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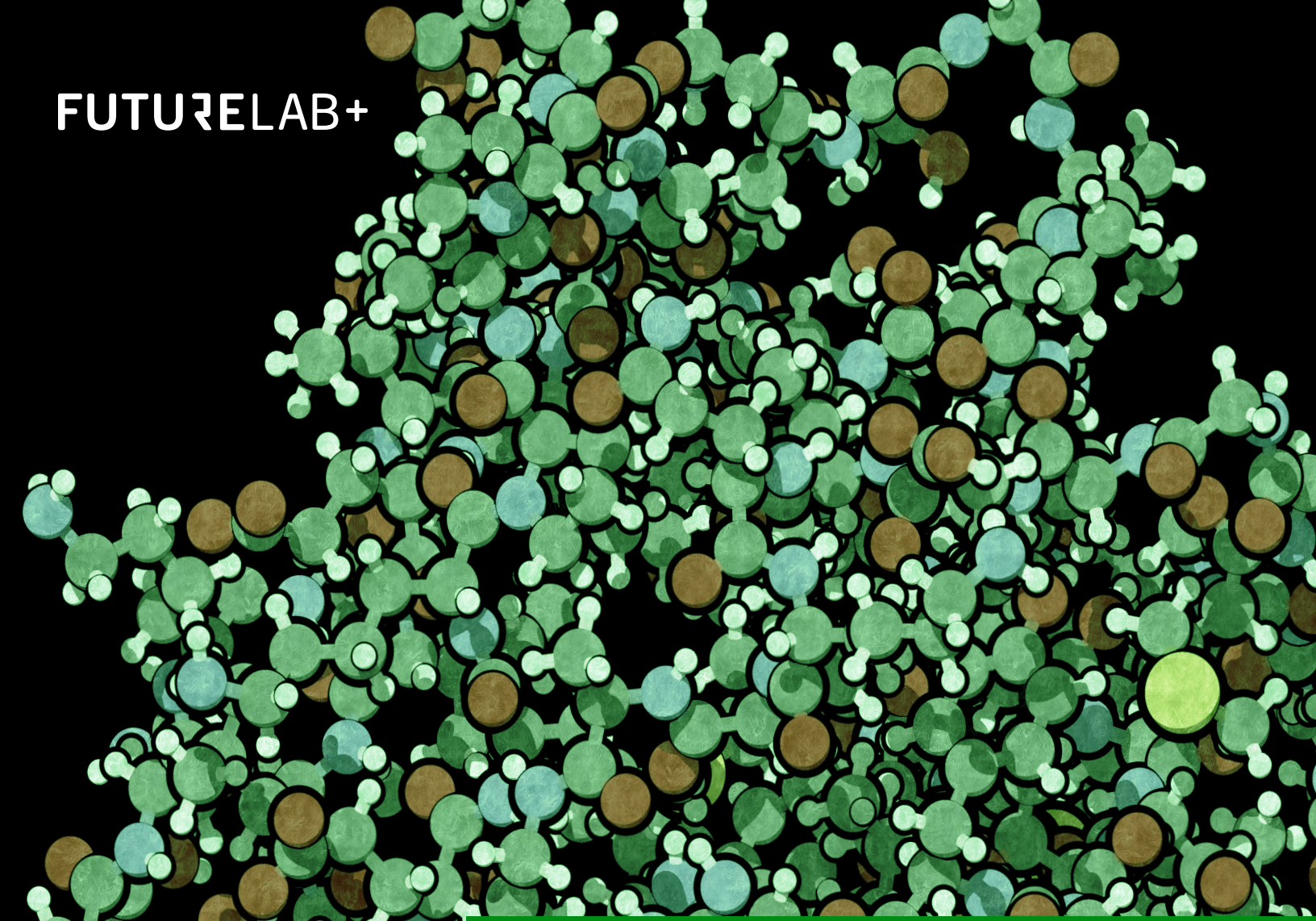


AG/Environmental

Alternative Proteins

Sustainability and Manufacturing

Developed in partnership with:

Discovery Education and Ignited

In this Lesson Plan:

Print the **Teacher Section** →

Print the **Student Section** →

This document is separated into two sections, For Teachers [T] *and* Student Resources [S]*, which can be printed independently.*

Select the appropriate printer icon above to print either section in its entirety.

Follow the tips below in the Range field of your Print panel to print single pages or page ranges:

Single Pages (use a comma): T3, T6

Page Range (use a hyphen): T3–T6

Cover Image
This model of a protein in cow's milk is a common allergen. Could a genetically engineered modification help?

AG/ENVIRONMENTAL / ALTERNATIVE PROTEINS

Sustainability and Manufacturing

DRIVING QUESTION

Why are GE products regulated and how does this influence their manufacturing?

OVERVIEW

Manufacturing a genetically engineered product involves many steps and government approvals. From identifying the need for the product to in-depth field testing to ensure the product is safe for both people and the environment, regulatory approval must be met prior to the product going on the market. The production of a GE product is not a quick measure, as it can take many years to move from concept to consumer (source: *Science and History of GMOs and Other Food Modification Processes*).

In this lesson, students will be asked to formulate a plan on how to produce their novel GE product by identifying local and global organizations or stakeholders that would play a role in production. Sustainability in both efficacy of product and in the environmental impact is also an important consideration that will be explored. The majority of this unit is about application of knowledge learned from previous lessons. Open-ended research will be required of students as they collaborate on the most effective way to obtain and communicate this information on their final website product.

ACTIVITY DURATION

Four class sessions
(40–50 minutes each)

ESSENTIAL QUESTIONS

How can a novel GE product be produced from lab to consumer?

What local and global stakeholders are involved in GE product production?

What sustainability and safety considerations must be taken into account when creating GE products?

OBJECTIVES

Students will be able to:

Describe sustainability practices that should be considered when manufacturing a novel GE product.

Identify a potential product pipeline for manufacturing a novel GE product.

Summarize safety and efficacy data or requirements when producing a novel GE product.

Provide feedback on a large-scale manufacturing plan for a novel GE product.

Materials

- **GE Product Production Pipeline Infographic**
- **Manufacturing of GMOs Webquest**
- **Article Exit Ticket**
- **Project Notebook**
- **Manufacturing Research Guide**
- **Lesson 9 Exit Ticket**
- **Sticky notes**
- **Computer**
- **Internet access**

Have you ever wondered…

How can a novel GE product be produced?

Students are tasked with the challenge to brainstorm how their novel GE product could realistically be manufactured using previous lesson tasks for reference.

What community stakeholders will play a part in the novel GE product production?

Students will list companies and people, both local and global, that would be important players in the production of their product. Exploring this will emphasize the group work required to produce bioengineered products.

What considerations must be taken into account when creating GE products from a sustainability and safety lens?

With EPA risk assessment a requirement prior to market launch, students will explore GE products from both sustainability in product efficacy and environmental sustainability. Safety data will also be explored from a model GE product to provide even further evidence for proof of concept.

MAKE CONNECTIONS!

How does this connect to the larger unit storyline?

GE product production was a large focus in the earlier lessons and now students will be asked to apply this knowledge to a novel GE product. Sustainability is also a focus between units and should always be a focus when considering products that will be given to consumers.

How does this connect to careers?

How does this connect to careers?

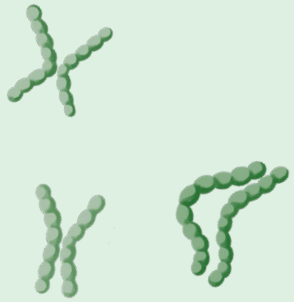
Students will be asked to highlight careers involved in the production of their novel GE product; careers may vary from group to group.

Sustainability directors and sustainability engineers work to solve problems in order to reduce resource use and promote a healthy planet for future generations. In the context of this lesson and the product life cycle, a sustainability director would focus on the human and environmental health implications of developing a new GE product.

Research and development teams include technicians, engineers, and scientists who research existing products and develop new products and techniques to create them. They might use market research to understand existing production, and lab or field-based research techniques to design new products or processes for a certain need.

How does this connect to our world?

Students will be exploring production from a local and global lens.



Pedagogical Framing

Instructional materials are designed to meet national education and industry standards to focus on in-demand skills needed across the full product development life cycle—from molecule to medicine—which will also expose students and educators to the breadth of education and career pathways across biotechnology.

Through this collection, educators are equipped with strategies to engage students from diverse racial, ethnic, and cultural groups, providing them with quality, equitable, and liberating educational experiences that validate and affirm student identity.

Units are designed to be problem-based and focus on workforce skill development to empower students with the knowledge and tools to be the change in reducing health disparities in communities.

SOCIAL-EMOTIONAL LEARNING

Students will be practicing responsible decision making as they anticipate and evaluate the decisions they are making around the production of their novel GE product. Students will also practice relationship skills as they communicate effectively and show leadership in groups. Lastly, self-management skills will be practiced as they accomplish and organize a large task as a group.

CULTURALLY AND LINGUISTICALLY RESPONSIVE INSTRUCTION

Students will bring real-world issues into the classroom as they brainstorm solutions around a real community challenge during this project. Opportunities to reach high expectations are present in this lesson as each student aims to meet deadlines and conduct research to the best of their ability. Lastly, respect for student differences is emphasized as students have creative freedom in their website designs.

ADVANCING INCLUSIVE RESEARCH

In this lesson, students will be considering how their GE product can be produced and thinking critically about which stakeholders will play a part in the production process. Students will purposefully seek out feedback from underrepresented groups and stakeholders to ensure their voices are heard in this stage of the development process.

COMPUTATIONAL THINKING PRACTICES

Students will design authentic learning activities to leverage a design process to solve problems in their community. They will be doing this with awareness of technical and human constraints and will defend their design choices with evidence.

CONNECTION TO THE PRODUCT LIFE CYCLE

During this lesson, students will be exploring the **develop** and **manufacture** stages of the product life cycle. The develop stage involves government agency approvals, and the manufacturing activities require students to dig deeper into how a product can be produced.

Day 1

Procedure

LEARNING OUTCOMES

Students will be able to:

Describe sustainability practices that should be considered when manufacturing a novel GE product.

Whole Group (10 minutes)

1 Reintroduce the *GE Product Production Pipeline Infographic* from Lesson 4 and facilitate a discussion on failure using the following questions as a guide:

- **a.** What is the likelihood that a GE product idea makes it from the discovery phase to market launch?
- **b.** At which stage of development are you at with your ideation of a novel GE product?
- **c.** If your novel GE product is accepted by the community to start production, what is the likelihood that it will reach market launch on the first attempt?
- **d.** Because there is high chance of failure, is it still worth brainstorming evidence-based ideas for new GE products?
- **e.** How may this pipeline compare in industries other than agriculture?
- **f.** What does sustainability mean and why may it be important when learning about GE products?

2 Ask each group to share an update on their community surveys and interviews.

3 Share with students that this week groups will be exploring the manufacturing of their novel GE product in five steps: 1) identifying community members that would be involved in the production, 2) brainstorming lab-to-table pipeline, 3) exploring the sustainability of production, 4) identifying safety and efficacy concerns, and 5) highlighting careers that will come in contact with the product.

4 Share the definition of sustainability with students: Everything that we need for our survival and well-being depends, either directly or indirectly, on our natural environment. To pursue sustainability is to create and maintain the conditions under which humans and nature can exist in productive harmony to support present and future generations (the EPA's *Learn About Sustainability*).

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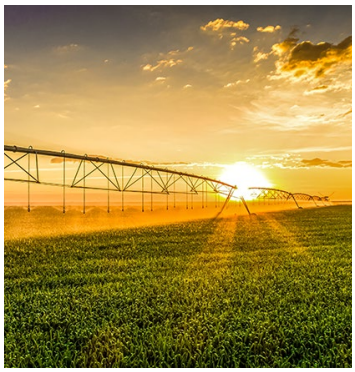
Day 1

Continued



Procedure

Individual Work (20 minutes)

1 To kickstart this process, invite students to work through the *Manufacturing of GMOs Webquest* and answer the provided questions to gain a deeper understanding of the regulation and manufacturing process.

Teacher Note > *Use of the word GMO here corresponds to the FDA document students are asked to use to complete the assignment.*

Group Work (10 minutes)

1 Ask students to compare answers to their webquest questions and complete *Article Exit Ticket* individually or as a group.

Teacher Note > *The Article Exit Ticket can be homework or an extension if there is not enough time to complete the webquest in class.*

Day 2

Procedure

LEARNING OUTCOMES

Students will be able to:

Identify a potential product pipeline for manufacturing a novel GE product.

Whole Group (5 minutes)

1 Facilitate a group meeting during which each group can report what they accomplished in Day 1 using the Daily Goal Capture Sheet from their **Project Notebook** as a guide. Brainstorm the following on the board.

a. What are some successes from yesterday in using the website resources to locate information about GMO regulation and manufacturing?

b. How are you going to use the information you collected to guide your own novel GE product?

Group Work (40 minutes)

1 Allow students time to work through the *Manufacturing Research Guide* as a group. They should be considering how to illustrate a pipeline similar to what was done in Lesson 4 with Golden Rice.

Teacher Note > *Obtaining information around this topic can be difficult. Encourage students to be creative in their approaches. Remind them that they can use their anchoring GE product as a starting point and can apply this product's production to their novel ideas. Reinforce the idea that there is no wrong answer as long as they can support their manufacturing plan with evidence.*

Day 3

Procedure

LEARNING OUTCOMES

Students will be able to:

Summarize safety and efficacy data and requirements when producing a novel GE product.

Collect and **analyze** data from community survey responses.

Describe sustainability practices that should be considered when manufacturing the novel GE product.

Whole Group (10 minutes)

1. Ask each group to display its website on an available computer.

2. Pass out sticky notes. Have groups use the notes to reflect on the following:
   - **a.** The biggest thing they are proud of from this week's work
   - **b.** One thing that needs more work

3. Have each group rotate to the right or left and review another group's website. Ask them to leave the following on a sticky note at that group's desk:
   - **a.** One positive thing about the website
   - **b.** One area that needs improvement, along with any advice to the group

Group Work (30 minutes)

1. Allow students time to work through the Final Project Outline—Manufacture (Part 3) from the **Project Notebook** as a group, using their Daily Goal Capture Sheet as a planning tool to manage the project.

Teacher Note > *Be sure to monitor student additions to their informational website and offer advice when needed. Student websites should be professional, but allow students some creative freedom. Check in with the Community liaison for each group to see how the surveys and interviews are coming along. Students should be continually thinking about how to analyze the results. The Genetic engineer should be brainstorming the "farm-to-store process." Frame this concept to students that do not have a product that is created via crops as thinking about the product production from beginning (lab, farm, etc.) to end (consumer, store, patient, etc.).*

Day 4

LEARNING OUTCOMES

Students will be able to:

Summarize safety and efficacy data and requirements when producing a novel GE product.

Collect and **analyze** data from community survey responses.

Describe sustainability practices that should be considered when manufacturing the novel GE product.

Procedure

Whole Group (10 minutes)

1. Facilitate a group meeting where each group can report out what they accomplished yesterday using the Daily Goal Capture Sheet from their **Project Notebook** as a guide. Brainstorm the following on the board:
   - **a.** What are some successes from yesterday?
   - **b.** What were some challenges from yesterday?
2. Allow students time to ask for advice or guidance from other groups.

Group Work (30 minutes)

1. Allow students time to finish the Final Project Outline—Manufacture (Part 3) from their **Project Notebook** as a group, using their Daily Goal Capture Sheet as a planning tool to manage the project.

Individual Work (5 minutes)

1. Give students the *Lesson 9 Exit Ticket* to assess their understanding of content; also use the website drafts as a formative assessment of the final product.
2. Ask students to individually complete the Manufacture—Farm to Store Process section of the Project Phase Chart Capture Sheet from their **Project Notebook**.
3. Ask students to individually complete the Manufacture—Sustainability section of the Project Phase Chart Capture Sheet from their **Project Notebook**.
4. Ask students to individually complete the Manufacture—Equity section of the Project Phase Chart Capture Sheet from their **Project Notebook**.

Teacher Note > *The individual tasks above can be assigned as homework if there is not enough time to complete in class.*

National Standards

Next Generation Science Standards	**ETS1-2 Engineering Design** Design a solution to a complex real-world problem by breaking it down into smaller, more manageable problems that can be solved through engineering.
	Science and Engineering Practice 3 Plan and conduct an investigation or test a design solution in a safe and ethical manner including considerations of environmental, social, and personal impacts
Career and Technical Education (CTE)	**A2.4** Understand the critical need for ethical policies and procedures for institutions engaged in biotechnology research and product development.
	A2.6 Prepare a presentation comparing the benefits and harm that can be the result of biotechnology innovations in both the research and application phases and which course of action will result in the best outcomes.
	A9.1 Describe the major steps of a product's move through a company's product pipeline.
	A9.3 Outline the steps in production and delivery of a product made through recombinant DNA technology.
	5.3 Use systems thinking to analyze how various components interact with each other to produce outcomes in a complex work environment.
	6.2 Interpret policies, procedures, and regulations for the workplace environment, including employer and employee responsibilities.
	7.5 Apply high-quality techniques to product or presentation design and development.

Manufacturing of GMOs Webquest
Regulation of GMO Products in the United States

ANSWER KEY **Do not share with students**

Directions
Use the FDA's How GMOS Are Regulated for Food and Plant Safety in the United States to answer the questions below.

1. In the left column below, identify the three federal agencies that regulate the production of GMOs in the United States.

2. All of these agencies have a common goal: to keep the people and the environment safe from potential consequences of GMOs. Summarize each agency's role in achieving this common goal in the right column.

	Name of Agency	Summary of Regulatory Role
a	US Food and Drug Administration (FDA)	Regulate ingredients in GE products to ensure they meet the same standards as all food found in the grocery store Regulations are in place at all stages of food production: production, process, storage, shipping, and sales.
b	US Environmental Protection Agency (EPA)	Regulation of pesticides, the substances that protect GE crops from disease and insects (called PIPs)
c	US Department of Agriculture (USDA)	Protects agriculture against pests and disease; this agency ensures that GE crops are not dangerous to other plants.

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Manufacturing of GMOs Webquest
Regulation of GMO Products in the United States

ANSWER KEY **Do not share with students**

Continued

3. After reading the Ensuring GMOs are Safe section, briefly describe the role of collaboration among these agencies. What could be a consequence of ineffective communication or collaboration?

Collaboration and coordination among these agencies is very important and helps make sure food developers understand the importance of a safe food supply and the rules they need to follow when creating new plants through genetic engineering. Ineffective communication or collaboration could result in careless actions which could impact the health of people or the environment.

4. What is the purpose of the Plant Biotechnology Consultation Program? Illustrate the process someone must go through to get a new GMO product approved by the FDA.

The Plant Biotechnology Consultation Program works with people to make sure new GMO products are safe for consumers.

GMO plant developer meets with FDA about a potential new product for use in human and animal food ⟶ GMO developer submits food safety assessment data and information to FDA ⟶ FDA evaluates the data and information and resolves any issues with the developer ⟶ Consultation is complete once FDA has no more questions about the safety of the human and animal food made from the new GMO plant variety ⟶ Completed consultations are all made public

Manufacturing of GMOs Webquest
GMO Manufacturing and Sustainability

ANSWER KEY **Do not share with students**

Directions
Use the GM Crops and the Environment to answer the questions below.

1. Summarize the current environmental situation related to GM crops according to this source.

Answers will vary. Example response: In less than 50 years, the world population is expected to increase by 3 billion. All these people will need food. Cropland and farmland are not evenly distributed. Habitat destruction, climate change, and water quality problems are also a consequence of growing populations.

2. There are environmental benefits of GM crops. Summarize by stating four statistics that provide evidence for this claim using the article.

a	Answers will vary. Example: The use of Bt cotton can substantially reduce the risk and incidence of pesticide poisoning of farmers.
b	
c	
d	

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Manufacturing of GMOs Webquest
GMO Manufacturing and Sustainability

ANSWER KEY **Do not share with students**

Continued

3. List the three specific issues the EPA considers when evaluating the unintentional effects of GMOs on the environment.

Impact on non-target organisms in the environment (insects), GMO crop may persist in an environment longer than usual; gene transferred unintentionally to another crop

4. Summarize the potential risks of GM crops below.

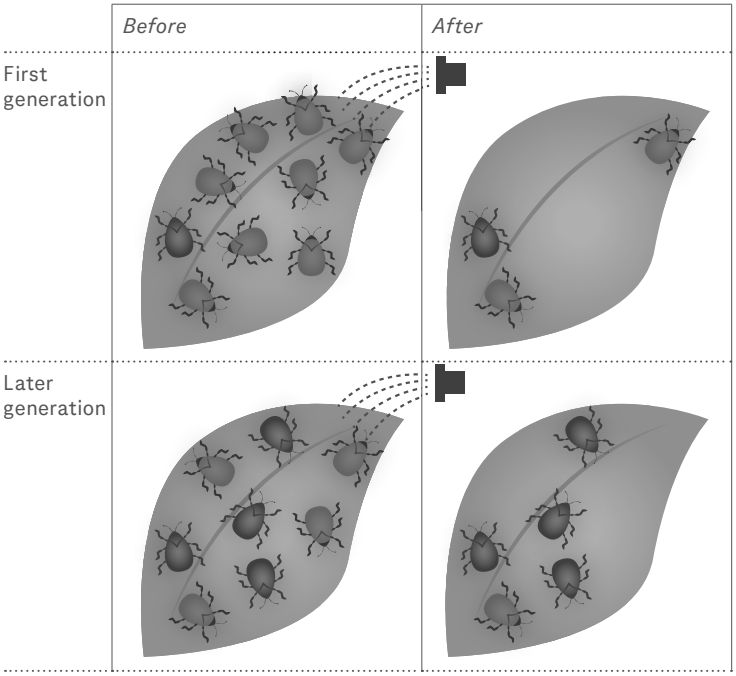
a	Out-crossing concern A big concern is the creation of unintentional weeds. The potential for the above to happen is assessed prior to introduction, and is monitored after the crop is planted as well.
b	Effects on non-target organisms The decline of the monarch butterfly has received a great deal of attention. One hypothesis blames GM crops and associated herbicide use on the monarch's food, milkweed. Some studies suggest an impact on larvae of butterflies, but other research shows that additional factors are contributing to the Monarch population decline. GMOs are not off the hook; they are just one factor among several that are affecting the butterflies.
c	Development of insect resistance Insects have the ability to develop resistance to some insecticides. Insects could also become resistant to the Bt proteins and overtime, natural selection could take place. Resistance management practices are in place.

Article Exit Ticket

ANSWER KEY **Do not share with students**

Directions
Reflect on the webquest and answer the following questions.

Pesticide application



1. What environmental focus from the articles does this graphic illustrate?

Development of insect resistance

2. Looking at this graphic, explain why this type of natural selection would be concerning to farmers or scientists.

Answers may vary. Farmers may find that over time, the insects will eat their crops again because they are not resistant to the toxic proteins. Scientists may see this as a limitation in their product and will need to work around natural selection.

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Article Exit Ticket

ANSWER KEY **Do not share with students**

Continued

3. Thinking about your novel GE product, brainstorm what aspects of manufacturing these agencies would explore prior to and during product production.

	Prior to *product production*	**During** *product production*
1 US Food and Drug Administration (FDA)	Answers will vary; refer to the webquest.	Answers will vary; refer to the webquest.
2 US Environmental Protection Agency (EPA)	Answers will vary; refer to the webquest.	Answers will vary; refer to the webquest.
3 US Department of Agriculture (USDA)	Answers will vary; refer to the webquest.	Answers will vary; refer to the webquest.

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GE Product Production Pipeline Infographic

Directions
Use this infographic to consider the likelihood that a GE product makes it from discovery to launch.

Agricultural Biotechnology Pipeline

			Total
Cost	Total expense	~$100M	$M

			Percent of total
Research and Discovery	Gene/trait identification	$2–5M	$M
	Average duration	24 to 48 months	
	Probability of success	5 percent	
	Candidates in this phase	Tens of thousands	
	Phase activities	High-throughput screening and model crop testing	
Phase I	Proof of concept	$5–10M	$M
	Average duration	12 to 24 months	
	Probability of success	25 percent	
	Candidates in this phase	Thousands	
	Phase activities	Gene optimization and crop transformation	
Phase II	Early development	$10–15M	$M
	Average duration	12 to 24 months	
	Probability of success	50 percent	
	Candidates in this phase	10s	
	Phase activities	Trait development, pre-regulatory data and large-scale transformation	

			Total
Duration	Time to market	8–10 years	

			Percent of total
Phase III	Advanced development	$15–30M	$M
	Average duration	12 to 24 months	
	Probability of success	75 percent	
	Candidates in this phase	Less than five	
	Phase activities	Trait development, field testing and regulatory data generation	
Phase IV	Pre-launch	$20–40M	$M
	Average duration	12 to 36 months	
	Probability of success	90 percent	
	Candidates in this phase	Pre-commercial product	
	Phase activities	Regulatory submission, seed bulk-up and pre-marketing	
Market Launch			

Key *Percent of total*

1	5	10	20	30	40	50	75

Source: *A look at product development with genetically modified crops*

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Manufacturing of GMOs Webquest

Regulation of GMO Products in the United States

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2. All of these agencies have a common goal: to keep the people and the environment safe from potential consequences of GMOs. Summarize each agency's role in achieving this common goal in the right column.

	Name of Agency	Summary of Regulatory Role
a		
b		
c		

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Manufacturing of GMOs Webquest

Regulation of GMO Products in the United States

Continued

3. After reading the Ensuring GMOs are Safe section, briefly describe the role of collaboration among these agencies. What could be a consequence of ineffective communication or collaboration?

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Manufacturing of GMOs Webquest

GMO Manufacturing and Sustainability

Directions

Use the GM Crops and the Environment to answer the questions below.

1. Summarize the current environmental situation related to GM crops according to this source.

2. There are environmental benefits of GM crops. Summarize by stating four statistics that provide evidence for this claim using the article.

a

b

c

d

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Manufacturing of GMOs Webquest
GMO Manufacturing and Sustainability

Continued

3. List the three specific issues the EPA considers when evaluating the unintentional effects of GMOs on the environment.

4. Summarize the potential risks of GM crops below.

a	Out-crossing concern
b	Effects on non-target organisms
c	Development of insect resistance

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Article Exit Ticket

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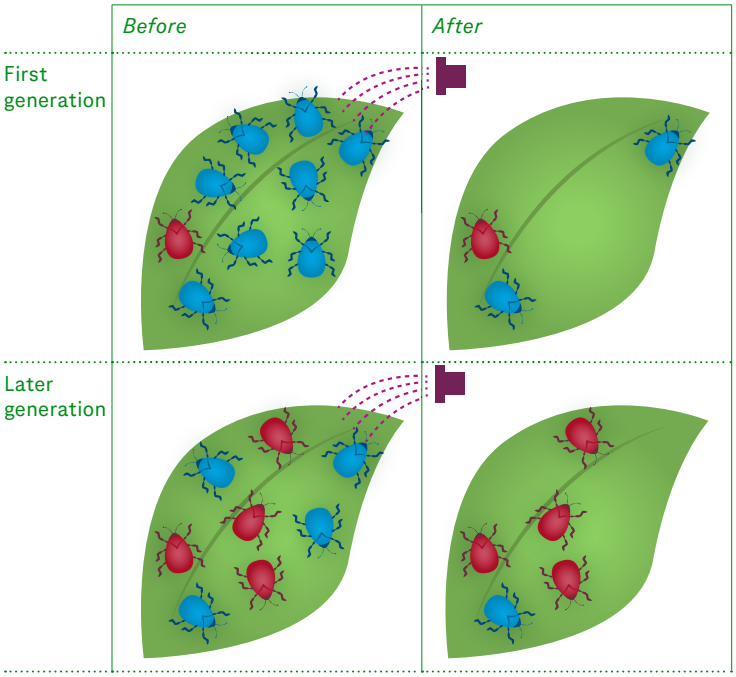

1. What environmental focus from the articles does this graphic illustrate?

2. Looking at this graphic, explain why this type of natural selection would be concerning to farmers or scientists.

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Article Exit Ticket

Continued

3. Thinking about your novel GE product, brainstorm what aspects of manufacturing these agencies would explore prior to and during product production.

	Prior to *product production*	**During** *product production*
1 US Food and Drug Administration (FDA)		
2 US Environmental Protection Agency (EPA)		
3 US Department of Agriculture (USDA)		

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Manufacturing Research Guide

Directions

Please complete the Community Stakeholders table. What community stakeholders would be involved in your novel GE product production? What community members might be interested in purchasing your product? What global stakeholders may be worth partnering with as well?

Community Stakeholders

List of stakeholders who would be involved

	Name	Description *Why would they help produce or purchase this product?*
Who would help produce the product?		
Who would purchase your GE product?		

Continues next page >

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Manufacturing Research Guide

Continued

Reflection

How is your group doing with community interviews? How have the responses guided your understanding of the community challenge associated with your novel GE product?

Teacher Approval

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Lesson 9 Exit Ticket

Directions
Reflect on your group's progress on your website and respond to the following questions.

1. What strategies have you used to divide up the work for your final website? Elaborate on where you are in the project.

2. What are some challenges you have encountered with your work this week?

3. What are some successes you have had with your work this week?

4. What progress has your group made on community communication? Elaborate in detail on successes and shortcomings.