b'xejn jew prodotti b'roħs fil-prezzijiet, kampjuni jew tipi oħra ta' rigali promozzjonali, direttament jew inkella indirettament mis-sistema tal-kura tas-sahha jew haddiema tas-sahha.

Tqassim ta' informazzjoni konsistenti fuq formuli għal trabi u formuli ta' prosegwiment.

11. (1) L-informazzjoni oġġettiva u konsistenti li tiġi provduta, fuq l-oġġetti ta' l-ikel għat-trabi u tfal żgħar, għall-użu tal-familja u għal dawk involuti fis-settur tan-nutrimient tat-trabi u tat-tfal żgħar li tkopri il-pjan, il-mizuri, id-diġinn u d-disseminazzjoni ta' l-informazzjoni u l-kontroll tagħhom.

(2) Informazzjoni u materjali edukattivi, miktubin jew awdjovizwali, fuq l-ikel tat-trabi intenzjonati biex jilhqnu nisa tqal u ommijiet tat-trabi u tfal żgħar, għandhom jinkludu informazzjoni ara fuq dawn il-punti li ġejjin:

(a) il-benefiċċji u s-superjorità tal-halib tas-sider;

(b) in-nutrimient waqt il-maternità u l-preparazzjoni għal manutenzjoni tal-halib tas-sider;

(c) l-effett negattiv possibli fuq il-halib tas-sider meta l-halib tal-bott jiġi introdott parzjalment;

(d) id-diffikultà li taqleb id-deċiżjoni biex ma treddghax;

(e) fejn hemm bżonn, l-użu kif suppost ta' formuli għal trabi.

Meta materjali bħal dawn ma jkollhomx informazzjoni fuq l-użu ta' formuli għal trabi, għandhom jinkludu l-implikazzjonijiet soċjali u finanzjarji ta' l-użu tagħhom, ir-riskji fuq is-saħħa ta' ikel mhux kif suppost jew metodi kif tagħti l-ikel, u, b'mod partikolari, ir-riskji fuq is-saħħa ta' użu mhux kif suppost ta' formuli għal trabi. Dan it-tip ta' materjal m'għandux juża stampi li jistgħu jidealizzaw l-użu ta' formuli għal trabi.

(3) Donazzjonijiet ta' informazzjoni jew apparat edukattiv jew materjali mill-manifattur jew distributtur għandhom, jintgħamlu biss fuq talba u bl-approvazzjoni miktuba ta' l-awtorità nazzjonali kif suppost jew mill-gwida mogħtija mill-awtorità għal dan l-iskop. Dan it-tip ta' apparat jew materjali jistgħu jkollhom l-isem jew il-*'logo'* tal-kumpanija li tkun għamlet id-donazzjoni, imma m'għandhiex tirreferi għal ditta ta' proprjetà esklussiva ta' formuli għal trabi u għanda tingħata lis-sistema' tal-kura tas-saħħa.

(4) Donazzjonijiet jew il-bejgħ ta' rifornimenti ta' formuli għal trabi b'rohs fil-prezzijiet għal istituzzjonijiet jew organizzazzjonijiet, kemm għall-użu fl-istituzzjoni stess jew għal distribuzzjoni barra l-istituzzjoni, għandhom jiġu użati jew imqassma għat-trabi li għandhom jingħataw formuli għal trabi u biss sakemm dawn it-trabi ikollhom bżonnhom.

12. Ir-rekwiżiti l-godda li huma mnizzlin f'paragrafi 7(1) u 7(2) ta' dawn ir-regolamenti m'għandhomx japplikaw bhala mandatorji għall-ikel dijetitiku għal skopijiet mediċi speċjali intenzjonati għat-trabi, b'referenza għal punt 4 ta' l-Iskeda tar-Regolamenti ta' 2001 dwar Ikel Dijetitiku għal skopijiet mediċi speċjali sal-1 ta' Jannar 2012 (A.L. 309 ta' 2001).

Ikel Dijetitiku għal skopijiet mediċi speċjali intenzjonati għat-trabi.

13. Ir-Regolamenti dwar Formuli għat-Trabi u Formuli ta' Prosegwiment, 2002 huma b'dawn imhassrin u kull tip ta' referenza għal dawk ir-regolamenti għandhom jiġu interpretati bhala referenza għal dawn ir-regolamenti.

Thassir ta' A.L. 208 ta' 1-2002.

L-EWWEL SKEDA

Kompożizzjoni Essenzjali għat-Trabi meta rikostitwiti skond l-istruzzjonijiet tal-manifattur

Il-valuri jirreferu għall-prodott lest biex jintuża, jinbiegħ jew rikostitwit skond l-istruzzjonijiet tal-manifattur.

1. ENERĠIJA

Minimu	Massimu
250 kJ/100 ml	295 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINI

(Kontenut ta' proteini = kontenut ta' nitroġenu × 6,25)

2.1 Formuli manifatturati minn proteini tal-halib tal-baqar

Minimu ⁽¹⁾	Massimu
0,45 g/100 kJ	0,7 g/100 kJ
(1,8 g/100 kcal)	(3 g/100 kcal)

⁽¹⁾ Formuli manifatturati minn proteini tal-halib tal-baqar b'kontenut ta' proteini bejn il-minimum u 0,5 g/100 kJ (2 g/100 kcal) għandhom jkunu skond it-tieni subparagrafu ta' paragrafu 7(1).

Biex jintlaħaq valur ta' enerġija ugwali, il-formula għanda jkollha kwantita` disponibbli ta' kull aċidu aminiku essenzjali mill-inqas ugwali għal dak li jinsab fil-proteina li għaliha ssir referenza (halib tas-sider, kif definit fil-Hames Skeda). Madankollu, għal skopijiet ta' kalkolu, il-koncentrazzjoni ta' metionina u ċistina tista' tingħad flimkien jekk il-porzjon ta' metionina:ċistina mhux ikbar minn 2, u l-koncentrazzjoni ta' fenilalanina u tirosina tista' tingħad flimkien jekk il-proporzjon ta' tirosina:fenilalanina mhux akbar minn 2. Il-proporzjon ta' metionina:ċistina m'għandux ikun ikbar minn 2 imma m'għandux jaqbeż 3, l-idonieta` ta' formuli għat-trabi għall-użijiet nutrittivi partikolari minn trabi għanda tiġi murija permezz ta' studji kif suppost, magħmulin fuq gwida esperta, li ġeneralment tkun aċċettata, fuq id-dizinn u kif dan it-tip ta' studju għandu jiġi magħmul.

2.2 Formuli manifatturati minn idrolisati ta' proteini

Minimu ⁽¹⁾	Massimu
0,45 g/100 kJ	0,7 g/100 kJ
(1,8 g/100 kcal)	(3 g/100 kcal)

⁽¹⁾ Formuli manifatturati minn idrolisati ta' proteini b'kontenut ta' proteini bejn il-minimum u 0,56 g/100 kJ (2,25 g/100 kcal) għandhom jkunu skond it-tieni subparagrafu ta' paragrafu 7(1).

Biex jintlaħaq valur ta' enerġija ugwali, il-formula għanda jkollha kwantita` disponibbli ta' kull aċidu aminiku essenzjali mill-inqas ugwali għal dak li jinsab fil-proteina li għaliha ssir referenza (halib tas-sider, kif definit fil-Hames Skeda). Madankollu, għal skopijiet ta' kalkolu, il-konċentrazzjoni ta' metionina u ċistina tista' tingħad flimkien jekk il-proporzjon ta' metionina:ċistina mhux ikbar minn 2, u l-konċentrazzjoni ta' fenilalanina u tirošina tista' tingħad flimkien jekk il-proporzjon ta' tirošina:fenilalanina mhux akbar minn 2. Il-proporzjon ta' metionina:ċistina m'għandux ikun ikbar minn 2 imma m'għandux jaqbeż 3, l-idonieta` ta' formuli għat-trabi għall-użijiet nutrittivi partikolari minn trabi għanda tiġi murija permezz ta' studji kif suppost, magħmulin fuq gwida esperta, li generalment tkun aċċettata, fuq id-dizinn u kif dan it-tip ta' studju għandu jiġi magħmul. Il-kontenut ta' l-karnitina għandu tkun mill-inqas ugwali għal 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3 Formuli manifatturati minn iżolati ta' proteina tas-soja, wahedhom jew imhalltin ma' proteini tal-halib tal-baqar

Minimu	Massimu
0,56 g/100 kJ	0,7 g/100 kJ
(2,25 g/100 kcal)	(3 g/100 kcal)

Fil-manifattura ta' dawn il-formuli għandhom jintużaw biss iżolati ta' proteini tas-soja.

Biex jintlaħaq valur ta' enerġija ugwali, il-formula għanda jkollha kwantita` disponibbli ta' kull aċidu aminiku essenzjali mill-inqas ugwali għal dak li jinsab fil-proteina li għaliha ssir referenza (halib tas-sider, kif definit fil-Hames Skeda). Madankollu, għal skopijiet ta' kalkolu, il-konċentrazzjoni ta' metionina u ċistina tista' tingħad flimkien jekk il-proporzjon ta' metionina:ċistina mhux ikbar minn 2, u l-konċentrazzjoni ta' fenilalanina u tirošina tista' tingħad flimkien jekk il-proporzjon ta' tirošina:fenilalanina mhux akbar minn 2. Il-proporzjon ta' metionina:ċistina m'għandux ikun ikbar minn 2 imma m'għandux jaqbeż 3, l-idonieta` ta' formuli għat-trabi għall-użijiet nutrittivi partikolari minn trabi għanda tiġi murija permezz ta' studji kif suppost, magħmulin fuq gwida esperta, li generalment tkun aċċettata, fuq id-dizinn u kif dan it-tip ta' studju għandu jiġi magħmul. Il-kontenut ta' l-karnitina għandu tkun mill-inqas ugwali għal 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.4 Fil-każijiet kollha, iż-zjieda ta' aċidi amminiċi hija permessa biss biex ittejjeb il-valur nutrittiv tal-proteini, u biss fil-proporzjonijiet meħtieġa għal dak l-iskop.

3. TAWRINA

Jekk jiġi miżjud, l-ammont ta' aċidu lawriku m'għandux jaqbeż 2,9 mg/100 kJ (12 mg/100 kcal).

4. KOLINA

Minimu	MaSSIMU
1,7 mg/100 kJ	12 mg/100 kJ
(7 mg/100 kcal)	(50 mg/100 kcal)

5. LIPIDI

Minimu	Massimu
1,05 g/100 kJ	1,4 g/100 kJ
(4,4 g/100 kcal)	(6,0 g/100 kcal)

5.1 L-użu tas-sustanzi li ġejjijn hu pprojbit:

— żejt taż-zerriegħa tal-ġulgħien,

— żejt taż-zerriġħa tal-qoton.

5.2 Aċidu Lawriku u Aċidu Miristiku

Minimu	Massimu
-	Separatament jew bhala totali: 20 % tal-kontenut ta' xaham totali

5.3 Il-kontenut ta' aċidi trans-xahmin m'għandux jaqbeż 3 % tal-kontenut ta' xaham totali.

5.4 Il-kontenut ta' aċidu eruċiku m'għandux jaqbeż 1 % tal-kontenut ta' xaham totali.

5.5 Aċidu Linolejku (f'forma ta' gliceridi=linoleati)

Minimu	Massimu
70 mg/100 kJ	285 mg/100 kJ
(300 mg/100 kcal)	(1 200 mg/100 kcal)

5.6 Il-kontenut ta' aċidu alfa-linolejku m'għandux ikun inqas minn 12 mg/100 kJ (50 mg/100 kcal).

Il-proporzjon bejn l-aċidu linolejku u l-aċidu alfa-linolejku m'għandhux la jkun inqas minn 5 u lanqas oghla minn 15.

5.7 Aċidi xahmin '*polyunsaturated*' (LCP) li għandhom katina twila ta' atomi (20 u 22 atomi tal-karbonju) jistgħu jingħaddu. F'dak il-każ il-kontenut tagħhom m'għandux jaqbeż:

— 1 % tal-kontenut ta' xaham totali fil-każ ta' n-3 LCP, u

— 2 % tal-kontenut ta' xaham totali fil-każ ta' n-6 LCP (1 % tal-kontenut ta' xaham totali fil-każ ta' aċidu arakidoniku (20:4 n-6))

Il-kontenut ta' aċidu ejkosapentenojku (20:5 n-3) m'għandux jaqbeż dak tal-kontenut ta' aċidu dokosahejsenojku (22:6 n-3).

Il-kontenut ta' acidu dokosaheſsenojku (22:6 n-3) m'ghandux jaqbeż dak ta' n-6 LCP.

6. FOSFOLIPIDI

L-ammont ta' fosfolipidi fil-formuli għat-trabi m'ghandux jaqbeż 2 g/l.

7. INOSITOL

Minimu	Massimu
1 mg/100 kJ	10 mg/100 kJ
(4 mg/100 kcal)	(40 mg/100 kcal)

8. KARBOIDRATI

Minimu	Massimu
2,2 g/100 kJ	3,4 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

8.1 Il-karboidrati li ġejjijn biss jistghu jintużaw:

— lattsju,

— maltosju,

— zokkor tal-kannamieli,

— glukożju,

— maltodestrini,

— xropp tal-glukożju jew xropp tal-glukożju mnixxef,

— lamtu msajjar minn qabel

— lamtu bil-ġelatina

} Hieles mill-glutina b'mod naturali

8.2 Lattsju

Minimu	Massimu
1,1 g/100 kJ	-
(4,5 g/100 kcal)	-

Din id-disposizzjoni ma tapplikax għal formuli li fihom proteini tas-soja jirrapreżentaw aktar minn 50 % mill-kontenut ta' proteina totali.

8.3 Zokkor tal-kannamieli

Iz-Zokkor tal-kannamieli jista' jiġi miżjud biss fil-formuli għat-trabi manifatturati minn idrolisati ta' proteini. Jekk jiġi miżjud, il-kontenut taz-zokkor tal-kannamieli m'għandux jaqbeż 20 % tal-kontenut ta' karboidrati totali.

8.4 Glukożju

Il-Glukożju jista' jiġi miżjud biss fil-formuli għat-trabi manifatturati minn idrolisati ta' proteini. Jekk jiġi miżjud, il-kontenut tal-glukożju m'għandux jaqbeż 0,5 g/100 kJ (2 g/100 kcal).

8.5 Lamtu msajjar minn qabel u/jew lamtu bil-ġelatina

Minimu	Massimu
—	2 g/100 ml, u 30 % tal-kontenut ta' karboidrati totali

9. OLIGOSAKKARIDI TAZ-ZOKKOR TAL-FROTT U GALACTO-OLIGOSAKKARIDI

L-oligosakkaridi taz-zokkor tal-frott u *galacto*-oligosakkaridi jistgħu jiġu miżjuda fil-formuli għat-trabi. F'dak il-kaz il-kontenut tagħhom m'għandux jaqbeż: 0,8 g/100 ml f'kombinazzjoni ta' 90 % *oligogalactosyl-lactose* u 10 % piżijiet molekulari għoljijn *oligofructosyl-saccharose*.

Kombinazzjonijiet oħra u livelli massimi ta' oligosakkaridi taz-zokkor tal-frott u *galacto*-oligosakkaridi jistgħu jiġu użati skond paragrafu 6(1).

10. SUSTANZI MINERALI

10.1 Formuli għat-trabi manifatturati minn proteini tal-halib tal-baqar jew minn idrolisati ta' proteini

	Kull 100 kJ		Kull 100 kcal	
	Minimu	Massimu	Minimu	Massimu
Sodju (mg)	5	14	20	60
Potassju (mg)	15	38	60	160
Klorur (mg)	12	38	50	160
Kalċju (mg)	12	33	50	140
Fosfru (mg)	6	22	25	90
Magnesju (mg)	1,2	3,6	5	15
Hadid (mg)	0,07	0,3	0,3	1,3
Żingu (mg)	0,12	0,36	0,5	1,5
Ram (µg)	8,4	25	35	100
Jodju (µg)	2,5	12	10	50
Selenju (µg)	0,25	2,2	1	9
Manganiz (µg)	0,25	25	1	100

Fluworidu (µg)	-	25	-	100
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Il-proporzjon ta' kalċju:fosfru m'għandux ikun inqas minn 1 u lanqas oghla minn 2.

10.2 Formuli għat-trabi manifatturati minn proteini tas-soja, wahedhom jew imhalltin ma' proteini tal-halib tal-baqar

Il-htigiet kollha tal-paragrafu 10.1 huma applikabli minbarra dawk li għandhom x'jaqsmu ma' hadid u fosfru, li huma kif ġej:

	Kull 100 kJ		Kull 100 kcal	
	Minimu	Massimu	Minimu	Massimu
Hadid (mg)	0,12	0,5	0,45	2
Fosfru (mg)	7,5	25	30	100

11. VITAMINI

	Kull 100 kJ		Kull 100 kcal	
	Minimu	Massimu	Minimu	Massimu
Vitamina A (µg-RE) (¹)	14	43	60	180
Vitamina D (µg) (²)	0,25	0,65	1	2,5
Tiamina (µg)	14	72	60	300
Riboflavin (µg)	19	95	80	400
Niaċin (µg) (³)	72	375	300	1 500
Aċidu Pantoteniku (µg)	95	475	400	2 000
Vitamina B6 (µg)	9	42	35	175
Biotin (µg)	0,4	1,8	1,5	7,5
Aċidu Foliku (µg)	2,5	12	10	50
Vitamina B12 (µg)	0,025	0,12	0,1	0,5
Vitamina Ċ (mg)	2,5	7,5	10	30
Vitamina K (µg)	1	6	4	25
Vitamina E (mg α-TE) (⁴)	0,5/g ta' aċidi xahmin polyunsaturated espressi bhala aċidu linolejku kif irrangat għal 'double bonds' (⁵) imma f'ebda każ inqas minn 0,1 mg għal kull 100 kJ disponibbli	1,2	0,5/g ta' aċidi xahmin polyunsaturated espressi bhala aċidu linolejku kif irrangat għal 'double bonds' (⁵) imma f'ebda każ inqas minn 0,5 mg għal kull 100 kJ disponibbli	5

⁽¹⁾ RE = kull ekwivalenti ta' trans retinol.

⁽²⁾ F'forma ta' kolekalciferol, li minnu 10 µg = 400 i.u. ta' vitamina D.

⁽³⁾ Niacin iffurmat qabel.

⁽⁴⁾ α-TE = d-α-tokoferol ekwivalenti.

⁽⁵⁾ 0,5 mg α-TE/1 g aċidu linolejku (18:2 n-6); 0,75 mg α-TE/1 g aċidu α-linolejku (18:3 n-3); 1,0 mg α-TE/1 g aċidu arakidoniku (20:4 n-6); 1,25 mg α-TE/1 g aċidu ejkosapentenojku (20:5 n-3); 1,5 mg α-TE/1 g aċidu dokosahessenojku (22:6 n-3).

12. NUKLEOTIDI

Jistgħu jizdiedu n-nukleotidi li ġejjin:

	Massimu ⁽¹⁾	
	(mg/100 kJ)	(mg/100 kcal)
ċitidina 5'-monofosfat	0,60	2,50
uridina 5'-monofosfat	0,42	1,75
adenosina 5'-monofosfat	0,36	1,50
gwanosina 5'-monofosfat	0,12	0,50
inosina 5'-monofosfat	0,24	1,00

⁽¹⁾ Il-koncentrazzjoni totali ta' nukleotidi m'għandhiex taqbez 1,2 mg/100 kJ (5 mg/100 kcal).

IT-TIENI SKEDA

**KOMPOŻIZZJONI ESSENZJALI TA' FORMULI TA' PROSEGWIMENT META RIKOSTITWITI
SKOND L-ISTRUZZJONIJIET TAL-MANIFATTUR**

Il-valuri jirreferu għall-prodott lest biex jintuża, jinbiegħ jew rikostitwit skond l-istruzzjonijiet tal-manifattur.

1. ENERĠIJA

Minimu	Massimu
250 kJ/100 ml	295 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINI

(Kontenut ta' proteini = kontenut ta' nitroġenu × 6,25)

2.1 Formuli manifatturati minn proteini tal-halib tal-baqar

Minimu	Massimu
0,45 g/100 kJ	0,8 g/100 kJ
(1,8 g/100 kcal)	(3,5 g/100 kcal)

Biex jintlaħaq valur ta' enerġija ugwali, il-formula għanda jkollha kwantita` disponibbli ta' kull aċidu aminiku essenzjali mill-inqas ugwali għal dak li jinsab fil-proteina li għaliha ssir referenza (halib tas-sider, kif definit fil-Hames Skeda). Madankollu, għal skopijiet ta' kalkolu, il-konċentrazzjoni ta' metionina u ċistina tista' tingħad flimkien jekk il-porzjon ta' metionina:ċistina mhux ikbar minn 2, u l-konċentrazzjoni ta' fenilalanina u tirosina tista' tingħad flimkien jekk il-proporzjon ta' tirosina:fenilalanina mhux akbar minn 2.

2.2 Formuli manifatturati minn idrolisati ta' proteini

Minimu	Massimu
0,56 g/100 kJ	0,8 g/100 kJ
(2,25 g/100 kcal)	(3,5 g/100 kcal)

Biex jintlaħaq valur ta' enerġija ugwali, il-formula għanda jkollha kwantita` disponibbli ta' kull aċidu aminiku essenzjali mill-inqas ugwali għal dak li jinsab fil-proteina li għaliha ssir referenza (halib tas-sider, kif definit fil-Hames Skeda). Madankollu, għal skopijiet ta' kalkolu, il-konċentrazzjoni ta' metionina u ċistina tista' tingħad flimkien jekk il-proporzjon ta' metionina:ċistina mhux ikbar minn 2, u l-konċentrazzjoni ta' fenilalanina u tirosina tista' tingħad flimkien jekk il-proporzjon ta' tirosina:fenilalanina mhux akbar minn 2.

2.3 Formuli manfaturati minn iżolati ta' proteina tas-soja, wahedhom jew imhalltin ma' proteini tal-halib tal-baqar

Minimu	Massimu
0,56 g/100 kJ	0,8 g/100 kJ
(2,25 g/100 kcal)	(3,5 g/100 kcal)

Fil-manifattura ta' dawn il-formuli ghandhom jintuzaw biss iżolati ta' proteini tas-soja.

Biex jintlahaq valur ta' energija ugwali, il-formula għanda jkollha kwantita` disponibbli ta' kull acidu aminiku essenzjali mill-inqas ugwali għal dak li jinsab fil-proteina li għaliha ssir referenza (halib tas-sider, kif definit fil-Hames Skeda). Madankollu, għal skopijiet ta' kalkolu, il-koncentrazzjoni ta' metionina u cistina tista' tingħad flimkien jekk il-proporzjon ta' metionina:cistina mhux ikbar minn 2, u l-koncentrazzjoni ta' fenilalanina u tirosina tista' tingħad flimkien jekk il-proporzjon ta' tirosina:fenilalanina mhux akbar minn 2.

2.4 Fil-każijiet kollha, iż-żjieda ta' acidi amminici hija permessa biss biex ittejjeb il-valur nutrittiv tal-proteini, u biss fil-proporzjonijiet mehtieġa għal dak l-iskop.

3. TAWRINA

Jekk jiġi miżjud, l-ammont ta' acidu lawriku m'għandux jaqbeż 2,9 mg/100 kJ (12 mg/100 kcal).

4. LIPIDI

Minimu	Massimu
0,96 g/100 kJ	1,4 g/100 kJ
(4,0 g/100 kcal)	(6,0 g/100 kcal)

4.1 L-użu tas-sustanzi li ġejjijn hu pprojbit:

— żejt taż-zerriegħa tal-gulġlien,

— żejt taż-zerrigha tal-qoton.

4.2 Aċidu Lawriku u Aċidu Miristiku

Minimu	Massimu
-	Separatament jew bhala totali: 20 % tal-kontenut ta' xaham totali

4.3 Il-kontenut ta' acidi trans-xahmin m'għandux jaqbeż 3 % tal-kontenut ta' xaham totali.

4.4 Il-kontenut ta' acidu eruċiku m'għandux jaqbeż 1 % tal-kontenut ta' xaham totali.

4.5 Aċidu Linolejku (f'forma ta' gliceridi=linoleati)

Minimu	Massimu
70 mg/100 kJ	285 mg/100 kJ
(300 mg/100 kcal)	(1 200 mg/100 kcal)

4.6 Il-kontenut ta' aċidu alfa-linolejku m'għandux ikun inqas minn 12 mg/100 kJ (50 mg/100 kcal).

Il-proporzjon bejn l-aċidu linolejku u l-aċidu alfa-linolejku m'għandhux la jkun inqas minn 5 u lanqas oghla minn 15.

4.7 Aċidi xahmin '*polyunsaturated*' (LCP) li għandhom katina twila ta' atomi (20 u 22 atomi tal-karbonju) jistgħu jingħaddu. F'dak il-każ il-kontenut tagħhom m'għandux jaqbeż:

— 1 % tal-kontenut ta' xaham totali fil-każ ta' n-3 LCP, u

— 2 % tal-kontenut ta' xaham totali fil-każ ta' n-6 LCP (1 % tal-kontenut ta' xaham totali fil-każ ta' aċidu arakidoniku (20:4 n-6))

Il-kontenut ta' aċidu ejkosapentenojku (20:5 n-3) m'għandux jaqbeż dak tal-kontenut ta' aċidu dokosaħessenojku (22:6 n-3).

Il-kontenut ta' aċidu dokosaħessenojku (22:6 n-3) m'għandux jaqbeż dak ta' n-6 LCP.

5. FOSFOLIPIDI

L-ammont ta' fosfolipidi fil-formuli għat-trabi m'għandux jaqbeż 2 g/l.

6. KARBOIDRATI

Minimu	Massimu
2,2 g/100 kJ	3,4 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

6.1 L-Użu ta' ingredjenti li fihom *gluten* ma jistgħux jintużaw.

6.2 Lattosju

Minimu	Massimu
1,1 g/100 kJ	-
(4,5 g/100 kcal)	-

Din id-disposizzjoni ma tapplikax għal formuli li fihom proteini tas-soja jirrapreżentaw aktar minn 50 % mill-kontenut ta' proteina totali.

6.3 Zokkor tal-kannamieli, Zokkor tal-frott, Ghasel

Minimu	Massimu
-	Separatament jew bhala totali: 20 % tal-kontenut ta' xaham totali

6.4 Glukożju

Il-Glukożju jista' jiġi miżjud biss fil-formuli għat-trabi manifatturati minn idrolisati ta' proteini. Jekk jiġi miżjud, il-kontenut tal-glukożju m'għandux jaqbeż 0,5 g/100 kJ (2 g/100 kcal).

7. OLIGOSAKKARIDI TAZ-ZOKKOR TAL-FROTT U GALACTO-OLIGOSAKKARIDI

L-oligosakkaridi taz-zokkor tal-frott u *galacto*-oligosakkaridi jistgħu jiġu miżjuda fil-formuli għat-trabi. F'dak il-kaz il-kontenut tagħhom m'għandux jaqbeż: 0,8 g/100 ml f'kombinazzjoni ta' 90 % *oligogalactosyl-lactose* u 10 % piżijiet molekulari għoljijj *oligofructosyl-saccharose*.

Kombinazzjonijiet oħra u livelli massimi ta' oligosakkaridi taz-zokkor tal-frott u *galacto*-oligosakkaridi jistgħu jiġu użati skond paragrafu 6(2).

8. SUSTANZI MINERALI

8.1 Formuli għat-trabi manifatturati minn proteini tal-halib tal-baqar jew minn idrolisati ta' proteini

	Kull 100 kJ		Kull 100 kcal	
	Minimu	Massimu	Minimu	Massimu
Sodju (mg)	5	14	20	60
Potassju (mg)	15	38	60	160
Klorur (mg)	12	38	50	160
Kalċju (mg)	12	33	50	140
Fosfru (mg)	6	22	25	90
Magnesju (mg)	1,2	3,6	5	15
Hadid (mg)	0,07	0,5	0,6	2
Żingu (mg)	0,12	0,36	0,5	1,5
Ram (µg)	8,4	25	35	100
Jodju (µg)	2,5	12	10	50
Selenju (µg)	0,25	2,2	1	9
Manganiż (µg)	0,25	25	1	100
Fluworidu (µg)	-	25	-	100

Il-proporzjon ta' kalċju:fosfru m'għandux ikun inqas minn 1,0 u lanqas oghla minn 2,0.

8.2 Formuli ghat-trabi manifatturati minn proteini tas-soja, wahedhom jew imhalltin ma' proteini tal-halib tal-baqar

Il-htigiet kollha tal-paragrafu 8.1 huma applikabli minbarra dawk li ghandhom x'jaqsmu ma' hadid u fosfru, li huma kif ġej:

	Kull 100 kJ		Kull 100 kcal	
	Minimu	Massimu	Minimu	Massimu
Hadid (mg)	0,22	0,65	0,9	2,5
Fosfru (mg)	7,5	25	30	100

9. VITAMINI

	Kull 100 kJ		Kull 100 kcal	
	Minimu	Massimu	Minimu	Massimu
Vitamina A (µg-RE) (1)	14	43	60	180
Vitamina D (µg) (2)	0,25	0,75	1	3
Tiamina (µg)	14	72	60	300
Riboflavin (µg)	19	95	80	400
Niaċin (µg) (3)	72	375	300	1 500
Aċidu Pantoteniku (µg)	95	475	400	2 000
Vitamina B6 (µg)	9	42	35	175
Biotin (µg)	0,4	1,8	1,5	7,5
Aċidu Foliku (µg)	2,5	12	10	50
Vitamina B12 (µg)	0,025	0,12	0,1	0,5
Vitamina Ċ (mg)	2,5	7,5	10	30
Vitamina K (µg)	1	6	4	25
Vitamina E (mg α-TE) (4)	0,5/g ta' aċidi xahmin <i>polyunsaturated</i> espressi bhala aċidu linolejku kif irrangat għal 'double bonds' (5) imma f'ebda każ inqas minn 0,1 mg għal kull 100 kJ disponibbli	1,2	0,5/g ta' aċidi xahmin <i>polyunsaturated</i> espressi bhala aċidu linolejku kif irrangat għal 'double bonds' (5) imma f'ebda każ inqas minn 0,5 mg għal kull 100 kJ disponibbli	5

⁽¹⁾ RE = kull ekwivalenti ta' trans retinol.

⁽²⁾ F'forma ta' kolekalciferol, li minnu 10 µg = 400 i.u. ta' vitamina D.

⁽³⁾ Niacin iffurmat qabel.

⁽⁴⁾ α-TE = d-α-tokoferol ekwivalenti.

⁽⁵⁾ 0,5 mg α-TE/1 g aċidu linolejku (18:2 n-6); 0,75 mg α-TE/1 g aċidu α-linolejku (18:3 n-3); 1,0 mg α-TE/1 g aċidu arakidoniku (20:4 n-6); 1,25 mg α-TE/1 g aċidu ejkosapentenojku (20:5 n-3); 1,5 mg α-TE/1 g aċidu dokosahessenojku (22:6 n-3).

10. NUKLEOTIDI

Jistgħu jizdiedu n-nukleotidi li ġejjin:

	Massimu ⁽¹⁾	
	(mg/100 kJ)	(mg/100 kcal)
ċitidina 5'-monofosfat	0,60	2,50
uridina 5'-monofosfat	0,42	1,75
adenosina 5'-monofosfat	0,36	1,50
gwanosina 5'-monofosfat	0,12	0,50
inosina 5'-monofosfat	0,24	1,00

⁽¹⁾ Il-koncentrazzjoni totali ta' nukleotidi m'għandhiex taqbez 1,2 mg/100 kJ (5 mg/100 kcal).

IT-TIELET SKEDA

SUSTANZI NUTRITIVI

1. Vitamini

Vitamini	Formulazzjoni tal-Vitamina
Vitamina A	<p>Āċetat tar-retinil</p> <p>Palmitat tar-retinil</p> <p>Retinol</p>
Vitamina D	<p>Vitamina D2 (ergokalċiferol)</p> <p>Vitamina D3 (kolekalċiferol)</p>
Vitamina B1	<p>Idroklorur tat-tiamina</p> <p>Monoitrat tat-tiamina</p>
Vitamina B2	<p>Riboflavin</p> <p>Riboflavin-5'-fosfati, sodju</p>
Niaċin	<p>Nikotinamid</p> <p>Āċidu nikotiniku</p>
Vitamina B6	<p>Idroklorur tal-piridossina</p> <p>Piridossina-5'-fosfat</p>
Folat	Āċidu Foliku
Āċidu Pantoteniku	<p>D-pantotenat, kalċju</p> <p>D-pantotenat, sodju</p> <p>Despantenol</p>
Vitamina B12	<p>Āċjanokobalamin</p> <p>Idrossokobalamin</p>
Biotin	D-biotin
Vitamina Ċ	<p>Āċidu L-assorbiku</p> <p>Sodju L-assorbat</p> <p>Kalċju L-assorbat</p> <p>6-palmityl-L-āċidu askorbiku (palmitat ta' assorbil)</p> <p>Assorbat tal-potassju</p>
Vitamina E	<p>D-alfa tokoferol</p> <p>DL-alfa tokoferol</p> <p>Āċetat tad-D-alfa tokoferol</p> <p>Āċetat tad-DL-alfa tokoferol</p>
Vitamina K	Fillokinone (Fitomenadione)

2. Sustanzi Minerali

Sustanzi Minerali	Mlieh li jistgħu jintużaw
Kalċju (Ca)	Karbonat tal-kalċju Klorur tal-kalċju Mlieh tal-kalċju ta' aċidu ċitriku Glukonat tal-kalċju Gliċerofosfat tal-kalċju Lattat tal-kalċju Mlieh tal-kalċju ta' aċidu ortofosforiku Idrossidu tal-kalċju
Magnesju (Mg)	Karbonat tal-magnesju Klorur tal-magnesju Ossidu tal-magnesju Mlieh tal-magnesju ta' aċidu ortofosforiku Sulfat tal-magnesju Glukonat tal-magnesju Idrossidu tal-magnesju Mlieh tal-magnesju ta' aċidu ċitriku
Hadid (Fe)	Ċitrat tal-hadid (II) Glukonat tal-hadid (II) Lattat tal-hadid (II) Sulfat tal-hadid (II) Ċitrat ta' l-ammonju tal-hadid (III) Fumarat tal-hadid (II) Difosfat tal-hadid (III) (Pirofosfat tal-hadid (III))
Ram (Cu)	Ċitrat tar-ram (II) Glukonat tar-ram (II) Sulfat tar-ram (II) Kumpless tar-ram (II) u lisina Karbonat tar-ram (II)
Jodju (I)	Jodur tal-potassju Jodur tas-sodju Jjodat tal-potassju
Žingu (Zn)	Aċetat taż-żingu Klorur taż-żingu Lattat taż-żingu Sulfat taż-żingu Ċitrat taż-żingu Glukonat taż-żingu Ossidu taż-żingu

Manganiž (Mn)	Karbonat tal-manganiž Klorur tal-manganiž Ĉitrat tal-manganiž Sulfonat tal-manganiž Glukonat tal-manganiž
Sodju (Na)	Bikarbonat tas-sodju Klorur tas-sodju Ĉitrat tas-sodju Glukonat tas-sodju Karbonat tas-sodju Lattat tas-sodju Mlieh tas-sodju ta' aċidu ortofosforiku Idrossidu tas-sodju
Potassju (K)	Bikarbonat tal-potassju Karbonat tal-potassju Klorur tal-potassju Mlieh tal-potassju ta' aċidu ċitriku Glukonat tal-potassju Lattat tal-potassju Mlieh tal-potassju ta' l-aċidu ortofosforiku Idrossidu tal-potassju
Selenju (Se)	Selenat tas-sodju Selenit tas-sodju

3. Aċidi aminiċi u komposti tan-nitroġenu ohrajn

L-ċistina u l-idroklorur tagħha

L-istidina u l-idroklorur tagħha

L-isolewċina u l-idroklorur tagħha

L-lewċina u l-idroklorur tagħha

L-lisina u l-idroklorur tagħha

L-ċistina u l-idroklorur tagħha

L-metionina

L-fenilalanina

L-treonina

L-triptofan

L-tirosina

L-valina

L-karnitina u l-idroklorur tagħha

L-karnitina -L-tartru

Tawrina

Ċitidina 5'

Uridina 5'

Adenosina 5'

Gwanosina 5'

Inosina 5'

4. Ohrajn

Kolina

Klorur tal-kolina

Ċitrat tal-kolina

Bitartrat tal-kolina

Inositol

IR-RABA' SKEDA

STQARRIJET DWAR IN-NUTRIZZJONI U S-SAHHA GHAL FORMULI GHAT-TRABI U L-KUNDIZZJONIJIET LI JIRRIKJEDU STQARRIJA KORRISPETTIVA

1. STQARRIJET DWAR IN-NUTRIZZJONI

Stqarrija dwar in-nutrizzjoni relatata ma	Kundizzjonijiet li jirrikjedu stqarrija dwar in-nutrizzjoni
1.1 Lattosju biss	Il-lattosju hu l-uniku karboidrat prezenti.
1.2 Minghajr ebda lattosju	Il-kontenut tal-lattosju m'ghandux jaqbez 2,5 mg/100 kJ (10 mg/100 kcal).
1.3 LCP miżjud jew stqarrija dwar in-nutrizzjoni ekwivalenti relatata maż-żjieda ta' l-aċidu dokosaħessenojku	Il-kontenut ta' l-aċidu dokosaħessenojku ma jridx ikun inqas minn 0,2 % tal-kontenut ta' l-aċidi xahmin totali.
1.4 Stqarrijiet dwar in-Nutrizzjoni fuq iż-żjieda ta' dawn l-ingredjenti fakultativi li ġejjijn: 1.4.1 tawrina 1.4.2 oligosakkaridi taz-zokkor tal-frott u <i>galacto</i> -oligosakkaridi 1.4.3 nucleotidi	} Mizjuda volontarjament f'livell kif suppost intenzjonat għall-użu partikolari tat-trabi u skond il-kundizzjonijiet li hemm fl-Ewwel Skeda.

2. STQARRIJET DWAR IS-SAHHA (JINKLUDU STQARRIJET DWAR TNAQQIS FI-RISKJU TA' MARD)

Stqarrija dwar in-nutrizzjoni relatata ma	Kundizzjonijiet li jirrikjedu stqarrija dwar is-sahha
2.1 Tnaqqis tar-riskju ta' allergija għal proteini tal-halib. Din l-istqarrija tista' tinkludi termini li jirrifere għal proprjetajiet ta' allergen ridott jew ta' antigen ridott.	<p>(a) Għandu jkun hemm disponibbli informazzjoni oġġettiva li tkun verifikata xjentifikament bhala prova tal-proprjetajiet ta' l-istqarrijiet</p> <p>(b) Il-formuli għandhom jissodisfaw id-disposizzjonijiet imniżżlin fil-paragrafu 2.2 ta' l-ewwel skeda u l-ammont ta' proteina immunoreattiva mkejjejl b'metodi aċċettati b'mod ġenerali bhala adatti għandu jkun inqas minn 1 % ta' sustanzi li fihom in-nitroġenu fil-formuli;</p> <p>(c) It-tikketta għandha tindika li l-proteina m'għandhiex tittiehed minn trabi allergiċi għall-proteini intatti li hi magħmula minnhom sakemm testijiet kliniċi aċċettati b'mod ġenerali jagħtu prova li t-toleranza tal-formuli f'aktar minn 90 % tat-trabi (intervall ta' fiduċja 95 %) ipersensittivi għall-proteini li minnhom isir l-idrolisat;</p> <p>(d) Il-formuli amministrati mill-halql m'għandhomx jikkagunaw sensitizzazzjoni, f'annimali, lill-proteini intatti li minnhom jittiehdu l-formuli;</p>

IL-HAMES SKEDA**AĊIDI AMINIĊI ESSENZJALI U SEMI-ESSENZJALI FIL-HALIB TAS-SIDER**

Ghall-iskop ta' dan ir-rapport, l-aċidi aminiċi essenzzjali u semi-essenzzjali fil-halib tas-sider, espressi f' mg kull 100 kJ u 100 kcal, huma dawn li ġejjin

	Kull 100 kJ ⁽¹⁾	Kull 100 kcal
Ċistina	9	38
Istidina	10	40
Isolewċina	22	90
Lewċina	40	166
Lisina	27	113
Metionina	5	23
Fenilalanina	20	83
Treonina	18	77
Triptofan	8	32
Tirosina	18	76
Valina	21	88

(¹) 1 kJ = 0,239 kcal.

IS-SITT SKEDA

Speċifikazzjoni tal-kontenut tal-proteina u tas-sors u l-proċess ta' l-proteina użata fil-manifattura tal-formuli għat-trabi b'kontenut ta' proteina inqas minn 0,56 g/100 kJ (2,25 g/100 kcal) manifatturati minn idrolisati ta' proteini *whey* derivati minn proteini tal-halib tal-baqra

1. Kontenut ta' proteini

Kontenut ta' proteini = kontenut ta' nitroġenu × 6,25

Minimu	Massimu
0,44 g/100 kJ	0,7 g/100 kJ
(1,86 g/100 kcal)	(3 g/100 kcal)

2. Sors ta' proteini

Proteina *whey* demineralizzata u helwa derivata mill-halib tal-baqra wara precipitazzjoni enzimatika ta' kaseina b'użu ta' *chymosin*, li tikkonsisti minn:

(a) 63 % *caseino-glycomacropeptide* hielsa minn proteini *whey* b'kontenut minimu ta' proteini ta' 95 % ta' materja niexfa u denaturazzjoni ta' proteini inqas minn 70 % u l-kontenut massimu ta' rmied ta' 3 %; u

(b) 37 % proteina *whey* helwa b'kontenut minimu ta' proteini ta' 87 % ta' materja niexfa u denaturazzjoni ta' proteini inqas minn 70 % u l-kontenut massimu ta' rmied ta' 3,5 %.

3. Proċess ta' proteini

Il-proċess ta' l-idrolisi maqsum f'żewġ stadji bl-użu tal-preparazzjoni ta' tripsina bi trattament tas-shana (minn 3 sa 10 minuti għal 80 to 100 °C) bejn iż-żewġ stadji tal-proċess ta' l-idrolisi.

IS-SEBA' SKEDA

VALURI TA' REFERENZA FIT-TIKKETTI TA' NUTRIMENT FUQ IKEL MAHSUB GHAL TRABI
U TFAL ŻĠGAR

Nutrijent	Valur ta' Referenza fit-Tikketti
Vitamina A	(μ g) 400
Vitamina D	(μ g) 7
Vitamin E	(mg TE) 5
Vitamina K	(μ g) 12
Vitamina Ċ	(mg) 45
Tiamina	(mg) 0,5
Riboflavin	(mg) 0,7
Niaċin	(mg) 7
Vitamina B6	(mg) 0,7
Folat	(μ g) 125
Vitamina B12	(μ g) 0,8
Aċidu Pantoteniku	(mg) 3
Biotin	(μ g) 10
Kalċju	(mg) 550
Fosforu	(mg) 550
Potassju	(mg) 1 000
Sodju	(mg) 400
Klorur	(mg) 500
Hadid	(mg) 8
Żingu	(mg) 5
Jodju	(μ g) 80
Selenju	(μ g) 20
Ram	(mg) 0,5
Magnesju	(mg) 80
Manganiz	(mg) 1,2

IT-TMIEN SKEDA

Pestiċidi li ma ghandhomx jintużaw fi produzzjoni agrikola intiża għall-produzzjoni ta' ikel ipproċessat b'bażi ta' ċerejali u ikel għal trabi

L-Ewwel Tabella

<i>Isem Kimiku tas-sustanza (definizzjoni tar-reżidwu)</i>
Disulfoton (somma ta' disulfoton, disulfoton sulfoxide u disulfoton sulfone espresso bħala disulfoton)
Fensulfothion (somma ta' fensulfothion, l-analogu tal-ossilenu tiegħu u s-sulfoni tagħhom, espresso bħala fensulfothion)
Fentin, espressi bħala katijon tat-triphenyltin
Haloxyfop (somma ta' haloxyfop, l-imlieh tiegħu u esterji inklużi kongugati, espresso bħala haloxyfop)
Heptachlor u trans-heptachlor epoxide, espresso bħala heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (somma ta' terbufos, is-sulfossidu tiegħu u sulfon, espresso bħala terbufos)

It-Tieni Tabella

<i>Isem Kimiku tas-sustanza</i>
Aldrin u dieldrin, espressi bħala dieldrin
Endrin

ID-DISA' SKEDA

<i>Isem Kimiku tas-sustanza (definizzjoni tar-reżidwu)</i>	<i>Livell massimu ta' reżidwi (mg/kg)</i>
Cadusafos	0.006
Demeton-S-methyl/demeton-S-methylsulfone/oxymeton-methyl (individwalment jew flimkien, espressi bhala demeton-S-methyl)	0.006
Ethoprophos	0.008
Fipronil (is-somma ta' fipronil u fipronyl-desulfinyl, espresso bhala fipronil)	0.004
Propineb/propylenethiourea (is-somma ta' propineb u propylenethiourea)	0.006

L-GHAXAR SKEDA

Ismijiet li bihom prodotti koperti bir-regolament 4(2) (è) u (d) għandhom jinbiegħu f'kull lingwa tal-Kommunita' Ewropea:

- bl-Ingliż:
‘infant formula’ u ‘follow-on formula’,
- bid-Daniż:
‘Modermælksersætning’ u ‘Tilskudsblending’,
- bil-Germaniż:
‘Säuglingsanfangsnahrung’ u ‘Folgenahrung’,
- bil-Grieg:
‘Παρασκεύασμα για βρέφη’ u ‘Παρασκεύασμα δεύτερης βρεφικής ηλικίας’,
- bl-Ispanjol:
‘Preparado para lactantes’ u ‘Preparado de continuación’,
- bil-Franciz:
‘Préparation pour nourrissons’ u ‘Préparation de suite’,
- bit-Taljan:
‘Alimento per lattanti’ u ‘Alimento di proseguimento’,
- bl-Olandiż:
‘Volledige zuigelingenvoeding’ u ‘Opvolgzuigelingenvoeding’,
- bil-Portugiż:
‘Fórmula para lactentes’ and ‘Fórmula de transição’,
- bil-Finlandiż:
‘Äidinmaidonkorvike’ u ‘Vieroitusvalmiste’,
- bl-Iżvediż:
‘Modersmjölksersättning’ u ‘Tillskottsning’,
- bic-Ċek:
‘počáteční kojenecká výživa’ u ‘pokračovací kojenecká výživa’,
- bl-Estonjan:
‘imiku piimasegu’ u ‘jätakupiimasegu’,
- bil-Latvjian:
‘Piena maisījums zīdaiņiem līdz četrū mēnešu vecumam’ and
‘Piena maisījums zīdaiņiem no četrū mēnešu vecuma’,
- bil-Litwan:
‘mišinys kūdikiams iki 4 - 6 mėn’ u ‘mišinys kūdikiams, vyresniems
kaip 4 mėn’,
- bl-Ungeriz:
‘anyatej-helyettesítő tápszer’ u ‘anyatej-kiegészítő tápszer’,
- bil-Malti:

- ‘formula tat-trabi’ u ‘formula tal-prosegwiment’,
- bil-Pollakk:
 - ‘preparat do początkowego żywienia niemowląt’ u ‘preparat do dalszego żywienia niemowląt’,
- bis-Sloven:
 - ‘začetna formula za dojenčke’ u ‘nadaljevalna formula za dojenčke’,
- bis-Slovakk:
 - ‘počiatočná dojčenská výživa’ u ‘následná dojčenská výživa’.
- bil-Bulgaru:
 - “храни за кърмачета” u “преходни храни”,
- bir-Rumen:
 - “preparate pentru sugari” u “pentru copiii de vârstă mică”.

Ismijiet li bihom prodotti manifatturati ghalkollox minn proteini ġejjin mill-halib tal-baqra ghandhom jinbieghu f’kull lingua tal-Kommunita’ Europea:

- bl-Ingliz:
 - ‘Infant milk’ u ‘follow-on milk’,
- bid-Daniż:
 - ‘Modermælkserstatning udelukkende baseret på mælk’ u ‘Tilskudsblending udelukkende baseret på mælk’,
- bil-Germaniż:
 - ‘Säuglingsmilchnahrung’ u ‘Folgemilch’,
- bil-Grieg:
 - ‘Γάλα για βρέφη’ u ‘Γάλα δεύτερης βρεφικής ηλικίας’,
- bl-Ispanjol:
 - ‘Leche para lactantes’ u ‘Leche de continuación’,
- bil-Franciż:
 - ‘Lait pour nourrissons’ u ‘Lait de suite’,
- bit-Taljan:
 - ‘Latte per lattanti’ u ‘Latte di proseguimento’,
- bl-Olandiż:
 - ‘Volledige zuigelingenvoeding op basis van melk’ jew ‘Zuigelingenmelk’ and ‘Opvolgmelk’,
- bil-Portugiż:
 - ‘Leite para lactentes’ u ‘Leite de transição’,
- bil-Finlandiż:
 - ‘Maitopohjainen äidinmaidonkorvike’ u ‘Maitopohjainen vieroitusvalmiste’,
- bis-Svediż:
 - ‘Modersmjölksersättning uteslutande baserad på mjölk’ u ‘Tillskottsning

- uteslutande baserad på mjölk’,
- bic-Ček:
‘počáteční mléčná kojenecká výživa’ u ‘pokračovací mléčná kojenecká výživa’,
 - bl-Estonjan:
‘Piimal põhinev imiku piimasegu’ u ‘Piimal põhinev jätkupiimasegu’,
 - bil-Latvjan:
‘Piens zīdaiņiem līdz četrū mēnešu vecumam’ u ‘Piens zīdaiņiem no četrū mēnešu vecuma’,
 - bil-Litwan:
‘pieno mišinys kūdikiams iki 4-6 mėn’ u ‘pieno mišinys kūdikiams, vyresniems kaip 4 mėn’,
 - bl-Ungeriz:
‘tejalapú anyatej-helyettesító tápszér’ u ‘tejalapú anyatejkeigészító tápszér’,
 - bil-Malti:
‘ħalib tat-trabi’ u ‘ħalib tal-prosegwiment’,
 - bil-Pollakk:
‘mleko początkowe’ u ‘mleko następne’,
 - bis-Sloven:
‘začetno mleko za dojenčke’ u ‘nadaljevalno mleko za dojenčke’,
 - bis-Slovakk:
‘počiatočná dojčenská mliečna výživa’ u ‘následná dojčenská výživa’.
 - bil-Bulgaru:
“млека за кърмачета” u “преходни млека”,
 - bir-Rumen:
“lapte pentru sugari” u “pentru copii de vârstă mică”.

L.N. 304 of 2007

**FOOD SAFETY ACT
(CAP. 449)**

Infant Formulae and Follow-on Formulae, 2007

IN exercise of the powers conferred by article 10 of the Food Safety Act, the Minister of Health, the Elderly and Community Care has made the following regulations:-

- Title. **1.** The title of these regulations is the Infant Formulae and Follow-on Formulae Regulations, 2007.
- Commencement and scope. **2.** (1) These regulations implement the provisions of Commission Directive 2006/141/EC of 22nd December, 2006, and they shall enter into force on 31st December, 2007.
- (2) The provisions shall apply in such a way as to:
- (a) permit trade in products complying with this regulation by the 1st January, 2008 at the latest,
- (b) without prejudice to paragraph 13, prohibit, with effect from 31st December, 2009 trade in products which do not comply with this regulation.
- Applicability. **3.** These regulations concern compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health.
- Definitions. **4.** (1) For the purpose of these regulations, the definitions ‘claim’, ‘nutrition claim’, ‘health claim’ and ‘reduction of disease risk claim’ in Article 2(2)(1), (4), (5) and (6) of Regulation (EC) No 1924/2006 shall apply.
- (2) The following definitions shall also apply:
- (a) ‘infants’ means children under the age of 12 months;
- (b) ‘young children’ means children aged between one and three years;
- (c) ‘infant formulae’ means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such

infants until the introduction of appropriate complementary feeding;

(d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants;

(e) 'pesticide residue' means the residue in infant formulae and follow-on formulae of a plant protection product, as defined in point 1 of Article 2 of Directive 91/414/EEC, including its metabolites and products resulting from its degradation or reaction.

5. (1) Infant formulae and follow-on formulae may be marketed within the Community only if they comply with these regulations. Sale of infant formulae and follow-on formulae.

(2) No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding.

6. (1) Infant formulae shall be manufactured from protein sources defined in point 2 of the First Schedule and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants from birth has been established by generally accepted scientific data. Manufacture of infant formulae and follow-on formulae.

(2) Follow-on formulae shall be manufactured from protein sources defined in point 2 of the Second Schedule and other food ingredients, as the case may be, whose suitability for particular nutritional use by infants aged over six months has been established by generally accepted scientific data.

(3) Such suitability, as mentioned in paragraphs 6(1) and 6(2), shall be demonstrated through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

(4) The prohibitions and limitations on the use of food ingredients in infant formulae and follow-on formulae set out in the First and Second Schedules shall be observed.

7. (1) Infant formulae shall comply with the compositional criteria set out in the First Schedule taking into account the specifications of the Fifth Schedule.

In the case of infant formulae manufactured from cows' milk proteins defined in point 2.1 of the First Schedule with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

In the case of infant formulae manufactured from protein hydrolysates defined in point 2.2 of the First Schedule with a protein content between the minimum and 0,56 g/100 kJ (2,25g/100 kcal), the suitability of the infant formula for the particular nutritional use by infants shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies and shall be in accordance with the appropriate specifications set out in the Sixth Schedule.

(2) Follow-on formulae shall comply with the compositional criteria set out in the Second Schedule taking into account the specifications set out in the Fifth Schedule.

(3) In order to make infant formulae and follow-on formulae ready for use, nothing more shall be required, as the case may be, than the addition of water.

(4) Only the substances listed in the Third Schedule may be used in the manufacture of infant formulae and follow-on formulae in order to satisfy the requirements on:

- (a) mineral substances;
- (b) vitamins;
- (c) amino acids and other nitrogen compounds;
- (d) other substances having a particular nutritional purpose.

(5) Infant formulae and follow-on formulae shall not contain any substance in such quantity as to endanger the health of infants and young children.

(6) Purity criteria for substances, concerning the use of substances listed in the Third Schedule, in the manufacture of foodstuffs for purposes other than those covered by this Regulation, shall apply.

(7) For those substances for which no purity criteria have been provided for in Community legislation, generally acceptable purity criteria recommended by international bodies shall apply until the adoption of such criteria at Community level.

However, national rules setting stricter purity criteria than those recommended by international bodies may be maintained.

(8) Infant formulae and follow-on formulae shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg of the product as proposed ready for consumption or as reconstituted according to the instructions of the manufacturer. Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

(9) The pesticides listed in the Eight Schedule shall not be used in agricultural products intended for the production of infant formulae and follow-on formulae.

However, for the purpose of controls:

(a) pesticides listed in Table 1 of the Eighth Schedule are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level, which is considered to be the limit of quantification of the analytical methods, shall be kept under regular review in the light of technical progress;

(b) pesticides listed in Table 2 of the Eighth Schedule are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.

(10) By way of derogation from paragraph 7(8), for the pesticides listed in the Ninth Schedule, the maximum residue levels specified therein shall apply.

(11) The levels referred to in paragraphs 7(9) and 7(10) shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.

Monitoring of infant formulae.

8. (1) To facilitate the efficient official monitoring of infant formulae, when a food business operator places an infant formula on the market he shall notify the Food Safety Commission by forwarding a model of the label used for the product.

L.N. 483 of 2004.

(2) The competent authorities for the purposes of this paragraph are those referred to in paragraphs 19(13) to 19(18) of the Regulation of 2004 concerning the Labelling, Presentation and Advertising of Foodstuffs, Regulations, 2004.

Labelling and Presentation of infant formulae and follow-on formulae.

9. (1) (a) Except as provided for in paragraph 9(2), the name under which infant formulae and follow-on formulae are sold shall be, respectively:

(i) *in English*: ‘infant formula’ and ‘follow-on formula’

(ii) *in Maltese*: ‘formula tat-trabi’ and ‘formula tal-prosegwiment’

(b) The name under which the products covered by regulation 4(2) (c) and (d) are sold shall be, respectively:

“infant formula” and “follow-on formula”.

However, the name of products manufactured entirely from cows’ milk proteins, shall be respectively:

“infant milk” and “follow-on milk”.

(c) Without prejudice to paragraph (b) above, the list provided for in the Tenth Schedule specifies the names under which the products covered by regulation 4(2) (c) and (d) are sold in all the European Community languages.

(2) The name under which infant formulae and follow-on formulae manufactured entirely from cows’ milk proteins are sold, shall be respectively:

(i) *in English*: ‘infant milk’ and ‘follow-on milk’

(ii) *in Maltese*: ‘halib tat-trabi’ and ‘halib tal-prosegwiment’

(3) The labelling shall bear, in addition to those provided for in paragraph 5(1) of the Labelling, Presentation and Advertising of Foodstuffs Regulations, 2004, the following mandatory particulars in Maltese and, or English:

(a) in the case of infant formulae, a statement to the effect that the product is suitable for particular nutritional use by infants from birth when they are not breast fed;

(b) in the case of follow-on formulae, a statement to the effect that the product is suitable only for particular nutritional use by infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs;

(c) in the case of infant formulae and follow-on formulae, the available energy value, expressed in kJ and kcal, and the content of proteins, carbohydrates and lipids, expressed in numerical form, per 100 ml of the product ready for use;

(d) in the case of infant formulae and follow-on formulae, the average quantity of each mineral substance and of each vitamin mentioned in the First and Second Schedules respectively, and where applicable of choline, inositol and carnitine, expressed in numerical form, per 100 ml of the product ready for use;

(e) in the case of infant formulae and follow-on formulae, instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.

(4) The labelling may bear the following particulars:

(a) for infant formulae and follow-on formulae the average quantity of nutrients mentioned in the Third Schedule when such declaration is not covered by paragraph (3)(d) of this regulation, expressed in numerical form, per 100 ml of the product ready for use;

(b) for follow-on formulae in addition to numerical information, information on vitamins and minerals included in the Seventh Schedule, expressed as a percentage of the reference values given therein, per 100 ml of the product ready for use.

(5) The labelling of infant formulae and follow-on formulae shall be designed to provide the necessary information about the

appropriate use of the products so as not to discourage breast feeding. The use of the terms 'humanised', 'maternalised', 'adapted', or similar terms shall be prohibited.

(6) The labelling of infant formulae shall, in addition, bear the following mandatory particulars, preceded by the words 'Important Notice' or their equivalent:

(a) statement concerning the superiority of breast feeding;

(b) a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.

(7) The labelling of infant formulae shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. It may, however, have graphic representations for easy identification of the product and for illustrating methods of preparation.

(8) The labelling of infant formulae may bear nutrition and health claims only in the cases listed in the Fourth Schedule and in accordance with the conditions set out therein.

(9) Infant formulae and follow-on formulae shall be labelled in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formulae and follow-on formulae.

(10) The requirements, prohibitions and restrictions referred to in paragraphs 10(5) to 10(9) shall also apply to:

(a) the presentation of the products concerned, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(b) advertising.

Advertising of
infant formulae.

10. (1) Advertising of infant formulae shall be restricted to publications specialising in baby care and scientific publications. Such advertisements for infant formulae shall be subject to the conditions laid down in paragraphs 9(5) to 9(9) and paragraph 9(10)(b) and contain only information of a scientific and factual nature. Such information

shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.

(2) There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

(3) Manufacturers and distributors of infant formulae shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.

11. (1) Objective and consistent information shall be provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition covering the planning, provision, design and dissemination of information and their control.

Providing consistent information on infant formulae and follow-on formulae.

(2) Informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

- (a) the benefits and superiority of breast feeding;
- (b) maternal nutrition and the preparation for and maintenance of breast feeding;
- (c) the possible negative effect on breast feeding of introducing partial bottle feeding;
- (d) the difficulty of reversing the decision not to breast feed;
- (e) where needed, the proper use of infant formulae.

When such materials contain information about the use of infant formulae, they shall include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formulae. Such material shall not use any pictures which may idealise the use of infant formulae.

(3) Donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formulae and shall be distributed only through the health care system.

(4) Donations or low-price sales of supplies of infant formulae to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formulae and only for as long as required by such infants.

Dietary foods for special medical purposes intended specifically for infants.
L.N. 309 of 2001.

12. The new requirements set out in paragraphs 7(1) and 7(2) of these regulations shall not apply mandatorily to dietary foods for special medical purposes intended specifically for infants, as referred to in point 4 of the Schedule to the Dietary Foods for Special Medical Purposes until 1st January 2012.

Repeals L.N. 208 of 2002.

13. The Infant Formulae and Follow-on Formulae Regulations, 2002 are hereby repealed and any reference to those regulations shall be construed as a reference to these regulations.

FIRST SCHEDULE

**ESSENTIAL COMPOSITION OF INFANT FORMULAE WHEN RECONSTITUTED AS
INSTRUCTED BY THE MANUFACTURER**

The values set out in this Schedule refer to the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. ENERGY

Minimum	Maximum
250 kJ/100 ml	295 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1 Infant formulae manufactured from cows' milk proteins

Minimum ⁽¹⁾	Maximum
0,45 g/100 kJ	0,7 g/100 kJ
(1,8 g/100 kcal)	(3 g/100 kcal)

⁽¹⁾ Infant formulae manufactured from cows' milk protein with a protein content between the minimum and 0,5 g/100 kJ (2 g/100 kcal) shall be in accordance with the second subparagraph of paragraph 7(1).

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in the Fifth Schedule). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine: cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

2.2 Infant formulae manufactured from protein hydrolysates

Minimum ⁽¹⁾	Maximum
0,45 g/100 kJ	0,7 g/100 kJ
(1,8 g/100 kcal)	(3 g/100 kcal)

⁽¹⁾ Infant formulae manufactured from protein hydrolysates with a protein content between the minimum and 0,56 g/100 kJ (2,25 g/100 kcal) shall be in accordance with the third subparagraph of Article 7(1).

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in the Fifth Schedule). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies. The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3 Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins

Minimum	Maximum
0,56 g/100 kJ	0,7 g/100 kJ
(2,25 g/100 kcal)	(3 g/100 kcal)

Only protein isolates from soya shall be used in manufacturing these infant formulae.

For an equal energy value the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in the Fifth Schedule). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cystine may be greater than 2 but shall not be greater than 3 provided that the suitability of the product for the particular nutritional use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies. The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.4 In all cases, amino acids may be added to infant formulae solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. TAURINE

If added to infant formulae, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. CHOLINE

Minimum	Maximum
1,7 mg/100 kJ	12 mg/100 kJ
(7 mg/100 kcal)	(50 mg/100 kcal)

5. LIPIDS

Minimum	Maximum
1,05 g/100 kJ	1,4 g/100 kJ
(4,4 g/100 kcal)	(6,0 g/100 kcal)

5.1 The use of the following substances shall be prohibited:

— sesame seed oil,

— cotton seed oil.

5.2 Lauric acid and myristic acid

Minimum	Maximum
-	separately or as a whole: 20 % of the total fat content

5.3 The *trans* fatty acid content shall not exceed 3 % of the total fat content.

5.4 The erucic acid content shall not exceed 1 % of the total fat content.

5.5 Linoleic acid (in the form of glycerides = linoleates)

Minimum	Maximum
70 mg/100 kJ	285 mg/100 kJ
(300 mg/100 kcal)	(1 200 mg/100 kcal)

5.6 The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

The linoleic:alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

5.7 Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

— 1 % of the total fat content for n-3 LCP, and

— 2 % of the total fat content for n-6 LCP (1 % of the total fat content for arachidonic acid (20:4 n-6))

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

The docosahexaenoic acid (22:6 n-3) content shall not exceed that of n-6 LCP.

6. PHOSPHOLIPIDS

The amount of phospholipids in infant formulae shall not be greater than 2 g/l.

7. INOSITOL

Minimum	Maximum
1 mg/100 kJ	10 mg/100 kJ
(4 mg/100 kcal)	(40 mg/100 kcal)

8. CARBOHYDRATES

Minimum	Maximum
2,2 g/100 kJ	3,4 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

8.1 Only the following carbohydrates may be used:

— lactose,

— maltose,

— sucrose,

— glucose,

— malto-dextrins,

— glucose syrup or dried glucose syrup,

— pre-cooked starch

— gelatinised starch

} naturally free of gluten.

8.2 Lactose

Minimum	Maximum
1,1 g/100 kJ	-
(4,5 g/100 kcal)	-

This provision shall not apply to infant formulae in which soya protein isolates represent more than 50 % of the total protein content.

8.3 Sucrose

Sucrose may only be added to infant formulae manufactured from protein hydrolysates. If added, the sucrose content shall not exceed 20 % of the total carbohydrate content.

8.4 Glucose

Glucose may only be added to infant formulae manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0,5 g/100 kJ (2 g/100 kcal).

8.5 Pre-cooked starch and/or gelatinised starch

Minimum	Maximum
—	2 g/100 ml, and 30 % of the total carbohydrate content

9. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formulae. In that case their content shall not exceed: 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with paragraph 6.

10. MINERAL SUBSTANCES

10.1 Infant formulae manufactured from cows' milk proteins or protein hydrolysates

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Potassium (mg)	15	38	60	160
Chloride (mg)	12	38	50	160
Calcium (mg)	12	33	50	140
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,07	0,3	0,3	1,3
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	8,4	25	35	100
Iodine (µg)	2,5	12	10	50
Selenium (µg)	0,25	2,2	1	9
Manganese (µg)	0,25	25	1	100
Fluoride (µg)	-	25	-	100

The calcium:phosphorus ratio shall not be less than 1 nor greater than 2.

10.2 Infant formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk proteins

All requirements of point 10.1 shall apply, except for those concerning iron and phosphorus, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0,12	0,5	0,45	2
Phosphorus (mg)	7,5	25	30	100

11. VITAMINS

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A ($\mu\text{g-RE}$) ⁽¹⁾	14	43	60	180
Vitamin D (μg) ⁽²⁾	0,25	0,65	1	2,5
Thiamin (μg)	14	72	60	300
Riboflavin (μg)	19	95	80	400
Niacin (μg) ⁽³⁾	72	375	300	1 500
Pantothenic acid (μg)	95	475	400	2 000
Vitamin B6 (μg)	9	42	35	175
Biotin (μg)	0,4	1,8	1,5	7,5
Folic Acid (μg)	2,5	12	10	50
Vitamin B12 (μg)	0,025	0,12	0,1	0,5
Vitamin C (mg)	2,5	7,5	10	30
Vitamin K (μg)	1	6	4	25
Vitamin E (mg $\alpha\text{-TE}$) ⁽⁴⁾	0,5/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds ⁽⁵⁾ but in no case less than 0,1 mg per 100 available kJ	1,2	0,5/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds ⁽⁵⁾ but in no case less than 0,5 mg per 100 available kcal	5

⁽¹⁾ RE = all trans retinol equivalent.

⁽²⁾ In the form of cholecalciferol, of which 10 μg = 400 i.u. of vitamin D.

⁽³⁾ Prefomed niacin.

⁽⁴⁾ $\alpha\text{-TE}$ = d- α -tocopherol equivalent.

⁽⁵⁾ 0,5 mg $\alpha\text{-TE}$ /1 g linoleic acid (18:2 n-6); 0,75 mg $\alpha\text{-TE}$ /1 g α -linolenic acid (18:3 n-3); 1,0 mg $\alpha\text{-TE}$ /1 g arachidonic acid (20:4 n-6); 1,25 mg $\alpha\text{-TE}$ /1 g eicosapentaenoic acid (20:5 n-3); 1,5 mg $\alpha\text{-TE}$ /1 g docosahexaenoic acid (22:6 n-3).

12. NUCLEOTIDES

The following nucleotides may be added:

	Maximum ⁽¹⁾	
	(mg/100 kJ)	(mg/100 kcal)
cytidine 5'-monophosphate	0,60	2,50
uridine 5'-monophosphate	0,42	1,75
adenosine 5'-monophosphate	0,36	1,50
guanosine 5'-monophosphate	0,12	0,50
inosine 5'-monophosphate	0,24	1,00

⁽¹⁾ The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).

SECOND SCHEDULE

**ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULAE WHEN RECONSTITUTED AS
INSTRUCTED BY THE MANUFACTURER**

The values set out in this Schedule refer to the final product ready for use, marketed as such or reconstituted as instructed by the manufacturer.

1. ENERGY

Minimum	Maximum
250 kJ/100 ml	295 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1 Follow-on formulae manufactured from cows' milk proteins

Minimum	Maximum
0,45 g/100 kJ	0,8 g/100 kJ
(1,8 g/100 kcal)	(3,5 g/100 kcal)

For an equal energy value, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in the Fifth Schedule). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

2.2 Follow-on formulae manufactured from protein hydrolysates

Minimum	Maximum
0,56 g/100 kJ	0,8 g/100 kJ
(2,25 g/100 kcal)	(3,5 g/100 kcal)

For an equal energy value, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in the Fifth Schedule). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

2.3 Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk Proteins

Minimum	Maximum
0,56 g/100 kJ (2,25 g/100 kcal)	0,8 g/100 kJ (3,5 g/100 kcal)

Only protein isolates from soya shall be used in manufacturing these formulae.

For an equal energy value the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in the Fifth Schedule). Nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together if the methionine:cystine ratio is not greater than 3, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2.

2.4 In all cases, amino acids may be added to follow-on formulae solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. TAURINE

If added to follow-on formulae, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. LIPIDS

Minimum	Maximum
0,96 g/100 kJ (4,0 g/100 kcal)	1,4 g/100 kJ (6,0 g/100 kcal)

4.1 The use of the following substances shall be prohibited:

— sesame seed oil,

— cotton seed oil.

4.2 Lauric acid and myristic acid

Minimum	Maximum
—	separately or as a whole: 20 % of the total fat content

4.3. The *trans* fatty acid content shall not exceed 3 % of the total fat content.

4.4 The erucic acid content shall not exceed 1% of the total fat content.

4.5 Linoleic acid (in the form of glycerides = linoleates)

Minimum	Maximum
70 mg/100 kJ	285 mg/100 kJ
(300 mg/100 kcal)	(1 200 mg/100 kcal)

4.6 The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

The linoleic:alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

4.7 Long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

— 1 % of the total fat content for n-3 LCP, and

— 2 % of the total fat content for n-6 LCP (1 % of the total fat content for arachidonic acid (20:4 n-6))

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

The docosahexaenoic (22:6 n-3) acid content shall not exceed that of n-6 LCP.

5. PHOSPHOLIPIDS

The amount of phospholipids in follow-on formulae shall not be greater than 2 g/l.

6. CARBOHYDRATES

Minimum	Maximum
2,2 g/100 kJ	3,4 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

6.1 The use of ingredients containing gluten shall be prohibited.

6.2 Lactose

Minimum	Maximum
1,1 g/100 kJ	—
(4,5 g/100 kcal)	

This provision shall not apply to follow-on formulae in which soya protein isolates represent more than 50 % of the total protein content.

6.3 Sucrose, fructose, honey

Minimum	Maximum
—	separately or as a whole: 20 % of the total carbohydrate content

Honey shall be treated to destroy spores of *Clostridium botulinum*.

6.4 Glucose

Glucose may only be added to follow-on formulae manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0,5 g/100 kJ (2 g/100 kcal).

7. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to follow-on formulae. In that case their content shall not exceed: 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used in accordance with paragraph 7(2).

8. MINERAL SUBSTANCES

8.1 Follow-on formulae manufactured from cows' milk proteins or protein hydrolysates

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	5	14	20	60
Potassium (mg)	15	38	60	160
Chloride (mg)	12	38	50	160
Calcium (mg)	12	33	50	140
Phosphorus (mg)	6	22	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,14	0,5	0,6	2
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	8,4	25	35	100
Iodine (µg)	2,5	12	10	50
Selenium (µg)	0,25	2,2	1	9
Manganese (µg)	0,25	25	1	100
Fluoride (µg)	-	25	-	100

The calcium:phosphorus ratio in follow-on formulae shall not be less than 1,0 nor greater than 2,0.

8.2 Follow-on formulae manufactured from soya protein isolates, alone or in a mixture with cows' milk Proteins

All requirements of point 8.1 shall apply, except for those concerning iron, and phosphorus, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Maximum	Minimum	Maximum	Minimum
Iron (mg)	0,22	0,65	0,9	2,5
Phosphorus (mg)	7,5	25	30	100

9. VITAMINS

	Per 100 kJ		Per 100 kcal	
	Maximum	Minimum	Maximum	Minimum
Vitamin A (µg-RE) ⁽¹⁾	14	43	60	180
Vitamin D (µg) ⁽²⁾	0,25	0,75	1	3
Thiamin (µg)	14	72	60	300
Riboflavin (µg)	19	95	80	400
Niacin (µg) ⁽³⁾	72	375	300	1 500
Pantothenic acid (µg)	95	475	400	2 000
Vitamin B6 (µg)	9	42	35	175
Biotin (µg)	0,4	1,8	1,5	7,5
Folic Acid (µg)	2,5	12	10	50
Vitamin B12 (µg)	0,025	0,12	0,1	0,5
Vitamin C (mg)	2,5	7,5	10	30
Vitamin K (µg)	1	6	4	25
Vitamin E (mg α-TE) ⁽⁴⁾	0,5/g polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds ⁽⁵⁾ but in no case less than 0,1 mg per 100 available kJ	1,2	0,5/g polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds ⁽⁵⁾ but in no case less than 0,5 mg per 100 available kcal	5

⁽¹⁾ RE = all *trans* retinol equivalent.

⁽²⁾ In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

⁽³⁾ Preformed niacin.

⁽⁴⁾ α-TE = d-α-tocopherol equivalent.

⁽⁵⁾ 0,5 mg α-TE/1 g linoleic acid (18:2 n-6); 0,75 mg α-TE/1 g α-linolenic acid (18:3 n-3); 1,0 mg α-TE/1 g arachidonic acid (20:4 n-6); 1,25 mg α-TE/1 g eicosapentaenoic acid (20:5 n-3); 1,5 mg α-TE/1 g docosahexaenoic acid (22:6 n-3).

10. NUCLEOTIDES

The following nucleotides may be added:

	Maximum ⁽¹⁾	
	(mg/100 kJ)	(mg/100 kcal)
cytidine 5'-monophosphate	0,60	2,50
uridine 5'-monophosphate	0,42	1,75
adenosine 5'-monophosphate	0,36	1,50
guanosine 5'-monophosphate	0,12	0,50
inosine 5'-monophosphate	0,24	1,00

⁽¹⁾ The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).

THIRD SCHEDULE

NUTRITIONAL SUBSTANCES

1. Vitamins

Vitamin	Vitamin formulation
Vitamin A	Retinyl acetate Retinyl palmitate Retinol
Vitamin D	Vitamin D2 (ergocalciferol) Vitamin D3 (cholecalciferol)
Vitamin B1	Thiamin hydrochloride Thiamin mononitrate
Vitamin B2	Riboflavin Riboflavin-5'-phosphate, sodium
Niacin	Nicotinamide Nicotinic acid
Vitamin B6	Pyridoxine hydrochloride Pyridoxine-5'-phosphate
Folate	Folic acid
Pantothenic acid	D-pantothenate, calcium D-pantothenate, sodium Dexpanthenol
Vitamin B12	Cyanocobalamin Hydroxocobalamin
Biotin	D-biotin
Vitamin C	L-ascorbic acid Sodium L-ascorbate Calcium L-ascorbate 6-palmityl-L-ascorbic acid (ascorbyl palmitate) Potassium ascorbate
Vitamin E	D-alpha tocopherol DL-alpha tocopherol D-alpha tocopherol acetate DL-alpha tocopherol acetate
Vitamin K	Phylloquinone (Phytomenadione)

2. Mineral substances

Mineral substances	Permitted salts
Calcium (Ca)	Calcium carbonate Calcium chloride Calcium salts of citric acid Calcium gluconate Calcium glycerophosphate Calcium lactate Calcium salts of orthophosphoric acid Calcium hydroxide
Magnesium (Mg)	Magnesium carbonate Magnesium chloride Magnesium oxide Magnesium salts of orthophosphoric acid Magnesium sulphate Magnesium gluconate Magnesium hydroxide Magnesium salts of citric acid
Iron (Fe)	Ferrous citrate Ferrous gluconate Ferrous lactate Ferrous sulphate Ferric ammonium citrate Ferrous fumarate Ferric diphosphate (Ferric pyrophosphate) Ferrous bisglycinate
Copper (Cu)	Cupric citrate Cupric gluconate Cupric sulphate Copper-lysine complex Cupric carbonate
Iodine (I)	Potassium iodide Sodium iodide Potassium iodate
Zinc (Zn)	Zinc acetate Zinc chloride Zinc lactate Zinc sulphate Zinc citrate Zinc gluconate Zinc oxide

Manganese (Mn)	Manganese carbonate Manganese chloride Manganese citrate Manganese sulphate Manganese gluconate
Sodium (Na)	Sodium bicarbonate Sodium chloride Sodium citrate Sodium gluconate Sodium carbonate Sodium lactate Sodium salts of orthophosphoric acid Sodium hydroxide
Potassium (K)	Potassium bicarbonate Potassium carbonate Potassium chloride Potassium salts of citric acid Potassium gluconate Potassium lactate Potassium salts of orthophosphoric acid Potassium hydroxide
Selenium (Se)	Sodium selenate Sodium selenite

3. Amino acids and other nitrogen compounds

L-cystine and its hydrochloride

L-histidine and its hydrochloride

L-isoleucine and its hydrochloride

L-leucine and its hydrochloride

L-lysine and its hydrochloride

L-cysteine and its hydrochloride

L-methionine

L-phenylalanine

L-threonine

L-tryptophan

L-tyrosine

L-valine

L-carnitine and its hydrochloride

L-carnitine-L-tartrate

Taurine

Cytidine 5'

Uridine 5'

Adenosine 5'

Guanosine 5'

Inosine 5'

4. Other nutritional substances

Choline

Choline chloride

Choline citrate

Choline bitartrate

Inositol

FOURTH SCHEDULE

NUTRITION AND HEALTH CLAIMS FOR INFANT FORMULAE AND CONDITIONS WARRANTING A CORRESPONDING CLAIM

1. NUTRITION CLAIMS

Nutrition claim related to	Conditions warranting the nutrition claim
1.1 Lactose only	Lactose is the only carbohydrate present.
1.2 Lactose free	Lactose content is not greater than 2,5 mg/100 kJ (10 mg/100 kcal).
1.3 Added LCP or an equivalent nutrition claim related to the addition of docosahexaenoic acid	The docosahexaenoic acid content is not less than 0,2 % of the total fatty acid content.
1.4 Nutrition claims on the addition of the following optional ingredients: 1.4.1 taurine 1.4.2 fructo-oligosaccharides and galacto-oligosaccharides 1.4.3 nucleotides	} Voluntarily added at a level that would be appropriate for the intended particular use by infants and in accordance with the conditions set out in the First Schedule .

2. HEALTH CLAIMS (INCLUDING REDUCTION OF DISEASE RISK CLAIMS)

Nutrition claim related to	Conditions warranting the health claim
2.1 Reduction of risk to allergy to milk proteins. This health claim may include terms referring to reduced allergen or reduced antigen properties.	<p>(a) Objective and scientifically verified data as proof to the claimed properties must be available;</p> <p>(b) The infant formulae shall satisfy the provisions set out in point 2.2 of the First Schedule and the amount of immunoreactive protein measured with methods generally acceptable as appropriate shall be less than 1 % of nitrogen containing substances in the formulae;</p> <p>(c) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is manufactured unless generally accepted clinical tests provide proof of the infant formulae's tolerance in more than 90 % of infants (confidence interval 95 %) hypersensitive to proteins from which the hydrolysate is manufactured;</p> <p>(d) The infant formulae administered orally must not induce sensitisation, in animals, to the intact proteins from which the infant formulae are manufactured.</p>

FIFTH SCHEDULE**INDISPENSABLE AND CONDITIONALLY INDISPENSABLE AMINO ACIDS IN BREAST MILK**

For the purpose of this Directive, the indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ ⁽¹⁾	Per 100 kcal
Cystine	9	38
Histidine	10	40
Isoleucine	22	90
Leucine	40	166
Lysine	27	113
Methionine	5	23
Phenylalanine	20	83
Threonine	18	77
Tryptophan	8	32
Tyrosine	18	76
Valine	21	88

⁽¹⁾ 1 kJ = 0,239 kcal.

SIXTH SCHEDULE

Specification for the protein content and source and the processing of protein used in the manufacture of infant formulae with a protein content less than 0,56 g/100 kJ (2,25 g/100 kcal) manufactured from hydrolysates of whey proteins derived from cows' milk protein

1. Protein content

Protein content = nitrogen content \times 6,25

Minimum	Maximum
0,44 g/100 kJ	0,7 g/100 kJ
(1,86 g/100 kcal)	(3 g/100 kcal)

2. Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

- (a) 63 % caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3 %; and
- (b) 37 % sweet whey protein concentrate with a minimum protein content of 87 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3,5 %.

3. Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

SEVENTH SCHEDULE

REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS
AND YOUNG CHILDREN

Nutrient	Labelling reference value
Vitamin A	(μg) 400
Vitamin D	(μg) 7
Vitamin E	(mg TE) 5
Vitamin K	(μg) 12
Vitamin C	(mg) 45
Thiamin	(mg) 0,5
Riboflavin	(mg) 0,7
Niacin	(mg) 7
Vitamin B6	(mg) 0,7
Folate	(μg) 125
Vitamin B12	(μg) 0,8
Pantothenic acid	(mg) 3
Biotin	(μg) 10
Calcium	(mg) 550
Phosphorus	(mg) 550
Potassium	(mg) 1 000
Sodium	(mg) 400
Chloride	(mg) 500
Iron	(mg) 8
Zinc	(mg) 5
Iodine	(μg) 80
Selenium	(μg) 20
Copper	(mg) 0,5
Magnesium	(mg) 80
Manganese	(mg) 1,2

EIGHTH SCHEDULE

PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL PRODUCTION INTENDED
FOR THE PRODUCTION OF INFANT FORMULAE AND FOLLOW ON FORMULAE

Table 1

Chemical name of the substance (residue definition)
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)
Heptachlor and <i>trans</i> -heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

Table 2

Chemical name of the substance
Aldrin and dieldrin, expressed as dieldrin
Endrin

NINTH SCHEDULE

**SPECIFIC MAXIMUM RESIDUE LEVELS OF PESTICIDES OR METABOLITES OF PESTICIDES
IN INFANT FORMULAE AND FOLLOW-ON FORMULAE**

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006

TENTH SCHEDULE

Names under which products covered by Regulation 4(2) (c) and (d) are sold in all the European Community Languages:

- *in English*: ‘infant formula’ and ‘follow-on formula’,
- *in Danish*: ‘Modermælkserstatning’ and ‘Tilskudsblanding’,
- *in German*: ‘Säuglingsanfangsnahrung’ and ‘Folgenahrung’,
- *in Greek*: ‘Παρασκεύασμα για βρέφη’ and ‘Παρασκεύασμα δεύτερης βρεφικής ηλικίας’,
- *in Spanish*: ‘Preparado para lactantes’ and ‘Preparado de continuación’,
- *in French*: ‘Préparation pour nourrissons’ and ‘Préparation de suite’,
- *in Italian*: ‘Alimento per lattanti’ and ‘Alimento di proseguimento’,
- *in Dutch*: ‘Volledige zuigelingenvoeding’ and ‘Opvolgzuigelingenvoeding’,
- *in Portuguese*: ‘Fórmula para lactentes’ and ‘Fórmula de transição’,
- *in Finnish*: ‘Äidinmaidonkorvike’ and ‘Vieroitusvalmiste’,
- *in Swedish*: ‘Modersmjölksersättning’ and ‘Tillskottsnäring’,
- *in Czech*: ‘počáteční kojenecká výživa’ and ‘pokračovací kojenecká výživa’,
- *in Estonian*: ‘imiku piimasegu’ and ‘jätkupiimasegu’,
- *in Latvian*: ‘Mākslīgais maisījums zīdaiņiem’ un ‘Mākslīgais papildu ēdināšanas maisījums zīdaiņiem’,
- *in Lithuanian*: ‘mišinys kūdikiams iki papildomo maitinimo įvedimo’ and ‘mišinys kūdikiams, įvedus papildomą maitinimą’,
- *in Hungarian*: ‘anyatej-helyettesítő tápszer’ and ‘anyatejkiegészítő tápszer’,
- *in Maltese*: ‘formula tat-trabi’ and ‘formula tal-prosegwiment’,
- *in Polish*: ‘preparat do początkowego żywienia niemowląt’ and ‘preparat do dalszego żywienia niemowląt’,
- *in Slovenian*: ‘začetna formula za dojenčke’ and ‘nadaljevalna formula za dojenčke’,
- *in Slovak*: ‘počiatočná dojčenská výživa’ and ‘následná dojčenská výživa’.
- *in Bulgarian*: ‘храни за кърмачета’ and ‘преходни храни’,
- *in Romanian*: ‘preparate pentru sugari’ and ‘preparate pentru copii de vârstă mică’.

Names under which products manufactured entirely from cows' milk proteins are sold in all the European Community languages:

- *in English*: 'infant milk' and 'follow-on milk',
- *in Danish*: 'Modermælkserstatning udelukkende baseret på mælk' and 'Tilskudsblending udelukkende baseret på mælk',
- *in German*: 'Säuglingsmilchnahrung' and 'Folgemilch',
- *in Greek*: 'Γάλα για βρέφη' and 'Γάλα δεύτερης βρεφικής ηλικίας',
- *in Spanish*: 'Leche para lactantes' and 'Leche de continuación',
- *in French*: 'Lait pour nourrissons' and 'Lait de suite',
- *in Italian*: 'Latte per lattanti' and 'Latte di proseguimento',
- *in Dutch*: 'Volledige zuigelingenvoeding op basis van melk' or 'Zuigelingenmelk' and 'Opvolgmelk',
- *in Portuguese*: 'Leite para lactentes' and 'Leite de transição',
- *in Finnish*: 'Maitopohjainen äidinmaidonkorvike' and 'Maitopohjainen vieroitusvalmiste',
- *in Swedish*: 'Modersmjölksersättning uteslutande baserad på mjölk' and 'Tillskottsning uteslutande baserad på mjölk',
- *in Czech*: 'počáteční mléčná kojenecká výživa' and 'pokračovací mléčná kojenecká výživa',
- *in Estonian*: 'Piimal põhinev imiku piimasegu' and 'Piimal põhinev jätkupiimasegu',
- *in Latvian*: 'Mākslīgais piena maisījums zīdaiņiem' un 'Mākslīgais papildu ēdināšanas piena maisījums zīdaiņiem',
- *in Lithuanian*: 'pieno mišinys kūdikiams iki papildomo maitinimo įvedimo' and 'pieno mišinys kūdikiams įvedus papildomą maitinimą',
- *in Hungarian*: 'tejalapú anyatej-helyettesítő tápszer' and 'tejalapú anyatej-kiegészítő tápszer',
- *in Maltese*: 'ħalib tat-trabi' and 'ħalib tal-prosegwiment',
- *in Polish*: 'mleko początkowe' and 'mleko następne',
- *in Slovenian*: 'začetno mleko za dojenčke' and 'nadaljevalno mleko za dojenčke',
- *in Slovak*: 'počiatočná dojčenská mliečna výživa' and 'následná dojčenská mliečna výživa',
- *in Bulgarian*: 'млека за кърмачета' and 'преходни млека',
- *in Romanian*: 'lapte pentru sugari' and 'lapte pentru copii de vârstă mică'.

