Use the Weed Risk Assessment (WRA) Work Instructions to fill out the fields below. Be sure to read all of the text associated with each question *every time* you conduct a WRA.

### Basic information (8 questions)

<table>
<thead>
<tr>
<th>(1) WRA version number</th>
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<td>2016-273-001</td>
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<table>
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<th>(3) GE or baseline</th>
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<th>(8) Reviewers</th>
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<tr>
<td>BRS</td>
<td>BRS</td>
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### Taxonomy and sexually compatible relatives (6 questions)

<table>
<thead>
<tr>
<th>(9) Common name</th>
<th>(10) Scientific name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corn (NRCS, 2015b)</td>
<td><em>Zea mays ssp. mays</em> L. (ITIS, 2015)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>(11) Other common names</th>
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<tr>
<td>Maize, Indian corn (NCBI_Taxonomy Browser, 2015)</td>
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</table>

<table>
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<th>(12) Scientific name synonyms</th>
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<tr>
<td><em>Zea alba</em> Mill.</td>
</tr>
<tr>
<td><em>Zea amylacea</em> Sturtev.</td>
</tr>
<tr>
<td><em>Zea everta</em> Sturtev.</td>
</tr>
<tr>
<td><em>Zea indentata</em> Sturtev.</td>
</tr>
<tr>
<td><em>Zea indurata</em> Sturtev.</td>
</tr>
<tr>
<td><em>Zea japonica</em> Van Houtte</td>
</tr>
<tr>
<td><em>Zea saccharata</em> Sturtev.</td>
</tr>
<tr>
<td><em>Zea tunicata</em> (Larrañaga ex A. St.-Hil.) Sturtev.</td>
</tr>
<tr>
<td><em>Zea mays ssp. ceratina</em> (Kuelshov) Zhuk. (ITIS, 2015)</td>
</tr>
</tbody>
</table>
There are others but these synonyms show up in the literature more often.

(13) Taxonomic scope

This weed risk assessment covers only *Zea mays* ssp. *mays*. There are other subspecies of *Zea mays* but they will not be addressed here.

14) Sexually compatible relatives

**Teosinte** - Teosinte is the closest relative of corn; it hybridizes with corn and hybrids can be fully fertile (Wilkes, 1977; OGTR, 2008). Teosintes are generally not present in the U.S. other than in breeding and research programs and as occasional botanical garden specimens (Iltis, 2003; EPA, 2010). Teosintes can be weedy in some regions or habitats (Mexico, Guatemala) (Iltis, 2003; OGTR, 2008; EPA, 2010; USDA-NRCS, 2005). Despite the ease of crossing between subspecies, gene flow occurs at low frequency and all the subspecies still coexist as genetically separate entities (Baltazar et al., 2005; Fukunaga et al., 2005). "The flow of genes has occurred in both directions" (Wilkes 1977; Doebley, 1990) "although a number of factors tend to favor gene flow from teosinte to maize rather than from maize to teosinte" (Baltazar et al., 2005). "There is also evidence of a restriction to crossability in some populations of *Z. mays* teosintes when teosinte is the female and maize the male parent and this has been linked to a teosinte gene or gene cluster known as *Teosinte crossing barrier1 (Tcb1)*" (Evans & Kermicle, 2001; Kermicle, 2006).

- **Zea mays** L. ssp. *mexicana* (Schrader) Iltis (English common name: Mexican annual teosinte) - Spontaneous hybridization occurs between corn and *Zea mays* ssp. *mexicana*, with hybrids exhibiting full fertility (Ellstrand et al., 2007; Fukunaga et al., 2005; Doebley, 2004). *Z. mays* ssp. *mexicana* grows primarily in central and northern Mexico, and is considered a troublesome weed of corn fields in central Mexico (Doebley, 2003; USDA NAL, 2012), and it may displace desirable vegetation if not properly managed (USDA-NRCS, 2005). Populations have been reported in FL, AL, and MD (USDA-NRCS, 2005; USDA-NRCS, 2014a), but local botanists have not documented any natural populations of *Zea mays* ssp. *mexicana* in Florida for over 30 years (EPA, 2010), and the AL and MD reports are over 30 years old.
  - Florida: there are reports of pressed and thoroughly dried plant sample deposited in a herbarium (Atlas of Florida Vascular Plants, 2015).
  - Alabama- last report was in 1965 in the *Castanea Index* - type of sample unknown
  - Maryland- last report was in 1984 in the *Herbaceous plants of Maryland* - type of sample unknown (Brown and Brown, 1984 as reported by USDA; NRCS, 2014a).

- **Zea mays** L. ssp. *parviglumis* Iltis and Doebley - Spontaneous hybridization is rare but does occur between corn and *parviglumis* teosinte (Ellstrand et al., 2007). Hand pollination is the most successful method of hybridization and the progeny are viable no matter how the hybrid was developed (Ellstrand et al., 2007). This subspecies is found along the western escarpment of Mexico from Nayarit to Oaxaca (Doebley, 2003). The NRCS (2015a; 2015f) lists a population of *Zea mays* ssp. *parviglumis* in Miami-Dade county Florida based on a University of Florida Herbarium accession collected in 1975 (FLAS 2015).

- **Zea mays** L. ssp. *huehuetenangensis* (Iltis and Doebley) Doebley (English common name: Huehuetenango teosinte) - This teosinte is found in western Guatemala (Doebley, 2003). Cannot find any references regarding hybridization ability with *Zea mays* ssp. *mays*.

- **Zea luxurians** (Durieu and Ascherson) Bird (English common name: Guatemala or Florida teosinte) - According to NRCS (2015c). *Zea luxurians* was grown for forage in the southern U.S. over a century ago
and sometimes is still used for forage in the southern United States, "but rarely hybridizes with maize" (Iltis, 2003). There are no other references except for Iltis (2003) to verify that Zea luxurians is still grown as forage in the U.S. This species is an annual native to southeastern Guatemala, Honduras and Nicaragua (Doebley, 2003).

- **Zea diploperennis** Iltis, Doebley and Guzman (English common name: diploperennial teosinte)- In 1980, a population of Zea mays "Colorado Klein" (Zea mays subsp. mays 'Colorado Klein'; Tropicos, 2015) was successfully crossed with Zea diploperennis. "Both species hybridize readily, and the F1 hybrid is not only fertile and vigorous but also preferably annual or biannual, except for 12% of the plants which are perennial" (Rosales & Molina, 1983). According to NRCS (2015d) Zea diploperennis is not found in the U.S. (Wilkes, 1977; EPA 2010). This species is found only in a small region of the Sierra de Manantlán in the southwestern part of the state of Jalisco, Mexico (Doebley, 2003).

- **Zea perennis** (Hitchcock) Reeves and Mangelsdorf (English common name: perennial teosinte)- Corn does produce non-fertile hybrids with the perennial Zea perennis under natural conditions. It has a narrow geographic distribution on the northern slopes of Volcán de Colima in the state of Jalisco at altitudes of 1500-2000 m (Doebley, 2003). (Iltis, 2003; OGTR, 2008). The NRCS (2015e) lists this species in Texas and Georgia. But the sample in Texas, "Zea perennis 'Winning Streak'" is an ornamental plant. A map (NRCS, 2015e2.) of the location of the Texas samples is included in the reference list.

*Tripsacum* spp. - Outcrossing of maize with *Tripsacum* species is not known to occur in the wild. However, "although it is extremely difficult, it is possible to produce outcrossing between Zea mays and Tripsacum spp. " in non-natural situations (OECD, 2003). "These hybrids have a high degree of sterility and are genetically unstable" (Mangelsdorf, 1974 as cited in OECD, 2003).

- **Tripsacum dactyloides** (L.) L. var. occidentale Cutler & Anders.- This plant is distributed across the eastern half of the United States in the U.S. (USDA-NRCS, 2002). There are no reports of crosses with corn in the wild.
- **Tripsacum floridanum Porter ex Vasey**- This plant is found in Florida (USDA-NRCS, 2015g). There are no reports of crosses with corn in the wild.
- **Tripsacum lanceolatum Rupr. ex Fourn.**- This plant is found in Arizona and New Mexico (USDA-NRCS, 2015h). There are no reports of crosses with corn in the wild.

### GE trait (4 questions)

<table>
<thead>
<tr>
<th>(15) GE phenotype category</th>
<th>(16) GE phenotype</th>
</tr>
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<tbody>
<tr>
<td>✓ PQ</td>
<td>A corn line was developed to produce high levels of lysine in the germ of the seed.</td>
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</table>

**Lysine Maize** **Intended phenotype:**
The LY038 corn has been genetically modified to express the **cordapA** gene from *Corynbacterium glutamicum*. The expression of **cordapA** is under the control of the maize Glb1 promoter, which directs cDHDPS expression predominately in the germ of the seed, resulting in accumulation of lysine in the grain.

High lysine content in the seed germ is conferred by directed expression in the corn seed of a bacterial (*Corynebacterium glutamicum*) derived dihydrodipicolinate synthase cDHDPS) enzyme which is lysine-insensitive, i.e. resistant to lysine feedback inhibition (Bonnassie *et al.* 1990; Vauterin *et al.* 2000) that is fused with a corn-derived chloroplast targeting sequence from the native maize DHDPS (Monsanto 2004). Free lysine is approximately 39 fold greater in grain expressing this enzyme than in the null comparator (Monsanto 2004, pg 98).

Another corn variety developed by conventional breeding is available. The USDA APHIS (2006) document states, “For example, cultivars developed through conventional breeding derived from the recessive gene *opaque*‐2 also have high levels of lysine in the seed and are commercially available. However, in these cultivars, the lysine levels are higher in the endosperm, and not in the germ, as is the case in LY038 corn. The endosperm of *opaque*‐2 is softer than conventional dent corn making it more susceptible to damage during harvesting and cracking during drying. The soft, chalky endosperm can also result in greater susceptibility to ear and kernel rots in certain genetic backgrounds (Thomison, accessed 2005). The yields of *opaque*‐2 varieties have generally been lower than those of most popular conventional dent hybrids (Wright, 1987).”

**Mechanism of action – Lysine Maize (LY038):**
Monsanto (2004) petition states, "The mechanism of action for dihydrodipicolinate synthase (DHDPS; EC4.2.1.52) has been well characterized (Karsten, 1997). The DHDPS protein is a member of the lyase subfamily of pyruvate‐dependent class I aldolases (Lawrence *et al.*, 1997) found in a wide range of organisms including bacteria, rodents, and humans. The DHDPS enzyme mediates a critical rate‐limiting step in the lysine biosynthetic pathway that in maize is controlled by lysine feedback inhibition. The enzyme catalyzes the condensation of L‐aspartate‐4‐semialdehyde and pyruvate to form 2,3‐dihydrodipicolinate that is then converted to lysine through a series of subsequent enzymatic reactions. In contrast to the native maize DHDPS, the variant of this enzyme from *C. glutamicum* (cDHDPS) is less sensitive to lysine feedback inhibition."

The **cordapA** gene derived from *C. glutamicum*, encodes a dihydrodipicolinate synthase (DHDPS). In plants, this enzyme is the rate‐limiting step in lysine production as it is highly susceptible to lysine feedback inhibition. The bacterial DHDPS enzyme is >50 fold less sensitive than the plant enzyme, allowing the synthesis of lysine to continue even in the presence of high lysine levels (Monsanto 2004).

**Potential unintended phenotype:**
The only unusual observation was the appearance of a white‐leaf phenotype in LY038 corn in some field test locations. Monsanto (2004) noted that the white leaf phenotype occurred at a low frequency (the mean percentage of white leaf plants observed across the 3 sites with the highest percentage was only 7.3%, and that the phenotype has been observed in other high lysine expressing plant species). The white‐leaf phenotype occurs at germination and persisted only to the V2 stage (when the second collar appears on the second leaf). Although there were some minor differences observed in VT plant height and shelled grain yield for white leaf vs control plants (Monsanto 2004, Table VII‐8), this did not affect the overall growth and development on a whole plot bases across sites (Monsanto, Table VII‐7).

APHIS has reviewed the data in the petition related to this white‐leaf phenotype, and concurs with the petitioner that this phenotype would not contribute a negative impact on the environment, either through increased weediness or other effects on plant health. This is because the trait is only transiently expressed from germination up to the second leaf stage, and only under certain planting conditions.
The high lysine corn is compositionally equivalent to those of conventional maize except for the intended increase in grain lysine content and an associated increase in lysine-related catabolites, saccharopine and alpha-aminoadipic acid. However, based upon the history of exposure/consumption of these two metabolites, there is a reasonable certainty that these levels are not harmful to animal or human health (see FDA Biotechnology Notification File (BNF) No. 000087 2005).

**Current Events with cordapA gene**: As determined by ISAAA.org
http://www.isaaa.org/gmapprovaldatabase/gene/default.asp?GeneID=49&Gene=cordapA

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<thead>
<tr>
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<tr>
<td>Name: LY038</td>
<td>Mavera™ Maize</td>
</tr>
<tr>
<td>Code: REN-ØØØ38-3</td>
<td></td>
</tr>
<tr>
<td>Name: LY038 x MON810</td>
<td>Mavera™ YieldGard™ Maize</td>
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<tr>
<td>Code: REN-ØØØ38-3 x MON-ØØ81Ø-6</td>
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</table>

(18) GE genotype description

**Lysine Maize Construct**: Lysine maize LY038 was generated through application of techniques of modern biotechnology by integrating the cordapA coding sequence into the maize genome using a biolistic transformation system. The nucleotide sequence of cordapA isolated from Corynebacterium glutamicum encodes the lysine-insensitive dihydrodipicolinate synthase (cDHDPS) enzyme. The transcription of cordapA is under the control of the maize Glb1 promoter, which directs cDHDPS expression predominantly in the germ, resulting in accumulation of lysine in grain (Monsanto 2004).

**Description of the gene**: The cordapA gene introduced into the maize genome to produce LY038 (the corn line) encodes expression of the lysine-insensitive dihydrodipicolinate synthase (cDHDPS) enzyme. The nucleotide sequence of cordapA was isolated from Corynebacterium glutamicum and encodes the lysine-insensitive dihydrodipicolinate synthase (cDHDPS) enzyme (Bonnassie et al., 1990; Vauterin et al, 2000). The transcription of cordapA is under the control of the maize Glb1 promoter, which directs cDHDPS expression predominantly in the germ, resulting in accumulation of lysine in grain. The coding region from dihydrodipicolinate synthase (dapA) from C. glutamicum in the lysine biosynthetic pathway confers resistance to lysine feedback inhibition. (Monsanto 2004)

The 5.9 kb Xho I DNA fragment (Xho I 8722 to Xho I 5820) of PV-ZMPQ76 originally incorporated into the maize genome during the transformation process to create LY038 corn contained not only the codapA expression cassette, but also a nptII expression cassette that was flanked by loxP sites. Subsequent breeding of the transformed plant with a Cre recombinase-containing maize plant resulted in the excision of the nptII gene cassette. The circular nptII gene cassette as well as the Cre recombinase was further segregated through breeding, which resulted in LY038 in which the inserted DNA consists only of the cordapA gene cassette described below plus the single recombined lox-P 2/1 site (Monsanto Petition 2004).

An overview of the functional cordapA expression cassette sequences remaining in LY038 is given below:
- Ly0- Glb1 promoter, originating from Z. mays
- rAct1 intron, intron from the rice (Oryza sativa) actin gene: promotes transcription
- mDHDPS CTP, chloroplast targeting sequence from dihydrodipicolinate synthase (DHDPS) derived from Z. mays
**Lysine Maize OECD Unique Identifier:**
REN-ØØØ38-3

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**Plant context (7 questions)**

(19) **Plant history**

**GE information:**
Based on the cordapA gene (high Lysine expression), there is no change expected that would alter plant history.

The LY038 maize line containing the cordapA gene which produces high lysine predominately in the germ of the seed, resulting in accumulation of lysine in the grain.

---

**Baseline information:**
Zea mays ssp. mays is the only domesticated taxon in the genus Zea. There is no agreement about where exactly corn was domesticated and there are several proposals in this regard (see references in OECD, 2003). Matsuoka et al., (2002) concluded that "all maize arose from a single domestication in southern Mexico about 9,000 years ago." It is thought to have been first introduced and cultivated in the U.S. in what is now New Mexico and Arizona by 2100 BC (Merrill et al, 2009). In the U.S., corn is grown as an annual row crop. It is the most widely produced feed grain in the United States and is processed into a wide range of food, feed and industrial products including fuel ethanol (USDA, ERS, 2013b). All parts of the corn kernel and stalk are used. Stalks are made into paper and wallboard; husks are used as filling material; cobs are used for fuel, to make charcoal, and in the preparation of industrial solvents.

There are several types of corn grown in the U.S., with the major types including field corn, sweet corn, and popcorn. All can naturally outcross with each other (Iowa State, 2014). Field corn (also known as dent corn or simply, corn) occupies the majority of the corn acres in the United States, with 93.6 million acres planted in 2007. Of this, 42% went to animal feed, 22% to produce ethanol, 17% to export, 9% for domestic food uses, and 10% surplus (Iowa State, 2014). Sweet corn was grown on approximately 380,000 acres nationwide in 2007, with the crop used as corn on the cob or for processing as canned or frozen corn (Iowa State, 2014). Popcorn is grown on less than 1 percent of the harvested corn acres (Duffy & Calvert, 2010) and in 2012 shelled popcorn was grown on over 218 thousand acres (USDA-NASS Quick Statistics, 2015). Most corn produced in the U.S. today is genetically engineered (USDA-ERS, 2014b; USDA-NASS, 2014). In 2014, herbicide tolerant (HT) corn was grown on 89 percent of U.S. corn acreage and Bt corn was grown on 80 percent of U.S. corn acreage (USDA-ERS, 2014b). Accordingly, 76 percent of all U.S. corn acreage was planted to HT/Bt stacked corn (USDA-ERS, 2014b).

(20) **Plant biology and ecology**

**GE information:**
Data collected and documented in this WRA demonstrates that the high expression of Lysine (an amino acid) results in no change in the basic plant biology and ecology of corn.
The results of no change in the basic plant biology and ecology of corn is documented in the Monsanto (2004) petition by (Tables VII-5, -6, -7, -9, and -10) on phenotypic growth characteristics and insect, disease, and abiotic stress response comparisons.

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**Baseline information:**
Zea mays is a robust monoecious annual plant (Cornell, 2006; OECD, 2003) in the Poaceae (grass) family (ITIS, 2015). Under natural conditions, corn reproduces only by seed (CERA, 2002; OECD, 2003) and requires human assistance (as discussed in question B01) to disperse its seeds for propagation and survival (OECD, 2003). Corn "is the most efficient plant for capturing the energy of the sun and converting it into food, it has a great plasticity adapting to extreme and different conditions of humidity, sunlight, altitude, and temperature" (OECD, 2003).

"The flowering stage in corn, which involves pollen shed and silking, is the most critical period in the development of a corn plant from the standpoint of grain yield determination" (Ohio State Extension, 1995). "Pollen shed usually begins two to three days prior to silk emergence and continues for five to eight days with peak shed on the third day" (Ohio State Extension, 1995). Normally, about 95% of the ovules in an ear are cross-pollinated and 5% are self-pollinated (Poehlman, 1995; Ohio State Extension, 1995), although plants are completely self-compatible (CERA, 2002). Pollen grains can survive for only 18-24 hours under favorable conditions (Ohio State Extension, 1995).

The critical soil moisture for seed germination to occur is 30% (Copeland, 1975 as referenced by Johnson, 2013). The temperature for seed germination is a minimum of 46°F with the optimum temperature 86°F (Isleib, 2012). Planting should not occur before soil temperatures are near 50°F (Johnson, 2013). At 50°F corn will take approximately 25 days to emerge; at 55-60°F corn will take 10-14 days to emerge; at 65-70°F corn only takes five to eight days to emerge (Meyer, 2011). "The energy storage structures of the seed remain below ground when the seed germinates" (Johnson, 2013).

"Corn prefers full sun and fertile, well drained soil for maximum yield" (Drost, 2010; Wright, n.d.) "with a pH from 5-8, (but 5.5-7 is optimal)" (CABI, 2012) and with "regular watering, so maintain soils near field capacity" (Drost, 2010). Corn is a heavy feeder - particularly of nitrogen - and may require several applications of fertilizer for best yields (Cornell, 2006).

There are many weeds of corn in the U.S. such as lambsquarters, pigweed, morninglory, panicum, foxtail, switchgrass, quackgrass, Johnsongrass, and Canada thistle (Bennett, 2003; Dow AgroSciences, 2009). The most common insect pests attacking the corn seed are the seedcorn maggots, wireworms, and seedcorn beetles. Wireworms and white grubs attack the corn root system throughout the growing season and may be found in the soil at any time of the year. Rootworms feed on the plant roots from mid season to late mid season. Billbugs, chinch bugs and black cutworms feed on the lower portion of the stem (Flanders et al., 2013). Common diseases include Stewart's bacterial wilt, Corn smut, Southern corn leaf blight, Grey leaf spot, Crazy top disease, Maize Streak Virus (MSV), and Maize Dwarf Mosaic Virus (MDMV) (Guantai et al., 2010).

(21) Agronomic practices

**GE information:**
Based on the *cordapA* gene (high Lysine expression), there is no change expected that would alter the agronomic practices used in corn cultivation.

However, according to the Monsanto petition (2004) one exception is that the harvested grain will need to be identity preserved to allow capture of the increased animal feed value resulting from the increased lysine content for this grain product as compared to conventional commodity maize grain.
According to the FDA, lysine is generally recognized as safe (GRAS) for use in animal diets. The FDA has determined that the essential amino acid, lysine, when added to animal diets at nutritional levels, is Generally Recognized As Safe (GRAS) (21 CFR 582.5411) and may be used safely as a human food additive when provided at nutrient levels (21 CFR 172.320). The FDA has assessed the Monsanto LY038 corn line (FDA (BNF) 000087, 2005) and agreed that maize event LY038 is not materially different in composition, safety, or any other relevant parameter from maize now grown, marketed, and consumed in the U.S., with the exception of the intentionally-increased lysine content in the grain. FSANZ (2006) also concluded that any potential consumption of LY038 corn by humans will not adversely affect the overall quality of protein/amino acid, vitamin, mineral, fat or fiber intakes of Australian and New Zealand populations.

Baseline information:
Corn is grown from seed. "The goal at planting time is to establish the highest population per acre that can be supported with normal rainfall without excessive lodging, barren plants, or pollination problems" (Nafziger, 2014). Nitrogen fertilizer are usually added to the soil and weed and insect control are commonly used (CIFA, 2014). When actively growing, corn obtains 90 percent of the water it uses from the top 3 feet of the soil profile (Rhoads & Yonts, 1991). Corn producers must supplement rainfall with irrigation to meet crop water needs (Farahani & Smith, 2014). "Supplemental irrigation minimizes crop water stress due to inadequate and/or untimely rainfall during the season" (Farahani & Smith, 2014). Several types of tillage are used in corn fields (University of Wisconsin, 2012): 1) Conservation tillage (e.g. no-till, ridge-till, mulch till, zone-till, strip-till), which leaves 30% or more crop residue in the field. 2) Reduced till, which leaves 15 - 30% crop residue in the field. 3) Conventional-till (e.g. mold-board plowing), which leaves less than 15% residue but leads to soil erosion and greater labor and fuel costs" (CIFA, 2014). Organic production practices are increasing, from 130,672 corn acres planted in 2005 to 234,470 corn acres in 2011 (USDA-ERS, 2013a).

Management practices

GE information:
Based on the cordapA gene (high Lysine expression), there is no change expected that would affect the ability to control volunteer corn in typical rotation crops (e.g., soybean). Therefore, no change to Management practices.

Data provided in the petitions indicated no differences in weediness potential as measured by differences in seed germination, dormancy, seedling vigor, dropped ears, root lodging, plant emergence (early stand count), plant height, ear height, stalk lodging, and yield (Monsanto 2004 - Tables VII-3, VII-5 and VII-7).

Furthermore, although seed over-wintering capacity was not measured, data provided in the Monsanto petition (2004), indicated that enhanced expression of lysine resulted in no differences in germination and seed dormancy characteristics under five temperature regimes (including optimal, low and high temperature regimes) (Monsanto 2004 - Table VII-3) or other characteristics that would alter the prevalence of volunteer maize in subsequent growing seasons.

Following-season maize volunteers producing high lysine would not be expected to present any unusual weed management challenges and can be dealt with in the same manner as conventional volunteers of maize (Monsanto 2004; OECD 2003; USDA-APHIS 2006).

Volunteers are easily controlled through tillage or use of appropriate herbicides (Monsanto 2004). Pre-plant tillage or in-crop cultivation is very effective in managing volunteer maize in subsequent crops. For instance, the appearance of corn seedlings in soybean fields following a corn crop is a common occurrence. Manual or chemical measures are often applied to remove these volunteers, but the plants that are not removed do not
typically result in feral populations in following years.

-----

**Baseline information:**
The presence of corn in soybean fields following the corn crop from the previous year is a common occurrence (Purdue, 2011; University of Minnesota, 2013; Hartzler, 2012). Volunteer corn may reduce yields, cause harvest problems, reduce soybean seed quality, and decrease the overall aesthetics of the field (Purdue, 2011; University of Minnesota, 2013). For example, researchers at South Dakota State University found that populations of volunteer corn ranging from 800 to 13,000 plants per acre resulted in yield losses of 0 to 54% in soybean and 0 to 13% in corn. Nebraska researchers also found that volunteer clumps were more competitive than individual plants. In soybean, 3,500 clumps of corn per acre reduced yield 40% while the same population of individual plants reduced yield 10% (University of Minnesota, 2013).

"Measures are often taken to either eliminate the plants with the hoe or use of herbicides to kill the plants in soybean fields, but the plants that remain and produce seed usually do not persist during the following years". (OECD, 2003). "Tillage provides immediate results and require more time relative to using burndown herbicides" (Martin, 2012). There are many reasons not to use tillage such as increased erosion and the possibility that by any remaining seed may germinate (Martin, 2012). The most common method of controlling volunteer corn is chemical application. Some of the chemicals (grass herbicides) used for volunteer corn control are glyphosate, glufosinate-ammonium, quizalofop, fluazifop, fluazifop + fenoxaprop, and sethoxydim (University of Nebraska, 2015). Most pre-emergence grass herbicides used in soybean will only partially control volunteer corn (Young & Hart, 1997). "Grass herbicides can't be used in-crop in a hybrid corn field for control of volunteer corn" (University of Nebraska, 2015).

(23) Current U.S. geographic distribution

**GE information:**
The *cordapA* gene inserted (high Lysine expression) in corn varieties is unlikely to alter the potential geographic distribution of corn to novel areas where corn could not previously be cultivated since it is not intentionally altered for any abiotic stress tolerances.

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**Baseline information:**
Corn is grown throughout the contiguous United States (see map attached). Most areas have a wide distribution of corn. The only areas where corn is grown sparsely are shorelines, mountain chains, alpine areas (growing in the biogeographic zone including the elevated slopes above timberline) and deserts. Hawaii and Puerto Rico both report some corn production in 2012.

Six states are responsible for more than 60% of corn planted and harvested in 2014 (Illinois, Indiana, Iowa, Minnesota, Nebraska and South Dakota) with 55 million acres out of the 90.5 million acres planted/harvested in the United States (USDA-NASS Quick Statistics, 2014; see attached table below).

There have been no reports of corn being naturalized, weedy or invasive in the United States. Corn cannot exist outside of cultivation and is and can not exist as a wild plant in its present form (OGTR, 2008; Gibson et al., 2002; OECD, 2003; CFIA, 2014).
(24) Plant hardiness and precipitation zones

Plant hardiness zones (Temperature range)

1 (-60 to -50 F)
   Presence  no  Certainty Very high
   Cultivation only

2 (-50 to -40 F)
   Presence  no  Certainty Very high
   Cultivation only

3 (-40 to -30 F)
   Presence  no  Certainty Very high
   Cultivation only

4 (-30 to -20 F)
   Presence  no  Certainty Very high
   Cultivation only

5 (-20 to -10 F)
   Presence  no  Certainty Very high
   Cultivation only

6 (-10 to 0 F)
   Presence  no  Certainty Very high
   Cultivation only

7 (0 to 10 F)
   Presence  no  Certainty Very high
   Cultivation only

8 (10 to 20 F)
   Presence  no  Certainty Very high
   Cultivation only
9 (20 to 30 F)
  Presence no  Certainty Very high
Cultivation only

10 (30 to 40 F)
  Presence no  Certainty Very high
Cultivation only

11 (40 to 50 F)
  Presence no  Certainty Very high
Cultivation only

12 (50 to 60 F)
  Presence no  Certainty Very high
Cultivation only

13 (60 to 70 F)
  Presence no  Certainty Very high
Cultivation only

Precipitation zones (Precipitation range)

1 (0 to 10 inches)
  Presence no  Certainty Very high
Cultivation only

2 (10 to 20 inches)
  Presence no  Certainty Very high
Cultivation only

3 (20 to 30 inches)
  Presence no  Certainty Very high
Cultivation only

4 (30 to 40 inches)
  Presence no  Certainty Very high
Cultivation only

5 (40 to 50 inches)
<table>
<thead>
<tr>
<th>Presence</th>
<th>Certainty</th>
<th>Height Range</th>
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<td>6 (50 to 60 inches)</td>
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<tr>
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<td>Very high</td>
<td>7 (60 to 70 inches)</td>
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<tr>
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<td>Very high</td>
<td>8 (70 to 80 inches)</td>
</tr>
<tr>
<td>no</td>
<td>Very high</td>
<td>9 (80 to 90 inches)</td>
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<td>10 (90 to 100 inches)</td>
</tr>
<tr>
<td>no</td>
<td>Very high</td>
<td>11 (100+ inches)</td>
</tr>
</tbody>
</table>

(25) Potential U.S. geographic distribution

**GE Information:**
The *cordapA* gene inserted (high Lysine expression) in corn varieties will not alter the current U.S. geographic distribution of currently existing corn since it is not intentionally altered for any abiotic stress tolerances.

------

**Baseline information:**
There are no reports of naturalized or invasive corn in the literature. Volunteers are not considered weeds for the purpose of this risk assessment.

Twenty two references from Randall's 2012 book "Global Compendium of Weeds, 2nd edition", were located and reviewed (See attached chart below). Many references were charts with abbreviations that do not explain the status of *Zea mays* in their country but none called *Zea mays* a weed. The references either do
not say that corn is naturalized or do not provide enough information to verify that *Zea mays* is naturalized in their country.

### Weed Risk Questions (25)

#### Weed risk - Biology (16 questions)

(B01) Current weed and invasive status

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>GE risk</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline certainty</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high</td>
<td>Very high</td>
</tr>
</tbody>
</table>

(B01) Current weed and invasive status - Risk documentation

**GE Information:**
The *cordapA* gene inserted (high Lysine expression) in corn varieties will not alter the **Negligible** risk rating of the current weed and invasive status of currently existing corn.

There is no indication that corn containing the *cordapA* gene possesses a selective advantage that would result in increased weediness (Monsanto 2004, USDA-APHIS 2006). The high Lysine expression corn was field tested in 2002 - 2003 and deregulated by USDA-APHIS in 2006. Thus far, in this limited time, there have been no reports of this GE corn becoming invasive, weedy, naturalized casual or escaped anywhere in the United States.

---

**Baseline information:**
Corn has been cultivated for over 100 years and "early as 1880, the United States grew over 62 million acres of corn" (Gibson *et al.*, 2002). Corn has become completely dependent of human intervention to grow and survive (Andersson & de Vicente, 2010; Doebley, 2004; OECD, 2003; OGTR, 2008; Owen, 2007). "Corn is unknown in the wild" and several traits selected during domestication "are not only individually non-adaptive in the wild, but their total combination is lethal to survival in the wild" (Galinat 1988). Corn also needs human intervention to disseminate its seed (OECD, 2003; Owen, 2007). Corn can be found on roadides and wastelands next to corn fields but is incapable of sustained reproduction outside of domestic cultivation (Gould, 1968). Although unharvested corn can overwinter and germinate the following year, and thus may volunteer in subsequent crops (Purdue, 2011; University of Minnesota, 2013; Hartzler, 2012), it cannot persist as a weed and volunteers are not considered weeds in this WRA. There is no indication that corn has great potential for ferality (Owen, 2007).

Twenty-two references from Randall's book, *Global Compendium of Weeds* (2012) were reviewed to determine whether *Zea mays* ssp. *mays* is actually a weed as proposed by Randall. The geography covered by these references include many countries in Europe, China, Taiwan, Australia, New Zealand and Ethiopia.

- Five sources said that *Zea mays* L. can escape from cultivation but some stated that corn can not survive as an escape.
- New Zealand said it can escape right next to its cultivated parent plant.
- Nine sources called it an alien, casual, exotic or non-native plant. Insufficient information is provided within these references to determine if corn is an occasional escape. The information was
presented in tables that just said "alien", "non-native", etc.

- The remaining seven references called it an agricultural crop or never mentioned *Zea mays* L. at all.
- There are 57 total references for *Zea mays* L. and four for *Zea mays* L. subsp. *mays* listed in Randall with 2 of the references being copies, for a total of 59 references. After an extensive search, the other 27 references could not locate the to verify the reports.

A Negligible risk rating is supported by the evidence above: 1) corn has been cultivated for well over 100 years, 2) the domestication of corn has made it dependent on human intervention and 3) when a corn plant is found outside a cultivated field it cannot sustain itself or reproduce without human intervention.

**(B01) Current weed and invasive status – Certainty documentation**

**GE information:**
Based on the *cordapA* gene (high Lysine expression) in corn varieties, there is no change expected that would alter the **Very high** certainty rating of the current weed and invasive status of corn.

There is no change in the GE certainty score from the baseline certainty score.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and one secondary source (USDA-APHIS 2006). The reliability and applicability ratings for the two sources are as follows: Monsanto’s petition (Very High and Very High, respectively) and the USDA-APHIS (Very High and Very High, respectively).

-----

**Baseline information:**
Andersson & de Vicente, 2010- High reliability; High applicability
Doebley, 2004- High reliability; Very High applicability
Galinat 1988- High reliability; High applicability
Gibson et al, 2002- Moderate reliability; High applicability
Gould, 1968- Moderate reliability; Moderate applicability
OECD, 2003- High reliability; High applicability
OGTR, 2008- High reliability; High applicability
Owen, 2007- High reliability; Moderate applicability

Based on the consensus of the references a Very High level of certainty is assigned.

**(B02) Weedy and invasive relatives**

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>Negligible</th>
<th>GE risk</th>
<th>Negligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline certainty</td>
<td>High</td>
<td>GE certainty</td>
<td>High</td>
</tr>
</tbody>
</table>

**(B02) Weedy and invasive relatives – Risk documentation**

**GE Information:**
N/A. This question is only applicable to the baseline. Therefore the GE risk rating remains unchanged from the **Negligible** baselinerisk rating of weedy and invasive relatives of corn.

-----

**Baseline information:**
Relatives of *Zea mays* ssp. *mays* (*Zea mays* ssp. *mexicana* and other teosintes) are reported as weedy even though they have not become established in the United States (USDA-NRCS, 2005). *Zea mays* L. ssp. *mexicana* is considered a troublesome weed of corn fields in central Mexico (Doebley, 2003; USDA NAL, 2012).
However, corn (*Zea mays* ssp. *mays*) is highly domesticated (Warwick & Stewart, 2005; Tian, et al., 2009). Many of the traits that lead to weediness in plants are absent in corn. For example, corn has limited ability to compete with other plants (Steinhardt *et al.*, 2002), lacks shade tolerance (Earley *et al.*, 1965) and depends on intentional human intervention to grow and survive, as discussed in question B01 (Andersson & de Vicente, 2010; Doebley, 2004; OECD, 2003; OGTR, 2008; Owen, 2007). Domestication involved a radical phenotypic transformation from the wild progenitor, *Zea mays* ssp. *parviglumis* resulting in an unbranched plant with seed attached to a cob and thereby making maize entirely dependent on humans for propagation (Hufford, 2012b and as discussed in question B01).

Based on the high domestication of corn in the United States a Negligible risk rate is given.

**B02) Weedy and invasive relatives – Certainty documentation**

**GE information:**

N/A. This question is only applicable to the baseline. Therefore the GE certainty rating remains unchanged from the High baseline certainty rating of weedy and invasive relatives of corn.

-----

**Baseline information:**

Andersson & de Vicente, 2010- High reliability; High applicability

Doebley, 2004- High reliability; Very High applicability

Doebley, 2003- High reliability; Very High applicability

Earley *et al.*, 1965- High reliability; High applicability

Hufford *et al.*, 2012b- High reliability; High applicability

OECD, 2003- High reliability; High applicability

OGTR, 2008- High reliability; High applicability

Owen, 2007- High reliability; Moderate applicability

Steinhardt *et al* 2002- Moderate reliability; Moderate applicability

Tian, et al 2009- High reliability; Moderate applicability

USDA NAL, 2012- High reliability; High applicability

USDA-NRCS, 2005- High reliability; Very high applicability

Warwick & Stewart- High reliability; Moderate applicability

Based on the consensus of the references a High level of certainty is assigned.

**B03) Ability to establish**

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>GE risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline certainty</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate</td>
<td>Moderate</td>
</tr>
</tbody>
</table>

**B03) Ability to establish – Risk documentation**

**GE Information:**

Based on the *cordapA* gene (high Lysine expression) in corn varieties, there is no change expected that would alter the Low risk rating of the ability of corn to establish.

This reasoning is based off of the inability of conventional corn to establish in undisturbed environments (Gould 1968; Steinhardt *et al.* 2002; OECD 2003). Corn is grown throughout the world without any report that it is a serious weed or that it forms persistent feral populations (Gould 1968). The data submitted by Monsanto (2004) for LY038 corn (*cordapA* gene (high Lysine expression)) do not indicate that hybrids derived from the modified corn line would be any more competitive or vigorous in their ability to germinate or establish in different environments or reproduce or have other characteristics that would increase their capacity to compete or...
The data submitted for corn containing the *cordapA* gene (high Lysine expression) do not show dramatic differences or biologically meaningful increases in final stand counts or early emergence vigor of the LY038 compared to non-LY038 maize in field trials assessing agronomic characteristics in different locations (Monsanto petition 2004, Tables VII-5 and VII-7, pp 84 and 88) or in percent germination experiments under different conditions (Monsanto petition 2004, Table VII-3, p79). However, there was no data provided on establishment in competition with other vegetation that could be used to support a risk rating higher than the rating for the baseline WRA.

---

**Baseline information:**

Corn can be planted in stubble but does not compete well with other plants and should not be planted into living plants because it creates too much competition for small corn plants in terms of available soil moisture and light for early growth. (Steinhardt *et al.*, 2002). Corn is an extremely heavy feeder, especially on nitrogen (Cornell, 2006) but human management practices can supply nitrogen in cultivated fields. Its ability to occasionally grow in uncultivated fields and by roadsides and to volunteer in subsequent cultivated crops (Gould, 1968; OECD, 2003) suggests it may have a minor ability to establish in existing vegetation. Most seed corn has a germination rate of 95% or higher but can vary considerably depending on planting conditions (Thomison, 2010).

In 2007, Monsanto field trials in which corn seed was planted to assess corn's survival outside of cultivation were planted in four different locations:

- **IL study** was agricultural land that had been converted to conservation land, was left fallow for two years, with a mix of native grasses, forbs, and weeds with an estimated ground cover of 60%. Early stand count 50 – 100%.
- **MO study** was agricultural land that was adjacent to a lake and consisted of annual grasses, broadleaf weeds, and volunteer wheat with an estimated ground cover of 98%. In the last two years the land had been cultivated with soybean (2006) and winter wheat (2005-2006). Early stand count 50 – 100%.
- **NE** was adjacent to agricultural land and contained a mixture of weeds with an estimated ground cover of 25%. The area was usually not used for crop production. Early stand count 1%.
- **TX study** was in a pasture of native grasses with an estimated ground cover of 85%. There were no (0%) early stands.

Since the Monsanto MO and IL sites had the highest estimated ground cover in which corn plants established, the risk assignment will be based on their data along with the other references. Monsanto does not explain how the percent ground cover was assessed. The MO site was highly disturbed in that it had experienced only a short growing season before the establishment of the experimental seedlings on May 29, 2007 but presumably they sowed an annual grass cover crop on the site earlier in spring 2007, which would be the usual practice for soil stabilization if the field was to remain fallow for the season, or perhaps in this case, was converted to be used for this experiment. Thus the MO site would have had recently planted vegetative cover that would be “very young” and the ground would be highly disturbed at planting time. In IL, the that the plants grew poorly, as reflected by their very short height (7 – 10 inches) at the late vegetative stage, while typically a corn plant in cultivated fields will be from 30 – 80 inches tall at V10 (Yin *et al.*, 2011; Freeman *et al.*, n.d.). The IL site best corresponds to Low risk because it was very open with little competition for other plant taxa and appeared to be highly disturbed (only 60% ground cover after two years left fallow).

Based on the above, a low risk rating is assigned.

**(B03) Ability to establish – Certainty documentation**

**GE information:**
Overall, the weight of evidence supports a certainty rating of **Moderate**.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and four secondary sources. (USDA-APHIS 2006; Steinhardt 2002; OECD 2003; and Gould 1968).

The reliability and applicability ratings for the five sources are as follows: Monsanto's petition (High and High, respectively); the USDA-APHIS (high and moderate, respectively); one University Extension report (Steinhardt et al. 2002; Moderate and High, respectively); one highly-cited government organization report (OECD 2003; High and High, respectively); and one book on grasses (Gould 1968; High and Moderate, respectively).

**Baseline information:**
Steinhardt *et al* 2002- Moderate reliability; High applicability
Cornell, 2006- Moderate reliability; Moderate applicability
Gould, 1968- High reliability; Moderate applicability
OECD, 2003- High reliability; High applicability
Thomison, 2010- Moderate reliability; High applicability
Monsanto 2009- High reliability; High applicability
Yin *et al*., 2011- High reliability; High applicability
Freeman *et al*., n.d- High reliability; Moderate applicability

A Moderate rating is being assigned because so many references are either moderate reliability or moderate applicability and the Monsanto reference is ambiguous about how ground cover was assessed.

**Baseline certainty**

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>Negligible</th>
<th>GE risk</th>
<th>Negligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline certainty</td>
<td>Very high</td>
<td>GE certainty</td>
<td>Very high</td>
</tr>
</tbody>
</table>

**GE Information:**
Based on the *cordapA* gene (high Lysine expression) in corn varieties, there is no change expected that would alter the **Negligible** risk rating of the ability of corn to form dense thickets or monospecific stands.

This reasoning is based off of the inability of conventional corn to form dense thickets or monospecific stands (e.g. increased tillering, rhizomes or stolons, alleleopathy) (see baseline corn description), coupled with no biologically meaningful differences in growth/development between *cordapA* gene (high Lysine expression) corn varieties and conventional corn (Monsanto 2004 - Tables VII-5 and VII-7; USDA-APHIS 2006).

Morphological characteristics associated with the ability of some weeds to form dense thickets or monospecific stands (e.g. increased tillering, rhizomes or stolons, alleleopathy) are not characteristic of corn and therefore were not directly assessed, but had they been observed, would likely have been noted in the petitions.

There is no plausible risk hypothesis to justify that the GE trait would influence the ability of corn to form dense thickets or monospecific stands without human assistance.

**Baseline information:**
The goal of corn in agriculture is to "establish the highest population per acre that can be supported with normal rainfall without excessive lodging, barren plants, or pollination problems" (Nafziger, 2014). Since corn cannot grow without intentional human assistance (as discussed in question B01) (Morgenstern, 2007), except for sporadic escapes, the chance of wild thickets/monospecific stands is Negligible.
**GE Information:**

Overall, the weight of evidence supports a certainty rating of **Very high**.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and one secondary source (USDA-APHIS 2006).

The reliability and applicability ratings for the two sources are as follows: Monsanto's petition (High and Moderate, respectively) and the USDA-APHIS (High and Moderate, respectively). The moderate applicability rating is justified because since the growth and development data analyzed for the GE corn and its comparators did not directly measure dense or monospecific stands in the absence of human assistance. Additionally, certainty regarding the inability of conventional corn to form dense thickets or monospecific stands outside of cultivation is based on common knowledge of a well-studied, domesticated crop plant, and there is no plausible risk hypothesis upon which the GE trait would affect this.

-----

**Baseline Information:**

Morgenstern, 2007- Moderate reliability; Very high applicability
Nafziger, 2014- High reliability; Moderate applicability

Corn is a domesticated crop that has never shown monospecific stands except during cultivation. Based on the references and because it is so widely cultivated and studied, a Very High certainty rating was given for this question.

---

**Baseline Risk**

Negligible

**GE Risk**

Negligible

**Baseline Certainty**

Very high

**GE Certainty**

Very high

---

**Shade Tolerance**

**GE Information:**

Based on the engineered trait in *cordapA* gene (high Lysine expression) in corn varieties, there is no change expected that would alter the **Negligible** shade tolerance rating of conventional corn.

This reasoning is based off of the inability of conventional corn to fully produce under shade conditions (see baseline corn description), coupled with no biologically meaningful differences in growth/development between *cordapA* gene (high Lysine expression) corn varieties and conventional corn (Monsanto 2004-Tables VII-5 and VII-7; USDA-APHIS 2006). The Monsanto (2004) studies on growth/development were not designed to evaluate shade tolerance. Conventional and GE corn prefer full sun and will not produce much corn under shade conditions.

There is no plausible risk hypothesis to justify that the GE trait would influence shade tolerance in corn.

Maize has been studied for the shade avoidance response and that it can be triggered by the presence of weeds prior to direct competition and has long-lasting effects on the growth and development of maize plants (Rajcan et al. 2004; Page et al. 2010, 2011). Maize plants that expressed shade avoidance set fewer kernels per plant; partitioned less biomass to the ear; and had increased plant-to-plant variability in time to silking, kernels per plant and harvest index (grain/shoot biomass) without impacting the mean or frequency distribution of plant size at maturity; and suggest that there is an association with tolerance of plant competition during early stage growth (Page et al. 2010). The above studies were not designed to evaluate shade tolerance only for shade avoidance response.
Baseline Information:
All corn prefers full sun and fertile, well-drained soil for maximum yield (Tropical Forages, 2005; Drost, 2010). Corn grows in areas that allow for full sunshine since shade will not produce much corn (Mierzejewski, 2015). There was a significant decrease in measured components (grain, stover, total protein, total oil, etc.) as light was decreased and a reduction of light by even 30% caused a decrease in production of plant material (Earley et al., 1965). Kiniry and Ritchie (1984) did a shade tolerance experiment that measured effect of kernel number as it is related to what stage the corn plant was at during short-term shading. They concluded that shade does decrease kernel number but shade during the crucial early kernel development, occurring near the end of the lag period of grain filling, was the most sensitive period for shade intolerance (Kiniry & Ritchie, 1984). If you can get light to the bottom of the canopy, especially during critical grain fill periods of growth in corn or soybeans, you can increase seed weight and you can increase yield significantly” (Roberson, 2014). Because corn can is so widely cultivated and studied, lack of specific evidence for shade tolerance in corn likely means that corn is not shade tolerant. Therefore, a Negligible rating was given.

(B05) Shade tolerance – Certainty documentation
GE information:
Overall, the weight of evidence supports a certainty rating of Very high.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and four secondary sources (Rajcan et al. 2004; Page et al. 2010, 2011; and USDA-APHIS 2006). The reliability and applicability ratings for the sources are as follows: Monsanto’s petition (High and Moderate, respectively) and the USDA-APHIS (High and Moderate, respectively); three articles (Very High and Moderate, respectively). The moderate applicability rating for the Monsanto and USDA-APHIS citations is justified since the growth and development data analyzed for the GE corn and its comparators did not directly measure shade tolerance.

Additionally, certainty regarding the inability of conventional corn to fully produce under shade conditions is based on common knowledge of a well-studied, domesticated crop plant, and there is no plausible risk hypothesis upon which the GE trait would affect this.

Baseline Information:
Drost, 2010- Moderate reliability; High applicability
Earley et al, 1965- Very High reliability; Very High applicability
Mierzejewski, 2015- Moderate reliability; High applicability
Roberson, 2014- Moderate reliability; Moderate applicability
Tropical Forages, 2005- High reliability; High applicability

Because no evidence was found that corn can tolerate shade and because it is so widely cultivated and studied, a Very High certainty rating was given.

(B06) Life form and growth habit
Baseline risk Very high GE risk Very high
Baseline certainty Very high GE certainty Very high

(B06) Life form and growth habit – Risk documentation
GE information:
Based on the cordonA gene (high Lysine expression) in corn varieties, there is no change expected that would alter the Very high rating of conventional corn.
This reasoning is based off the fact that there are no biologically meaningful differences in growth/development between cordapA gene (high Lysine expression) corn varieties and conventional corn (Monsanto 2004, USDA-APHIS 2006).

Conventional and GE corn are members of the Maydeae tribe of the grass family, Poaceae (see below). -----

**Baseline Information:**
"Maize, or corn, is a member of the Maydeae tribe of the grass family, Poaceae" (OECD,2003; USDA-NRCS, 2015b). A very High risk rating is assigned on this risk trait.

(B06) Life form and growth habit – Certainty documentation

**GE information:**
Overall, the weight of evidence supports a certainty rating of Very high.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and one secondary source (USDA-APHIS 2006). The reliability and applicability ratings for the two sources are as follows: Monsanto's petition (High and High, respectively) and the USDA-APHIS (High and High, respectively).

Since the determining factor affecting the risk rating is that corn is a grass (with or without this trait) the certainty rating remains unchanged from the baseline.

-----

**Baseline Information:**
OECD, 2003- High reliability; Very high applicability
USDA-NRCS 2015b- High reliability; Very high applicability

Based on the reliability/applicability of the above references and because it is so widely cultivated and studied, a Very High certainty rating was given.

(B07) Time to reproductive maturity

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>GE risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
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</table>

<table>
<thead>
<tr>
<th>Baseline certainty</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high</td>
<td>Very high</td>
</tr>
</tbody>
</table>

(B07) Time to reproductive maturity – Risk documentation

**GE information:**

Based on the cordapA gene (high Lysine expression) in corn varieties, there is no change expected that would alter the High rating for the time to reproductive maturity of corn.

This reasoning is based off of the well-known time to reproductive maturity of conventional corn (OECD 2003; OGTR 2008), coupled with an absence of substantial differences in agronomic attributes that measure time to reproductive maturity, such as germination, dormancy, days to 50% pollen shed, and days to 50% silking between cordapA gene (high Lysine expression) corn varieties and conventional corn (Monsanto 2004, USDA-APHIS 2006).

Monsanto (2004) submitted data on the following evaluated traits: germination results for LY038, LY038(-) and reference seed (Table VII-3, p 79) to seedling vigor, early stand count, days to 50% pollen shed, days to 50% silking, plant height, and yield (Table VII-5 and Table VII-7, pp 84 and 88). All the Monsanto (2004) field trials, from planting to harvest, were conducted within one growing season, indicating no change in the risk rating.

The traits were assessed by the USDA-APHIS (2006) and conventional corn compared to corn with the cordapA gene (high Lysine expression) had no measurable differences in attributes (e.g. timing of pollen shed or silking, plant height, etc.) (Monsanto 2004, USDA-APHIS 2006).
Baseline Information:
Corn is an annual (OECD, 2003; CABI, 2012; OGTR, 2008). "Corn can take from 60 to 100 days to reach harvest depending upon variety and the amount of heat during the growing season" (Albert, 2015). Corn takes a whole growing season to reach reproductive maturity thus it also has only one generation per year, except in tropical and subtropical climates where corn can be grown throughout the year with human intervention (as discussed in question B01). Corn must reach maturity before the first autumn freeze which is closely related to the normal corn crop growing season across the U.S Corn Belt. Therefore more than one generation per year is not possible (Neild and Newman, 1990), and a High risk rating is given to this question.

(B07) Time to reproductive maturity – Certainty documentation

GE Information:
Overall, the weight of evidence supports a certainty rating of Very High.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and three secondary sources (USDA-APHIS 2006, OECD 2003; and OGRT 2008). Since the primary source provides direct data on corn with the GE trait, it justifies a Very High rating. Even though the data is based on planted field trials, there is evidence to support that volunteer corn with the GE trait would take more than 1 year to reach maturity or that multiple generations per year would be possible.

The reliability and applicability ratings for the four sources are as follows: Monsanto’s petition (Very High and Very High, respectively); the USDA-APHIS (High and Very High, respectively); one highly-cited government organization report (OECD 2003; High and Moderate, respectively); and one Australian government OGTR report (High and Moderate, respectively).

-----

Baseline Information:
Albert, 2015- Low reliability; Moderate applicability
CABI, 2012- High reliability; Moderate applicability
Neild and Newman, 1990- Moderate reliability; High applicability
OECD, 2003- High reliability; Moderate applicability
OGTR, 2008- High reliability; Moderate applicability

Based on common knowledge gained over centuries of cultivation and because the references all agree and corn does not grow without intentional human assistance (as discussed in question B01), a Very High certainty rating is assigned.

(B08) Propagule dispersal

Baseline risk Negligible GE risk Negligible
Baseline certainty Very high GE certainty High

(B08) Reproductive potential – Risk documentation

GE Information:
Based on the cordapA gene (high Lysine expression) in corn varieties, there is no change expected that would alter the Negligible risk rating of the reproductive potential of corn.

As a highly domesticated crop, corn has lost the ability to reproduce without human intervention.

Moreover, no data exists on the cordapA gene (high Lysine expression) transgenic corn being grown outside of cultivation. According to Gould (1968), modern day maize cannot survive outside of cultivation. When analyzed
together, the indirect data generated in in lab tests or intentionally planted and managed agricultural fields on germination or early emergence (seedling vigor and early stand count) combined with seed production parameters as determined by yield and test weight of the grain (Monsanto 2004 - Tables VII-3, VII-5 and VII-7) do not indicate a trend in significant increases of establishment and viable seed production in corn expressing the GE trait.

Baseline Information:
The average ear of cultivated corn has approximately 400 to 600 kernels arranged in 16 rows (Iowa State, 2014). Only one reference was found that examined the ability of corn to reproduce outside of cultivation, when corn was planted in existing vegetation on land which had been in agricultural production 2-5 years previously, plants established at a high rate, but very little yield was obtained (Monsanto 2009), suggesting that the reproductive potential of corn outside of cultivation could be very low. A typical corn plant produces one ear although multiple ears per plant can exist if resources (space, water, nutrients, etc.) are not limited.

No references were found that says that corn in a non-cultivated area has any potential to reproduce. The risk is therefore Negligible.

(B08) Reproductive potential – Certainty documentation

GE information:
Overall, the weight of evidence supports a certainty rating of High.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) one secondary source (Gould, 1968), and the sources cited in the baseline corn WRA.

The reliability and applicability ratings for the two sources cited here are as follows: Monsanto’s petition (High and Moderate, respectively) and Gould (High and High, respectively).

The baseline certainty rating of Very high is based on very low yield when corn was grown outside of cultivation. As stated above, no data exists on the cordapA gene (high Lysine expression) transgenic corn outside of cultivation or that the reproductive potential of GE corn would be different based on characteristics related to reproductive potential generated in cultivated fields; therefore the GE risk rating is reduced to High.

Baseline Information:
Iowa State, 2014-High reliability; Very high applicability
Monsanto, 2009- High reliability; High applicability

Corn generally does not grow without intentional human assistance except as sporadic escapes, as discussed in question B01, so a Very High certainty rating is assigned.

(B09) Propagule dispersal

Baseline risk: Low  GE risk: Low
Baseline certainty: Very high  GE certainty: Very high

(B09) Propagule dispersal – Risk documentation

GE information:
Based on the cordapA gene (high Lysine expression) in corn varieties, there is no change expected that would alter the Low risk rating of the propagule dispersal of corn.
Within the Monsanto petition (2004), field data relevant to propagule dispersal is presented for two years (2002 and 2003) (Table VII-1, Table VII-5 and Table VII-7, pp 77, 84 and 88). Seed dispersal of individual kernels does not occur naturally because of the structure of the ears of maize. The kernels are held inside the husks of the cob and are too heavy to be wind-blown.

There were however, at two of the ten test sites in 2002 a statistically significant difference in dropped ears showing an increase for the test (LY038) compared to the control corn (Monsanto 2004-Appendix 4 Tables 9 and 10). Overall, there was no significant difference in the propensity of the \textit{cordapA} gene (high Lysine expression) corn to drop ears compared to conventional corn. There are no biologically significant differences in total weight (yields and test weight of the grain) and dropped ears between the \textit{cordapA} gene (high Lysine expression) corn varieties and conventional corn (Monsanto 2004; USDA-APHIS 2006).

The long domestication of maize has resulted in the seed being the only structure capable of perpetuating the species and, as such, requires human assistance to persist or be disseminated (Gould, 1968, Troyer, 2004, OECD, 2003).

-----

**Baseline information:**
Corn requires human assistance to disperse its seeds for propagation and survival (OECD, 2003). "During its domestication from teosinte, maize lost its ability to disperse and thus survive in the wild" (Andersson & de Vicente, 2010). It has become so domesticated that seeds in cobs are tightly covered by tight husks so they cannot be separated (shattering) from the cob and disseminated without human intervention (as discussed in question B01) (CFIA, 2014; Farnham et al. 2003; Fedoroff 2003). Additionally, the maize cob lacks any abscission layers between its basic units and the cob remains intact at maturity with no shattering (Doebley et al. 1990). Studies show that harvesting and subsequent cultivation in silage maize can cause spread of plant seeds (OGTR, 2008). In one experiment, corn seeds did not pass intact through the digestive tract of four bird species associated with corn cultivation who are known to eat corn and were not found in the fecal material from these birds (Cummings et al., 2008). Corn seed is not dispersed by the wind because it has no physical attributes to do so and corn seed remains attached to the cob. (Fedoroff, 2003). A Low risk rating is assigned because corn needs human intervention (as discussed in question B01) to disseminate the corn seed to start a new generation but it can be moved by farming equipment (Andersson and de Vicente, 2010).

(B09) Propagule dispersal – Certainty documentation

**GE information:**
Overall, the weight of evidence supports a certainty rating of **Very high**.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and four secondary sources (Gould, 1968, Troyer, 2004, OECD, 2003; USDA-APHIS 2006).

The reliability and applicability ratings for the sources are as follows: Monsanto's petition (Very High and Very High, respectively); USDA-APHIS (High and High, respectively); one highly-cited government organization report (OECD 2003; High and High, respectively); and one book on grasses (Gould 1968; High and Moderate, respectively); and one article (Troyer 2004, High and High, respectively).

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**Baseline information:**
Andersson & de Vicente, 2010- High reliability; High applicability
CFIA, 2014- High reliability; High applicability
Cummings et al., 2008- High reliability; High applicability
A Very High certainty level as given based on the numerous sources who reported human dependence (as discussed in question B01) of corn propagule dispersal.

(B10) Dormancy

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<thead>
<tr>
<th>Baseline risk</th>
<th>Negligible</th>
<th>GE risk</th>
<th>Negligible</th>
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<tr>
<td>Baseline certainty</td>
<td>High</td>
<td>GE certainty</td>
<td>High</td>
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</table>

(B10) Dormancy – Risk documentation

**GE information:**
Based on the *cordapA* gene (high Lysine expression) in corn varieties, there is no change expected that would alter the Negligible risk rating of seed dormancy in corn.

Monsanto conducted dormancy and germination testing on LY038 corn and conducted agronomic field trials at a total of 17 locations in the U.S. Corn Belt during two growing seasons (2002 and 2003). Field tests showed no significance difference in early stand counts which otherwise could occur if the high lysine trait had increased seed dormancy. Dormancy and germination testing, under laboratory conditions, showed that there were no differences in percent germinated (categorized as percent normal germinated and percent abnormal germinated, percent viable hard (dormant), percent dead, and percent viable firm swollen seed (Monsanto petition 2004, Table VII-3, p 79) (USDA-APHIS 2006).

Monsanto (2004) compared LY038 (high lysine) and LY038(-), for dormancy, and evaluated potential changes that would impact plant pest potential and plant weed potential. Assessment detected no biologically significant differences between these corn varieties indicative of a selective advantage that would result in increased weed potential for LY038 or other plants if the trait were transferred to other corn varieties (Monsanto 2004; USDA-APHIS 2006).

These results were expected since in conventional corn there is the absence of significant seed dormancy (OGTR 2008), coupled to the absence of substantial differences in seed dormancy and germination between the *cordapA* gene (high Lysine expression) corn varieties and conventional corn (Monsanto 2004; USDA-APHIS 2006). Consequently, corn has no innate dormancy as stated in the baseline.

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**Baseline Information:**
Seeds from one maize crop can survive over winter and germinate in warmer weather (OGTR, 2008). Maize seeds dispersed during the harvesting process can only survive for up to one year in the soil, due to their poor dormancy (Andersson & de Vicente, 2010). "One of the first effects of domestication would be a genetic removal of the dormancy trait" (Galinat, 1988). "Dormancy is not associated with modern maize cultivars although it does occur in other Zea spp." (Simpson, 1990 as reported in OGTR, 2008). A Negligible risk rating is given for lack of dormancy beyond a year.

(B10) Dormancy – Certainty documentation

**GE Information:**
Overall, the weight of evidence supports a certainty rating of **High**.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto...
2004) and two secondary sources (USDA-APHIS 2006; and OGTR 2008).

The reliability and applicability ratings for the sources are as follows: Monsanto petition (Very High and High, respectively); and the USDA-APHIS (High and High, respectively); and one Australian government OGTR report (High and Very High, respectively).

-----

**Baseline Information:**
Ndersson & de Vicente, 2010- High reliability; Very high applicability
Galinat, 1988 Moderate reliability; Moderate applicability
OTGR, 2008- High reliability; Very high applicability

Based on common knowledge gained over centuries of cultivation along with the above references a High certainty rating is assigned.

**(B11) Regeneration**

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<thead>
<tr>
<th>Baseline risk</th>
<th>Negligible</th>
<th>GE risk</th>
<th>Negligible</th>
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<tr>
<td>Baseline certainty</td>
<td>Moderate</td>
<td>GE certainty</td>
<td>Moderate</td>
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</table>

**(B11) Regeneration – Risk documentation**

**GE Information:**

Based on the *cordapA* gene (high Lysine expression), there is no change expected that would alter the Negligible risk rating of regeneration. There is no change in the GE risk score from the baseline risk score.

A literature search on the ability of corn to regenerate in fields did not yield results.

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**Baseline Information:**

The only reports of regeneration of corn are through the use of from embryogenic callus in a lab environment (Kamo et al., 1985). There are no references saying that corn can regenerate without human intervention (as discussed in question B01). Nielsen (2003) reports that if the corn plant is injured early enough in the season, the tillers on corn plant may be able to grow and produce harvestable ears. But if the damage occurs later, then tillers may not have enough time before the killing frost to form harvestable ears.

A Negligible risk rating was assigned but tillers may enable the corn plant to continue its growth after early season damage.

**(B11) Regeneration – Certainty documentation**

**GE Information:**

Based on the *cordapA* gene (high Lysine expression) corn varieties, there is no change expected that would alter the High certainty rating of the regeneration of corn. There is no change in the GE certainty score from the baseline certainty score.

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**Baseline Information:**
Kamo *et al.*, 1985- Very High reliability; High applicability
Nielsen, 2003- High reliability; High applicability
Based on common knowledge gained over centuries of cultivation a High certainty rating is assigned. A very high rating was not used because of the one reference that addressed how corn tillers have the ability to take over for damaged plants if the damage is early in the plant’s development. There are no sources that address non-human intervention areas.

(B12) Flood or drought tolerance

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>Moderate</th>
<th>GE risk</th>
<th>Moderate</th>
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<tbody>
<tr>
<td>Baseline certainty</td>
<td>High</td>
<td>GE certainty</td>
<td>High</td>
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</table>

(B12) Flood or drought tolerance— Risk documentation

GE Information:
There is no change in the GE risk score from the baseline risk score of Moderate.

Flood and drought tolerance were assessed in the Monsanto petition (2004). Tolerance of high-lysine corn to natural incidences of flood and drought conditions was qualitatively assessed for 2 years (Monsanto 2004, Table VII-6, pg 85 and Table VII-9, pp 90-91). Drought tolerance was rated in 2 locations in 2002 and 4 locations in 2003. Flood tolerance was rated in 1 location in 2002 and 2 locations in 2003. In no case was the range of responses to drought or flood different between high-lysine corn and its control; and the data were not subject to statistical analysis. These results support the conclusion that reactions to flood and drought for high lysine maize (LY038) were not unintentionally altered compared to the control (USDA-APHIS 2006). Furthermore, yield data for each of the locations and years evaluated for these stressors only indicated a statistically significant difference in yield at one location (MN in 2003 which was also rated for drought tolerance) (Monsanto 2004 Appendix 4 Tables 3, 4, 9 and 12-16); so there was no detectable trend for increased yield of LY038 in response to drought or flood. The results in the Monsanto petition (2004, Table VII-9, p 90) support the conclusion that the ecological interactions for high lysine producing maize (LY038) were not unintentionally altered compared to the control (USDA-APHIS 2006).

Cultivated corn may volunteer in agricultural fields in the year following cultivation and may produce some seed. Corn has a general inability to grow without intentional human assistance (OGTR 2008), it is not likely that the cordapA gene (high Lysine expression) would alter the moderate rating of corn surviving flood or drought.

Furthermore, based upon the baseline information, no change is expected that would alter the Moderate risk rating of flood or drought tolerance. There is no change in the GE risk score from the baseline risk score.

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Baseline Information:
The major stress caused by flooding is lack of oxygen needed for the root system to function properly (Olson/Sander, 1988). "When plants reach the six- to eight-leaf stage, they can tolerate a week or more of standing water" (Nafziger, 2014). Saturated soils inhibit root growth, leaf area expansion, and photosynthesis because of the lack of oxygen and cooler soil temperatures. "Prior to V6, corn may survive only two to four days of totally saturated soils" (Butzen, 2014). The six to eight leaf stage is V5, and V6 is the 8 – 12 leaf stage. The different references have slightly different times of maximum susceptibility (prior to V5 versus prior to V6), but this difference is minor and may reflect cultivation of corn in different areas of the U.S.

Drought stress is the major cause of yield reduction in corn (Wyffels, 2011; Clemson 2014; Pioneer, 2012). "Stress during pollen shed and silking can cause more yield loss than almost any other period in the crop's development" (Nielsen, 2015). Drought later in grain fill causes the kernels not to fill completely due to loss of root function (Nafziger, 2014). Through the late vegetative stage corn is fairly tolerant of dry soils, and mild drought and can be beneficial because roots generally grow downward more strongly as surface soils dry" (Nafziger, 2014). High temperatures during pollination can cause damage and reduce yield if plants are also under drought stress (Clemson, 2014). During peak water use (which includes the critical silking to milk stage), yield loss due to water stress is substantial and estimated at 6-8% per day of stress (Farahani and Smith, 2014). "Stressed plants are also often more susceptible to diseases, so drought stress or poor drainage should be avoided" (Cartwright et al., 2015).
Corn can survive and reproduce (albeit with a reduction in reproductive capacity) under intermittent drought/flooding, but prolonged drought/flooding has severe detrimental effects on growth and reproduction. Therefore, a rating of Moderate is appropriate.

**B12) Flood or drought tolerance – Certainty documentation**

**GE information:**
Overall, the weight of evidence supports a certainty rating of **High**.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and two secondary sources (USDA-APHIS 2006, and OGTR 2008).

The reliability and applicability ratings for the two sources are as follows: Monsanto's petition (Very High and High, respectively); the USDA-APHIS (High and High, respectively); and one Australian government OGTR report (High and High, respectively).

**Baseline Information:**
- Butzen, 2014- Moderate reliability; Moderate applicability
- Clemson, 2014- Moderate reliability; Moderate applicability
- Farahani and Smith 2014- Moderate reliability; Moderate applicability
- Nafziger, 2014- High reliability; High applicability
- Nielsen, 2015- Low reliability; High applicability
- Pioneer, 2012- Moderate reliability; High applicability
- Cartwright *et al.*, 2015- High reliability; High applicability
- Wyffels, 2011- Moderate reliability; High applicability

A High certainty rating is assigned because the references all agree with each other even though there are no sources that address non-human intervention areas.

**B13) Tolerance to poor soils**

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>GE risk</th>
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<tbody>
<tr>
<td>Negligible</td>
<td>Negligible</td>
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<table>
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<tr>
<th>Baseline certainty</th>
<th>GE certainty</th>
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</thead>
<tbody>
<tr>
<td>Moderate</td>
<td>Moderate</td>
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</table>

**B13) Tolerance to poor soils – Risk documentation**

**GE information:**
Based upon the Baseline information below and the common observation that corn possesses a reduced ability to establish and reproduce in poor soils (OGTR 2008), there is no change expected that the corn modified with the *cordapA* gene (high Lysine expression) would alter the **Negligible** risk rating to tolerance of corn to poor soil.

Tolerance to all characteristics of poor soils was not specifically tested, since "All plots at each site were maintained according to standard maize production practices for the respective region." (Monsanto 2004). However, qualitative ratings were made in a very limited number of locations for responses to soil compaction (one each in 2002 and 2003) and for soil crusting (two locations in 2003) (Monsanto 2004, Tables VII-6 and VII-9) and the ranges in the ratings for LY038 were the same or overlapped those for the control corn. Therefore the limited data available do not suggest that LY038 would respond differently than control corn to some characteristics of poor soils.

There is no plausible mechanism by which corn with the *cordapA* gene (high Lysine expression) would alter the tolerance level of corn to poor soils, and therefore the GE risk rating is the unchanged from the Negligible baseline risk rating.
Baseline information:
Corn likes rich soil with good drainage (Ross et al., 2015; National Gardening Assoc., 2014). The ideal soil for corn is a loamy sand or sandy loam that stays moist, without being too wet (National Gardening Assoc., 2014; New Hampshire University, 2001). As a general guide, plant early corn in light soil (sand or loam) and late corn in heavier soil (silt, clay) when there is an option (New Hampshire University, 2001). Maize is not very tolerant of saline soils (OGTR, 2008). Corn can grow on a wide range of soils with different physical and chemical properties. However, management techniques and nutrient additions tuned to the particular soil characteristics are used to obtain high yields (Olson and Sander, 1988). No references were found that says that corn can grow in poor soils and survive, and cultivated fields generally need applied fertilizers (CABI, 2012; CIFA, 2014). Therefore, a Negligible risk is assigned.

(B13) Tolerance to poor soils– Certainty documentation

GE information:
Overall, the weight of evidence supports a certainty rating of Moderate. Based on the variability degree of reliability and applicability of the sources for the baseline certainty resulting in a moderate rating, and without strong evidence supporting a change for the GE high lysine trait, the certainty rating should remain at moderate.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and one secondary source.

The reliability and applicability ratings for the two sources are as follows: Monsanto’s petition (High and High, respectively); and one Australian government OGTR report (High and Low, respectively). In addition, since there is no change from the baseline, the certainty rating is not changed.

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Baseline information:
CABI, 2012- Moderate reliability; High applicability
CIFA, 2014- High reliability; High applicability
National Gardening Assoc., 2014- Moderate reliability; High applicability
New Hampshire, 2001- Moderate reliability; Low applicability
OGTR, 2008-High reliability; Low applicability
Olson/Sander, 1988- High reliability; Low applicability
Ross et al., 2015- High reliability; High applicability

Sources were good only for cultivated corn. They were included to show how corn needs human intervention (as discussed in question B01). There were no sources that addressed corn growing without intentional human assistance. A Moderate certainty rating is being given because there are no sources that address soil tolerance in non-human intervention areas.

(B14) Cold tolerance

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>Moderate</th>
<th>GE risk</th>
<th>Moderate</th>
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<tbody>
<tr>
<td>Baseline certainty</td>
<td>High</td>
<td>GE certainty</td>
<td>Moderate</td>
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</table>

(B14) Cold tolerance – Risk documentation

GE information:
Based on the cordapA gene (high Lysine expression) in corn varieties, there is no change expected that would alter the Moderate risk rating of cold tolerance in corn.

Cold tolerance was assessed in the Monsanto petition (2004, Table VII-9, p 90). Qualitative ratings were made in a very limited number of locations for responses to cold (one in 2002 and two in 2003) (Monsanto 2004, Tables VII-6 and VII-9, respectively) and the ranges in the ratings for LY038 were the same as those for the control corn. But the degree of cold tolerance (e.g. the temperature experienced) relative to the rating scale for the WRA is not indicated. Therefore the limited data available do not accurately inform the rating. The results in
the Monsanto petition (2004, Table VII-9, p 90) support the conclusion that the ecological interactions for LY038, including abiotic stressors, were not unintentionally altered compared to the control (USDA-APHIS 2006).

Furthermore, the risk reasoning is based off of the absence of cold tolerance in conventional corn (Cornell University 2006; Nafziger "2016"), coupled to the absence of substantial differences in cold tolerance between the cordapA gene (Lysine protein) corn and conventional corn (Monsanto 2004).

No new evidence or information was found that the high Lysine corn would be any different from the baseline risk documentation.

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**Baseline Information:**

Cold injury damages leaves at temperatures in the low 40s or upper 30s Farenheit, and photosynthesis can be reduced even if the only symptom is a slight loss of leaf color (Nafziger, 2014). The growing point region of a corn plant remains below ground until about the 5-leaf collar stage and, thus, is reasonably protected from the effects of aboveground frost (Purdue, 2002). "Consequently, the effects of “simple” frost damage to corn are usually minor and limited to death of aboveground plant parts. Corn can easily recover from this type of damage early in its development and suffer no yield loss whatsoever" (Purdue, 2002). Growth decreases once temperature drops to about 41°F and prolonged cold temperatures at the seedling stage (soil temperatures to below freezing two inches below the surface) may kill corn" (Clemson, 2014). Extended low temperatures at seedling stage that reduce the soil temperatures to below freezing two inches below the surface may kill corn but brief periods of temperatures between 32 and 28°F have very little effect on corn (Clemson, 2014).

Lethal cold temperatures for corn and soybean are those at or below 28°F (Purdue University, 2002). Based on the references which say corn will slow its growth below 41°F, die at 28°F, but survive short periods of low temperatures, a Moderate risk rating is given.

(B14) Cold tolerance – Certainty documentation

**GE information:**

Overall, the weight of evidence supports a certainty rating of Moderate. This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and three secondary sources (USDA-APHIS 2006; Cornell University 2006; and Nafziger 2016).

The reliability and applicability ratings for the sources are as follows: Monsanto petition (Moderate and Moderate, respectively); the USDA-APHIS (Moderate and Moderate, respectively); one university webpage (Cornell 2006; Low and High, respectively); and one university extension report (Nafziger 2016; Very High and High, respectively). The small number of observations for cold stress and lack of information about the actual cold temperatures experienced in the field trials by Monsanto and referred to by APHIS warrant the moderate ratings assigned for these references.

-----

**Baseline information:**

Clemson, 2014- Moderate reliability; Moderate applicability
Nafziger, 2014- Very High reliability; High applicability
Purdue, 2002- Moderate reliability; Moderate applicability

Based on the references found on cold temperatures and the absence of conflicting reports, a High certainty rating is assigned even though there are no sources that address non-human intervention areas. A very high
rating was not given because some of the references were not primary references or highly supported secondary references.

(B15) Biotic stress tolerance

<table>
<thead>
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<th></th>
<th>Baseline risk</th>
<th>GE risk</th>
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<tbody>
<tr>
<td>Baseline certainty</td>
<td>High</td>
<td>GE certainty</td>
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</table>

(B15) Biotic stress tolerance – Risk documentation

**GE information:**
Based on the *cordapA* gene (high Lysine expression) in corn varieties, there is no change expected that would alter the Moderate risk rating to biotic stress tolerance.

Monsanto (2004) did assess ear drop in corn and noted a small increase in the number of dropped ears detected at the two sites. A consistent trend toward an increased number of dropped ears may indicate an increase in weed potential; however, no difference in the number of dropped ears was observed at the other eight sites (Monsanto petition 2004, Table VII-5 and VII-7, pp 84 and 88). The USDA-APHIS (2006) agreed with the assessment of the Monsanto petition (2004). Furthermore, qualitative observations on response to incidental disease and pests in field trials of LY068 and the controls in 2002 and 2003 are indicated in Tables VII-6 and VII-9. The Monsanto petition says for 2002: "Ecological evaluations (plant interactions with insect pest, disease, and abiotic stressors) revealed qualitative differences between LY038 and LY038(-) for anthracnose, leaf spot, seedling blight, and leaf curl incidence (Table VII-6)." Likewise in 2003 slight differences in the range of response was noted for different pests (flea beetle, maize dwarf mosaic virus and stalk rot) and for both years the qualitative differences between LY038 and LY038(-) were of small magnitude and the incidence of each pest or stressor was within the range of incidence observed for the reference hybrids.

Moreover, the agronomic trials were conducted with pesticide treatments to control the pests, which indicates, "intentional human assistance". Monsanto (2004) petition says (pg. 80) "All plots at each site were maintained according to standard maize production practices for the respective region. At each site, soil insecticide was applied at planting to control corn rootworm larvae and an insecticide spray program was used throughout the growing season to control all above ground lepidopteran pests including European corn borer, corn earworm, and fall armyworm." Therefore, it can be stated that some of the pest observations did include pests that were targeted for control.

The rating is based upon the Monsanto petition (2004), and the USDA-APHIS (2006) assessment.

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**Baseline information:**
Biotic stress can effect corn grain directly and indirectly. Two examples of direct effects on corn yield are ear rot and ear drop diseases. Some indirect effects are a reduction of the "factory" size such as plant stunting or a reduction in "factory" output such as leaf diseases (Nielsen, 2002). Across 22 states and Ontario, diseases caused an overall estimated 10.9 percent loss — or more than 1.3 billion bushels with the largest culprit being *Fusarium* stalk rot with more than 124 million bushels lost (Purdue, 2014). Corn diseases are important yield-limiting factors in many production areas of the U.S (Cartwright et al., 2015). Corn has resistance to some diseases, depending on variety (Wisser, 2011, Balint-Kurti and Johal, 2009). Maize is most susceptible to damage by insects during the establishment phase when soil insects can cause up to 30% losses and necessitate replanting of the crop, and from tasselling to harvest (O’Gara, 2007).

With corn yield being decreased by as much as 30% by insects and almost 11% by diseases, a Moderate risk rating is assigned.

(B15) Biotic stress tolerance – Certainty documentation
**GE Information:**
Overall, the weight of evidence supports a certainty rating of Moderate.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto (2004). The reliability and applicability ratings for the source are as follows: Monsanto petition (High and Moderate, respectively); and the USDA-APHIS (2006) (Moderate and Moderate, respectively).

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**Baseline information:**
Balint-Kurti and Johal, 2009- Very High reliability; High applicability
Nielson, 2002- High reliability; High applicability
O'Gara, 2007- High reliability; Moderate applicability
Purdue, 2014- Moderate reliability; High applicability
Cartwright et al., 2015- High reliability; Very High applicability
Wisser, 2011- Very High reliability; High applicability

No conflicting references were found. Based on these references, a High certainty rating is given.

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**Baseline risk**  
Negligible  
**Baseline certainty**  
High

**GE risk**  
Negligible  
**GE certainty**  
High

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**Biology risk summary**

**GE Information**
Based on the *cordapA* gene (high Lysine expression) in corn, there are no changes in the weed risk ratings of corn.

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**Baseline Information:**
Corn poses a low biology risk. Corn has been cultivated for thousands of years and the domestication of corn has made it completely dependent on human assistance for survival. Corn does not shatter and thus the spread of corn seed is dependent on human intervention although unclean farm equipment can transfer some corn seed locally. Corn seed lacks dormancy beyond a year and regeneration is limited to plants damaged early in the season that have already produced tillers. Corn’s ability to occasionally grow in uncultivated fields and by roadsides and to volunteer in subsequent cultivated crops suggests it may have a minor ability to establish in existing vegetation but when a plant is found outside a cultivated field it cannot sustain itself or reproduce without human assistance.

Corn has some tolerance, albeit with a reduction in reproductive capacity, to stresses such as intermittent drought/flooding, short periods of low temperatures and occasional shade.

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**Biology certainty summary**
GE Information:
Based on the *cordapA* gene (high Lysine expression) in corn, there are no changes expected that would alter the Lysine WRA and the non-GE baseline corn WRA. For many of the traits in the WRA there was no plausible risk hypothesis upon which the *cordapA* gene (high Lysine expression) in corn would adversely affect corn. The data in the Monsanto petition (2004) supported the baseline WRA. For some of the questions in the WRA, either no new data was generated to address the questions or no literature was found. Where data did exist, it had little or no impact on the certainty rating compared to the baseline.

The only changes between the non-GE baseline corn WRA and High Lysine corn WRA were in regards to Reproductive Potential, Cold Tolerance and Biotic Stress Tolerance. The baseline has an overall rating of Very High for Reproductive Potential compared to the *cordapA* gene (high Lysine expression) rating of High. The certainty rating was lowered for the *cordapA* gene (high Lysine expression) corn since no data was provided for the high Lysine transgenic corn outside of a managed agricultural field or that the reproductive potential of GE corn would be different. The GE certainty was lowered to Moderate for Cold Tolerance (compared to High for the baseline) because the agronomic trial observations for cold response did not specify the temperature of the cold experienced. The GE certainty was lowered to Moderate for Biotic Stress Tolerance (compared to High for the baseline) because the agronomic trials in which biotic stress observations were made were conducted with pesticide treatments to control at least some of the pests, which indicates, "intentional human assistance".

Baseline Information:
Certainty for biology risk in corn is very high overall. Certainty was moderate for flood/drought tolerance, tolerance to poor soils, and ability to establish due to the moderate applicability or reliability of several references and the lack of references that address tolerance outside of cultivation.

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**Weed risk – Impact (9 questions)**

<table>
<thead>
<tr>
<th>(I01) Agriculture yield</th>
<th>Baseline risk</th>
<th>GE risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negligible</td>
<td>Negligible</td>
</tr>
<tr>
<td>Baseline certainty</td>
<td>Very high</td>
<td>GE certainty</td>
</tr>
<tr>
<td></td>
<td>Very high</td>
<td>Very high</td>
</tr>
</tbody>
</table>

---

**GE Information:**
Based on the high Lysine expression in corn, there is no change expected that would alter the Negligible risk rating to agriculture yield. There is no change in the GE risk score from the baseline risk score. Effect of yield on agricultural plants without intentional human assistance was not tested by Monsanto (2004).

Apart from the expected high Lysine expression benefits, corn containing the *cordapA* gene are agronomically equivalent to their non-transgenic counterparts (Monsanto 2004).

Corn containing the high lysine expression (LY038) does not change the facts that: 1) Corn does not establish outside of agricultural fields without human assistance (see B03: Ability to Establish). 2) Corn has limited ability to move beyond field edges except small amounts in or on farm equipment or dispersal by small animals (see B09: Propagule dispersal). 3) Corn lacks seed dormancy and does not generally volunteer for more than one growing season after it is intentionally grown (see B10 - Dormancy and B01: Current weed and invasive status).

Therefore there should be no significant reduction in yield of other agricultural plants and no change from the baseline.
Baseline Information:
There are no reports of corn acting as a weed to reduce crop yields, other than as volunteer corn in subsequent crops. Volunteer corn is not considered in this WRA. Therefore, a Negligible risk rating was given.

(I01) Agriculture yield – Certainty documentation

GE Information:
Based on the *cordapA* gene (high Lysine expression) in corn, there is no change expected that would alter the Very high certainty rating of agriculture yield. There is no change in the GE certainty score from the baseline certainty score.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004). The reliability and applicability ratings for the source is as follows: (Monsanto 2004, Very High and Very High, respectively).

Baseline Information:
Because corn does not grow outside of cultivated fields and because it is so widely cultivated and studied, a Very High certainty rating was given.

(I02) Agriculture quality

Baseline risk  Negligible  GE risk  Negligible
Baseline certainty  Very high  GE certainty  Very high

(I02) Agriculture quality – Risk documentation

GE Information:
Based on the *cordapA* gene (high Lysine expression) in corn, there is no change expected that would alter the Negligible risk rating on agriculture quality. There is no change in the GE risk score from the baseline risk score.

The expression of the *cordapA* gene was tested for impacts on the compositional components of importance to corn grain and forage (Monsanto 2004). Even if seed or forage from the high Lysine expression corn is comingleing with other agricultural plants or plant products, food and feed safety have been evaluated (FDA 2005 and FSANZ 2006).

Corn containing the high lysine expression (LY038) does not change the facts that:
1) Corn does not establish outside of agricultural fields without human assistance (see B03: Ability to Establish).
2) Corn has limited ability to move beyond field edges except small amounts in or on farm equipment or dispersal by small animals (see B09: Propagule dispersal).
3) Corn lacks seed dormancy and does not generally volunteer for more than one growing season after it is intentionally grown (see B10: Seed Dormancy and B01: Current weed and invasive status).

Therefore there should be no significant reduction in agricultural quality of other agricultural plants and no change from the baseline.

Baseline Information:
There are no reports of corn acting as a weed to reduce crop quality, other than as volunteer corn in subsequent crops. Volunteer corn is not considered in this WRA. Therefore, a Negligible risk rating was given.
(I02) Agriculture quality – Certainty documentation

**GE Information:**
Based on the *cordapA* gene (high Lysine expression) in corn, there is no change expected that would alter the **Very high** certainty rating of agriculture quality. There is no change in the GE certainty score from the baseline certainty score.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004) and two secondary sources (FDA 2005 and FSANZ 2006). The reliability and applicability ratings for the source is as follows: (Monsanto 2004, Very High and Very High, respectively); (FDA 2005, High and Very High, respectively); and (FSANZ 2006, High and Very High, respectively). Given the high consensus between these sources related to food and feed safety, and very high certainty regarding no substantial change in agronomic characteristics affecting establishment, persistence and dispersal ability of the GE corn, a very high certainty rating was given.

-----

**Baseline Information:**
Because corn does not grow outside of cultivated fields and because it is so widely cultivated and studied, a **Very High** certainty rating was given.

---

(I03) Harm to agriculturally important organisms

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>Negligible</th>
<th>GE risk</th>
<th>Negligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline certainty</td>
<td>Very high</td>
<td>GE certainty</td>
<td>Very high</td>
</tr>
</tbody>
</table>

(I03) Harm to agriculturally important organisms – Risk documentation

**GE Information:**
Based on the *cordapA* gene (high Lysine expression) in corn, there is no change expected that will alter the **Negligible** risk rating regarding harm to agriculturally important organisms. There is no change in the GE risk score from the baseline risk score.

Plant interactions with insect pests and diseases were evaluated as part of the Monsanto petition (2004, Table VII-6 and Table VII-9, pp 85 and 90) for the LY038 corn. The direct impacts on non-target beneficial invertebrates and microorganisms were not specifically assessed in the Monsanto petition. In addition, DHDPS proteins are not known to be associated with feeding behavior or preference in their host organisms (Monsanto 2004). A history of the safe exposure for the cDHDPS protein has been demonstrated, based on the similarity of the cDHDPS protein in LY038 to DHDPSs naturally present in feed and food (e.g., maize) (Monsanto 2004, Section VII).

When added to animal diets at nutritional levels, the essential amino acid, lysine, is Generally Recognized As Safe (GRAS) by the U.S. Food and Drug Administration (21 CFR 582.5411) and may be used safely as a human food additive when provided at nutrient levels (21 CFR 172.320). Furthermore, the FDA (2005) and FSASZ (2006) have assessed the Monsanto LY038 corn and agree that it is not materially different in composition, safety, or any other relevant parameters from conventional maize. The FDA (2005) stated; "Based on the safety and nutritional assessment Monsanto has conducted, it is our understanding that Monsanto has concluded that maize grain and forage derived from the new variety are not materially different in composition, safety, and other relevant parameters from maize grain and forage currently on the market, with the exception of the intentionally-increased lysine content in the grain. ... Based on the information Monsanto has presented to FDA, we have no further questions concerning grain and forage derived from maize event LY038 at this time.".
Baseline Information:
No references were found that indicate corn can harm agriculturally important organisms. Therefore, a Negligible risk rating was given.

(I03) Harm to agriculturally important organisms – Certainty documentation

GE Information:
Overall, the weight of evidence supports a certainty rating of Very high.

The data submitted by Monsanto petition (2004) to both the FDA (2005) and FSANZ (2006) support the certainty rating. This certainty rating is based off the reliability and applicability ratings for the primary source and two secondary sources. The reliability and applicability ratings are as follows: the Monsanto petition (Very High and Very High, respectively); the FDA and FSANZ reviews (High and Very High, respectively).

Baseline Information:
Exposure to agriculturally important organisms can happen in fields. Because corn is so widely cultivated and studied, a Very High certainty rating was given.

(I04) Competition with plants

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>GE risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>Negligible</td>
</tr>
</tbody>
</table>

Baseline certainty

<table>
<thead>
<tr>
<th>Baseline certainty</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very high</td>
<td>Very high</td>
</tr>
</tbody>
</table>

(I04) Competition with plants – Risk documentation

GE Information:
Based on the cordapA gene (high Lysine expression) in corn, there is no change expected that will alter the Negligible risk rating regarding competition with plants. There is no change in the GE risk score from the baseline risk score.

There is no indication that corn containing the cordapA gene possesses a selective advantage that would result in increased weediness (Monsanto 2004, USDA-APHIS 2006). Phenotypic comparisons between LY038 and conventional corn (Appendix 4, Tables 1-17) substantiate that there is no change in the GE plant morphology or growth that could lead to increased shading (e.g. plant height), and no biochemical changes resulting from the expression of the gene for high lysine that would lead to allelopathy.

The data submitted by Monsanto (2004) for LY038 corn (cordapA gene (high Lysine expression)) do not indicate that hybrids derived from the modified corn line would be any more competitive or vigorous in their ability to germinate or establish in different environments or reproduce or have other characteristics that would increase their capacity to compete or persist as a weed (USDA-APHIS 2006).

As with other corn varieties, LY038 corn lacks the ability to persist as a troublesome weed, and there would be no significant impact on current weed management practices to control corn as a volunteer (Monsanto 2004; USDA-APHIS 2006). This rational is based on the absence of weedy traits in cordapA gene (high Lysine expression) maize (Monsanto 2004; USDA-APHIS 2006), and the common knowledge that corn is a poor competitor outside the agricultural environment (OGTR 2008).
Corn can not grow outside of cultivated fields except as sporadic escapes that do not persist (see B01 and B02 above). It does not compete with other plants outside of cultivation. Therefore, a negligible risk rating was given.

**(I04) Competition with plants – Certainty documentation**

**GE Information:**
Overall, the weight of evidence supports a certainty rating of **Very high**.

This certainty rating is based off the reliability and applicability ratings for one primary source (Monsanto 2004), and two secondary sources (USDA-APHIS 2006; OGTR 2008). The reliability and applicability ratings for the three sources are as follows: Monsanto petition (High and High, respectively); the USDA-APHIS (High and High, respectively); and the one Australian government OGTR report (High and High, respectively).

**Baseline Information:**
Because corn does not grow outside of cultivated fields and because it is so widely cultivated and studied, a **Very High** certainty rating was given.

**(I05) Hydrology**

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>GE risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>Negligible</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline certainty</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

**(I05) Hydrology – Risk documentation**

**GE Information:**
Based on the *cordapA* gene (high Lysine expression) in corn, there is no change expected that will alter the **Negligible** risk rating regarding hydrology. There is no change in the GE risk score from the baseline risk score.

Based on the GE phenotype, there is no plausible risk hypothesis for how it could affect hydrology.

A Negligible risk rating was assigned because there were no sources that found that the hydrology of natural areas is effected by the growth of corn. Monsanto (2004) did not include data on root mass or evapotranspiration studies that could potentially assess hydrology.

**Baseline Information:**
Corn does not grow outside of cultivation except as sporadic escapes (See B01 and B02 above) and therefore does not have negative impacts on hydrology except as a result of the grower’s choice to cultivate it. No references about corn’s effect on the availability of water resources to future crops or other native plants was found. A Negligible risk rating was assigned because there were no sources that found that the hydrology of natural areas is effected by the growth of corn.

**(I05) Hydrology – Certainty documentation**

**GE Information:**
Overall, the weight of evidence supports a certainty rating of **High**. This certainty rating is based off the baseline information reliability and applicability ratings.

**Baseline Information:**
A High certainty rating was assigned based on the lack of non-agricultural hydrology references. Despite the fact
that corn is extremely well studied, a very high rating was not used because of the possibility that the hydrology near a corn field might be effected, though no references addressing this possibility were found.

### (I06) Soil quality

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>GE risk</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>Negligible</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline certainty</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

#### (I06) Soil quality – Risk documentation

**GE Information:**

Based on the *cordapA* gene (high Lysine expression) in corn, there is no change expected that will alter the Negligible risk rating regarding soil quality. There is no change in the GE risk score from the baseline risk score. Monsanto (2004) did assess, in field trials, the LY038 corn on various types of loam soils and showed that grain yields vary considerably from state to state due to rainfall/irrigation, climatic conditions and soil productivity, as was expected (Table VII-4, p 82). Furthermore, in the Monsanto petition, total plant biomass or root biomass was not measured, nor was nutrient uptake measured directly, and lastly, the compositional analysis was for grain and forage.

The rational for this is based on the absence of substantial differences in composition between *cordapA* gene (high Lysine expression) corn and conventional corn (Monsanto 2004; USDA-APHIS 2006). This absence of substantial compositional difference suggests that no nutrient uptake differences occur between corn containing the *cordapA* gene (high Lysine expression) and conventional corn.

Compositional analyses evaluating 85 different analytical components were assessed by Monsanto (2004) (summarized on page 95 of the petition). Due to the absence of substantial compositional differences, there should be no change in the rate of decomposition in the soil.

---

**Baseline Information:**

The high yield of maize is a heavy drain on soil nutrients (OGTR, 2008; CABI, 2012; Salem, 2010). These effects are the result of the grower's deliberate choice to grow corn.

Corn does not persist outside of managed agricultural systems, so there are no effects on soil outside of cultivated fields. Therefore a Negligible risk rating was assigned.

#### (I06) Soil quality – Certainty documentation

**GE Information:**

Overall, the weight of evidence supports a certainty rating of High.

This certainty rating is based off the reliability and applicability ratings for the baseline information ratings, as well as one primary source (Monsanto petition 2004), and one secondary source (USDA-APHIS 2006).

The reliability and applicability ratings for the Monsanto petition is (High and High, respectively); and for the USDA-APHIS (High and High, respectively).

---

**Baseline Information:**

Because corn does not grow outside of cultivated fields and because it is so widely cultivated and studied, a High certainty rating was given. Despite the fact that corn is extremely well studied, a very high rating was not used because of the possibility that soil quality near a corn field might be affected, though no references
(I07) Fire regime

<table>
<thead>
<tr>
<th></th>
<th>Baseline risk</th>
<th>GE risk</th>
<th>Baseline certainty</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline risk</td>
<td>Negligible</td>
<td>Negligible</td>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

(I07) Fire regime – Risk documentation

**GE Information:**
Based on the *cordapA* gene (high Lysine expression) in corn, there is no change expected that will alter the Negligible risk rating regarding fire regime. There is no change in the GE risk score from the baseline risk score. Fire regime was not assessed by the Monsanto petition (2004).

However, in the petition (Appendix 6) they do assess Forage and grain composition across all sites (combined sites) and it can be inferred that no substantial changes in composition were observed that could affect fire load, e.g. significant increases in dry matter or oil content compared to controls.

****

**Baseline Information:**
Corn is not able to grow outside of cultivated fields and thus is not able to change the fire regime of non-cultivated ecosystems. The Negligible risk score was given based on the familiarity with agricultural corn.

(I07) Fire regime – Certainty documentation

**GE Information:**
Based on the *cordapA* gene (high Lysine expression), there is no change expected that would alter the High certainty rating of fire regime. Therefore, there is no change in the GE certainty score from the baseline certainty score.

This certainty rating is based off the reliability and applicability ratings for the baseline information ratings, as well as one primary source (Monsanto petition 2004).

The reliability and applicability ratings for the Monsanto petition is (Very High and High, respectively);

****

**Baseline Information:**
Because corn does not grow outside of cultivated fields and because it is so widely cultivated and studied, a High certainty rating was given. Despite the fact that corn is extremely well studied, a very high rating was not used because of the possibility that the fire regime near a corn field might be affected, though no references examining this possibility were found.

(I08) Physical obstructions

<table>
<thead>
<tr>
<th></th>
<th>Baseline risk</th>
<th>GE risk</th>
<th>Baseline certainty</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline risk</td>
<td>Negligible</td>
<td>Negligible</td>
<td>Very high</td>
<td>Very high</td>
</tr>
</tbody>
</table>

(I08) Physical obstructions – Risk documentation

**GE Information:**
Based on the *cordapA* gene (high Lysine expression) in corn, there is no change expected that will alter the Negligible risk rating of physical obstructions. Physical obstructions was not assessed by Monsanto (2004).

In the Monsanto petition there is no substantive change in the GE plant morphology or growth in managed
agricultural fields resulting from the transgene expression, and therefore there should be no physical obstruction. Moreover, based upon the low GE risk rating for ability to establish (B03), the risk for physical obstructions is considered Negligible.

Therefore, there is no change in the GE risk score from the baseline risk score.

-----

**Baseline Information:**
While a corn field may be crowded and tall making human or vehicular movement difficult, it does not naturally grow in dense thickets or otherwise cause physical obstruction. The Negligible risk score was given based on the familiarity with agricultural corn.

(I08) Physical obstructions – Certainty documentation

**GE Information:**
Based on the cordapA gene (high Lysine expression), there is no change expected that would alter the Very high certainty rating of physical obstructions. There is no change in the GE certainty score from the baseline certainty score.

-----

**Baseline Information:**
Because no evidence was found that corn can be a physical obstruction and because it is so widely cultivated and studied, a Very High certainty rating was given.

(I09) Other impact weediness traits

<table>
<thead>
<tr>
<th>Baseline risk</th>
<th>GE risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>Negligible</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Baseline certainty</th>
<th>GE certainty</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>High</td>
</tr>
</tbody>
</table>

(I09) Other impact weediness traits – Risk documentation

**GE and Baseline information:**
None

(I09) Other impact weediness traits – Certainty documentation

**GE and Baseline information:**
Not applicable

Impact risk summary

**GE Information:**
There are no changes to any impact risk characteristics, and thus no change to the baseline impact risk rating of Negligible.

-----

**Baseline Information:**
Corn is an agricultural crop that does not have a significant impact on cultivated or natural environments except as volunteer corn in subsequent crops; volunteer impacts are not considered in the WRA. Corn cannot grow outside of cultivated fields except as sporadic escapes that do not persist and have little to no ability to compete for resources.

Impact certainty summary
GE Information:
There is no change from the baseline impact certainty rating of Very high.

-----

Baseline Information:
Certainty for impact risk in corn is very high.

Overall summary

Risk summary

GE Information:
Due to a lack of changes in risk characteristics, the cordapA gene (high Lysine expression) in corn, does not increase the weed risk posed by conventional corn.

The engineered trait does not change the biology and impact risk scores relative to baseline, nor are they likely to result in changes in risk characteristics that would increase weed risk and are insufficient to increase the risk scores.

-----

Baseline Information:
Zea mays ssp. mays poses a negligible weed risk based on this analysis. Domestication has made corn dependent on human assistance for survival. The occasional corn plants found outside a cultivated field do not form self-sustaining populations.

Certainty summary

GE Information:
The overall certainty for the risk assessment of corn with the inserted the cordapA gene (high Lysine expression) remains Very High; the same as the baseline.

Due to a lack of changes in certainty, the cordapA gene (high Lysine expression) does not alter the certainty ratings posed by conventional corn except for the reproductive potential which was reduced to High in GE corn due to lack of data and Cold Tolerance and Biotic stress tolerance which was reduced to Moderate.

-----

Baseline Information:
There is very high certainty associated with this risk assessment. Corn is well studied, well referenced and well known. The lack of research and quality references on some of the questions has minimal impact on the certainty scores since familiarity with corn is so high.

Bibliography

GE Lysine Corn WRA References:

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Baseline Corn WRA References


Beckett & Stoller (1988) "Volunteer corn (Zea mays) interference in soybeans (Glycine max)." Weed Sci., 36; 159–166.


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Hufford et al. (2012a) “Teosinte as a model system for population and ecological genomics.” Trends in Genetics, 28(12); 606-615.

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Purdue (2014) "Corn Disease Loss Estimates From the United States and Ontario, Canada — 2012." Purdue Extension publication BP-96-12--W. Retrieved October 20, 2015 from


Yin, McClure, Jaja et al. (2011) "In-Season Prediction of Corn Yield Using Plant Height under Major Production Systems." Agronomy Journal, 103(3); 923-929.

Young & Hart (1997) "Control of volunteer sethoxydim-resistant corn (Zea mays in soybean (Glycine max)." Weed Technology, 11(4); 649-655.
<table>
<thead>
<tr>
<th>Country</th>
<th>Established-weed/cult</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Yes-cult</td>
<td>Zea mays-1049N</td>
</tr>
<tr>
<td>Austria</td>
<td>No weed</td>
<td>Zea mays 1012N-1030N</td>
</tr>
<tr>
<td>Belgium</td>
<td>Yes casual</td>
<td>Zea mays 1012N-1030N</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>No weed/Yes casual</td>
<td>Zea mays 1012N-1030N; Zea mays 400-U</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Yes cult</td>
<td>Zea mays-241-N</td>
</tr>
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<td>France</td>
<td>Yes</td>
<td>Zea mays 1012N-1030N</td>
</tr>
<tr>
<td>Greece</td>
<td>Yes; yes casual</td>
<td>Zea mays 1012N-1030N; Zea mays-1142U</td>
</tr>
<tr>
<td>Ireland</td>
<td>No weed; yes casual</td>
<td>Zea mays 1012N-1030N; Zea mays-519-N</td>
</tr>
<tr>
<td>Italy</td>
<td>No weed/Yes exotic&amp;cult</td>
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</tr>
<tr>
<td>New Zealand</td>
<td>Yes casual; weedy?</td>
<td>Zea mays-919U; Zea mays 382-W</td>
</tr>
<tr>
<td>Country</td>
<td>Status</td>
<td>Cultivation</td>
</tr>
<tr>
<td>------------------</td>
<td>----------</td>
<td>-------------</td>
</tr>
<tr>
<td>Portugal</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Romania</td>
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<td></td>
</tr>
<tr>
<td>Spain</td>
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<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>No weed</td>
<td></td>
</tr>
<tr>
<td>Taiwan</td>
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<td></td>
</tr>
<tr>
<td>Turkey</td>
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</tr>
<tr>
<td>Randall reference #</td>
<td>Location covered</td>
<td>Notes</td>
</tr>
<tr>
<td>--------------------</td>
<td>------------------</td>
<td>-------</td>
</tr>
<tr>
<td>Zea mays 317-UZ</td>
<td>British Isles</td>
<td>Zea mays is not known in the wild, but was apparently domesticated about 7000 years ago. Can be a relic or an escape from cultivation, a casual plants whose seeds are found in bird-seed, pet food and food refuse on tips.</td>
</tr>
<tr>
<td>Zea mays 382-W</td>
<td>unknown</td>
<td>This is a chart with non-explained headers. Can't make a judgement.</td>
</tr>
<tr>
<td>Zea mays 400-U</td>
<td>Czech</td>
<td>Refers to Zea mays only being in human made habitats as a casual inhabitant.</td>
</tr>
<tr>
<td>Zea mays 519-N</td>
<td>Britian &amp; Ireland</td>
<td>Zea mays can be a relic or an escape from cultivation.</td>
</tr>
<tr>
<td>Zea mays 611-Z</td>
<td>unknown</td>
<td>This site is only for seed identification and seed containment.</td>
</tr>
<tr>
<td>Zea mays 777N</td>
<td>Taiwan</td>
<td>Zea mays is an annual plant that can be used for forage.</td>
</tr>
<tr>
<td>Zea mays 812-UC</td>
<td>England</td>
<td>Zea mays is called non-native but never mentioned it as a weed.</td>
</tr>
<tr>
<td>Zea mays 819-N</td>
<td>Europe</td>
<td>Zea mays is alien to Europe or non-native. Never mentioned it as a weed.</td>
</tr>
<tr>
<td>Zea mays -907W</td>
<td>Germany</td>
<td>Zea mays is called non-native but never mentioned it as a weed.</td>
</tr>
<tr>
<td>Zea mays- 919U</td>
<td>New Zealand</td>
<td>Zea mays is called a casual inhabitant that passively regenerates only in the immediate vicinity of the cultivated parent plant.</td>
</tr>
<tr>
<td>Zea mays- 1154U</td>
<td>Romania</td>
<td>Zea mays is intentionally planted and can escape. &quot;an alien plant that reproduces occasionally in an area, but requires repetitive introductions for its persistence&quot;</td>
</tr>
<tr>
<td>Zea mays 1157CN</td>
<td>Galapagos</td>
<td>Zea mays was never mentioned.</td>
</tr>
<tr>
<td>Zea mays 1220-U</td>
<td>Belgium</td>
<td>Zea mays is in agriculture only.</td>
</tr>
<tr>
<td>Zea mays 1264N</td>
<td>Romania</td>
<td>Zea mays is deliberately grown and is a casual inhabitant.</td>
</tr>
<tr>
<td>Zea mays-241-N</td>
<td>Ethiopia</td>
<td><em>Zea mays</em> mentioned as major crop not a weed</td>
</tr>
<tr>
<td>----------------</td>
<td>-----------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td>Zea mays-251-U</td>
<td>Italy</td>
<td><em>Zea mays</em> is a casual, non-native inhabitant.</td>
</tr>
<tr>
<td>Zea mays-643uc</td>
<td>Ukraine</td>
<td><em>Zea mays</em> can occasionally escape beyond cultivation but can't survive.</td>
</tr>
<tr>
<td>Zea mays-1049N</td>
<td>Australia</td>
<td><em>Zea mays</em> is cultivated with an occasional roadside growth.</td>
</tr>
<tr>
<td>Zea mays-1142U</td>
<td>Greece</td>
<td><em>Zea mays</em> is a casual/alien inhabitant.</td>
</tr>
<tr>
<td>Zea mays-1149U</td>
<td>Spain</td>
<td><em>Zea mays</em> is a casual inhabitant from agriculture.</td>
</tr>
<tr>
<td>Zea mays-1265N</td>
<td>Italy</td>
<td><em>Zea mays</em> is an exotic plant.</td>
</tr>
<tr>
<td>Zea mays-1270U</td>
<td>Spain</td>
<td><em>Zea mays</em> is used in cultivation</td>
</tr>
</tbody>
</table>