

EVALUATION OF THE RISKS POSED IN EUROPE
BY UNINTENDED MIXING OF
FOOD CROPS AND FOOD
CROPS DEVELOPED FOR
NON-FOOD USES



REPORT

Commissioned by the ILSI Europe Environment and Health
Task Force

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REPORT

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2. INTRODUCTION

Starch, sugars and oils derived from food crops have been used for non-food applications for centuries. Technical advances, along with developments in breeding techniques and plant biotechnology, have led to increased opportunities and potential for the use of food crops for non-food use (FCNFU).

Currently, large volumes of oilseed rape, palm and soya oil are used for biodiesel production globally. Similarly, maize, cereal and sugar crops are widely used for bio-ethanol production. The same cultivars are typically used for food and feed as well as biofuel applications.

Conventional breeding has led to the development of food crops with enhanced metabolic profiles, improving their suitability for industrial uses. Examples include potato varieties with high starch content for industrial production and oilseed rape (OSR) containing elevated levels of erucic acid (high erucic acid rapeseed – HEAR) destined for the industrial production of erucamide (used as a slip agent in the plastics industry).

The development of genetically modified (GM) technologies has the potential to give rise to novel crop traits designed for non-food applications. For example, a GM potato variety has been approved for cultivation for production of industrial starch. Maize varieties have also been modified to express high levels of starch amylase enzymes to reduce the cost of enzymes in starch fermentation to ethanol. Theoretically, a wide range of modified food crops for non-food use could be developed.

There are major advantages in using existing food and feed crops for industrial uses, these include:

- High yields
- Established and optimised crop management and knowledge
- Well-developed supply and processing chains.

The range of potential industrial uses of food crops is significant and growing. FCNFU have been cultivated for many years without any problems of unintended mixing or commingling (see Section 2.1, for definition) being reported in the food and feed industry. With the potentially increasing use and development of FCNFU, it is necessary to examine whether current procedures and control measures in the agricultural supply, food and feed industry are capable of addressing potential risks to consumers.

Where crops used for non-food uses are identical to and are treated the same as traditional food crops there is no increase in hazard as a result of any unintended commingling. However, where the modification of food crops for non-food purposes renders them increasingly undesirable or unsafe for human or animal consumption, the potential risk level increases. As a result, risks and risk management procedures need to be re-evaluated.

Crop by-products entering the food chain from FCNFU are subject to the same food and feed legislation as those from food crops. This requires the food and feed industry to ensure that any risks are effectively addressed, controlled and monitored

European legislation and industry practices ensure the safety of European food and feed chains. This study reviews how current EU seed, food and feed and agrochemical legislation, along with industry practices, are used to contain risks associated with a range of potential FCNFU.

For comparison with European policies and approaches, information was also sought on Canadian and US approaches to procedures for approval to release and cultivate non-food crops.

2.1 Definitions

For clarification, the following definitions are provided for terms used in this review. Most of these definitions draw on Regulation (EC) No 178/2002, covering the general principles and requirements of food law and matters of food safety.

Food: Any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

Feed: Any substance or product, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.

Hazard: A biological, chemical or physical agent in, or condition of, food or feed with the potential to cause adverse health effects.

Risk: A function of the probability of an adverse health effect and the severity of that effect, consequent on the presence of a hazard. Risk is assessed by a process of hazard identification, hazard characterisation, exposure assessment and risk characterisation ('risk assessment'). 'Risk management' represents the process of weighing policy alternatives, risk assessment, selection and use of appropriate prevention and control options.

Traceability: The ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

Unintended commingling: Situations where food crops developed or intended for non-food use (or their processed by-products) and the same crops intended for food use have accidentally or inadvertently become mixed.

3. KEY QUESTIONS FOR THE REVIEW

The key considerations of this review are:

- Does current European legislation relating to approval for cultivation of crops (both conventionally bred and GM) appropriately consider the risks posed by FCNFU to the food and feed chain?
- Are EU food and feed law requirements sufficient to protect the food and feed chain from unintended commingling risks posed by a potentially harmful FCNFU?
- Is there a risk that the use of plant protection products would differ between food crops and FCNFU, and if so, does this pose a risk to the food and feed chain?
- Are existing industry practices sufficient to reduce risks in the food chain from hazards that might be presented by the development of FCNFU?

4. APPROACHES

For a range of example FCNFCU (both real and theoretical), the potential hazards associated with the crop itself, use of its by-products or its management were identified. Points at each stage of the food and feed supply chain where unintended commingling could occur were identified. The ability of current European legislation and industry methods in place to deal with the related identified risks was evaluated. In addition, procedures for approval and release of both conventionally bred and GM FCNFCU were reviewed to examine how these addressed the potential related risks to the food and feed chain and the requirements placed on developing risk management procedures.

The terms of reference for this review include consideration of pathways of unintended commingling, and the risks (assuming there is an identified hazard) this may present to neighbouring or subsequent food crops following cultivation of FCNFCU, plus potential food chain hazards arising from various unintended commingling risks, including potential mixture with food crops or crop by-products during storage, transport and processing.

This review does not consider risks to the environment, gene flow, worker exposure or risks associated with unintended consumption of the crop in the field by animals or humans. In the case of traits introduced by GM, such risks are addressed through legislation granting approval to cultivate GM crops. This work complements work by the European Food Safety Authority (EFSA) to assess risks associated with the development of genetically modified plants for non-food uses¹, and the European Medicines Agency (EMA) in developing procedures to deal with the use of higher plants to produce active substances for pharmaceutical use².

4.1 Case studies


A range of FCNFCU examples, both existing and theoretical, were derived to develop a scenario of increasing potential risk to consumers if ingested. The potential routes of unintended commingling of conventional and FCNFCU seed, crops, produce and by-products at different points in food and feed supply chains were evaluated. These were used to examine whether the management requirements and procedures developed to comply with the current EU regulatory framework for food and feed effectively deal with such situations, eliminating the risk of exposure, or whether there are any potential areas of weakness.

Crops with modified metabolic profiles do not automatically pose an increased hazard because this depends on the nature of the crop modification and the history of safe use of the host crop. For example, a product in a FCNFCU may be benign (e.g. vitamin E at enhanced levels). The risk of exposure to any hazards also depends on controls placed on production and use of the crop variety.

However, for the objectives of this review, example traits posing a potentially increasing risk to consumers are used to examine how control of exposure is, or would be, addressed within the existing agricultural and food and feed legislative framework.

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1. EFSA guidance for the risk assessment of genetically modified plants used for non-food or non-feed purposes (*EFSA Journal* 2009; 1164: 1–42). Available to view at <http://www.efsa.europa.eu/en/press/news/gmo090807.htm>
 2. EMA guideline on the quality of biological active substances produced by stable transgene expression in higher plants. Available to view at <http://www.ema.europa.eu/pdfs/human/bwp/4831606enfin.pdf>

Table 1. Potential routes of unintended commingling of conventional and FCNFCU seed, crops, produce and by-products at different points in food and feed supply chains

Case study perceived hazard	Case study
<p style="text-align: center;">Low</p> 	1. Use of unmodified OSR for biodiesel production.
	2. Use of conventionally bred starch potatoes for industrial starch production.
	3. Use of conventionally bred OSR (high erucic acid cultivars) for erucic acid and erucamide production.
	4. Production of polymer precursors in the foliage of OSR crops (theoretical GM case). For the benefits of this case study it is assumed that in this case any product (seed oil or crop residue) would be undesirable in food and feed chains.
<p style="text-align: center;">High</p>	5. Use of a food crop for production of a medicinal product or vaccine (e.g. vaccine production in maize grains) deemed undesirable in food and feed.

It is recognised that where GM technologies are used, and where crops are intended for medicinal use, such crops are already subject to specific legislation and approval for release through procedures overseen by EFSA and the EMA. For case studies 4 and 5, traits are selected that would pose a potential hazard to humans and animals if these crops were consumed. In practice, the actual hazard posed by individual modified crops will depend on the associated trait, assessed on a case-by-case basis.

Each case study is examined in relation to potential risks at several stages, including: approval to cultivate, field production, storage, processing, and risks arising from potential use of by-products. For each of these steps in the supply chain, potential risks are identified and the controls provided by existing legislation or by industry are outlined for each case study. The scope and potential issues that could arise at different stages of the production chain are listed below.

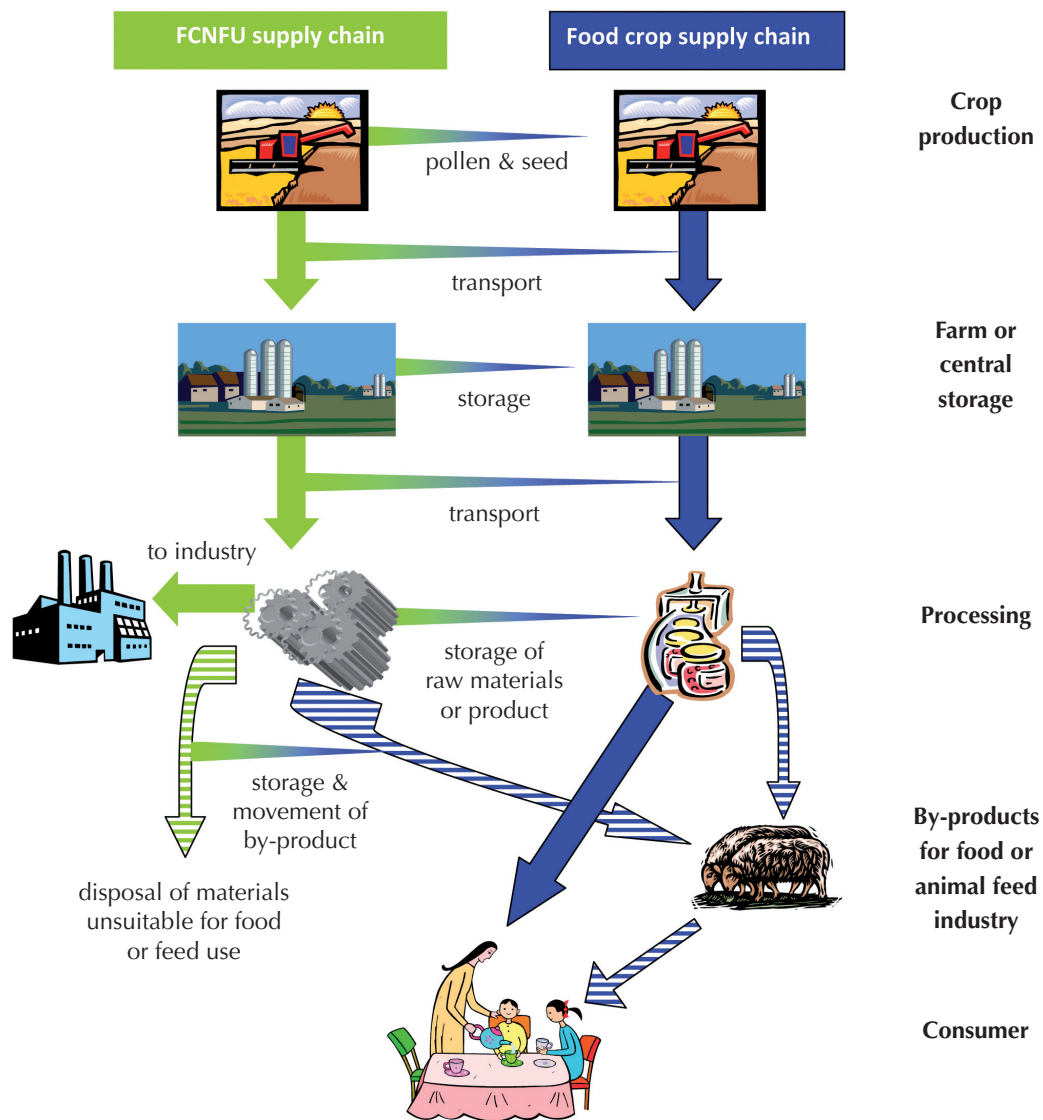
Table 2. Potential issues at different stages of the production chain

Stage	Includes	Associated issues
Approval to cultivate	Approval to cultivate Marketing of seed	A FCNFU may have been bred in such a way that it is no longer as safe for humans or animals as the parent food crop, presenting a potential risk at all subsequent stages. This imposes the need for controls and restrictions on its use, including development of identity preservation and tracing systems.
Field	Sowing of seed Growing of crop Harvesting	Where FCNFU contain different traits to common food cultivars, an unintended commingling hazard is presented by dislodged or spilt seed (giving rise to so-called 'volunteer' plants) and cross-pollination (where this is possible). At high levels of incidence, batches of harvested seed might no longer be safe for human or animal consumption.
Storage	Storage of crop	Where FCNFU are stored with food crops, and their appearance is similar, there is a risk the FCNFU will mistakenly enter the food and feed chain through mis-handling, in addition to general unintended commingling risks in the system.
Processing	Processing of crop and disposal of by-products	Where FCNFU are processed at the same facility as food crops, there is a risk of contaminating food and feed products with products derived from non-food crops.
By-products	By-products	By-products of FCNFU may contain residues of materials intended for industrial use that render them unsafe for human or animal consumption and therefore undesirable in traditional by-product food or feed markets. This could pose a risk where FCNFU are processed at the same facility as food crops.

Development of identity preservation systems entails significant cost for the supply chain in development of handling, storage, transport and processing procedures. The costs of this will fall on the final product and should be taken into consideration when developing the use of food crops for non-food uses.

The potential points of inadvertent commingling in the supply chain are shown in Figure 1.

Figure 1. Potential routes of inadvertent commingling of FCNFU and food crop supply chains. Inadvertent commingling is most likely to occur in situations where any equipment or infrastructure is shared with food crop supply chains



Key: Dual-colour arrows (green merging into blue): Potential routes of inadvertent commingling
 Block arrows: Main product material flow
 Hashed arrows: By-product material flow

5. CASE STUDY 1: OILSEED RAPE FOR BIODIESEL

The OSR varieties cultivated for the production of biodiesel are currently the same as those for food. Unless the agronomic management of crops for food use and non-food use is significantly different, OSR grown for biofuel production, and any supply-chain by-products, can currently be treated and used in the same way as food cultivars.

Areas of concern are the potential differences in agronomic practices (e.g. plant protection product use) between OSR food and non-food cultivars.

Table 3. Assessment of potential risks to conventional supply chains arising from use of OSR for biodiesel production and identified legislative controls in place to reduce any potential risks

Approval to cultivate	<p>Hazard posed: None. Same cultivars used for both food and non food use.</p> <p>Control: None at this stage. EU legislation for approval to cultivate seed is concerned only with the characteristics of the variety of seed and suitability for cultivation. Approval to cultivate crops does not consider potential downstream food safety issues.</p> <p>Potential risk: None.</p>
Field	<p>Hazard posed: Plant protection product used on OSR biofuel cultivars could be different to that used on OSR food cultivars and may therefore render biofuel cultivars unsafe for human or animal consumption (i.e. if non-approved plant protection products are used, or higher rates are used that affect plant protection product residue levels in crops).</p> <p>Control: Council Directive 91/414/EEC³ ensures that approval for use of plant protection products (including products used, rates of use and application timing) is granted by crop, regardless of end use. Regulation (EC) No 396/2005⁴ relating to maximum permissible residue levels (MRL) for plant protection products in specific crops, applies to all crops and crop by-products destined for food or feed use, irrespective of planned end use.</p> <p>Potential risk: Negligible in practice. Risk is controlled by EU legislation and associated monitoring programmes to identify illegal and non-approved use.</p>
Storage	<p>Hazard posed: Increased risk (or concern) related to potential microbial contamination as a result of different crop production practices (e.g. use of sewage sludge applications or reduced fungicide use).</p> <p>Control: Existing food quality assurance (QA) requirements of buyers and associated requirement for segregated storage.</p> <p>Potential risk: In practice, no risk is posed by storing OSR food cultivars and OSR biofuel cultivars together if of similar (food-grade) quality and if QA requirements have been met.</p>

3. Council Directive 91/414/EEC: concerning the placing of plant protection products on the market (*Official Journal* L230 19.08.1991 p. 1).

4. Regulation (EC) No 396/2005: on maximum residue levels of pesticides in or on food and feed of plant and animal origin (*Official Journal* L70 16.03.2005 p. 1).

Processing	<p>Additional controls at this stage: Origin of all seed batches must be recorded in adherence with traceability requirements of EU food and feed law [Regulation (EC) No 178/2002⁵].</p> <p>Potential risk: There is no risk posed by OSR food cultivars and OSR biofuel cultivars being processed in the same facility unless there is a difference in seed quality (unlikely in practice; see storage risk above).</p>
By-products	<p>Additional controls at this stage: Subject to EU food and feed law Regulation (EC) No 178/2002. Under Regulation (EC) No 183/2005⁶ (requirements for feed hygiene), feed business operators are identified as being responsible for feed safety and are required to ensure traceability and appropriate testing schemes are in place, and that hazard analysis and critical control point procedures and principles are in place to protect feed safety.</p> <p>Potential risk: No additional risk. Any risks posed by unintended commingling at this stage and subsequent risks are controlled by EU legislation.</p>

6. CASE STUDY 2: USE OF HIGH-STARCH POTATO FOR INDUSTRIAL STARCH PRODUCTION

Potato varieties grown for industrial starch production have higher minimum starch content than conventional ‘table’ potatoes and this is regulated by Regulation (EC) No 571/2009⁷. The starch from high-starch potatoes is used for both food and non-food uses.

Although human and animal consumption of high-starch potatoes and their by-products poses no additional risk, unintended commingling could reduce the quality of produce destined for other food use (food potatoes).

Table 4. Assessment of hazards and potential risks to conventional supply chain arising from use of conventionally bred high-starch potatoes for industrial starch production, and identified legislative and industry controls in place to reduce any potential risks

Approval to cultivate	<p>Hazard posed: No additional hazard, but wide-scale release of high-starch cultivars increases potential for unintended commingling of conventional potato supply chains, downgrading product quality.</p> <p>Control: Specific designated varieties are required for starch production to meet requirements of Regulation (EC) No 571/2009. There are no specific restrictions affecting the release of conventionally bred potato crop cultivars for industrial use. However, all starch potato cultivars are required to be grown to contract under Regulation (EC) No 571/2009, Article 3, paragraph 5. By this method, supply of specific varieties, segregation and integrity is controlled through industry contracts and supply chain management practices.</p> <p>Potential risk: None to humans and animals. Commercial risk posed is controlled by contracted and regulated production.</p>
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5. Regulation (EC) No 178/2002: laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (*Official Journal* L31 1.02.2002 p. 1–24).

6. Regulation (EC) No 183/2005: laying down requirements for feed hygiene (*Official Journal* L35 08.02.2005 p. 1–22).

7. Commission Regulation (EC) No 571/2009: laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the establishment of a quota system in relation to the production of potato starch (*Official Journal* L171 01.07.2009 p. 6–16).

<p>Field</p>	<p>Hazard posed: Use of non-approved plant protection product on high-starch potato varieties could render them unsuitable for human or animal consumption.</p> <p>Control: As for case 1, Directive 91/414/EEC relating to approval for use of a plant protection product and Regulation (EC) No 396/2005 relating to MRL, control the types, timings, rates of use and maximum residue limits of plant protection products that might accrue in any specific crop, irrespective of end use.</p> <p>Potential risk: Negligible. Risk posed is controlled by EU legislation and associated monitoring programmes for food products to detect illegal or non-approved use.</p> <hr/> <p>Commercial risk: High-starch potato cultivars left in soil after harvest may contaminate subsequent conventional food potato cultivars.</p> <p>Control: Industry control through specified rotations and other volunteer control practices to ensure crop quality.</p> <p>Potential risk: Controlled by existing rotational and volunteer control practices in place by industry to control risks to quality posed by volunteers.</p>
<p>Storage</p>	<p>Commercial risk: Commingling of industrial high-starch and food potato cultivars in storage may downgrade quality.</p> <p>Control: Because crops are grown on contract and have to meet specific end-user requirements, careful on-farm segregation is practiced and high-starch potato chains are physically separated from table potato chains, thus minimising the risk of unintended commingling.</p> <p>Potential risk: Negligible. Controlled by compliance with industry contract requirements and segregation policies.</p>
<p>Processing</p>	<p>Commercial risk: Commingling of high-starch and conventional potato cultivars during processing may downgrade quality.</p> <p>Control: Strict industry contract requirements and quality testing. Starch processing normally carried out in dedicated facilities.</p> <p>Potential risk: None to humans. Commingling risks controlled by compliance with industry contract requirements and segregation policies.</p>
<p>By-products</p>	<p>Hazard posed: No additional hazard if measures above are complied with. By-products from high-starch potato processing can safely enter food and feed chains.</p> <p>Control: Not required. High-starch potatoes and by-products are safe for human and animal consumption.</p> <p>Potential risk: None to humans and animals. Risks controlled by existing EU legislation and compliance with the imposed requirements on food and feed producers.</p>

7. CASE STUDY 3: USE OF CONVENTIONALLY BRED HIGH-ERUCIC-ACID OILSEED RAPE (HEAR) FOR ERUCIC ACID PRODUCTION

Erucic acid is a long-chain fatty acid commonly found in many oil crops. It is commercially derived from modified OSR cultivars. In HEAR cultivars, erucic acid accounts for 50–60% of the total fatty acid content of the oil (compared to less than 2% in conventional OSR cultivars used for food use). Although there have been no confirmed reports of links between erucic acid or rapeseed consumption and myocardial lipidoses in humans, high levels of erucic acid have been linked to the formation of fatty deposits in animal heart muscle (reported by UK Food Standards Agency). Therefore, as a precaution, high levels of erucic acid are considered undesirable in products intended for human consumption and for use in animal feed in the EU.

Additional potential areas of concern to those in cases 1 and 2:

- Unintended presence of HEAR trait in conventional cultivars via pollen transfer and from HEAR ‘volunteers’ (OSR seed has the potential to remain dormant for several growing seasons under suitable conditions)
- Risk of commingling on-farm or in storage
- Potential use of crop by-products (meal) in the animal food chain.

Table 5. Assessment of hazards posed and potential risks to conventional OSR supply chain arising from use of conventionally bred HEAR, and identified legislative and industry controls in place to reduce any risks

Approval to cultivate	<p>Hazard posed: Increased human and animal exposure to erucic acid through exposure to oil or oilseed meal (left after oil extraction).</p> <p>Control: Only HEAR cultivars listed in the EU common catalogue (Council Directive 2002/53/EC⁸) are permitted to be marketed within the EU. However, this legislation does not include any requirement to consider any potential risks to food safety that could arise from wide-scale cultivation.</p> <p>Potential risk: Will depend on scale of production and use of control procedures detailed in sections below. As production is very small scale compared to conventional OSR, and due to industry control procedures, overall risk is negligible. The potential for increased risk of unintended commingling posed by wide-scale release for cultivation is not controlled by legislation in this case.</p>
	<p>Hazard posed: Pollen flow from HEAR cultivars to neighbouring conventional OSR seed cultivars that are then multiplied for wide-scale release could increase erucic acid content in conventional food crops.</p> <p>Control: Council Directive 2002/57/EC⁹ includes clear specifications on crops grown for seed production, including minimum distances from neighbouring pollen sources, to ensure ‘sufficient varietal identity and varietal purity’. Specific crop separation distances are included in the directive for OSR (400 m for basic seed multiplication, 200 m for certified seed for commercial sale).</p> <p>Potential risk: None. Risk is effectively controlled by existing EU legislative requirements imposed on OSR cultivars grown for seed production.</p>

8. Council Directive 2002/53/EC: on the common catalogue of varieties of agricultural plant species (*Official Journal* L193 20.07.2002 p. 1).

9. Council Directive 2002/57/EC: on the marketing of seed of oil and fibre plants (*Official Journal* L193 20.07.2002, p. 74–97).

Field	<p>Hazard posed: Contamination of neighbouring conventional OSR cultivars by pollen from HEAR cultivars could increase erucic acid content in conventional food crop.</p> <p>Control: Industry practice is to impose a 50 m separation distance between HEAR and other OSR cultivars in the locality to reduce pollen transfer.</p> <p>Potential risk: Negligible. Exposure is controlled by industry self-regulation and associated stipulations in production protocols and contracts and between growers and processors or their intermediaries.</p>
	<p>Hazard posed: HEAR seed remaining in soil may produce viable plants that could contaminate any conventional OSR cultivars planted in subsequent seasons.</p> <p>Control: Conventional OSR grown to contract typically requires growers to specify if HEAR has been grown on the same land in the previous five years (to highlight any high-risk situations). Farmers growing HEAR also tend to convert fields growing HEAR to HEAR-only production. Erucic acid levels in conventional OSR are also routinely tested as part of storage receipt QA procedures to identify 'at risk' batches that can then be traced.</p> <p>Potential risk: Negligible (HEAR-only production) to moderate (HEAR grown in rotation with conventional OSR). Exposure is controlled by industry self-regulation and associated QA requirements listed in production contracts between growers and processors or their intermediaries.</p>
	<p>Hazard posed: Non-approved plant protection products used on crop.</p> <p>Control: According to EU plant protection product legislation (see case 1), no difference in types of product used, periods of use, maximum permitted dosage or residue limits is permitted, therefore no additional risk is posed. Food surveillance programmes monitor compliance.</p> <p>Potential risk: None where existing legislation is complied with.</p>
Storage	<p>Hazard posed: Contamination of conventional OSR cultivars with HEAR cultivars during storage and transport operations.</p> <p>Control: HEAR must be stored separately to conventional OSR food cultivars and limits are specified for erucic acid levels (max 5%) in food oils by EU food and feed law (see below). This triggers the need for segregation, traceability procedures and testing as part of an identity preservation system. Seed samples from loads of conventional OSR crop cultivars are checked for erucic acid content prior to loading into storage.</p> <p>Potential risk: Negligible. Exposure is controlled by compliance with industry practices introduced to ensure that limits imposed by food safety legislation are met.</p>
Processing	<p>Hazard posed: Contamination of conventional OSR with HEAR during processing.</p> <p>Control: The maximum level of erucic acid permitted in oils, fats and mixtures is 5% (Council Directive 76/621/EEC¹⁰). Quality assurance procedures (batch testing) are used by the processing industry to check erucic acid levels in conventional food oil samples. The requirements of this legislation feeds back into supply-chain industry actions (as detailed above) to secure uncontaminated supplies of conventional OSR via use of identity preservation systems.</p> <p>Potential risk: Negligible. Exposure controlled by batch testing for erucic acid and industry QA procedures to ensure compliance with EU food safety legislation.</p>

10. Council Directive 76/621/EEC relating to the fixing of the maximum level of erucic acid in oils and fats intended as such for human consumption and in foodstuffs containing added oils or fats (*Official Journal* L202 28.07.1976 p. 35–37).

By-products	<p>Hazard posed: HEAR meal by-products might enter the animal feed chain.</p> <p>Control: EU food and feed law [Regulation (EC) No 178/2002] is applicable to all stages of food and feed production, processing and distribution. All feed must be safe and traceable throughout the food chain. 'Unsafe' feed should not be placed on the market nor fed to any food-producing animal. Feed hygiene legislation [Regulation (EC) No 183/2005] places the responsibility for ensuring feed safety with feed business operators, who must implement a quality control plan with sampling and testing. In addition, Regulation (EC) No 882/2004¹¹ details official controls required by all Member States to ensure compliance with Regulation (EC) No 178/2002.</p> <p>Directive 2002/32/EC¹² identifies a number of substances regarded as undesirable in animal feed, including volatile mustard oil (42% erucic acid). Feed is required to be tested to ensure limits for these substances are not exceeded. Identity preservation systems can help track, trace and isolate in case of problems.</p> <p>Potential risk: Negligible. Exposure controlled by batch testing and industry QA procedures to ensure compliance with EU food safety legislation.</p>
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8. CASE STUDY 4: USE OF GM-DERIVED FOOD CROPS FOR NON-FOOD USE; OILSEED RAPE PLANT CONTAINING POLYMER PRECURSORS

Case study examples 4 and 5 involve traits that are currently only likely to arise in current food crops through GM approaches. As such, the current procedures and legislative framework in place to gain approval for release of such GM crops is examined from a generic perspective. In addition, there are a further set of considerations where the new trait is designed to produce materials in plants for medicinal use. These additional considerations for case study 5 (production of a vaccine in corn) are considered in Section 9.

8.1. Risk assessment and approval procedure for release of non-food cultivars developed by genetic modification

A regulatory risk assessment procedure has been developed to appraise the risks to both the environment and human health posed by the growth and use of GM crop material and resulting from use of any by-products. For crops destined for food use, this process is overseen by the EFSA, and for crops destined for medicinal uses by a combination of both the EFSA and the EMA. Recognising that development of GM FCNFDU may pose additional risks, EFSA recently undertook a review of the issues from a GM perspective. As a result, a guidance note was issued (April 2009) to assist and advise the EFSA GM approval process in such circumstances.

11. Regulation (EC) No 882/2004: on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (*Official Journal* L165 30.04.2004 p. 1–141).

12. Directive 2002/32/EC: on undesirable substances in animal feed (*Official Journal* L140 30.05.2002 p. 10–22).

A comparative approach to risk assessment is required (i.e. considering the differences between the GM and non-GM counterparts and the risks relating to these differences) on a case-by-case basis for all GM crops, including FCNFM. It was recognised in the EFSA work that existing procedures for approval of GM food crops were adequate to cover most cases, but that special attention was required in relation to FCNFM for any possible risks posed by accidental human and animal exposure and that appropriate means of mitigating any potential risks should be found.

A GM food crop developed for non-food use is unlikely to gain approval for release if any risk of inadvertent introduction into the food and feed chain is identified (from any part of the crop) and that risk cannot be controlled. The process of approval for the release of a GM organism (GMO) is subject to Directive 2001/18/EC¹³. An extensive risk assessment procedure has to be followed prior to gaining approval. The requirements of the risk assessment include:

- Hazard identification: Identification of any hazard capable of causing adverse side effects
- Risk identification: Quantitative evaluation of the nature of the adverse effects including, where possible, a dose-response assessment
- Exposure assessment: Identification of sources, routes, levels, intensity, frequency and duration of exposure
- Risk characterisation: Assessment of the probability of occurrence and the severity and reversibility of adverse effects in a given population or environment.

Any potential direct or indirect effect on the environment following the release of a GM plant must also be addressed. For example, interactions with non-target organisms and gene transfer potential must be identified and evaluated.

Where any specific risk associated with the release of a GM plant is identified, the risk must be controlled entirely by a fit-for-purpose measure whose effectiveness must be monitored before and after release (to ensure compliance with Directive 2001/18/EC).

Any GM food and feed product (including any by-products derived from GM FCNFM) authorised for marketing in the EU must have been subject to thorough scientific evaluation of any risks posed to human or animal health or to the environment [Regulation (EC) No 1829/2003¹⁴]. These scientific evaluations are the responsibility of EFSA.

13. Directive 2001/18/EC: on the deliberate release into the environment of genetically modified organisms (*Official Journal* L106 17.04.2001 p. 1–39).

14. Regulation (EC) No 1829/2003: on genetically modified food and feed (*Official Journal* L268 18.10.2003 p. 1–23).

Table 6. Analysis of current legislative requirements to control the risks associated with cultivation of GM FCNFU

Approval to cultivate	<p>A GM food crop developed for non-food use will fail to gain approval for cultivation if any uncontrollable risks in the whole supply chain are identified by the extensive risk assessment procedure defined by Directive 2001/18/EC (covering deliberate release into the environment of GMOs).</p> <p>All GM seed is subject to EU seed regulations (Directive 2002/53/EC) and relevant seed marketing directives covering issues such as purity and separation distances for seed crops.</p>
Field/Storage/ Processing	<p>Any safety risks posed by a GM crop at the field, storage or processing stage should have been identified prior to approval for release during the risk assessment process (Directive 2001/18/EC). Where risks have been identified, risk management measures (control of wastes, identification-preserved storage etc.) proven to be fit for purpose prior to approval for release, must be put in place. After release, these measures are subject to monitoring for effectiveness.</p> <p>In addition, potential GM co-existence legislation (yet to be ratified) is designed to keep GM plants separate from non-GM plants to protect farmer and consumer choices; however, co-existence legislation itself is not intended as a safety measure.</p> <p>Measures for dealing with any residual biomass wastes and/or routes of disposal are also required to be documented to control any returns to the environment.</p>
	<p>Any proposed changes in use of plant protection products on any GM crop must be subject to an environmental risk assessment (Annex II Directive 2001/18/EC and Commission decision 2002/623/EC¹⁵). All plant protection products used must be approved under Council Directive 91/414/EEC. Any plant material destined for feed use must also comply with existing MRL [Regulation (EC) No 396/2005].</p>
By-products	<p>Any by-product destined for food or feed use is subject to general EU food and feed law requirements for food and feed safety [Regulation (EC) No 178/2002]. In addition, Regulation (EC) No 1829/2003 requires a thorough scientific safety assessment of any GM food or feed product, including any by-products, that are likely to appear in the food and feed chain.</p> <p>The general approval procedure under Directive 2001/18/EC also includes a requirement to assess risks associated with possible accidental intake through any inadvertent entry into the food and feed chain. This includes any risks arising from inadvertent use of non-food crop by-products.</p>

In the theoretical case of an oilseed plant containing polymer precursors in all plant parts (and judged to pose a risk to human health), the risks to human and animal health from consumption of the raw material and by-products would have been assessed as part of the approval process. Where risks are identified, to gain approval for release, applicants would have to demonstrate appropriate confinement measures that reduce the risks to an acceptable level. This would be checked through post-market monitoring (PMM) procedures. The approach for FCNFU cultivars produced by GM technologies, outlined above, identifies the more pro-active assessment of hazard and risk that is required before approval for release can be granted and the additional PMM that may also be required compared to that associated with conventionally bred FCFNU. PMM is used to check that the risk management measures are effective.

15. Commission Decision establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (*Official Journal* L200 30.07.2002 p. 22–33).

9. CASE STUDY 5: VACCINE PRODUCTION IN GM CORN

The evaluation of the legislation and industry procedures affecting control of any food-crop-derived vaccine accidentally entering the food and feed chain is undertaken on the assumption that the vaccine would arise through GM technologies. It would therefore be subject to the same hazard and risk analysis as detailed for case 4 above. However, there are some additional controls that specifically relate to the production of plant-derived vaccines.

In reviewing the current situation regarding the use of plants for therapeutic vaccine production, the World Health Organization (WHO) identified containment of plants and the disposal of waste materials as areas that require specific consideration in any approval to cultivate. However, the existing legislation surrounding the approval for cultivation of plants with novel traits was deemed to be sufficient to control the risks posed by these crops, although additional more specific guidance may be required in some cases. In the EU, this guidance is provided via EMA guidelines detailed in "The quality of biological active substances produced by stable transgene expression in higher plants" (effective since February 2009). This guidance builds on existing GM legislation (e.g. Directive 2001/18/EC). Compliance with this approval process ensures that controls to prevent all potential risks of contamination of food crops should be in place prior to granting of approval to cultivate.

The EMA guideline also specifically states that (with regard to Directive 2001/18/EC) "the [control] measures in place should include those intended to prevent deliberate or accidental ingestion of transgenic plant parts by animals or human beings, either via direct consumption, or through inadvertent release into food or feed supply". These guidelines also impose stringent requirements to ensure traceability.

Annex 1 of Directive 2001/83/EC¹⁶ requires an evaluation of the clinical and non-clinical safety of a medicinal product (including plant-derived vaccines). The results of such studies must be submitted to EMA in any application for market release. In the case of a plant-derived vaccine, the results of such studies would also be expected to be provided to EFSA for inclusion in its evaluation for approval to release.

16. Directive 2001/83/EC: the Community code relating to medicinal products for human use (*Official Journal* L311 28.11.2001 p. 67–128).

Table 7. Analysis of current legislative requirements to control the risks associated with cultivation of a GM plant for production of medicinal compounds

Note: The measures outlined in this table are in addition to those described in Table 4.

Approval to cultivate	Approval to cultivate a GM plant producing vaccines is subject to the same risk assessment procedures required for any GM crop approved for release under Directive 2001/18/EC. In addition, EFSA requires sight of non-clinical and clinical safety evaluations of the medicinal products involved (as per Directive 2001/83/EC) to assist in the assessment of human hazards. The potential for unintentional commingling of the GM plant producing vaccines with the food and feed chain is also reviewed as part of this assessment.
Field/Storage/processing	Traceability must be ensured to comply with EMA guidelines and EU legislation. In addition, Directive 2001/18/EC requires that measures are in place to prevent deliberate or accidental ingestion of transgenic plant parts by animals or human beings, either via direct consumption or through inadvertent release into food or feed supply.
By-products	In compliance with the normal risk assessment procedures adopted under GM legislation, any plant constituents intended for use in animal feed applications would be subject to a core set of studies to establish if there are any potential risks.

By this regulatory risk assessment procedure, any risks from using food crops for production of medicinal substances would be highlighted and independently reviewed. This would identify whether the risks associated with approval for wide-scale release are acceptable, or whether production should be constrained by specific measures. The risk control measures required would be assessed on a case-by-case basis and depend on the scale of risk perceived at any point.

10. COMPARISON OF REGULATORY AND OTHER CONTROLS IN PLACE TO REDUCE POTENTIAL RISKS TO FOOD AND FEED CHAIN POSED BY CULTIVATION OF FOOD CROPS FOR NON-FOOD USE

Table 8. Comparison of control systems to reduce potential risks to food and feed chain posed by cultivation of food crops for non-food use

	Conventionally bred FCNFCU	GM FCNFCU	Key areas of difference
Approval to cultivate	Approval to market seed does not take into consideration any possible food and feed risk implications.	Full risk assessment is required to gain approval to cultivate (which may be constrained further, based on step-wise risk assessment of potential impacts).	When approval to cultivate a conventionally bred FCNFCU is granted, no food risk assessment is currently required.
	Must comply with EU seed regulations. All varieties must be included in the EU common catalogue to be commercially marketed and comply with relevant marketing requirements.		
Field	Risk of unintended commingling of crops by volunteers or by cross-pollination with neighbouring crops is controlled by industry and Good Agricultural Practice.	If any risks of escape are identified, fit-for-purpose confinement measures must be used to minimise or remove the risks, or approval to cultivate will not be granted.	Conventionally bred FCNFCU are reliant on industry best practice to prevent potential unintended commingling risks arising from volunteers and cross-pollination.
	Must comply with plant protection product approval regulations and maximum residue levels if any part of the crop is destined for the food or feed chain.		
Storage	Any risks arising from unintended commingling of FCNFCU and food crops during storage are managed by industry best practice and contractual obligations, to meet food and feed Directives.	If, following risk assessment at approval to cultivate stage, any potential risks have been identified, then fit-for-purpose confinement measures must be put in place to prevent them. If the risks cannot be prevented, approval to cultivate will not be granted.	Conventionally bred FCNFCU rely on industry best practice and procedures to prevent inadvertent contamination of food crops during storage.

Processing	Any risks arising from unintended commingling of FCNFU and food crops during processing are managed by industry best practice and contractual obligations. In many cases, where food crops and FCNFU have been processed by the same facility, testing for contamination will be carried out.	If, following risk assessment at approval to cultivate stage, any potential risks have been identified, then fit-for-purpose confinement measures must be put in place to prevent them. If the risks cannot be prevented, approval to cultivate will not be granted.	Conventionally bred FCNFU rely on industry best practice to prevent unintended commingling with food crops during processing. Traceability, segregation systems and batch testing (where specific FCNFU contaminants are recognised) are used to ensure the quality and safety of food and feed chains from FCNFU contamination.
By-products	Risks to the feed chain are addressed through tracing systems and liabilities placed on feed suppliers through EU food and feed legislation.	If, following risk assessment at approval to cultivate stage, any risks have been identified, then fit-for-purpose confinement measures must be put in place to prevent them. If the risks cannot be prevented, approval to cultivate will not be granted. If any part of the GM crop is destined for the food and feed chain then it is further subject to GM food and feed safety risk assessment requirements.	Food and feed law is extensive and places a requirement for risk assessments and due diligence at all stages of the supply chain.
	Must comply with overarching EU food and feed law and other relevant food and feed legislation if any part of the crop is destined for the food or feed chain.		

The key difference between conventionally bred and GM FCNFU is that GM FCNFU are subject to a rigorous risk assessment before approval to release is granted and, as a result, any specific requirements to protect food supplies from contamination would need to be communicated to the supply chain and demonstrated to be reliable and robust to ensure continued approval to cultivate. In the case of conventionally bred FCNFU, it is the responsibility of the supply industry to develop an appropriate set of management procedures to minimise any risks to the supply chain to protect its interests. In effect and practice, the two systems are very similar in the way that they operate. For conventionally bred FCNFU, it must be proven that their use complies with the safety requirements of, primarily, plant protection and food and feed law, or effective segregation procedures must be adopted, as with GM FCNFU.

11. APPROACHES AND PROCEDURES DEVELOPED OUTSIDE EUROPE TO DEAL WITH DEVELOPMENT OF FOOD CROPS FOR NON-FOOD USE

11.1 Canada

In Canada, the Canadian Food Inspection Agency (CFIA) has a regulatory and authorisation process for approval of plants with a novel trait (PNT)¹⁷ developed for food and feed uses (irrespective of whether GM traits are involved). The CFIA has developed a science-based regulatory framework that has to be met before any release to the environment can be approved. Under current legislation, PNT for food and feed are evaluated by comparison to their conventional cultivated counterparts with respect to:

- Weediness and/or invasiveness
- Gene flow to wild relatives
- Plant pest properties
- Impact(s) on non-target organisms (including humans)
- Impact(s) on biodiversity.

Under the Canadian Directive 2000-07 (Research Field Trials for PNT), plant breeders are recommended to choose a crop that has no or little use as a food or feed crop. However, many factors (as mentioned previously) make established food crops more attractive to breeders. If food or feed crops are used, the CFIA recommends that risk mitigation tools need to be built in to avoid adventitious presence in food and feed supplies. Mitigation tools suggested by CFIA include:

- Limiting the expression of the novel molecule to a specific growth phase, tissue or organ
- Triggering the expression of the molecule by a specific event, e.g. chemical application
- Limiting the potential gene flow to wild and domestic relatives.

However, these issues mainly address factors associated with escape from the field and do little to address potential risks associated with inadvertent admixture in later stages of the supply chain.

For PNT, a so called 'no-split' approval process is adopted. Under this process all food and feed crops put forward for approval for cultivation (whether for food, feed or PNT for industry) have to receive authorisation for their release, as well as for use for food or as a livestock feed. If a food crop is developed for a purpose other than food or feed, it will not receive authorisation for use as a food or feed crop but it will still have to undergo a risk assessment by CFIA's Feed Section and Health Canada's Food Directorate to assess toxicity and allergenicity. CFIA is considering developing 'categories of risk' for different PNT to ensure that appropriate levels of control are applied, proportionate to the risk involved.

11.2 United States of America

In the USA, crops produced by genetic engineering for commercial use are regulated by the US Department of Agriculture (USDA), the US Food and Drug Administration (US FDA) and the US Environmental Protection Agency (US EPA). The regulatory framework for GM crops in the USA is the 'Federal Government Coordinated Framework for the Regulation of Biotechnology', developed in 1986.

17. PNT (plant with a novel trait) is a plant that contains a trait that is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment and human health. These traits can be introduced using biotechnology, mutagenesis or conventional breeding techniques and have some potential to impact on weediness, gene flow, plant pest potential, non-target organisms, food, feed or biodiversity.

The US FDA, US EPA and the USDA Animal and Plant Health Inspection Service (APHIS) provide the guidance for approval and commercial release of GMOs. Products are regulated according to their intended end use. All crops must be tested and studied to ensure that they pose no significant risk to consumers or the environment. The USDA and US EPA assess the potential risks to minimise harmful consequences, including those for transfer of novel traits to wild relatives.

Following several incidences of GM contamination of food supply in the USA (e.g. by the GM corn StarLink in 2000) and in field contamination by crops modified to produce pharmaceutical products (e.g. ProdiGene cases in 2002) there is now a zero tolerance approach for biologically derived therapeutic drugs and proteins in food or feed. To ensure compliance with 'zero tolerance', such materials must not be genetically engineered into food crops in the USA.

12. DISCUSSION

Where conventionally bred food crops are used for industrial uses, it can be seen from case studies 1–3 that risks to human and animal health in Europe are currently reduced by a combination of industry best practices and food and feed legislation imposed by the EU.

Relevant legislation reducing the risk (assuming a hazard has been identified) of unintended commingling from conventionally bred FCNFCU includes:

- Seed marketing legislation, designed to meet seed quality standards, and requirements for appropriate and defined crop separation distances for seed production of species vulnerable to cross-pollination.
- Food and feed legislation that is designed to ensure the safety of food and animal feed from contamination by placement of due-diligence requirements on operators. Limits for some specific named undesirable contaminants are also set, including some non-food crop contaminants (e.g. erucic acid), which are then incorporated into quality testing routines.

Industry practices to reduce contamination risks, introduced as part of due-diligence procedures, include:

- Preference for visual distinction between crops for food and industrial use, e.g. through seed colour
- Guidelines for minimum rotational separation of the same crop types used for industrial and food uses
- Adoption of precautionary isolation distances between conventional crops and those with novel traits where pollen flow is a potential risk
- Testing of produce at food storage intake for contaminants.

Food crops destined for non-food use are subject to the same restrictions and controls on plant protection product use as those destined for food chains. So as long as existing regulations and controls are adequately enforced, there should be no issues associated with the use of non-approved plant protection products or unacceptable levels of plant protection product residues in products in cases where any unintended commingling occurs.

For GM FCNFCU, release of crops can only be approved after a detailed case-by-case assessment. Where any specific hazard is identified, appropriate risk management measures must be developed and monitoring procedures established before allowing release for cultivation. Information on areas of potential risk must be well documented, facilitating information flow and delegation of appropriate

responsibilities for reporting and testing in the supply chain. This ensures that there is a formal process for ensuring dialogue and for development of appropriate containment procedures. However, such legislation is also burdensome in that any part or by-product from a GM crop remains classed as 'GM' irrespective of whether it carries the modified trait or a GM marker and so must be accounted for within a tracing system.

In contrast, development of conventionally bred food crops for industrial use is not constrained by any specific legislation to control release based on assessment of potential downstream risks (assuming a hazard has been identified). The relevant industry interests bear much of the burden, working on controlled supply contracts to control production and developing segregation procedures for produce and by-products, ensuring compliance with relevant legislation by working with the supply chain. This approach means that regulatory bodies need to be aware of FCNFU developments to make sure that appropriate mandatory testing procedures are adopted to ensure the safety of food and feed.

13. CONCLUSIONS

To date, the approaches adopted in the EU by both regulatory bodies and industry to control human and animal exposure to risks arising from use of food crops for non-food use have been shown to be effective.

The success of current systems relies on appropriate information exchange and raising of awareness between partners in the supply chain, and with appropriate responsible regulatory and monitoring bodies. This success also relies on governments effectively enforcing and updating relevant legislation and ensuring that food and feed monitoring is undertaken to quickly address any new emerging risks.

Currently, there are very few examples of FCNFU that present a potential hazard to humans or animals (the obvious example being HEAR, as used in one of the case studies) therefore there have been few real pressures on the systems and approaches adopted to date in terms of the range of risks that need to be monitored and addressed. However, the growing interest in the use of plant-derived products is likely to accelerate breeding developments in this sector, which may place additional pressures, for example on monitoring regimes, that would need to be addressed.

In the case of conventionally bred FCNFU, there is a need to ensure that information on any new developments is widely circulated to relevant supply chain stakeholders so that appropriate steps can be taken to address any food and feed industry concerns. It is highly unlikely that any commercial interest would undertake FCNFU development without discussing implications with industry and relevant regulatory bodies and agencies.

Any measures adopted to ensure food and feed safety must not place additional undue burdens on the supply chain where there is no additional risk involved, for example where it can be shown that by-products from FCNFU are identical in nature and quality to those of conventional food crops.

The scope of this review and its conclusions are based on legislation and practices adopted by EU Member States. It cannot be assumed that such controls extend outside the EU and in particular to less-developed countries. However, imports from such countries for food or feed use would be subject to the same quality and testing requirements as European produce.

The conclusions also assume that relevant EU legislation and other industry controls are strongly enforced in Member States and that appropriate monitoring and sampling action is undertaken to both ensure compliance with existing legislation and identify any emerging risks.

14. GLOSSARY OF EU LEGISLATION¹⁸

Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species (Official Journal L193 20.07.2002 p. 1–11)

Crop stage relevant to: Approval to cultivate

Concerns: All varieties of beet, fodder plant, cereal, potato, oil and fibre plant seeds; GM and conventional

Seed may only be marketed if it is a species or variety on the EU common catalogue. This Directive details the uniform criteria and minimum requirements for acceptance for inclusion in the common catalogue. Varieties must be:

- *Distinct:* Capable of precise recognition and precise definition; clearly distinguishable on one or more important characteristics from any other variety known in the EU.
- *Stable:* After successive propagation or multiplications or at the end of each cycle it remains true to the description of its essential characteristics.
- *Sufficiently uniform:* Plants from which composed must be similar or genetically identical as regards characteristics.
- *Of satisfactory value for cultivation and use:* Compared to other varieties in the catalogue its qualities in any given region offer improvement in cultivation.

In addition to Directive 2002/53/EC, each type of plant has its own marketing directive and requirements thereof:

- Council Directive 66/401/EEC on the marketing of fodder plant seed
- Council Directive 66/402/EEC on the marketing of cereal seed
- Council Directive 2002/54/EC on the marketing of beet seed
- Council Directive 2002/55/EC on the marketing of vegetable seed
- Council Directive 2002/56/EC on the marketing of seed potatoes
- Council Directive 2002/57/EC on the marketing of seed of oil and fibre plants (*Official Journal L193 20.07.2002 p. 74–97*).

Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Official Journal L230 19.08.1991 p. 1–32)

Crop stage relevant to: Field

Concerns: All plant species; GM and conventional

European Council Directive 91/414/EEC is intended to harmonise national arrangements for the authorisation of plant protection products within the European Community. Under the provisions of this Directive, Member States are responsible for authorisation within their own territory of products containing active substances that appear in a list agreed at Community level; this list is known as Annex 1. Approval of active substances is granted by crop, regardless of the end use of the crop, thus approvals for use for a food crop will be the same as those for a FCNFCU of the same species.

18. Note that all legislation directly referred to in this review is listed in bold in the first instance in this glossary.

Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (Official Journal L70 16.03.2005 p. 1–16)

Crop stage relevant to: Field

Concerns: All plant species destined for food or feed use; GM and conventional

A small number of plant protection products may leave residues in foodstuffs, even when applied correctly. Where residues occur, statutory limits known as MRL have been established. MRL provide a check that products have been used as directed; they are not safety limits. However, they do take account of consumer safety because MRL are set at levels that ensure that normal dietary intake of residues present no risk to human health. It is an offence to put into circulation any produce for which the MRL is exceeded. MRL are set on an EU-wide basis, and apply to imported as well as home-grown food stuffs.

Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Official Journal L31 01.02.2002 p. 1–24)

Crop stage relevant to: Processing by-products destined for food or feed use; GM and conventional

Concerns: All plant species destined for food or feed use; GM and conventional

This regulation provides the basis to ensure a high level of protection of human health and consumer interest in relation to food. It includes common principles and responsibilities, requirements for scientific basis, and efficient procedures and arrangements to underpin all decision making in matters of food and feed safety. It is applicable to all stages of food or feed production, processing and distribution. This regulation states that food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (Official Journal L165 30.04.2004 p. 1–141)

Crop stage relevant to: Processing by-products destined for food or feed use; GM and conventional

Concerns: All plant species destined for food or feed use; GM and conventional

Official controls are required by all Member States to ensure compliance with requirements of food and feed law [Regulation (EC) No 178/2002], in order to prevent, eliminate or reduce to acceptable levels risks to humans and animals, either directly or through the environment. The regulation includes food and feed labelling requirements.

Regulation (EC) No 183/2005 laying down requirements for feed hygiene (Official Journal L35 08.02.2005 p. 1–22)

Crop stage relevant to: Processing by-products destined for feed use; GM and conventional

Concerns: All plant species destined for feed use; GM and conventional

Feed business operators are responsible for feed hygiene and safety, at all stages of production, from and including primary production of feed, up to and including the placing of feed on the market. Quality control plans, including sampling and testing, must be implemented.

Directive 2002/32/EC on undesirable substances in animal feed (*Official Journal L140 30.05.2002 p. 10–22*)

Crop stage relevant to: Processing by-products destined for feed use; GM and conventional

Concerns: All plant species destined for feed use; GM and conventional

The legislation includes a list of substances that are undesirable in feed. Statutory limits for these substances are set in this Directive, and all feed is required to be tested to ensure that limits have not been exceeded.

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (*Official Journal L106 17.04.2001 p. 1–39*)

Crop stage relevant to: All stages of GM crop

Concerns: All GM plant species

The primary aim of the measures required by this Directive is the protection of human health and the environment when a GMO is released into the environment, or when it is placed on the market. The measures included in the Directive to gain approval for release of a GMO include a thorough risk assessment requirement and implementation of fit-for-purpose confinement measures to control any perceived risks. These must be monitored post-release. Any GMO that is considered to be of too high a risk to human or animal health, or the environment, will not gain approval for release into the environment or onto any market.

Guidance on this legislation:

2002/623/EC: Commission Decision establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (*Official Journal L200 30.07.2002 p. 22–33*).

Regulation (EC) No 1829/2003 on genetically modified food and feed (*Official Journal L268 18.10.2003 p. 1–23*)

Crop stage relevant to: All stages of GM crop destined for food or feed use

Concerns: All GM plant species destined for food or feed use

The regulation includes measures to ensure a high level of protection of human life and health, animal health and welfare, and environmental and consumer interests in relation to GM food or feed. It includes a requirement for a scientific food or feed safety assessment for any GM food or feed. It also includes requirements for all food or feed products containing any GM material to be adequately labelled.

Directive 2001/83/EC on the Community code relating to medicinal products for human use (*Official Journal L311 28.11.2001 p. 67–128*)

Crop stage relevant to: End use – plant-derived medicinal products

Concerns: All plant species destined for human medicinal use; GM and conventional

This Directive includes provisions that apply to all industrially produced medicinal products for human use intended to be placed on the market in EU Member States. Any plant product destined for medicinal use must comply with the requirements of this Directive.

Also relevant: **Regulation (EC) No 726/2004** on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

Commission Regulation (EC) No 571/2009 laying down the detailed rules for the application of the Council Regulation (EC) No 1234/2007 as regards to the establishment of a quota system in relation to the production of potato starch (*Official Journal* L171 01.07.2009 p. 6–16)

Crop stage relevant to: Starch potatoes – all stages

Concerns: Potatoes for starch production only

This regulation includes matters that should be covered by a starch potato cultivation contract and requirement for starch potatoes to have a minimum starch content of 13%. Also includes details of quota system.

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