EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

COMMISSION WORKING DOCUMENT[1]

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Fish dietary burden calculator

The contents of this working document have been finalised in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 22/23 February 2021. It becomes only applicable upon its inclusion in the Commission Communications 2013/C 95/01[2] and 2013/C 95/02[3] and will then be completed with an implementation schedule.

1 This document has been conceived as Working Document of the Commission Services which was elaborated in co-operation with the Member States. It does not represent the official position of the Commission. It does not intend to produce legally binding effects. Only the European Court of Justice has jurisdiction to give preliminary rulings concerning the validity and interpretation of acts of the institutions of the EU pursuant to Article 267 of the Treaty.

2 Commission Communication in the framework of the implementation of Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

3 Commission Communication in the framework of the implementation of Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

CONTENTS

ABBREVIATIONS

CC	Carbohydrate concentrate
CL	Crude lipids
CP	Crude protein
DM	Dry matter
F	Fat
IFN Code	International Feed Nomenclature Code
log P_{OW}	Logarithm of the *n*-octanol/water partition coefficient
MRBD	Maximum reasonably balanced diet
MRL	Maximum residue level
NfE	Nitrogen free extract
PC	Protein concentrate
STMR	Supervised trials median residue
STMR-P	Supervised trials median residue in processed commodity

INTRODUCTION

1. Feed of plant origin is getting increasingly important in fish farming. Pesticide residues may be carried over from feed to aquaculture products. Residues in fish need to be assessed with respect to consumer safety and with respect to setting appropriate maximum residue levels (MRLs). The European regulation setting out data requirements for pesticides (European Commission, 2013) requires studies on the nature of pesticides residues in fish (fish metabolism studies) (European Commission, 2021) and studies on the magnitude of pesticides residues in fish (fish feeding studies) (European Commission, 2021a). Prerequisite for requiring such studies for a pesticide is a $\log P_{OW} > 3$ and that residues of the pesticide in question can reasonably be expected in fish feed, i.e.

- the plant protection product is used or intended to be used on crops whose parts or products, also after processing, are relevant for aquaculture diets and
- significant residues in feed may occur from these uses.

"Significant" is interpreted as residues in fish feed being expected at ≥ 0.1 mg/kg of the total diet (dry matter basis). It is anticipated that lower residues in fish feed do not result in measurable residues in fish commodities. Fish testing is not required in these cases.

2. Fish dietary burden calculations are therefore an important prerequisite to decide on further experimental testing (metabolism and/or feeding studies) as part of the consumer risk assessment. In this Working Document the principles of dietary burden calculation for fish are described.

PURPOSE

3. The primary purpose of this Working Document is

- to provide an overview of those crops whose parts or products, also after processing, are fed to fish and
- to explain how the fish dietary burden is calculated.

4. The Working Document should only be used in connection with residues in fish feed. Residues resulting from environmental contamination of waters with persistent chemicals (arising from historic pesticide use) or from the direct treatment of water bodies or from spray drift/run-off/drainage after treatment along water bodies are not within the scope of this Working Document and might require separate consideration.

COMPOSITION OF FISH FEED

5. Fish in aquaculture are fed based on a "maximum reasonably balanced diet (MRBD)" approach using fixed percentages of carbohydrate concentrate (CC; contains < 30% protein), protein concentrate (PC; contains > 30% protein) and fat (F). Plant commodities commonly used for feeding purposes (all animals) are principally attributed to the feedstuff categories forages/fodders, roots/tubers, cereal grains/crop seeds, plant by-products and vegetable oils.

Not all of them are necessarily used also for fish feeding. An overview of currently used plant-derived feedstuffs and their maximum percentages in fish diets is provided in Table 1. All feedstuffs used in aquaculture so far fall into the feed categories cereal grains/crop seeds, plant by-products and vegetable oils. Forages/fodders and roots/tubers are not yet of relevance. The table may however be adapted in future along with changes in fish feeding practice.

6. Residue values are obtained from supervised crop residue trials which have been conducted under the most critical conditions of use allowed on the label of the plant protection product. As far as plant commodities with small single units are concerned or commodities which have undergone processing prior to consumption, the realistically expected residue level in feed is best characterised by the median residue seen in the crop residue trials. Blending and mixing leads to compensation of single high residues. For cereal grains/crop seeds the supervised trials median residue (STMR) is therefore used as the relevant residue value. Plant by-products are derived during processing of plant commodities. Vegetable oils also result from processing operations. The raw commodity is likely to be blended or originate from a number of sources prior to processing. For plant by-products and for vegetable oils the supervised trials median residue multiplied by a processing factor (STMR-P) is used as the relevant residue value. The processing factor accounts for changes in residue level due to processing.

CALCULATION OF THE DIETARY BURDEN

7. The dietary burden is calculated based on the formulation of Maximum Reasonable Balanced Diets (MRBD) considering all the potential plant commodities and their by-products relevant for aquaculture diets, which are derived from existing and/or proposed uses of the pesticide (Schlechtriem et al., 2016). The plant derived feed commodities, which are considered potentially relevant for fish feeding, are listed in Table 1 and are further described in Table 2. The diet on which the dietary burden calculation is based should reflect best feeding practices and represent a reasonably balanced diet that is nutritionally suitable for fish. The result of the dietary burden calculation is expressed in mg/kg feed on a dry matter (DM) basis. The calculation is made for rainbow trout, common carp and Atlantic salmon as representatives of two different feeding habits (carnivorous vs omnivorous) as well as freshwater and marine fish species. It is not necessary to choose the species with the highest dietary burden for the experimental studies elucidating the nature and magnitude of residues in fish.

8. The MRBD should be formulated in a way representing the maximum burden of pesticide residues, considering the target protein and lipid content and the recommended maximum inclusion rate of each plant commodity used. The MRBD should be calculated by linear programming to optimise the dietary burden estimates (see Annex 1 for details). As a calculation tool, a *Dietary Burden Calculator* has been developed (Fraunhofer IME, 2021). Software and a tutorial are available for free download together with this Working Document.

9. It is recommended that this *Dietary Burden Calculator* is used to calculate the reasonable worst case dietary burden for fish, which has to be considered in the framework of pesticide authorisation. In principle it is based on the expected residue level(s) of a

particular pesticide in fish feed items (see Table 1) and a worst case combination of those feed items with respect to the residue intake by fish. If the selection of feed items potentially containing the pesticide is not sufficient to compose a nutritionally balanced diet for fish, it is supplemented during feed formulation by feed items not containing the pesticide (PC: fish meal, CC: starch, F: plant oil). The target composition of MRBD (% of DM) is 42 %, 35 % and 36 % crude protein and 15 %, 10 % and 33 % crude fat for rainbow trout, common carp and Atlantic salmon, respectively (Kamphues, 2014; Ytrestoyl et al. 2015).

10. The following steps are to be followed to derive the dietary burden relevant for regulatory purposes:

- For the pesticide of interest, the most complete list of known uses, preferably obtained in the framework of evaluation of the existing MRLs according to Art. 12 of Regulation (EC) No 396/2005 (European Commission, 2005), should be retrieved and compared to the list of fish feed items displayed in Table 1. All fish feedstuffs which could potentially contain residues of the respective pesticide are selected from the substance database in the *Dietary Burden Calculator*.

- The specific residue value (mg/kg) is entered for each feedstuff. As only blended and/or processed commodities (cereal grains/crop seeds, by-products, vegetable oils) are used, the respective median residue from the supervised residue trials (STMR, STMR-P, see Table 1) is selected.

- When no information on processing factors is available for the particular commodity/pesticide combination, expert judgement is required to decide on a generic factor or possible extrapolations. If no processing factor can be obtained, the STMR value is used together with a processing factor of 1 (assuming that residue levels do not change upon processing).

- All available components (feed items with specific residue value) are used for the formulation of the MRBD.

- Separate calculations are made for rainbow trout, common carp and Atlantic salmon. The reasonable worst case dietary burden for each of the three different species is obtained. The highest of these three values is the dietary burden relevant for regulatory decisions, i.e. the value possibly triggering further experimental work on fish.

11. As studies on the nature or magnitude of residues in fish are conducted for one species only (e.g. rainbow trout, common carp or Atlantic salmon) and results obtained for this species are extrapolated to all other fish species, it is important that the highest calculated dietary burden forms the basis for selecting the appropriate dose levels in the studies – independent on the species for which this dietary burden was originally calculated.

Table 1: Plant derived feed commodities for dietary burden calculation

Raw agricultural commodity	MRL Commodity Code[1]	Commodity	IFN Code[2]		Class[3]	Residue Input value[4]	CP[5] (% of DM)	NfE[5] (% of DM)	CL[5] (% of DM)	DM (%)	Carp[6] (max. % of diet)	Trout[6] (max. % of diet)	Atlantic salmon[7] (max. % of diet)
Forages/Fodders													
Dried grass commodities (e.g. alfalfa meal) are potential minor ingredients in fish and shrimp feeds as a source of carotenoids. Limited value in fish feeds except for herbivorous fish. Not to be considered in the calculation of the dietary burden.													
Roots and tubers													
Limited value as ingredients for aquaculture feeds; usually only used in small quantities e.g. as binders increasing the water stability of diets. Not to be considered in the calculation of the dietary burden.													
Cereal Grains/Crop Seeds													
Faba bean	0300010	dry seed	5-09-262		CC	STMR	28.3	34.9	8.4	88.0	15	15	1.9*
Chick pea	0300030	dry seeds	---		CC	STMR	20.6	64.0	4.4	90.8	15	15	--
Cow pea	0300030	dry seed	5-01-661		CC	STMR	25.1	58.7	4.9	88.0	15	15	--
Lupin seed (white)	0300040	dry seed	5-02-707		PC	STMR	34.5	40.2	6.1	88.0	15	15	--
Pea	0300030	dry seed	5-03-600		CC	STMR	23.7	64.3	1.7	90.0	15	15	3**
Rice	0500060	ground grains	4-03-938		CC	STMR	8.1	90.2	0.6	88.0	50	10	--
Soybean	0401070	seed, heat processed	5-04-597		PC	STMR-P	38.0	56.6	5.4	89.2	9	3	2**
Wheat	0500090	grain, extruded	---		CC	STMR-P	13.5	80.2	1.9	87.7	15	10	9.9*
Plant By-Products													
Barley	0500010	brewers dried grains	5-00-516		CC	STMR-P	25.9	44.5	7.0	92.3	15	10	10**
Barley	0500010	mill run	4-00-523		CC	STMR-P	10.5	58.8	14.1	90.0	15	10	--

Raw agricultural commodity	MRL Commodity Code[1]	Commodity	IFN Code[2]		Class[3]	Residue Input value[4]	CP[5] (% of DM)	NfE[5] (% of DM)	CL[5] (% of DM)	DM (%)	Carp[6] (max. % of diet)	Trout[6] (max. % of diet)	Atlantic salmon[7] (max. % of diet)
Canola/Rape seed	0401060	meal, pre-press solvent extracted[8]	5-05-145		PC	STMR-P	38.0	33.3	3.8	93.0	10	8	5**
Coconut/ Copra	0120050	meal, mechanically or solvent extracted	5-01-572 5-01-573		CC	STMR-P	21.9	45.1	2.2	90.2	15	10	3**
Corn/Maize	0500030	feed meal	4-02-880		CC	STMR-P	10.2	80.6	4.8	87.8	35	20	--
Corn/Maize	0500030	bran	4-02-841		CC	STMR-P	15.0	63.7	5.7	87.5	20	5	--
Corn/Maize	0500030	gluten feed	5-02-903		CC	STMR-P	24.7	55.4	3.5	90.1	20	10	--
Corn/Maize	0500030	gluten meal	5-02-900		PC	STMR-P	59.9	31.6	3.6	91.3	20	15	4**
Corn/Maize	0500030	starch, cooked	4-08-023		CC	STMR-P	0.2	99.6	---	88.0	35	15	--
Corn/Maize	0500030	distiller's dried grains with solubles	5-02-843		CC	STMR-P	27.8	---	10.0	90.8	35	10	5**
Corn/Maize	0500030	distiller's dried grains	5-02-842		CC	STMR-P	28.5	46.9	10.2	92.3	10	3	--
Corn/Maize	0500030	distiller's dried solubles	5-02-844		CC	STMR-P	29.5	---	11.3	90.6	10	3	--
Cotton seed	0401090	meal, mechanically or solvent extracted	5-01-625 5-01-632		PC	STMR-P	44.2	28.9	1.2	90.8	15	5	5**
Linseed	0401010	meal, mechanically or solvent extracted	5-30-287 5-30-288		PC	STMR-P	35.0	37.6	2.0	90.0	7	5	--

Raw agricultural commodity	MRL Commodity Code[1]	Commodity	IFN Code[2]		Class[3]	Residue Input value[4]	CP[5] (% of DM)	NfE[5] (% of DM)	CL[5] (% of DM)	DM (%)	Carp[6] (max. % of diet)	Trout[6] (max. % of diet)	Atlantic salmon[7] (max. % of diet)
Lupin seed (white)	0300040	meal, solvent extracted	5-27-717		PC	STMR-P	34.5	40.2	6.1	89.5	15	9	9**
Mustard seed	0401080	meal, solvent extracted	5-12-149		PC	STMR-P	42.4	30.3	1.8	89.9	10	5	--
Palm kernel	0402020	meal	5-03-486		CC	STMR-P	16.3	50.4	1.4	90.0	10	8	5**
Peanuts	0401020	decorticated, meal, mechanically or solvent extracted	5-03-649 5-03-650		PC	STMR-P	46.5	29.1	1.0	90.2	15	10	5**
Potato	0211000	protein	---		PC	STMR-P	81.8	12.2	2.8	89.4	3	2	--
Rice	0500060	bran	4-03-928		CC	STMR-P	9.0	41.0	7.4	90.0	50	10	--
Rice	0500060	bran, solvent extracted	4-03-930		CC	STMR-P	15.1	52.8	1.7	89.5	50	10	--
Rice	0500060	polishings	4-03-943		CC	STMR-P	13.6	59.4	14.5	100	50	10	--
Rice	0500060	hulls	1-08-075		CC	STMR-P	3.1	34.2	1.0	100	5	0	--
Rye	0500070	distiller's dried grains	5-04-023		CC	STMR-P	21.2	56.3	6.9	90.0	10	3	--
Sesame seed	0401040	meal	5-04-220		PC	STMR-P	45.0	24.2	4.8	92.4	20	10	--
Safflower seed	0401110	meal, mechanically or solvent extracted	5-04-109 5-04-110		PC	STMR-P	45.2	20.9	6.9	91.0	7	5	--
Soybean	0401070	meal, mechanically or solvent extracted	5-04-600 5-04-604		PC	STMR-P	45.9	31.1	1.0	90.6	30	15	10**

Raw agricultural commodity	MRL Commodity Code[1]	Commodity	IFN Code[2]		Class[3]	Residue Input value[4]	CP[5] (% of DM)	NfE[5] (% of DM)	CL[5] (% of DM)	DM (%)	Carp[6] (max. % of diet)	Trout[6] (max. % of diet)	Atlantic salmon[7] (max. % of diet)
Soybean	0401070	without hulls, meal, solvent extracted	5-04-612		PC	STMR-P	49.8	30.1	0.8	89.5	30	15	10**
Soybean	0401070	protein concentrate	5-32-183		PC	STMR-P	84.3	12.1	0.1	92.0	20	20	21.3*
Sunflower seed	0401050	without hulls, meal, mechanically or solvent extracted	5-30-033 5-30-034		PC	STMR-P	43.5	28.2	3.2	92.6	20	10	6*
Sunflower seed	0401050	meal, mechanically or solvent extracted	5-27-477 5-30-032		PC	STMR-P	30.8	26.9	1.5	90.3	20	10	6*
Wheat	0500090	bran	4-05-190		CC	STMR-P	15.6	61.8	4.7	88.7	5	2	--
Wheat	0500090	flour	4-05-199		CC	STMR-P	14.3	81.9	1.7	88.0	15	10	9.9*
Wheat	0500090	germ meal	5-05-218		CC	STMR-P	28.5	54.3	8.8	88.7	5	2	--
Wheat	0500090	gluten meal	5-05-221		PC	STMR-P	80.1	17.2	1.5	91.4	5	2	6*
Wheat	0500090	middlings	4-05-205		CC	STMR-P	16.9	66.2	4.4	89.4	20	10	9.9*
Wheat	0500090	distiller's dried grains	5-05-193		PC	STMR-P	31.8	54.6	6.6	89.5	10	3	--
Fat													
Oilseeds and oilfruits[9]	various	vegetable oil	various		F	STMR-P	---	---	100	---	10	15	18.3*

[1] MRL Commodity Code: Code Numbers according to Annex I to Reg. (EC) No 396/2005. Codes refer to the raw agricultural commodities.

[2] IFN Code: International Feed Nomenclature code; listed for most commonly used feedstuffs of plant origin according to FAO, 2009 and re-checked with AAFCO (Association of American Feed Control Officials), 2018: official Publication. AAFCO, Champaign, IL; FAO 2009, OECD 2013a.

[3] CC: carbohydrate concentrate; PC: protein concentrate; F: Fat.

[4] STMR: Supervised trials median residue; STMR-P: Supervised trials median residue multiplied by a processing factor.

[5] CP = crude protein; NfE = Nitrogen free extract; CL = Crude lipids. Proximate composition (% dry matter (DM)) according to Hertrampf & Piedad-Pascual, 2000 and FAO, 2009.

[6] Recommended maximum inclusion rates are based on Hertrampf & Piedad-Pascual, 2000 and FAO, 2009.

[7] Recommended maximum inclusion rates are based on Ytrestoyl et al. 2015 (*) and FAO, 2009 (**).

[8] Covers also differently extracted canola/rapeseed meals

[9] All types of oilseeds and oil fruits which can be used for vegetable oil production such as rapeseed, cotton seed, safflower seed, soybean, sunflower seed, oil palm kernels, peanuts, linseed, corn/maize, coconut etc.

Table 2: Further information on commodities representing cereal grains/crop seeds and plant by-products

Feed commodity	IFN Code	Description of the feed commodity	Reference
Cereal grains/Crop seeds			
Bean, cow pea, chick pea, lupin seed, pea	---	Dried beans are the residue of the normal packaging and processing of dried beans for human consumption. This residue shall consist of the broken, small, shriveled and cull beans. They shall be identified by variety such as navy, northern, pinto, kidney, etc. Where further processing, such as grinding, roasting, etc., has occurred, ground, roasted or other acceptable description may be part of the name, i.e. ground roasted dried beans	FAO 2009
Grain products	---	Grain products in any of the normal forms such as whole, ground, cracked, screen cracked, flaked, kibbled, toasted or heat processed: barley, wheat, corn, rice-ground brown, ground paddy, ground rough, grain sorghum, broken or chipped rice, mixed feed oats, rice (brewers), oats, rye and triticale.	FAO 2009
Rice grains	4-03-938	Ground rough rice or ground paddy is the entire product obtained in grinding the whole rice grain including the hulls.	FAO 2009
Soybean seed	5-04-597	Product resulting from heating whole soybeans without removing any of the component parts. It may be ground, pelleted, flaked or powdered.	FAO 2009
Plant By-Products			
Barley, brewer's dried grains	5-00-516	Dried extracted residue of barley malt alone or in mixture with other cereal grain or grain products resulting from the manufacture of wort or beer and may contain pulverised dried spent hops in an amount not to exceed 3 %, evenly distributed.	FAO 2009
Barley, mill run	4-00-523	Entire residue from the milling of barley flour from clean barley and is composed of barley hulls and barley middlings.	AAFCO 2018
Canola/Rape seed meal	5-05-145	Canola meal prepress solvent extracted, low erucic acid, low glucosinolate.	FAO 2009
Canola/Rape seed meal	5-05-146	Canola meal solvent extracted, low erucic acid, low glucosinolate) consists of the meal obtained after the removal of most of the oil, by a direct solvent or prepress solvent extraction process, from the whole seeds of the species *Brassica napus, Brassica campestris* or *Brassica juncea*.	FAO 2009
Coconut/Copra meal	5-01-572	Coconut kernels with coats meal mechanical extracted is the ground residue, which remains after removal of most of the oil from dried meat of coconuts by a mechanical extraction process. May also be called "Copra Meal."	FAO 2009

Feed commodity	IFN Code	Description of the feed commodity	Reference
Coconut/Copra meal	5-01-573	Coconut kernels with coats meal solvent extracted) is the ground residue, which remains after removal of most of the oil from dried meat of coconuts by a solvent extraction process. May also be called “Copra Meal”.	FAO 2009
Corn/Maize feed meal	4-02-880	Fine siftings obtained from screened cracked corn, with or without its aspiration products added.	AAFCO 2018
Corn/Maize bran	4-02-841	Outer coating of the corn kernel with little or no starchy parts of the germ.	AAFCO 2018
Corn/Maize gluten feed	5-02-903	Part of the commercial shelled corn that remains after the extraction of the larger portion of the starch, gluten and germ by the processes employed in wet milling manufacture of corn starch or syrup.	FAO 2009
Corn/Maize gluten meal	5-02-900	Dried residue from corn after the removal of the larger part of the starch and germ, and the separation of the bran by the process employed in wet milling manufacture of corn starch or syrup, or by enzymatic treatment of the endosperm.	FAO 2009
Corn/Maize starch	4-08-023	Maize starch heat hydrolysed.	AAFCO 2018
Corn/Maize distiller’s dried grains	5-02-842	Obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by separating the resultant coarse grain fraction of the whole stillage and drying it by methods employed in the grain distilling industry.	FAO 2009
Corn/Maize distiller’s dried solubles	5-02-844	Obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by condensing the thin stillage fraction and drying it by methods employed in the grain distilling industry	FAO 2009
Cotton seed meal	5-01-625	Obtained by finely grinding the cake, which remains after removal of most of the oil from the cottonseed either by a mechanical or solvent extraction process.	FAO 2009
Cotton seed meal	5-01-632	Obtained by finely grinding the flakes, which remain after removal of most of the oil from cottonseed by a solvent extraction process. It must contain not less than 36 % crude protein.	FAO 2009
Distiller's dried grains with solubles	5-02-843	Obtained after distillation of ethyl alcohol from grain or grain mixture, which has under gone yeast fermentation. Moisture content should be defined.	FAO 2009
Linseed meal	5-30-287	Obtained by grinding the cake or chips, which remain after removal of most of the oil from flaxseed by a mechanical extraction process. It must contain not more than 10 % fibre.	FAO 2009
Linseed meal	5-30-288	Obtained by grinding the flakes, which remain after removal of most of the oil from flaxseed by a solvent extraction process.	FAO 2009
Lupin seed meal	–	The ground residue, which remains after removal of most of the oil from the whole lupin seed by a mechanical or solvent extraction process.	OECD 2013
Mustard seed	5-12-149	Obtained by grinding the cake, that remains after removal of some of the oil by mechanical extraction, and removing most of the remaining oil by solvent extraction.	FAO 2009
Palm kernel meal	5-03-486	The ground residue, which remains after removal of most of the oil from the whole palm kernel by a mechanical or solvent extraction process.	OECD 2013

Feed commodity	IFN Code	Description of the feed commodity	Reference
Peanut meal	5-03-649	Peanut seeds without coats meal mechanical extracted: is a ground product of shelled peanuts, composed principally of the kernels, with such portion of the hull, or fibre, and oil as may be left in the ordinary course of manufacture.	FAO 2009
Peanut meal	5-03-650	Peanut seeds without coats meal solvent extracted: is a ground product of shelled peanuts, composed principally of the kernels, with such portion of the hull, or fibre, and oil as may be left in the ordinary course of manufacture.	FAO 2009
Potato protein	---	Derived from de-starched potato juice from which the proteinaceous fraction has been precipitated by thermal coagulation followed by dehydration.	FAO 2009
Rice bran	4-03-928	Rice bran is the pericarp or bran layer and germ of the rice, with only such quantity of hull fragments, chipped, broken, or brewers' rice, and calcium carbonate as is unavoidable in the regular milling of edible rice. It must contain not more than 13 % crude fibre. When the calcium carbonate exceeds 3 %, the percentage must be declared in the brand name i.e. "Rice Bran with Calcium Carbonate not exceeding %".	FAO, 2009
Rice bran, solvent extracted	4-03-930	Rice bran with germ meal solvent extracted) is obtained by removing part of the oil from rice bran by the use of solvents and must contain not less than 14 % crude protein and not more than 14 % crude fibre.	FAO, 2009
Rice polishings	4-03-943	By-product of rice obtained in the milling operation of brushing the grain to polish the kernel.	FAO 2009
Rice hulls	1-08-075	Consist primarily of the outer covering of the rice grain (with bran).	FAO 2009
Rye distillers dried grains	5-04-023	Obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by condensing the thin stillage fraction and drying it by methods employed in the grain distilling industry	FAO 2009
Sesame seed meal	5-04-220	Obtained after oil extraction. Unlike for other oil meals, this meal is usually obtained by mechanical extraction only and its residual oil content is high.	OECD 2013
Safflower meal	5-04-109	Safflower seeds meal mechanical extracted) is the ground residue obtained after extracting the oil from whole safflower seed by a mechanical extraction process.	FAO 2009
Safflower meal	5-04-110	Ground residue obtained after extracting the oil from whole safflower seed by a solvent extraction process.	FAO 2009
Soybean meal	5-04-600	Obtained by grinding the cake or chips, which remain after removal of most of the oil from soybeans by a mechanical extraction process.	FAO 2009
Soybean meal	5-04-604	Obtained by grinding the flakes, which remain after removal of most of the oil from soybeans by a solvent extraction process.	FAO 2009
Soybean meal	5-04-612	Obtained by grinding the flakes remaining after removal of most of the oil from dehulled soybeans by a solvent extraction process.	FAO 2009
Soy protein concentrate	5-32-183	Prepared from high-quality sound, clean, dehulled soybean seeds by removing most of the oil and water soluble non-protein constituents and must contain not less than 65 % protein on a moisture-free basis.	FAO 2009
Sunflower seed	5-30-034	Obtained by grinding the residue remaining after extraction of most of the oil from dehulled sunflower seed by a solvent extraction process.	FAO 2009
Sunflower seed	5-30-033	Obtained by grinding the residue remaining after the extraction process.	FAO 2009
Sunflower seed	5-30-032	Obtained by grinding the residue remaining after extraction of most of the oil from whole sunflower seed by a solvent extraction process.	FAO 2009
Sunflower seed	5-27-477	Obtained by grinding the residue remaining after extraction of the oil from whole sunflower seed by a mechanical extraction process.	FAO 2009
Wheat bran	4-05-190	Coarse outer covering of the wheat kernel as separated from cleaned and scoured wheat in the usual process of commercial milling.	FAO 2009

Feed commodity	IFN Code	Description of the feed commodity	Reference
Wheat distillers dried grains	5-05-193	Obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by condensing the thin stillage fraction and drying it by methods employed in the grain distilling industry.	FAO 2009
Wheat flour	4-05-199	Consists principally of wheat flour together with fine particles of wheat bran, wheat germ and the offal from the "tail of the mill". This product is obtained in the usual process of commercial milling and must contain no more than 1.5 % crude fibre.	FAO 2009
Wheat germ meal	5-05-218	Consists chiefly of wheat germ together with some bran and middlings or shorts. It must contain not less than 25 % crude protein and 7 % crude fat.	FAO 2009
Wheat gluten meal	5-05-221	By-product in the manufacture of starch from wheat. Water insoluble protein complex.	OECD 2013; Hertrampf and Piedad-Pascual 2000
Wheat middlings	4-05-205	Consists of fine particles of wheat bran, wheat shorts, wheat germ, wheat flour and some of the offal from the "tail of the mill". This product is obtained in the usual process of commercial milling and must contain no more than 9.5 % crude fibre.	FAO 2009
Wheat distiller's dried grains	5-05-193	Obtained after the removal of ethyl alcohol by distillation from the yeast fermentation of a grain or a grain mixture by separating the resultant coarse grain fraction of the whole stillage and drying it by methods employed in the grain distilling industry.	FAO 2009

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ANNEX 1 Dietary Burden Calculation

The maximum dietary burden in fish food can be estimated by linear programming using the Simplex method presented in 1947 by Dantzig (Shenoy, 2007).

Assumptions

1. Three different fish species (rainbow trout, common carp, Atlantic salmon) with specific nutrient requirements (different dietary target compositions) are considered.

2. The feed consists of several plant-derived commodities such as corn meal or peanut meal (Feedstuff table, Table 1) for which residue data are available.

3. The feed commodities have different characteristics with respect to their protein and lipid content (percentage of dry matter) and specific inclusion limits owing to their specific nutritional properties (e.g. content of antinutritional factors).

4. Median residues (mg/kg) from supervised field trials (STMR, STMR-P) are assigned to each feed commodity.

5. Feed commodities for which residue data are available will be selected for feed formulation to estimate, for the three different fish species, the maximum reasonable balanced diet (MRBD) having the highest dietary burden.

6. Each feed commodity in the formulated MRBD has a percentage between 0 % and 100 %. The sum of feed commodities as part of the formulated diet is 100 %.

The above-mentioned conditions are formulated using linear equations and a linear system is obtained.

Model

The maximum dietary burden [max S(x)] has to be calculated as the sum of the product of the commodity specific residue (S_i) and the percentage of each single commodity (x_i). The objective function is $\max S(x) = S_1 \cdot x_1 + \ldots + S_n \cdot x_n$. The constraints determining the set of all possible solutions (feasible set) are:

Protein content:	$P_1 \cdot x_1 + \ldots + P_n \cdot x_n = P_{Fish}$
Lipid content:	$L_1 \cdot x_1 + \ldots + L_n \cdot x_n = L_{Fish}$
Inclusion limit:	$x_i \leq (R_{Fish})_i$, i = 1, … , n
Logical constraint:	$x_1 + \ldots + x_n = 1$
Positive percentages:	$0 \leq x_i$, i = 1, … , n

Considering the first couple of constraints guarantees that the total protein and lipid content of the formulated diet corresponds to the fish-specific requirements (P_{fish} and L_{fish}). The inclusion limit (R_{fish}) of each commodity depends on the commodity-specific nutritional properties. The last couple of constraints defines limits for the resulting percentage values. Negative percentages and percentages greater than 100 % are not allowed. The parameters used in the dietary burden calculation are described in Table A1.

Table A1: List and description of parameters of the dietary burden calculation

Parameter	Range	Description
L_{Fish}	[0,1]	Target content of lipid in feed with respect to the fish species (DM)
L_i	[0,1]	Lipid content of feed component i = 1, … , n (DM)
P_{Fish}	[0,1]	Target content of protein in feed with respect to the fish species (DM)
P_i	[0,1]	Protein content of feed component i = 1, … , n (DM)
$(R_{Fish})_i$	[0,1]	Max. reasonable content of feed component i = 1, … , n (DM)
S_i	$\mathbb{R}_+$	Residue value in mg/kg of feed component i = 1, … , n (DM)
S	$\mathbb{R}_+$	Total residue value in mg/kg of feed (DM)
x_I	$[0, (R_{Fish})_i]$	content of feed component in diet i = 1, … , n (DM)

The Simplex Algorithm either solves above discussed linear program in finite number of steps or proves the insolubility of the problem.

Parametrisation

The dietary burden calculation includes commodity specific parameter values (protein/lipid content as well as residue level) and species-specific parameter values (target needs of protein and lipid, restriction of the feed commodities). Feed commodities and their maximum reasonable inclusion rates on a dry matter basis are presented in Table 1.

Table A2 shows the protein and lipid requirements of rainbow trout (*Oncorhynchus mykiss*), Atlantic salmon (*Salmo salar*) and common carp (*Cyprinus carpio*) which represent carnivore and omnivore species.

Table A2: Lipid and protein requirements of common carp and rainbow trout (% of DM)

Fish species	CL in %	CP in %
Common carp	10	35
Rainbow trout	15	42
Atlantic salmon	33	36

CL = crude lipids (% DM)
CP = crude protein (% DM)

The Dietary Burden Calculator

Above described linear programming can be solved easily using the Dietary Burden Calculator, which is a user-friendly stand-alone software developed by Judith Klein, Michael Klein and Christian Schlechtriem (Fraunhofer IME) in 2014 and updated in 2021.

The list of feed components coincides with the feed components listed in Table 1. For each feed commodity of relevance for the active substance, the user has to enter the respective residue value (STMR, STMR-P). These input values are converted to dry weight basis by the calculator using the % DM values listed in Table 1. All commodities for which residue values have been entered are shown in the table "Available components". The user then selects the feed components that shall be considered in the dietary burden calculation, usually the whole "Available components" list.

Feed commodities are classified as CC (carbohydrate concentrate), PC (protein concentrate) and F (fat). In addition to the feed components given in the feedstuff table (Table 1), the program considers the feed commodities fishmeal (PC), starch (CC) and oil (F) as uncontaminated feed components for feed optimisation (Table A3). These feed components may account for a share between 0 % and 100 %.

Table A3: Supplementary feed commodities considered as uncontaminated components

Feed Component	CL in %	CP in %
Fish meal (PC)	5	75
Starch (CC)	0.1	0.1
Oil (F)	100	0

The dietary burden calculator calculates the maximum dietary burden for rainbow trout (*Oncorhynchus mykiss*), common carp (*Cyprinus carpio*) and Atlantic Salmon (*Salmo salar*) based on the selected feed ingredients. A report is created that contains the input data and the results as text summary, table and pie chart.

More information about the calculator can be found in the tutorial.

Reference

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