**RESOLUÇÃO DE DIRETORIA COLEGIADA - RDC N° 26, DE 26 DE MAIO DE 2009**

**(Publicada em DOU nº 99, de 27 de maio de 2009)**

**(Revogada pela Resolução - RDC nº 53, de 07 de outubro de 2014)**

~~A~~ **~~Diretoria Colegiada da Agência Nacional de Vigilância Sanitária~~**~~, no uso da atribuição que lhe confere o inciso IV do art. 11 do Regulamento aprovado pelo Decreto Nº 3.029, de 16 de abril de 1999, e tendo em vista o disposto no inciso II e nos §§ 1º e 3º do art. 54 do Regimento Interno aprovado nos termos do Anexo I da Portaria Nº 354 da ANVISA, de 11 de agosto de 2006, republicada no DOU de 21 de agosto de 2006, em reunião realizada em 19 de maio de 2009, e~~

~~considerando a necessidade de constante aperfeiçoamento das ações de controle sanitário na área de alimentos, visando à proteção da saúde da população;~~

~~considerando que antes de ser autorizado o uso de uma substância em alimentos, esta foi submetida a uma adequada avaliação toxicológica;~~

~~considerando que o uso dos aditivos e coadjuvantes de tecnologia deve ser limitado a alimentos específicos, em condições específicas e ao menor nível para alcançar o efeito desejado;~~

~~considerando que as enzimas constam de pelo menos uma das referências validadas para aprovação de seu uso, conforme Regulamento Técnico específico - Resolução RDC Nº. 205 de 14 de novembro de 2006;~~

~~considerando que a CTNBio - Comissão Técnica Nacional de Biossegurança classificou as enzimas, proteínas heterólogas, aminoácidos e vitaminas produzidas por organismos geneticamente modificados como substâncias quimicamente definidas (§2º do Art. 3º da Lei Nº. 11.105/05), ou seja, não se submetem à apreciação da CTNBio, desde que se apresentem purificadas, sem formas viáveis dos organismos que as produziram e, ainda, sem traços de material genético (ácidos nucléicos);~~

~~considerando que este Regulamento Técnico foi submetido ao processo de Consulta Pública Nº. 53, publicado no D.O.U. em 10 de setembro de 2008;~~

~~adota a seguinte Resolução da Diretoria Colegiada e eu, Diretor-Presidente, determino a sua publicação:~~

~~Art. 1º Aprovar a lista de enzimas permitidas para uso em alimentos destinados ao consumo humano conforme a sua origem, constante do Anexo desta Resolução, em substituição ao Anexo I da Resolução RDC Nº. 205 de 14 de novembro de 2006.~~

~~Art. 2º O descumprimento desta Resolução constitui infração sanitária, sujeitando os infratores às penalidades previstas na Lei Nº. 6.437, de 20 de agosto de 1977, e demais disposições aplicáveis.~~

~~Art. 3º Esta Resolução entra em vigor na data de sua publicação.~~

~~DIRCEU RAPOSO DE MELLO~~

**~~ANEXO~~**

**~~ENZIMAS PERMITIDAS PARA USO EM ALIMENTOS DESTINADOS AO CONSUMO HUMANO, CONFORME A SUA ORIGEM~~**

~~-~~ **~~ENZIMAS DE ORIGEM ANIMAL~~**

|  |  |
| --- | --- |
| **~~Nome da Enzima ou Complexo~~** | **~~Fonte(s)~~** |
| ~~Alfa-amilase~~ | ~~Pâncreas suíno e bovino~~ |
| ~~Catalase~~ | ~~Fígado de cavalo ou bovino~~ |
| ~~Quimosina~~ | ~~Abomaso de bezerro e caprino~~ |
| ~~Lactoperoxidadese~~ | ~~Leite bovino~~ |
| ~~Lipase~~ | ~~Abomaso e glândula salivar de bovino, suíno, caprino e ovino~~  ~~Estômago bovino~~  ~~Pâncreas suíno e bovino~~ |
| ~~Lisozima~~ | ~~Clara de ovo~~ |
| ~~Pepsina bovina~~ | ~~Abomaso (4ª parte do estômago)~~ |
| ~~Pepsina suína~~ | ~~Mucosa vermelha (como mucosa gástrica)~~ |
| ~~Pepsina ave~~ | *~~Proventicum~~* ~~de frango~~ |
| ~~Fosfolipase A2~~ | ~~Pâncreas suíno~~ |
| ~~Fosfolipase A2~~ | ~~Pâncreas suíno expresso em~~ *~~Aspergillus niger~~* |
| ~~Pancreatina~~ | ~~Pâncreas suíno e bovino~~ |
| ~~Proteases - coalho complexo~~ | ~~Abomaso de ruminantes~~ |
| ~~Tripsina ou quimotripsina~~ | ~~Pâncreas suíno e bovino~~ |

**~~- ENZIMAS DE ORIGEM VEGETAL~~**

|  |  |
| --- | --- |
| **~~Nome da Enzima ou Complexo~~** | **~~Fonte(s)~~** |
| ~~Alfa-amilase~~ | ~~Malte, cereais e leguminosas maltada~~ |
| ~~Beta-amilase~~ | ~~Malte, cereais e leguminosas maltadas~~  ~~Batata doce (~~*~~Ipomoea batatas~~*~~)~~ |
| ~~Bromelina~~ | ~~Caule, folhas e frutos da família Bromeliaceae (~~*~~Ananas sativus~~* ~~e~~ *~~Ananas comosus~~*~~)~~ |
| ~~Coagulase vegetal~~ | ~~Cardo~~ *~~Cynara cardunculus~~*  ~~Figo~~ *~~Ficus carica~~* |
| ~~Ficina~~ | ~~Caules, folhas e frutos da família Ficus (~~*~~Ficus glabrata~~* ~~e~~ *~~Ficus carica~~*~~)~~ |
| ~~Lipoxigenase~~ | ~~Farinha de soja~~ |
| ~~Papaína~~ | ~~Caule, folhas e frutos de plantas da família Carica (~~*~~Carica papaya~~* ~~e~~ *~~Ananas bracteatus~~*~~)~~ |
| ~~Peroxidase~~ | ~~Raiz forte, farinha de soja, farinha de trigo~~ |

~~-~~ **~~ENZIMAS DE ORIGEM MICROBIANA~~**

|  |  |
| --- | --- |
| **~~Nome da Enzima ou Complexo~~** | **~~Fonte(s)~~** |
| ~~Alfa-acetolactato decarboxilase~~ | *~~Bacillus brevis~~* ~~expresso em~~ *~~Bacillus subtilis~~* |
| ~~Alfa-amilase~~ | *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~*  *~~Bacillus licheniformis~~*  *~~Bacillus licheniformis~~* ~~expresso em~~ *~~Bacillus licheniformis~~*  *~~Bacillus licheniformis~~* ~~e~~ *~~Bacillus amyloliquefaciens~~* ~~expresso em~~ *~~Bacillus licheniformis~~*  *~~Bacillus megaterium~~* ~~expresso em~~ *~~Bacillus subtilis~~*  *~~Bacillus stearothermophilus~~*  *~~Bacillus stearothermophilus~~* ~~expresso em~~ *~~Bacillus licheniformis~~*  *~~Bacillus stearothermophilus~~* ~~expresso em~~ *~~Bacillus subtilis~~*  *~~Bacillus subtilis~~*  *~~Rhizopus delemar~~*  *~~Rhizopus oryzae~~*  *~~Thermoccocales~~* ~~expresso em~~ *~~Pseudomonas fluorecens~~* |
| ~~Alfa-galactosidase~~ | *~~Aspergillus niger~~*  *~~Mortierella vinacea~~*  *~~Saccharomyces carlsbergensis~~* |
| ~~Amilase maltogênica~~ | *~~Bacillus stearothermophilus~~* ~~expresso em~~ *~~Bacillus subtilis~~* |
| ~~Amiloglucosidase ou glucoamilase~~ | *~~Aspergillus awamori~~*  *~~Aspergillus niger~~*  *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~*  *~~Rhizopus arrhizus~~*  *~~Rhizopus delemar~~*  *~~Rhizopus niveus~~*  *~~Rhizopus orizae~~*  *~~Talaromyces emersonii~~* ~~expresso em~~ *~~Aspergillus niger~~*  *~~Trichoderma reesei~~* |
| ~~Aminopeptidase leucina~~ | *~~Lactococcus lactis~~* |
| ~~Arabinofuranosidase~~ | *~~Aspergillus niger~~* |
| ~~Asparaginase~~ | *~~Aspergillus oryzae~~* ~~expresso em~~ *~~Aspergillus oryzae~~* |
| ~~Beta-amilase~~ | *~~Bacillus cereus~~*  *~~Bacillus megaterium~~*  *~~Bacillus subtilis~~* |
| ~~Beta-glucanase~~ | *~~Aspergillus aculeatus~~*  *~~Aspergillus niger~~*  *~~Bacillus subtilis~~*  *~~Disporotrichum dimorphosphorum~~*  *~~Humicola insolens~~*  *~~Penicillium emersonii~~*  *~~Talaromyces emersonii~~*  *~~Trichoderma harzianum~~*  *~~Trichoderma longibrachiatum~~*  *~~Trichoderma reesei~~* |
| ~~Beta-glucosidase ou celobiose~~ | *~~Aspergillus niger~~*  *~~Trichoderma harzianum~~*  *~~Trichoderma reesei~~* |
| ~~Catalase~~ | *~~Aspergillus niger~~*  *~~Micrococcus lysodeicticus~~* |
| ~~Celulase~~ | *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~*  *~~Penicillium funiculosum~~*  *~~Rhizopus delemar~~*  *~~Rhizopus oryzae~~*  *~~Sporotrichum dimorphosporum~~*  *~~Thielavia terrestris~~*  *~~Trichoderma longibrachiatum~~*  *~~Trichoderma reesei~~* |
| ~~Dextranase~~ | *~~Bacillus subtilis~~*  *~~Chaetomium erraticum~~*  *~~Chaetomium gracile~~*  *~~Klebsiella aerogenes~~*  *~~Penicillium funiculosum~~*  *~~Penicillium lilacinum~~* |
| ~~Esterase~~ | *~~Aspergillus niger~~*  *~~Mucor miehei~~*  *~~Trichoderma reesei~~* |
| ~~Fitase~~ | *~~Aspergillus niger~~* |
| ~~Fosfolipase A1~~ | *~~Fusarium venenatum~~* ~~expresso em~~ *~~Aspergillus oryzae~~* |
| ~~Fosfolipase A2~~ | *~~Streptomyces violaceoruber~~* |
| ~~Fosfolipase C~~ | *~~Pichia pastoris~~* |
| ~~Glucose isomerase ou xilose isomerase~~ | *~~Actinoplanes missourienses~~*  *~~Bacillus coagulans~~*  *~~Microbacterium arborensens~~*  *~~Streptomyces albus~~*  *~~Streptomyces murinus~~*  *~~Streptomyces olivaceus~~*  *~~Streptomyces olivochromogenes~~*  *~~Streptomyces rubiginosus~~*  *~~Streptomyces violaceoniger~~* |
| ~~Glucose-oxidase~~ | *~~Aspergillus niger~~*  *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus niger~~*  *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus oryzae~~*  *~~Penicillium amagasakiense~~* |
| ~~Hemicelulase~~ | *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~*  *~~Bacillus subtilis~~*  *~~Rhizopus delemar~~*  *~~Rhizopus oryzae~~*  *~~Sporotrichum dimorphosporum~~*  *~~Trichoderma reesei~~* |
| ~~Hexose oxidase~~ | *~~Chondrus crispus~~* ~~expresso em~~ *~~Hansenula polymorpha~~* |
| ~~Inulinase~~ | *~~Aspergillus niger~~*  *~~Kluyveromyces fragilis~~*  *~~Sporotrichum dimorphosporum~~* |
| ~~Invertase ou beta-frutofuranosidase~~ | *~~Aspergillus niger~~*  *~~Bacillus subtilis~~*  *~~Kluyveromyces fragilis~~*  *~~Saccharomyces carlsbergensis~~*  *~~Saccharomyces cerevisiae~~* |
| ~~Lacase~~ | *~~Myceliophthora thermophila~~* ~~expresso em~~ *~~Aspergillus oryzae~~* |
| ~~Lactase ou beta-galactosidase~~ | *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~*  *~~Candida pseudotropicalis~~*  *~~Kluyveromyces fragilis~~*  *~~Kluyveromyces lactis~~*  *~~Kluyveromyces marxianus~~*  *~~Saccharomyces sp~~* |
| ~~Lipase~~ | *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~*  *~~Brevibacterium lineus~~*  *~~Candida antarctica~~* ~~expresso em~~ *~~Aspergillus niger~~*  *~~Candida lipolytica~~*  *~~Candida rugosa~~*  *~~Fusarium oxysporum~~* ~~expresso em Aspergillus oryzae~~  *~~Humicola lanuginosa~~* ~~expresso em~~ *~~Aspergillus oryzae~~*  *~~Mucor javanicus~~*  *~~Mucor pusillus~~*  *~~Penicillium camembertii~~*  *~~Rhizomucor miehei~~*  *~~Rhizopus arrhizus~~*  *~~Rhizopus delemar~~*  *~~Rhizomucor miehei~~* ~~expresso em~~ *~~Aspergillus oryzae~~*  *~~Rhizopus nigrican~~*  *~~Rhizopus niveus~~*  *~~Thermomyces lanuginosus~~* ~~expresso em~~ *~~Aspergillus oryzae~~*  *~~Thermomyces lanuginosus~~* ~~e~~ *~~Fusarium oxysporum~~* ~~expresso em~~ *~~Aspergillus oryzae~~* |
| ~~Maltase ou alfa-glucosidase~~ | *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~*  *~~Rhizopus oryzae~~*  *~~Trichoderma reesei~~* |
| ~~Nitrato redutase~~ | *~~Micrococcus violagabriella~~* |
| ~~Pectina esterase~~ | *~~Aspergillus aculeatus~~* ~~ou~~ *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus oryzae~~*  *~~Aspergillus niger~~*  *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus niger~~* |
| ~~Pectinaliase~~ | *~~Aspergillus aculeatus~~* ~~ou~~ *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus niger~~*  *~~Aspergillus niger~~*  *~~Aspergillus niger~~* ~~expresso em~~ *~~Trichoderma reesei~~* |
| ~~Pectinase~~ | *~~Aspergillus awamori~~*  *~~Aspergillus foetidus~~*  *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~*  *~~Penicillium simplicissium~~*  *~~Rhizopus oryzae~~*  *~~Trichoderma reesei~~* |
| ~~Poligalacturonase~~ | *~~Aspergillus niger~~*  *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus niger~~* |
| ~~Protease~~ | *~~Aspergillus melleus~~*  *~~Aspergillus niger~~*  *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~*  *~~Bacillus amyloliquefaciens~~* ~~expresso em~~ *~~Bacillus amyloliquefaciens~~*  *~~Bacillus cereus~~*  *~~Bacillus licheniformis~~*  *~~Bacillus subtilis~~*  *~~Endothia parasitica~~*  *~~Lactobacillus casei~~*  *~~Micrococcus caseolyticus~~*  *~~Mucor pusillus~~*  *~~Rhizomucor miehei~~*  *~~Rhizomucor miehei~~* ~~expresso em~~ *~~Aspergillus oryzae~~*  *~~Streptomyces fradiae~~* |
| ~~Pululanase~~ | *~~Bacillus acidopullulyticus~~*  *~~Bacillus acidopullulyticus~~* ~~expresso em~~ *~~Bacillus subtilis~~*  *~~Bacillus deramificans~~* ~~expresso em~~ *~~Bacillus licheniformis~~*  *~~Bacillus deramificans~~* ~~expresso em~~ *~~Bacillus subtilis~~*  *~~Bacillus naganoensis~~* ~~expresso em~~ *~~Bacillus subtilis~~*  *~~Bacillus subtilis~~*  *~~Klebsiella aerogenes~~*  *~~Klebsiella pneumoniae~~* |
| ~~Quimosina~~ | *~~Aspergillus niger var. awamori~~*  *~~Escherichia coli K-12~~* ~~contendo gene de Proquimosina A~~  *~~Kluyveromyces lactis~~* ~~contendo gene de Proquimosina B~~ |
| ~~Renina~~ | *~~Bacillus cereus~~*  *~~Endothia parasitica~~*  *~~Rhizomucor miehei~~*  *~~Rhizomucor pusillus~~* |
| ~~Tanase~~ | *~~Aspergillus niger~~*  *~~Aspergillus oryzae~~* |
| ~~Transglutaminase~~ | *~~Streptoverticillium mobaraense~~*  *~~Streptomyces mobaraense~~* |
| ~~Xilanase~~ | *~~Aspergillus aculeatus~~* ~~ou~~ *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus oryzae~~*  *~~Aspergillus niger~~*  *~~Aspergillus niger~~* ~~expresso em~~ *~~Aspergillus niger~~* |
| *~~Bacillus subtilis~~* ~~expresso em~~ *~~Bacillus subtilis~~*  *~~Humicola insolens~~*  *~~Sporotrichum dimorphosporum~~*  *~~Thermomyces lanuginosus~~* ~~expresso em~~ *~~Aspergillus oryzae~~*  *~~Thermomyces lanuginosus~~* ~~expresso em~~ *~~Fusarium venenatum~~*  *~~Trichoderma reesei~~* |