SAFE BY DESIGN
TAKE CARE OF THE FUTURE

Rijksinstituut voor Volksgezondheid en Milieu
Ministerie van Volksgezondheid, Welzijn en Sport

Serious Game
Safe by Design

Background info to help you choose your response!

Design your solution and remember: innovation is an iterative process, not linear!

A case contains a message from an external actor, and response options suggested by your project manager!

Problem description
Describe the characteristics of the problem that needs to be solved

Design criteria
Describe the various design criteria that your solution to the problem has to meet

Development
Describe how your product is constructed to realize the required design criteria

Testing
Describe how to evaluate whether your products meets the design criteria

Production
Describe what is required to scale-up production and prepare for market release

Market aftercare
Describe what, if anything, needs to be done after market release

Record your final score here!

Resources spent ____ points

Uncertainty reduction ____ points

Systemic awareness ____ points

Cases, choices and consequences provide valuable clues to improve the design of your solution!

Think about the technical design and development process!

Consider how cases influence design choices!

Prepare to pitch the design of your solution, not your responses to the events!

1
Case
Response: _____
Response

2
Case
Response: _____
Response

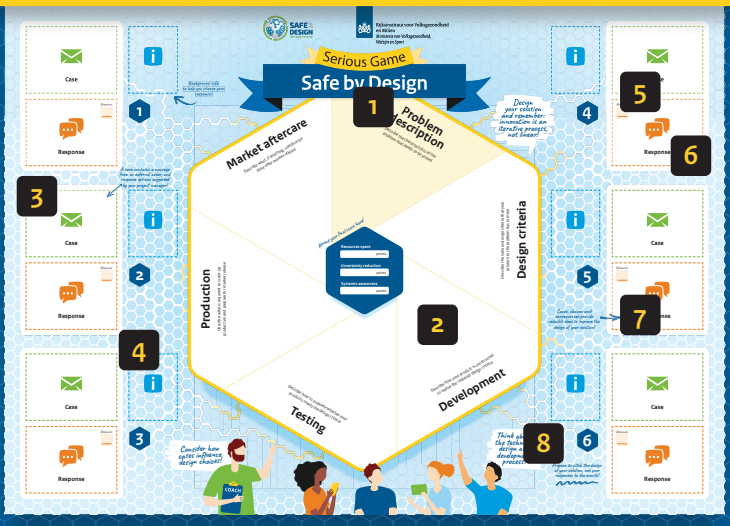
3
Case
Response: _____
Response

4
Case
Response: _____
Response

5
Case
Response: _____
Response

6
Case
Response: _____
Response

Quick game overview



On the table in front of you is the development board for the product or solution that you will be developing to address a societal challenge. Keep in mind that it should be ethically acceptable, in line with the needs, demands and wishes of the various stakeholders involved, and, of course, that it is safe by its design!

1. The hexagon contains six phases of innovation; for each phase you must continuously deliberate what should be done to achieve your goal.

2. Write down the actions or criteria that you will aim for during different inno-vation phases in the corresponding phase on the game board.

3. While you are busy innovating, things happen in the world that may affect your development. Throughout the game, you will be given case cards that contain issues that demand a response!

4. Of course, you don't want to make uninformed decisions. That is why the information cards pro-vide general background information that may help you decide which response option to choose.

5. Deliberate which choice best serves your goals, and note it down in the response box.

6. After a choice is made, a Response Card provides feedback on the consequences through a point-system and a description.

7. The cases & responses provide you with insights on which ethical and safety issues may be relevant for your project, and which interests other stakeholders have.

8. Remember to account for new insights obtained from discussing the cases in your design. You should be able to present convincingly why you have made the best possible design choices!

END GAME: After one hour, the work on your solution or product must stop, and you should prepare to present it to the other teams. Remember that it is about the process and technical design rather than your response choices. During the debriefing, the implications of your design choices and your final score will be discussed!

SAFE BY DESIGN
TAKE CARE OF THE FUTURE

Notes:

Proclaimer: The Safe-by-Design Serious Game was designed to facilitate discussion about how to address a wide scope of safety issues during technological innovation. Although the game aims to provide accurate information, some viewpoints and processes described in its contents have been deliberately simplified for practical or educational purposes.

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1

Case card

Response options

A. Create a cell factory to produce a toxin

B. Create a sense & kill bacterium

C. Create a resistant bee

Propose a technical approach

The Ministry of Information & Technology (MIT) acknowledges the severe risk Varroa mites pose to honeybee populations. In response, a call for proposals is put out within the field of synthetic biology to find a solution to this problem. The grant provides resources for a research group to develop a solution, from idea all the way to market readiness. Submit your approach and argumentation why your proposed solution should receive a grant to the MIT as soon as possible!

1

Info card

A

Cell factory

Organisms can be developed as a production facility, a so-called cell factory. In the current situation, a bacterium can be genetically modified to produce a toxin that is lethal to the mite. The bacteria produce the toxins in a bioreactor, after which the toxin is extracted and purified. Of course, the purified toxin still needs to reach a place where the mites are exposed to it.

1

Info card

B

“Sense and kill” system

A bacterium is able to respond to the detection of a specific biomarker with the production & release of a chemical. This mechanism can be used to construct a bacterial sense-and-kill system that releases a toxin when it detects a specific biomarker that indicates the presence of the Varroa mite. These bacteria can then be released within the bee colony. However, be mindful of the natural tendencies of such organisms.

1

Info card

C

GM resistant bee

It appears that some bees develop a natural resistance to the presence of the Varroa mite. Recently a gene was discovered that seems to be the source of this resistance. Although it is unknown by which mechanism the gene causes resistance, this discovery makes it possible to construct a strain of honeybees that is resistant to the effects of the Varroa mite. Be sure to take into account that this kind of solution has often met societal resistance.

Info card

1

Response card

A

[redacted]:

points

[redacted]

points

[redacted]

points

Bacterial cell factory

You have chosen to develop a genetically modified micro-organism that produces a Varroa-specific toxin under highly controlled conditions (a bioreactor).

Deliberate with your team on what will need to happen in the different innovation phases to create a product ready for market launch.

1

Response card

B

[redacted]:

points

[redacted]:

points

[redacted]:

points

Bacterial “sense and kill” system

You have chosen to develop a genetically modified bacterium that will respond to the presence of the Varroa mite with a lethal toxin.

Deliberate with your team on what will need to happen in the various innovation phases to create a product ready for market launch.

1

Response card

C

[redacted]:

points

[redacted]:

points

[redacted]:

points

GM resistant bee

You have chosen to develop genetically modified bees that are resistant to the virus spread by the Varroa mite.

Deliberate with your team on what will need to happen in the different innovation phases to create a product ready for market launch.

1

Response card

D

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

2

Case card

Grant allocated!

Congratulations, the MIT research committee has evaluated your proposal positively! You receive a grant to develop a functional solution within twelve months. Keep them informed about your progress! By the way, we don't need to remind you that there are some rules about working with GMOs, do we?

Response options

A. First, assess feasibility

B. Send notification to the GMO office

C. Request contained use permit

D. Request environmental introduction permit

2

Info card

A

A detailed description of intended activities

The GMO office assesses all GMO research to ensure safe working procedures. For this reason, you must submit a detailed description of your intended activities, including the organisms you want to work with, the modifications you aim for, and an assessment of the potential risks. Paradoxically, the more you experiment, the better you can describe your activities.

2

Info card

B

Contained use notification

‘Contained use’ refers to all activities with GMOs in a closed environment. For research with nonpathogenic organisms, it is sufficient to send a notification about your project to the GMO office. You are responsible for maintaining safety protocols to ensure that the correct procedures are followed.

2

Info card

C

Contained use permit

You will need a permit if your solution involves working in a closed environment with pathogenic organisms and/or involves large-scale application of genetically modified organisms for commercial purposes. Such projects will be thoroughly assessed by the GMO office.

2

Info card

D

Introduction into the environment

When activities with GMOs take place outside a controlled environment (e.g., laboratory or reactor vessel), it is considered an ‘introduction into the environment’. For all activities in this category, a permit is mandatory. The risk assessment must comprehensively cover the potential impact on human health and the environment.

2

Response card

A

Resources spent:

 points

Uncertainty reduction:

points

System awareness:

 points

Your first experiments are hopeful. However...

After a month, you are confronted with an inspection. The inspectorate cannot believe that you are doing GM research without following proper procedures. You receive a fine and are not allowed to continue until you have sent a proper notification to the GMO office. And remember, you will need a permit for any future production or environmental application!

2

Response card

B

Resources spent:

P points

Uncertainty reduction:

points

System awareness:

P P points

The GMO office responds to your notification

You sent a notification to the GMO office. The office calls your team to clarify a few details and offers some useful suggestions. They thank you for your notification and remind you that for future commercial activities in production facilities or the environment, you must request a permit.

2

Response card

C

Resources spent:

P P points

Uncertainty reduction:

points

System awareness:

P points

The GMO office responds to your application

You apply for a permit with the GMO office. They applaud your thorough approach but indicate that, at this stage of R&D, it is not yet necessary to request a permit. For now, a notification is enough. Any future production or environmental application requires a permit. The GMO office helps you navigate the proper procedures, but this detour has cost you some resources.

2

Response card

D

Resources spent:

 points

Uncertainty reduction:

points

System awareness:

 points

The GMO office offers input on your application

Your permit for introduction into the environment has been rejected. It is still too early to assess (due to insufficient data) whether your solution can be released into the environment. Instead, you first have to do R&D, for which a notification is sufficient. Any future production or environmental application requires a permit. Requesting the wrong permit has cost you some resources.

3

Case card

Citizen concerns

The Civil Society Centre for public interests (CSC) indicates your project has become a topic of fierce societal debate. Many are worried about using biotechnology to interfere with the honey bee hives. They see an abundance of risks and would not feel safe with such technology near them. Moreover, environmental activists argue that supporting honeybees will put further pressure on wild bee colonies and the ecosystem. How do you respond to this?

Response options

A. Hire the "Science Awareness PR Group"

B. Engage with selected NGOs

C. Request the MIT to clarify rules and regulations

D. Organize an open citizen dialogue

3

Info card

A

Informing the public

Some people argue that the resistance to GMOs is caused by unfounded societal fear of their consequences or distrust of some specific organizations in the field. If public awareness about the minimal risks and enormous benefits of GMO technology were improved, their concerns should quickly disappear

3

Info card

B

Engaging NGOs

To obtain a good overview of the public's concerns, some research groups may decide to cooperate with NGOs that represent public interests. These NGOs often have good insight into the most pressing issues for the public and are open to cooperation. However, it is important to them that their input actually influences the design, even if that means you have to start all over again.

3

Info card

C

GMO Regulation

Some researchers argue that the GMO regulation is comprehensive and sufficient to guide the safe development of GMO technology. The government enforces compliance by researchers, so if citizens have any concerns, it is up to the government to address them. Either by clarifying the rules and regulations, or by adapting them if they find it necessary to address public demand.

3

Info card

D

Citizen dialogue

Some argue that GMO technology has such profound implications that the desirability of using GMO organisms must be decided by society at large. To facilitate this, researchers may decide to organize citizen dialogues, so that citizens can become involved in the project and share their opinions and concerns. That does imply that researchers need to be prepared to adjust or halt their project in response to citizen input.

3

Response card

A

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

The PR group reframes the discussion

You have decided to ask the Science Awareness PR company to reframe the discussion. This reduces the intensity of the debate, but people accuse you of manipulating public opinion. As a result, more people have negative associations with GMOs and become principally opposed to genetic modification. They continue to protest against your research.

3

Response card

B

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

You collaborate with a select group of NGOs

You have decided to seek cooperation with NGOs that represent the public's worries. They have brought forward some important concerns, which could have a significant impact on your design. Although your innovation may benefit from the effort, the continuation of your project is severely delayed.

3

Response card

C

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

The MIT studies the clarity of the GMO regulations

The government's evaluation of the clarity for the greater public of current policy regulation on this type of biotechnology takes a lot of time. The evaluation is not expected to have any meaningful impact within the timeframe of your project. This causes some people to suggest that you used this as a strategy to avoid dealing with legitimate concerns.

3

Response card

D

Resources spent:

 points

Uncertainty reduction:

 points

System awareness:

 points

A diverse group attends your citizen dialogues

At first, the CSC compliments you on your inclusive approach. However, the diversity of the participants means that you were unable to incorporate everyone's worries in a meaningful way. Quite a few people loudly claim you did not listen to them sufficiently and accuse you of win-dow-dressing. This diminishes the positive effect on your reputation.

4

Case card

Economic concerns

We, the Apiculture Association (AA), are enthusiastic about your project to support the honeybees. However, we have been advised that your new innovation could have a negative impact on the quantity or quality of the honey produced by the bee colonies treated with your product. The uncertainty about the risks to our income is not acceptable to us beekeepers! We therefore demand that you take action!

Response options

A. Project scope does not compel you to action

B. Deliberate with scientists and experts

C. Adopt goal to preserve honey quality and quantity

D. Deliberate with Apiculture Association

4

Info card

A

Permit coverage

When research and development with a specific goal in mind leads to the introduction of a new technology, it may have unexpected impacts on other societal domains. To what extent you are liable for the unforeseen downstream effects of your design is debatable. The legal procedure you have followed proves that the potential impact of your project was sufficiently assessed.

4

Info card

B

Expert advice

Researchers may decide to ask fellow scientists from other disciplines for advice on broader impacts. This could allow them to make a more comprehensive analysis of the various risks, which helps to decide if and how the design needs to be adapted. Of course, to do so, research data needs to be shared with the external researchers who will be involved.

4

Info card

C

Inherently safe product

A product focus on designing for safety implies that the final product released to the market is free from any foreseeable risks. To this end, every concern has to be translated into a design requirement for the product. During development, you then continuously evaluate and adapt the product, until no more negative (unintended) impacts are present.

4

Info card

D

Acceptable risk

Quality is relative, and risk is the probability of a hazard occurring. So, during development, decisions are constantly made on what probability and quality are deemed acceptable. To make these decisions, an inventory of the potential losses and gains for each stakeholder must be made for different scenarios. Agreement must be reached on what scenario will satisfy all parties involved.

4

Response card

A

Resources spent:

points

Uncertainty reduction:

points

System awareness:

– Ⓟ Ⓟ points

You don't take further action

Your research and accompanying permit cover rescuing of the honey bee. Any potential concerns about the quality or quantity of honey production are not up to you. As a result, fewer beekeepers are using your product in practice. This means that your solution contributes less to saving the honey bee.

4

Response card

B

Resources spent:

P P points

Uncertainty reduction:

P P points

System awareness:

P P points

You collaborate with a select group of NGOs

You ask for input from other scientists who indicate there is no reason for concern. This takes some extra time, but your cautious course of action improves your reputation. However, one of the research groups that you've asked for advice is now conducting a very similar study, profiting from the progress you have already made...

4

Response card

C

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

Stable honey production is now a design requirement

You have decided that you need to avoid every foreseeable risk before you can continue the development of your product. In doing so, you take on a lot of responsibility to act cautiously. Doing this research has resulted in an improved product, but has taken up a large part of your available resources.

4

Response card

D

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

You agree on a solution with the beekeepers

You have decided to discuss the issue with the Apiculture Association. They are thrilled that you are involving them in the process. It does take a long time before everyone is on the same page, but in the end, everyone is satisfied with the decision that a maximum of 13.5% decrease in honey production is acceptable if the bees are saved.

5

Case card

A production problem

The Centre for Industry and Commerce (CIC) received news that the company you are collaborating with to realize the upscaling towards the required production has measured a low concentration of a potentially hazardous chemical in one of the waste streams of their production process. For scaling-up, the company has specifically adapted an existing production method. How are you going to respond to this?

Response options

A. The company should resolve the issue

B. Research the chemical while production continues

C. Develop a new, safe production method

D. Collaborate with the company

5

Info card

A

Distributed responsibility

Some people argue that although researchers have a large responsibility for safety, it is unfair and inefficient to put the entire responsibility on their shoulders. The innovation chain is segmented into various steps, with various actors. These other actors, such as a production company, have to take responsibility for their part.

5

Info card

B

Evidence informed decisions

Some argue that it is not feasible to stop innovation every time a potential risk is identified, as development would slow down to a snail's pace. Evidence-based decision making first requires evidence. So, only risks for which sufficient data is available to make an accurate risk assessment can be properly managed. This means that if a potential risk is identified, it needs to be studied in parallel to the innovation process.

5

Info card

C

Safety throughout

Some people argue that to have a product that is Safe-by-Design, risks need to be addressed throughout the life-cycle of a product, starting at the earliest stage possible. That means assessing everything from lab procedures, operational use, production, distribution, and disposal. Next, the forthcoming risks should be resolved before the market introduction of that product.

5

Info card

D

Shared responsibility

Some argue that responsibility for the safety of a process should always be shared among several actors. After all, although a certain actor is in the lead on a certain task, other actors may provide crucial information to resolve safety issues. And that could benefit everyone. Even though there are many the practical barriers and it is a challenge to distribute both the costs and the benefits of such shared responsibility.

5

Response card

A

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

The company says it will look into the matter...

You have decided that these risks are no longer your responsibility. In the meantime, some people claim that the chemical is indeed toxic to some important organisms. They start a public campaign about the dangers of the production method. Most of the attention is directed at the company but your research group is also mentioned. This harms your reputation.

5

Response card

B

Resources spent:

Ⓟ Ⓟ Ⓟ points

Uncertainty reduction:

Ⓟ Ⓟ points

System awareness:

Ⓟ points

A comprehensive tox study is carried out a.s.a.p.

You have decided to do more research on the potential risks. The toxicology research takes a lot of your resources, which delays your project. You conclude that the concentration of chemicals is not harmful to humans or the environment. Despite this, some environmental activists say the chemicals pose a risk to the integrity of the ecosystem.

5

Response card

C

Resources spent:

4 points

Uncertainty reduction:

2 points

System awareness:

1 points

Production is halted without reimbursement

Because you want to avoid every risk, you have decided to search for a different production method that is completely safe. However, after spending a lot of resources on the development, you have not yet found an alternative production method that avoids introducing some fraction of the hazardous chemical into the waste product.

5

Response card

D

Resources spent:

 points

Uncertainty reduction:

 points

System awareness:

 points

Combining practice with science proves fruitful

You have decided to cooperate with the company to improve the production method. In this way, you take part of the responsibility for safety upon you. Together, you find a solution that does not change the production method but treats the waste stream in such a way that the chemical is neutralized. This process has cost you some resources.

6

Case card

Unexpected success!

The Centre for Industry and Commerce (CIC) notices that your product is selling much better than was anticipated for exclusive use against Varroa mite infection. After some research, the CIC found out that your product is also used off-label for other purposes (i.e., the toxin-bacterium is also effective against other pests, or the bees are also resistant against another pest organisms). How do you respond to this?

Response options

A. Ask MIT inspection to investigate

B. Redesign your product to avoid off-label use

C. Include new use in your marketing strategy

D. Develop a user manual to describe intended use

6

Info card

A

Inspection agencies

Some people argue that it is not up to the researchers, but to the inspection, to decide if potential risks from unintended applications are acceptable. If an unintended use is identified, the decent thing to do is inform the inspection and ask them to evaluate the consequences and, if necessary, take the necessary actions.

6

Info card

B

‘Fool-proof’ design

Some people argue that the best way to safeguard something against unintended use is to design it in such a way that its use is limited to just one setting and application. A so-called ‘fool-proof’ design prevents users from using the technology in new, creative, and unsafe ways. Moreover, it only allows it to be used as envisioned by its designers.

6

Info card

C

Marketing strategy

Some people argue that if the development of a technology has followed the correct safety procedures, it is safe for all different applications. There is no reason to prevent a wider group of users from benefiting from the creative use of an innovative technology, and no reason not to let anyone profit from that unintended use.

6

Info card

D

User manual

Some product developers argue that some of the responsibility for safety should be transferred to the users because their behavior impacts the safety level. This can be done by developing a user manual, which describes how to handle the product safely. If users then use the product in a different way, the consequences are their responsibility.

6

Response card

A

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

Your product comes under close scrutiny

You have decided to ask the inspection authorities to evaluate whether extra regulation is required. As a result, new regulation has been adopted that restricts the use of your product only to the application that you envisioned.

6

Response card

B

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

You redesign your innovation

You have decided to adapt your product to make it “fool-proof”, by integrating design elements to make sure it can only be used as you intended. Some customers can no longer use the product like they did before, leading to many calls and e-mails from displeased consumers accusing you of paternalism.

6

Response card

C

Resources spent:

− Ⓟ Ⓟ Ⓟ Ⓟ Ⓟ points

Uncertainty reduction:

− Ⓟ Ⓟ Ⓟ points

System awareness:

− Ⓟ points

Clever marketing increases your income

You have decided to adapt your marketing strategy, and your sales results improve even more. But it is still unclear whether the unintended use introduces any new safety concerns. Moreover, the expanded use of your product increases the burden on the environment. Maybe you should invest in a legal team to protect you against any liability.

6

Response card

D

Resources spent:

points

Uncertainty reduction:

points

System awareness:

points

Communication experts discuss the instructions

You have decided to develop a user manual with safety instructions. However, as it is not feasible to write a comprehensive manual – which no one will read anyway – the producer decided to stick to a few sentences about risks on the packaging. As a result, not every risk of possible uses can be discussed in the manual.