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Series on the Safety of Novel Foods and Feeds No. 1

CONSENSUS DOCUMENT ON KEY NUTRIENTS AND KEY TOXICANTS IN LOW ERUCIC ACID RAPESEED (CANOLA)

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No. 1, Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola) (2001)

No. 2, Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-nutrients (2001)

OECD Environmental Health and Safety Publications

Series on the Safety of Novel Foods and Feeds

No. 1

CONSENSUS DOCUMENT ON
KEY NUTRIENTS AND KEY TOXICANTS IN LOW ERUCIC ACID RAPESEED (CANOLA)

Environment Directorate

Organisation for Economic Co-operation and Development

Paris 2001

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or contact:

OECD Environment Directorate,
Environmental Health and Safety Division

2 rue André-Pascal
75775 Paris Cedex 16
France

Fax: (33) 01 45 24 16 75

E-mail: ehscont@oecd.org

FOREWORD

The OECD's Task Force for the Safety of Novel Foods and Feeds decided at its first session, in 1999, to focus its work on the development of science-based ***consensus documents,*** which are mutually acceptable among member countries. These consensus documents contain information for use during the regulatory assessment of a particular food/feed product. In the area of food and feed safety, consensus documents are being published on the nutrients, anti-nutrients or toxicants, information of the product's use as a food/feed and other relevant information.

This consensus document identifies the key nutrients, toxicants, and other constituents that may contribute to the nutritional or anti-nutritional properties of low erucic acid rapeseed (canola). It contains a general description of the use of low erucic acid rapeseed as both a food and a feed product. The main nutrients, toxicants, and other constituents in both low erucic acid rapeseed oil and low erucic acid rapeseed meal are presented for consideration in any proposed changes to the composition of these products.

In preparation of this document, Canada served as the lead country.

The Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology has recommended that this document be made available to the public. It is published on the authority of the Secretary-General of the OECD.

TABLE OF CONTENTS

PREAMBLE

Food and feed products of modern biotechnology are being commercialised and marketed in OECD Member countries. The need has been identified for detailed technical work aimed at establishing appropriate approaches to the safety assessment of these products.

At a workshop held in Aussois, France (OECD, 1997), it was recognised that a consistent approach to the establishment of substantial equivalence might be improved through consensus on the appropriate components (e.g., key nutrients, key toxicants and anti-nutritional compounds) on a crop-by-crop basis, which should be considered in the comparison. It is recognised that the components may differ from crop to crop. The Task Force therefore decided to develop consensus documents on compositional data. These data are used to identify similarities and differences following a comparative approach as part of a food and feed safety assessment. They should be useful to the development of guidelines, both national and international and to encourage information sharing among OECD Member countries.

These documents are a compilation of current information that is important in food and feed safety assessment. They provide a technical tool for regulatory officials as a general guide and reference source, and also for industry and other interested parties and will complement those of the Working Group on Harmonization of Regulatory Oversight in Biotechnology. They are mutually acceptable to, but not legally binding on, Member countries. They are not intended to be a comprehensive description of all issues considered to be necessary for a safety assessment, but a base set for an individual product that supports the comparative approach. In assessing an individual product, additional components may be required depending on the specific case in question.

In order to ensure that scientific and technical developments are taken into account, Member countries have agreed that these consensus documents will be reviewed periodically and updated as necessary. Users of these documents are invited to provide the OECD with new scientific and technical information, and to make proposals for additional areas to be considered.

The Role of Comparative Approach as Part of a Safety Assessment

In 1990, a joint consultation of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) established that the comparison of a final product with one having an acceptable standard of safety provides an important element of safety assessment (WHO, 1991).

In 1993 the Organisation for Economic Co-operation and Development (OECD) further elaborated this concept and advocated the approach to safety assessment based on substantial equivalence as being the most practical approach to addressing the safety of foods and food components derived through modern biotechnology (as well as other methods of modifying a host genome including tissue culture methods and chemical or radiation induced mutation). In 2000 the Task Force concluded in its report to the G8 that the concept of substantial equivalence will need to be kept under review.

The Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology in 2000 concluded that the safety assessment of genetically modified foods requires an integrated and stepwise, case-by-case approach, which can be aided by a structured series of questions. A comparative approach focusing on the determination of similarities and differences between the genetically modified food and its conventional counterpart aids in the identification of potential safety and nutritional issues and is considered the most appropriate strategy for the safety and nutritional assessment of genetically modified foods. The concept of substantial equivalence was developed as a practical approach to the safety assessment of genetically modified foods. It should be seen as a key step in the safety assessment process although it is not a safety assessment in itself; it does not characterise hazard, rather it is used to structure the safety assessment of a genetically modified food relative to a conventional counterpart. The Consultation concluded that the application of the concept of substantial equivalence contributes to a robust safety assessment framework.

A previous Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety (1996) elaborated on compositional comparison as an important element in the determination of substantial equivalence. A comparison of critical components can be carried out at the level of the food source (i.e., species) or the specific food product. Critical components are determined by identifying key nutrients and key toxicants and antinutrients for the food source in question. The comparison of critical components should be between the modified variety and non-modified comparators with an appropriate history of safe use. The data for the non-modified comparator can be the natural ranges published in the literature for commercial varieties or those measured levels in parental or other edible varieties of the species (FAO and WHO, 1996). The comparator used to detect unintended effects for all critical components should ideally be the near isogenic parental line grown under identical conditions. While the comparative approach is useful as part of the safety assessment of foods derived from plants developed using recombinant DNA technology, the approach could, in general, be applied to foods derived from new plant varieties that have been bred by other techniques.

Section I - Background

A. Developments in Low Erucic Acid Rapeseed[1]

Interest in rapeseed breeding intensified soon after the crop was introduced in the 1940s. The initial goals of breeding were directed towards improving agronomic characteristics and oil content of rapeseed. Nutritional experiments conducted as early as 1949 indicated that consumption of large amounts of rapeseed oil with high levels of erucic acid could be detrimental to experimental animals (Boulter G.S., 1983). Concerns about the nutritional safety of rapeseed oil and the potential impact on human health stimulated plant breeders to search for genetically controlled low levels of erucic acid in rapeseed oil. After ten years of backcrossing and selection to transfer the low erucic acid trait into agronomically adapted cultivars, the first low erucic acid varieties, *B. napus* and *B. campestris* were released in 1968 and 1971, respectively (Eskin et al., 1996). In Canada, the terms LEAR (low erucic acid rapeseed oil) and Canbra (Canadian Brassica) were used to identify rapeseed oil containing less than 5% erucic acid.

Rapeseed meal is used exclusively as a high protein feed supplement for livestock and poultry. Prior to the late 1970s, the use of this oilseed processing by-product as an animal feed was limited by the presence of glucosinolates in the seed. Glucosinolates themselves are generally considered to be innocuous, however the hydrolysis products have negative effects on animal production. The low palatability and the adverse effects of glucosinolates due to their antithyroid activity led to the development of varieties of rapeseed which have combined low levels of both glucosinolates and erucic acid (also known as “double low” varieties).

Low erucic acid rapeseed breeding programs in the 1980s and 1990s have produced cultivars with higher yields, increased oil and protein contents, earlier maturity, yellow seeds, reduced green seed and improved disease, insect and herbicide resistance (Eskin et al., 1996).

The successful lowering of erucic acid led to continued interest in compositional modifying low erucic acid rapeseed oil. For example, plant breeders have used mutagenesis to genetically alter the plant’s fatty acid biosynthetic pathways to obtain specialised fatty acid compositions. Low erucic acid rapeseed oil has been developed with the linolenic acid content reduced from approximately 10% to <3%. Although high levels of linolenic acid are desirable from a nutritional point of view, they are undesirable in terms of chemical stability. High levels of polyunsaturated fatty acids led to oxidative rancidity, a reduction in shelf life of the oil, and the development of off-flavours and odours after prolonged storage or repeated frying use (Eskin et al., 1996). Reducing the level of linolenic acid also reduces the need for partial hydrogenation of edible oils used in the liquid form.

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1 . The term canola has been registered and adopted in Canada to describe the oil (seeds, plants) obtained from the cultivars *Brassica napus* and *Brassica campestris*. In 1986, the definition of canola was amended to refer to *B. napus* and *B. campestris* (now *Brassica rapa*) lines containing <2% erucic acid in the oil and <30 μmol/g glucosinolates in the air-dried, oil-free meal. Throughout this document, the term “low erucic acid rapeseed” refers to low erucic acid, low glucosinolate rapeseed, or canola.

Other recent developments in low erucic acid rapeseed oil include the application of mutagenesis to produce high levels of oleic acid (i.e., from 60% to 85% total fatty acid content). The resulting high oleic acid producing cultivar was then crossed to low-linolenic cultivars to create a high-oleic/low-linolenic line. Similarly, recombinant DNA technology has been applied to increase the levels of lauric and myristic acids in low erucic acid rapeseed oil.

Processing of Low erucic acid rapeseed

See Figure 1 for a schematic illustration of the processing of low erucic acid rapeseed meal and low erucic acid rapeseed oil.

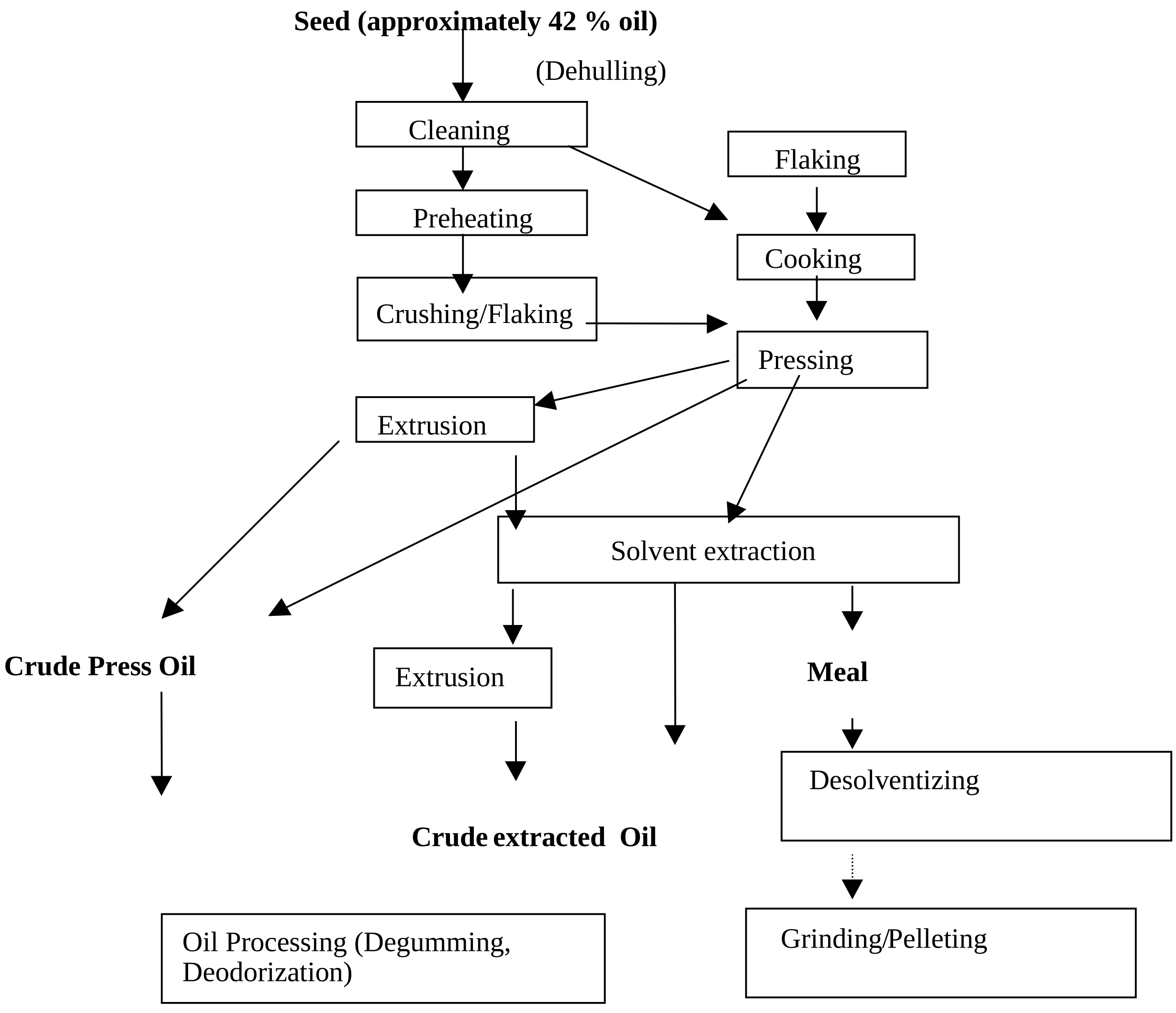

Figure 1: Processing of low erucic acid rapeseed

Critical components are determined by identifying key nutrients and key toxicants for the food source in question. The comparison of key nutrients should be between the modified variety and non-modified comparators with an appropriate history of safe use.

Key Nutrients are those components in a particular product that may have a substantial impact in the overall diet. These may be major constituents (fats, proteins, and carbohydrates) or minor compounds (vitamins and minerals).

Key Toxicants are those toxicologically significant compounds known to be inherently present in the species, i.e., those compounds whose toxic potency and level may impact on human and animal health.

Other Constituents - For the purposes of this document this category includes antinutrients and other compounds that should also be considered if there is an intentional modification of a food or feed component, or if there is an indication from other traits that there may be an unintended effect[2] of a genetic modification. For example, the introduction of a gene to confer herbicide tolerance by altering an amino acid synthetic pathway, could result in altered amino acid composition, protein content, or digestibility. In this case, an alteration in the amino acid composition would be an important indication of an unintended effect of the genetic modification.

Intentional modifications in the composition of low erucic acid rapeseed oil may lead to the production of low erucic acid rapeseed varieties that are not like other commercial varieties. For these low erucic acid rapeseed varieties the fatty acid profiles and levels will not fall within the ranges defined in the Codex standard for Edible Low Erucic Acid Rapeseed Oil (Codex Alimentarius Commission, 1992) or the Codex draft standard for Named Vegetable Oils, which includes low erucic acid rapeseed oil (Codex Alimentarius Commission, 1999). In cases where the fatty acid composition of low erucic acid rapeseed oil has been intentionally modified so that commercial low erucic acid rapeseed varieties cannot be used as a comparator, alternative strategies for safety assessment would be considered.

In the case of oil derived from a genetically modified low erucic acid rapeseed, where the inserted gene and its gene product (e.g., protein) are removed (i.e., during oil extraction and subsequent refinement processes including degumming, refining, bleaching and deodorising), comparison at the food product level would permit a determination of substantial equivalence even though a comparison at the species level would consider the product not to be substantially equivalent. In cases where substantial equivalence cannot be established, the safety assessment would focus on those differences possibly requiring nutritional and/or toxicological data.

In addition to fatty acid profiles and levels, modifications may also result in alterations in the chemical structure (e.g., saturation, chain length, and triglyceride structure) that may have nutritional consequences or result in changes in digestibility. Chemically altered fatty acids will need to be evaluated on their merit and may involve a combination of nutritional and toxicological *in vivo* and *in vitro* testing.

For livestock feed, additional nutritional data would be required, on a case-by-case basis when the composition of a proposed feed ingredient is judged not to be substantially equivalent to that of an approved feed ingredient. The required data would be a function of the nature and degree of the difference

2 . In addition to compositional comparison, other considerations that could be used to assess the potential for unintended effects are beyond the scope of this document. For example, agronomic characteristics including morphology, growth, yield and disease resistance are important considerations since unspecific or unpredicted phenotypic traits or changes in phenotypic traits may be indicative of unintended effects of potential safety concern that would require further investigation.

of the feed ingredient from an accepted source, target animal species, and also the potential dietary exposure.

Intended alterations to the composition of low erucic acid rapeseed meal, e.g., reduced glucosinolates or increased phosphorous bioavailability etc., where substantial equivalence with respect to the intended trait is neither intended nor expected, the requirement would be to demonstrate safe and efficacious (i.e., no deleterious effect on palatability or digestibility) use of the product. In addition to the analysis of key nutrients and toxicants, feeding trials using appropriate species and dietary inclusion rates may be warranted. Feeding trials must use appropriate comparators and be designed to facilitate statistical analysis. Intentional introduction of a trait that would improve phosphorus availability would require analysis of key nutrients and phosphorus bioavailability, as well as any component expected to be influenced by the introduction of the trait (e.g., phytate, phytase, nitrogen, other minerals).

Section II – Food Use

Refined low erucic acid rapeseed oil has been widely used in both salad and cooking oil products, and is also acceptable in hydrogenated products such as margarine and shortenings (Vaisey-Genser, M. and N.A.M. Eskin, 1987). Although consumption data is not available, domestic production data from 1996 (Statistics Canada, 1996) indicates that canola oil accounted for 78% of the total vegetable oils produced in Canada. In the Netherlands, 92,000 tons of processed rapeseed oil ("double zero" varieties[1]) were produced in 1999, accounting for 5.2% of the total vegetable oils produced in that country. In the Slovac Republic, it is estimated that approximately 29,000 tons of low erucic acid rapeseed oil was consumed in 1999 based upon production data.

Canola oil was granted GRAS (Generally Recognized As Safe) status in the U.S.A. in 1987. Low erucic acid rapeseed oil has the lowest content of saturated fatty acids (<7%) of the vegetable oils (Orthoefer, F.T., 1996) and it is also characterised by a relatively high level of monounsaturated fatty acids and an appreciable amount of alpha linolenic acid (Eskin et al., 1996).

A. Identification of Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed Oil

Key Nutrients

Dietary fat serves several important nutritional functions. It is the source of essential fatty acids that are important constituents of cell membranes and it serves as a precursor for many biologically active compounds. Fat also serves as a carrier for the fat-soluble vitamins and it is an important source of energy (Eskin et al., 1996). The following profile of fatty acids should be quantified in low erucic acid rapeseed oil for the purpose of compositional comparison between a modified low erucic acid rapeseed and appropriate comparators (e.g. commercial low erucic acid rapeseed varieties).

palmitic (C16:0) gadoleic (C20:1)

palmitoleic (C16:1) eicosadienoic (C20:2)

stearic (C18:0) behenic (C22:0)

oleic (C18:1) erucic (C22:1)

linoleic (C18:2) lignoceric (C24:0)

linolenic (C18:3)

1. In Europe, "double zero" rapeseed varieties are defined as those producing seed with a maximum glucosinolate content of 25 •moles/g (seed weight) and with a moisture content of 9% (determined by method EN ISO 9167-1:1995) and, having erucic acid content of not more than 2% of the total fatty acid content (determined by method EN ISO 5508:1995).

Examples of fatty acid ranges are given for each of 3 varieties of genetically modified low erucic acid rapeseed in Table 1. These ranges are compared to those ranges published in the literature (commercial varieties of low erucic acid rapeseed); non-genetically modified controls and those Codex standards for fatty acid ranges for low erucic acid rapeseed oil from the Codex Draft Standard for Named Vegetable Oils (Codex Alimentarius Commission, 1999).

Key Toxicants

Erucic Acid

Due to the concerns raised about the nutritional safety of erucic acid, countries have adopted food safety standards defining the amount of erucic acid that is acceptable in low erucic acid rapeseed oil as well as other edible oils. For example, Section B.09.022 of the Canadian Food and Drugs Regulations prohibits the sale of cooking oils, margarines, salad oils, simulated dairy products, shortenings, or foods that resemble margarines or shortenings if the products contain more than 5% C22 monoenoic fatty acids (calculated as a proportion of the total fatty acids in the product). In Switzerland, according to the Ordinance on Foodstuffs, Annex 2 (SR 817.02), the level of erucic acid in infant formula must not exceed 1 % of total fat content. The specification for erucic acid in low erucic acid rapeseed oil has been reduced from 5% to 2% in the Codex Standard for Named Vegetable Oils (Codex Alimentarius Commission, 1999).

Other Constituents of Low Erucic Acid Rapeseed oil

Tocopherols and Sterols

The main nonsaponifiable components of vegetable oils are tocopherols and sterols, although the amounts vary in different oils. Tocopherols (the alpha isomer is also known as Vitamin E) are natural antioxidants and their level in plants is governed by the level of unsaturated fatty acids. A simple increase in unsaturation will result in the formation of higher levels of antioxidants to protect the oil (Eskin et al., 1996). The distribution of natural tocopherols vary with the different vegetable oils both quantitatively and in the amount of different isomers. The amount of total sterols present in low erucic acid rapeseed oil is approximately twice that found in soybean oil and slightly lower than the amount found in corn oil. The potential health effects of plant sterols have yet to be confirmed. Although plant sterols may have a possible beneficial dietary role in lowering plasma cholesterol levels (Jones et al., 1997); they may also have a potential adverse effect on membrane fluidity (Ratnayake et al., 2000). Although processing of the oil reduces the levels of both tocopherols and sterols (Eskin et al., 1996), low erucic acid rapeseed oil is still an important source of these compounds.

Table 1: Examples of Data from Applications of Low Erucic Acid Rapeseed Plants (Genetically Modified to Improve Agronomic Traits)

Fatty Acid (% Total FA)	**Example #1 - Herbicide Tolerant**			**Example #2 - Herbicide Tolerant**		**Example #3 - Fertilization Restorer**		**Example #6 - Fertilization Restorer**		**Codex[4] (ALINORM 99-17)**
	Lit[1]	Control[2]	GM[3]	Control	GM	Control	GM			
C16:0 Palmitic Acid	3.3 - 6.0	4.4 - 6.25	4.1 - 4.5	3.6 - 4.0	3.6 - 4.0	3.6-4.9	–3.4-4.5	3.6 - 4.9	3.4 - 4.5	2.5 - 7.0
C16:1 Palmitoleic Acid	0.1 - 0.6	0.0 - 0.2	0.0 - 0.2	0.2 - 0.3	0.2 - 0.3	0.2-0.4	0.1-0.6	0.2 - 0.4	0.1 - 0.6	ND - 0.6
C18:0 Stearic Acid	1.1 - 2.5	1.4 - 2.0	1.7 - 2.2	1.6 - 2.0	1.8 - 2.0	1.2-2.4	–1.3-2.1	1.2 - 2.4	1.3 - 2.1	0.8 - 3.0
C18:1 Oleic Acid	52.0 -66.9	61.70-63.8	64.1 - 67.0	59.6 - 64.8	60.7 - 64.6	54.3-71.5	57.4-69.7	54.3 -71.5	57.4 -69.7	51.0 - 70.0
C18:2 Linoleic Acid	16.1 -24.8	17.0 -21.15	17.3 - 20.1	16.6 - 20.2	16.5 - 19.4	13.5-24.1	14.0-21.8	13.5 -24.1	14.0 -21.8	15.0 - 30.0
C18:3 Linolenic Acid	6.4 - 14.1	6.70 - 9.30	7.1 - 7.5	8.4 - 11.0	9.2 - 10.0	6.3-13.1	–5.9-12.7	6.1 - 13.1	5.9 - 12.7	5.0 - 14.0
C20:0 Arachidic Acid	0.2 - 0.8	0.4 - 0.70	0.6 - 0.7	0.6 - 0.7	0.6 - 0.7	0.0-0.8	0.4-0.8	0.0 - 0.8	0.4 - 0.8	0.2 - 1.2
C20:1 Eicosenoic or Gadoleic Acid	0.1 - 3.4	1.15 - 2.7	1.3 - 1.4	1.2 - 1.8	1.4 - 1.6	0.0-0.26	–1.0-2.3	0.0 - 0.26	1.0 - 2.3	0.1 - 4.3
C20:2 Eicosadienoic Acid	0.0-0.1			0.1	0.1	0	0	0	0	ND[5] - 0.1
C22:0 Behenic Acid	0.0-0.5	0.25 - 0.4	0.3 - 0.4	0.3 - 0.4	0.4	0.0-0.5	–0.1-0.5	0.0 - 0.5	0.1 - 0.5	ND - 0.6
C22:1 Erucic Acid	0.0 - 2.0	0.5 - 1.4	0	0.0 - 0.8	0.0 - 0.1	0.0-0.16	0.0-0.7	0.0 - 0.16	0.0 - 0.7	ND - 2.0
C24:0 Lignoceric Acid	0.0-0.2			0.2	0.2					ND - 0.3
C24:1 Nervonic Acid	0.0-0.04									ND - 0.4

[1] Literature ranges for Commercial Varieties of low erucic acid rapeseed.
[2] Non-genetically modified low erucic acid rapeseed
[3] Genetically modified low erucic acid rapeseed identified by trait
[4] Codex Standard for low erucic acid rapeseed oil
[5] ND = Not Detectable (<0.05%)

Pigments

The presence of pigments in oilseeds is significant because they impart undesirable colour to the oil and can promote oxidation in the presence of light as well as inhibit catalysts used for hydrogenation (Eskin et al., 1996). Chlorophylls without phytol such as chlorophyllides and pheophorbides may present a nutritional effect because of their phototoxicity, which may be followed by photosensitive dermatitis (Endo et al., 1992).

A bleaching step in the processing of low erucic acid rapeseed oil removes chlorophyll-related pigments and other colour bodies. In order to mitigate the “poisoning” effect of catalysts during hydrogenation, grading standards for low erucic acid rapeseed seed specify tolerance levels for the number of “green seeds” permitted. Lots of seed which exceed the maximum tolerance level are rejected.

Other Identity Characteristics of Oil

Non-specific measurements such as Saponification Values, Unsaponifiable Matter, Iodine Values, and Crismer Values are not considered to be necessary in the context of determining substantial equivalence. These measurements are required to compare with the Codex Standard for Edible Low Erucic Acid Rapeseed Oil (Codex Alimentarius Commission, 1992).

Section III – Livestock Feed Use

Low erucic acid rapeseed meal is a protein feed for all classes of livestock. It is typically balanced with other protein ingredients (e.g., soybean meal, field peas). Because low erucic acid rapeseed meal contains about 30% hulls, it has a high fibre content, which limits its use in monogastric diets (to approximately 15% of the total diet). Higher inclusion rates are practical in ruminant rations. Low erucic acid rapeseed meal can be used as the sole protein supplement for ruminants (i.e., approximately 30% of the total diet). De-hulled low erucic acid rapeseed meal has the potential to compete with soybean meal in swine and poultry diets. Low erucic acid rapeseed meal has also been used in aquaculture. Typical inclusion rates of low erucic acid rapeseed meal in livestock rations are shown in Table 2.

Table 2: Typical rates of inclusion of seed, oil, cake, and meal from low erucic acid rapeseed (% of total diet)

Rapeseed/Canola fraction	Beef cattle	Dairy cattle	Poultry	Swine
Whole seed	8	5	10	10
Oil	3	2	4	3
Cake	15	10	10	10
Meal	30	15	15	15

Low erucic acid rapeseed seed and low erucic acid rapeseed oil are also used in livestock feeds when economical. Low erucic acid rapeseed oil would be used at up to 5% of the total ration. Crushed seed could be used at a rate similar to meal. A similar maximum oil incorporation (5%) is estimated in cases where crushed seed is used.

A. Identification of Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed Meal

Proximate analysis (energy, protein, fibre [including crude fibre, acid detergent fibre, and neutral detergent fibre], fat, and ash) is used by livestock nutritionists to evaluate feed ingredients and to formulate least cost rations for livestock. These components have been well established for virtually all feedstuffs and these values are readily available in feed ingredient tables in publications such as the United States National Research Council's or the UK Agricultural Research Council's Nutrient Requirements for various species of livestock. Amino acid balance and digestibility must also be considered when formulating rations based on low erucic acid rapeseed meal. Typical ranges of nutrient composition of low erucic acid rapeseed, mechanically extracted meal (rape cake), and solvent extracted meal (rape meal) are shown in Tables 3-7.

Key Nutrients

Protein, fat, and fibre are the key indicators of livestock feed quality. These three components are considered essential in defining a feed (Church, 1979). The amino acid profile is a key indication of protein quality. Typical amino acid profile for low erucic acid rapeseed is shown in Table 4.

Key Toxicants

Glucosinolates: The major glucosinolates in low erucic acid rapeseed are 3-butenyl glucosinolate, 4-pentenyl glucosinolate, 2- hydroxy-3-butenyl glucosinolate and 2-hydroxy-4-pentenyl glucosinolate. The standard for glucosinolates in dried canola meal is maximum 30 µmoles/g in Canada (Canadian Food Inspection Agency, 1995) and the U.S.A. (American Association of Feed Control Officials Inc., 1998).

Other Constituents of Low Erucic Acid Rapeseed Meal

The following constituents may be considered, in addition to the key nutrients and toxicants in the evaluation of intended or unintended effects (see paragraph 15: Other Constituents):

- Minerals
- Tannins
- Sinapine
- Phytic Acid

Macro and trace minerals may be considered in the evaluation of low erucic acid rapeseed (see Table 5 for ranges). Tannins and sinapine are considered to be minor antinutrients in low erucic acid rapeseed meal. Sinapine is the major phenolic compound in low erucic acid rapeseed which imparts a bitter taste. Phytic acid is the major form of phosphorous in plants. Although largely unavailable to the animal, phytic acid may have an impact on other mineral bioavailability. Research to further reduce the minor anti-nutrients and glucosinolates, and enhance nutrient composition and bioavailability is ongoing. Table 6 shows toxin and antinutrient concentrations in low erucic acid rapeseed meal.

B. Identification of Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed Oil

Low erucic acid rapeseed oil is used mainly as an energy supplement in livestock feeds. However, the fatty acid profile of feedstuffs must be considered because of the dietary essentiality of n-3 and n-6 fatty acids (varies with animal species). A fatty acid balance also influences the organoleptic qualities of the resulting milk, meat and eggs from livestock.

Key Nutrients

The profile of fatty acids (similar to that considered under Section II - Food Use) should be quantified (% of total fatty acids) in low erucic acid rapeseed oil for the purpose of compositional comparison between a modified low erucic acid rapeseed and appropriate comparators (e.g., commercial low erucic acid rapeseed varieties).

Key Toxicants

Erucic acid

The Canadian Feeds Regulations (Schedule IV, Part 1) definition of canola seed includes a standard of maximum 2% erucic acid in the oil component.

Minor Constituents of Low Erucic Acid Rapeseed Oil

The use of crushed seed as livestock feed (i.e., not oil extracted) may warrant monitoring of the minor constituents, as well as, digestibility of the oil as an energy feed. Minor constituents in low erucic acid rapeseed oil include tocopherols, sterols, and pigments. See discussion for Other Constituents of Low Erucic Acid Rapeseed Oil under Section II - Food Use.

Table 3: Proximate nutrient content of low erucic acid rapeseed, mechanically extracted seed (rape cake; canola meal) and solvent extracted seed (rape meal, canola meal)[1]

Nutrient	Rapeseed Whole seed	Rapeseed Mech. extracted	Rapeseed Solv. extracted
Dry matter	90.0 - 92.6	89.0 - 94.0	87.9 - 92.0
Crude ash	4.1 - 5.0	6.5 - 8.2	5.4 - 7.5
Crude protein	18.7 - 26.0	32.0 - 37.9	34.6 - 37.6
Ether extract	24.0 - 43.6	6.5 - 9.8	1.5 - 3.7
Crude fibre	4.4 - 10.5	11.0 - 12.5	8.5 - 13.5
Neutral detergent fibre	16.0 - 18.5	24.4 - 25.5	18.2 - 29.0
Acid detergent fibre	10.0 - 10.8	17.4 - 17.5	13.3 - 20.0

[1](% of 88% DM; Source: NOVUS table, 1996; ranges of means)

Table 4: Amino acid composition of low erucic acid rapeseed, mechanically extracted seed (rape cake; canola meal) and solvent extracted seed (rape meal, canola meal)[1]

	Rapeseed Whole Seeds	Rapeseed Mech. Extracted	Rapeseed Solv. Extracted
Lys	1.03 - 1.19	1.38 - 1.88	1.73 - 2.16
Met	0.42 - 0.44	0.54 - 0.79	0.53 - 0.78
Cys	0.52 - 0.54	0.30 - 0.89	0.30 - 0.97
Thr	0.87 - 0.94	1.44 - 1.59	1.47 - 1.68
Try	0.23 - 0.27	0.40 - 0.51	0.41 - 0.52
Iso	0.80 - 0.86	1.24 - 1.47	1.33 - 1.57
Leu	1.35 - 1.47	2.01 - 2.44	2.25 - 2.75
Val	1.02 - 1.13	1.63 - 2.01	1.68 - 2.00
His	0.51 - 0.66	0.78 - 1.11	0.86 - 1.02
Arg	1.13 - 1.21	1.79 - 2.32	1.93 - 2.41
Gly	1.04 - 1.06	1.77 - 1.95	1.67 - 1.85
Ser	0.90 - 0.94	1.45 - 1.78	1.41 - 1.59
Phe	0.75 - 0.82	1.25 - 1.65	1.38 - 1.64
Tyr	0.51 - 0.59	0.85 - 1.26	0.79 - 1.31
Pro	1.19 - 1.33	2.05 - 2.35	2.04 - 2.63
Ala	0.93 - 0.96	1.38 - 1.79	1.47 - 1.64

[1](based on 88% DM, Source: NOVUS, 1996, ranges of means)

Table 5: Mineral composition of low erucic acid rapeseed, mechanically extracted seed (rape cake; canola meal) and solvent extracted seed (rape meal, canola meal)[1]

	Rapeseed Whole Seeds	Rapeseed Mech. Extracted	Rapeseed Solv. Extracted
Major elements %			
Ca	0.29 - 0.48	0.59 - 0.75	0.49 - 0.77
P	0.48 - 0.85	0.93 - 1.13	0.92 - 1.10
Mg	0.29 - 0.31	0.42 - 0.52	0.37 - 0.58
Na	0.05	0.02 - 0.46	0.01 - 0.09
K	0.83 - 0.91	0.83 - 1.30	1.04 - 1.35
Trace elements (mg/kg)			
Fe	nd*	175 - 640	160 - 493
Mn	nd	43 - 56	43 - 73
Zn	62	43 - 66	55 - 74
Cu	7	5 - 8	4 - 10
Se	nd	0.33 - 0.98	0.13 - 0.98
I	nd	nd	0.09 - 0.60
Co	nd	0.10 - 0.25	0.10 - 0.21

*nd: not determined ; [1](based on 88% DM, Source: NOVUS, 1996, ranges of means)

Table 6: Toxins and antinutrients in low erucic acid rapeseed meal

Toxins	
Glucosinolates (μmole/g oil-free meal)	6-29
Antinutrients	
Tannins (%)	1.5-3
Sinapine (%)	0.6-1.8
Phytic acid (%)	2.0-5.0

(Source: Canola Council of Canada, 1998; and "Meal and By-product Utilization in Animal Nutrition," J.M. Bell, in: Brassica Oilseeds. D. Kimber and D.I. McGregor, CABI, 1995, UK.)

Table 7: Digestibility of Canola (low erucic acid rapeseed) meal

Ruminant Total Digestible Nutrients (%)	Poultry Metabolizable Energy (kcal/kg, kJoule/kg)	Swine Metabolizable Energy (kcal/kg, kJoule/kg))
64	2285 kcal, 9,560 kJ	2700 kcal, 11,300kJ

(Source: Feedstuffs Ingredient Analysis Table: 1991 Edition)

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