



Market aftermarket release

en Milieu

Serious Game Safe by Design

_Background info to help you choose your response!

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СОАСН

Rijksinstituut voor Volksgezondheid Ministerie van Volksgezondheid, Welzijn en Sport





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needs to be solved



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Describe how your producted design Describe the required design to realize the required design below your producted design.

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

Think about the technical design and development process!

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



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!

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

1

2

3

4

Write down the actions or criteria that you will aim for during different inno-vation phases in the corresponding phase on the game board. After a choice is made, a Response Card

and note it down in the response box.

Deliberate which choice best serves your goals,

5

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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!

Of course, you don't want to make uninformed decisions. That is why the information cards provide general background information that may help you decide which response option to choose. provides feedback on the consequences through a point-system and a description.

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.

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!



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.

Acknowledgements: The development of the Safe-by-Design Serious Game was funded by the Dutch Ministry of Infrastructure and Water management, and co-developed with students and teachers from several different Dutch (applied) universities, as well as by students & coaches taking part in the international Genetically Engineered Machines (iGEM) competition.



Response options

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Lutum Consilio

- A. Low reflective solar cells
- B. Transparent solar cells
- C. Flexible solar cells

Choose a technical approach

The European Union underscores the huge potential of carbon-based nanomaterials. Due to the major challenges around the energy transition, an important topic of concern is the improvement of solar cell technologies. Specific grants have been made available for research groups developing solar cells enhanced with carbon nanomaterial. Recent scientific progress suggests that three different nanomaterial applications are especially promising. In order to receive one of these grants, your application must describe more than your approach to increasing performance. You also need to take into account a broad range of safety-related factors. Hand in your approach and argumentation why your proposed solution should receive a grant as soon as possible.



Carbon monolayer flakes (CMF)

Graphene is a sheet of carbon with a thickness of a single atom. It is exceptionally strong, flexible, conductive, impermeable and nearly transparent. CMF can be used to significantly decrease the reflectance of regular solar panels, which increases their yield. It may also enhance the durability of panels so that they can be used for longer, or in more corrosive circumstances. However, the flakes are easily spread in the air as particulate matter, where they may enter the lungs of people and animals.



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Carbon buckyballs

Fullerenes are spherical carbon. not unlike a football, also known as buckyballs. They were amongst the first nanomaterials discovered. They are exceptional electron acceptors that can help the transfer of electrons over a relatively large distance. Many derivatives can be made with different functionalities. Buckyballs may be essential for creating efficient transparent solar cells with different interesting applications. However, they have been shown to cross biological cell-barriers and have a high potential to build up in living tissue.



C

Carbon nanotubes

Carbon nanotubes are sheets of graphene rolled up into a tube. They show remarkable conductivity and tensile strength, are easily produced, can be of various thickness and lengths, and consist of one or multiple walls. Carbon nanotubes can be fabricated with photovoltaic properties and could for example be used to create flexible thin-film solar cells for use in wearables. However, the size and shape of these materials may give them asbestos-like properties in terms of potential health risks.





Efficiënt & durable solar cells

You have chosen to develop solar panels with unique qualities by using graphene monolayer flakes. Discuss/consult with your team what needs to happen in the different innovation phases to develop a product that benefits from the added durability and efficiency that CMFs provide, and is ready to launch on the market. Keep note of your design choices and consider how people and the environment may come into contact with the product or its component materials throughout its life-cycle.

points

points

points

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Transparent solar cells

You have chosen to develop solar cells with unique qualities by using buckyballs. Discuss/consult with your team what needs to happen in the different innovation phases to develop a product that benefits from the transparent cells that buckyballs enable, and that is ready to launch on the market. Keep note of your design choices and consider how people and the environment may come into contact with the product or its component materials throughout its life-cycle.

Flexible solar cells

You have chosen to develop solar cells with unique qualities by using carbon nanotubes. Discuss/consult with your team what needs to happen in the different innovation phases to develop a product that benefits from the flexible solar cells that CNTs enable, and that is ready to launch on the market.

points

points

points

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Keep note of your design choices and consider how people and the environment may come into contact with the product or its component materials throughout its life-cycle.





Response options

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Lutum Consilio

- A. Find a dissimilar alternative
- B. Find a similar alternative
- **C.** Adapt the production process
- D. Apply for an R&D exception

A material may be restricted

Congratulations! You have received the grant and may continue development. However, one of the materials you need within your production process is on a list with potentially hazardous substances. Materials on this list will probably be considered for future regulatory action by being included in REACH (the key chemical control regulation in the European Union). Depending on the risks associated with the material, regulatory action could mean anything from "not being allowed to use the material anymore for specific applications" to "requiring authorization from REACH to be able to work with the material after provision of comprehensive (and costly) safety data." How will you proceed?





Substitution

'Substitution' is a common safety practice within the field of chemistry. It means that, whenever possible, hazardous substances are replaced with less harmful ones, while trying to maintain the same functional role and efficiency. However, sometimes the properties that make a substance functionally desirable in the first place are also the properties that make it harmful. This is why choosing a different material that is demonstrably safer may come at a price somewhere else in the process or the application/usage of a product.



Structural similarity

In order to find materials with similar functional properties, an often-used approach is to look for alternative materials with structural similarities to the one that needs to be replaced. Such structurally similar materials is most likely to be able to perform the required function at the desired efficiency within the existing production process. This is why they are often the most cost-efficient alternatives. Of course, you have to look for substances that are not flagged as potentially hazardous by REACH.



C

Mechanical alternative

To solve the problems around the use of hazardous substances, you can also search for a mechanical alternative instead of a chemical one. This would make the hazardous material obsolete within the production process, so that the hazard is eliminated altogether. For example, instead of using glue to attach two materials, maybe you could weld them together. Whether such an option is doable depends on which stage of development the production process is in at the moment: the further along it is, the more expensive it becomes.



D

Research provisions

REACH regulations include specific provisions to facilitate research into the properties of chemicals. Applying for such an exception often excuses the applicant from the regular requirements, as long as the material is being used in a research and development phase. This gives you the opportunity to learn much more about the specific characteristics of the material, and about its functional role in the production process. But once commercial use becomes an option, a decision must still be made on how to approach the REACH requirements.

2

Substitution

You have chosen to use an alternative substance which has been used by other companies for many years and is seen as safe for use. However, as predicted, it is nowhere near as efficient for its intended use as the nano substance you were planning to use. This means you have to find other ways to increase the efficiency. As a result, one specific step in the production process of your solar panel will increase in length by 30 percent!

Resources spent:

Uncertainty reduction:

System awareness:

points

points

points

2

Regrettable substitution

You found a very similar material that allows you to adjust your production process with minimal disruptions. It looks like a good decision as researchers show the previous material to be indeed highly toxic, leading to strict controls. But further research indicates that specific structural properties were responsible for its toxicity, and that similar materials probably have similar hazards. To prevent companies from following your example, regulators consider a general ban on all materials with these structural characteristics...

Resources spent:

 $-\mathbf{P}$

Uncertainty reduction:

System awareness:

points

points

points

2


Innovate the production process

The functional role of the material could not be replaced directly through a mechanical solution in the production process. However, through a complex change in design, a previously integrated functional system has been technically separated into two isolated systems. This change has made the potentially hazardous material obsolete, so you can completely remove it from the production process. Although it has become more complex, your product now has fewer potential risks.

Study & postpone decisions

The research provision allows you to postpone a decision on the use of the material until after you have developed a good understanding of the material's characteristics and its place in the production process. Your studies indicate the material is highly toxic and these results will speed up stricter control of the material. This means that, sadly, you still have the same dilemma as before, but at this later stage you are much less flexible in adapting your product or process.

Resources spent:

Uncertainty reduction:

System awareness:

points

points

points



Response options

Public Inter

Civil Society

- A. Initiate a positive campaign
- B. Engage with selected NGOs
- **C.** Defer the issue to government
- **D.** Organize an open citizen dialogue

Concerned citizens

After a popular documentary revealed a large pollution scandal involving multiple big chemical and engineering companies, who are also involved in nanotechnology, a fierce societal debate on the risks for both health and environment that come with the large-scale use of nanomaterials is developing. Environmental activists vocally argue that the negative effects of nanomaterials on the environment are being downplayed and understudied, and may well be much more serious than we know. As a result, many people question whether it is safe to have nanomaterials around and why one would choose to introduce new materials that may be hazardous and bio persistent? Your project has specifically been mentioned in the debate, you must decide on a response!



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Informing the public

Many supporters of technological innovation argue that resistance to innovation is caused by unfounded societal fears and distrust stemming from poor understanding. Back in the day, scary stories were being spread about the introduction of electricity like now about the introduction of 5G. If only the public would be better informed on the minimal risks and enormous benefits of nanotechnology, their concerns would quickly disappear.



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Engaging with NGOs

In order to get a good overview of the public's concerns, companies can decide to cooperate with Non-Governmental Organizations (NGOs) that represent public interests. These NGOs often have good insights into the most important issues for citizens and are open to cooperation. However, it is important to them that their input does not fall on deaf ears, even if that means you have to start over again.



Safety rules and regulations

Many innovators argue that the existing regulations on the use of chemicals and substances are comprehensive, legally compelling and organized on a solid international scale. They are designed to ensure the safety of developments in fields such as nanotechnology. Therefore, if citizens have any concerns, it is up to politics and policymakers to address these. Either by clarifying the rules and regulations, or by adapting them if deemed necessary to address public concerns.





Citizen dialogue

Some science & society scholars argue that emerging technologies such as nanotechnology may have such profound implications that the desirability of their introduction must be decided by society at large. To facilitate this, researchers and developers may decide to organize citizen dialogues, in which citizens become involved in the project and share their opinions and concerns from early phases onwards. This implies that researchers need to be prepared to rigorously adjust their innovation development in response to the input obtained.

A	
Resources spen	t: points
Uncertainty red	uction:
	points
System awaren	ess:
-0	points

Your campaign positively reframes carbon materials

Several talk shows cover the miraculous properties and potential benefits of carbon nanomaterials. Moreover, several movies are announced such as 'Fast&Furious: Craving Carbon' and 'Kung-Fu Panda: Fists of Carbon.' Although public opinions seem to turn around, some people accuse you of manipulation. As a result, a significant group sees their distrust of nanotechnology reinforced and starts a vocal movement against projects such as yours.



A collaboration with a select group of NGOs

You have decided to seek cooperation with NGOs that voice the different concerns of citizens. They have brought forward some important concerns, which could have a significant impact on your product design. They also point out some additional relevant issues that you would never have considered yourself this early in the innovation development. Although your innovation will probably benefit from addressing these issues, the continuation of your project is severely delayed.



You forward the concerns to the relevant authorities

The authorities start an evaluation of how clear current policy regulations concerning nanotechnology are to the general public. This takes a lot of time. The evaluation is not expected to have any meaningful impact within the timeframe of your project. This causes some to suggest that you do not take the concerns of citizens seriously and that you use this as a strategy to avoid dealing with legitimate concerns. As a result, protests against your research are continued.

Resources sp	pent:
	points
Uncertainty	reduction:
	points
System awar	reness:
	points

Dialogue sessions with a variety of participants

At first, many societal organizations compliment you on your inclusive approach. However, the diversity of concerns identified resulted in the inability to address all of them in a meaningful way. As a result, several people claim you did not listen to them sufficiently and accuse you of window-dressing. Although some concerns could be resolved or clarified, resulting in a better product, many participants are still unsatisfied and continue to raise questions and concerns.



Response options

A. Continue development

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- B. Deliberate with experts
- C. Review the fabrication process
- **D.** Conduct biodegradability research

Not that safe and sustainable?

Although carbon nanomaterials can increasingly be made biodegradable, a report of the National Institute for Public Health and Environment states that some composite materials created during the fabrication of your solar-cells are likely to be non-biodegradable. This may indicate that those materials are persistent and will accumulate in the environment, which is often a sign of trouble. Unfortunately, the report does not offer certainty on its persistence or on the impact of the material if it does accumulate. What do you do with this information?



Α

Actionable information

Meaningful data that is useful to make a decision or solve a problem is called actionable information. If there is no conclusive evidence to support the harmful characteristics of a material, and it is not listed as a substance of (very) high concern, you could argue that there is no actionable information, and thus no legal or scientific motive to refrain from using the material in research and development.



Expert advice

Fellow scientists from other disciplines and research institutes may give their expert opinion on the characteristics of the material and its expected effects. This contributes to a more thorough analysis of the safety and sustainability of the end product and of potential (harmful) effects. Such information may be very useful in understanding if, why and how the design may need to be adapted. Of course, sharing research data with other experts compromises the confidentiality of your project.



C

Precautionary principle

When a certain decision may cause harm, and conclusive evidence is lacking, policymakers often invoke the precautionary principle: pausing for a thorough review of possible side effects before leaping into new innovations that may prove disastrous. Such an approach may encourage early identification of potential harms, but it may also lead to halting the innovation process if too much uncertainty remains. This is why opponents argue that the principle only obstructs technological progress.



Environmental monitoring

Gaining insight into potentially harmful effects for the environment requires thorough monitoring for the presence of potentially harmful materials, their dispersion and persistence, and their impacts. Also, relevant environmental parameters must be selected so that observed changes can be correlated with the presence of the material. Thus, the impact of the material on its environment can be worked out. However, such a study can obviously only yield meaningful results if the material is already present in the environment

Resources spent:

points

points

Uncertainty reduction:

points
System awareness:

No action taken

The composite material created in the fabrication process is not on any list for (potential) substances of high concern and can therefore be used with no explicit practical or legal objections. In time, harmful effects may or may not materialize, but that should not prevent the progress of your R&D or the long-term viability of your project. For now...



Respected scientists gladly discuss your project

You ask for input from respected scientists who are having a hard time figuring out the potential effects of the composite material. In the end, they all – besides one – conclude that no harmful consequences for humanity and the environment can be identified. Waiting for the conclusions of the scientists took quite some time, but your cautious approach did demonstrate that the composite material is highly unlikely to present a safety issue.
Resources	spent:
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Uncertaint	y reduction:
- <mark> </mark>	points
System aw	vareness:
0	points
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A cautious approach

You have decided that, before you can continue the development of your product, you need to avoid every potential harmful consequence and develop the product in a safe and sustainable way. This means exploring and identifying a different fabrication process resulting in similar qualities that does not create the composite material. Your cautious and responsible approach works to your credit, but it does require significant resources.

Resources sp	pent:	
	points	
Uncertainty reduction:		
	points	
System awareness:		
	points	

Longitudinal study

You have decided to closely investigate and monitor potential, foreseeable harmful effects of the composite materials in question and to explore safety and sustainability issues. At the same time, you progress with your research and development. But before these studies yield any significant result, your product will already be widely used in society. You decide to set aside a significant portion of any future income to ensure you are able to pay for sanitation efforts or damage claims.



Response options

to industry &

Commerce

- **A.** The company should resolve the issue
- B. Conduct an exposure assessment
- **C.** Develop a new, safe production method
- **D.** Collaborate with the company

Exposure risk during production

To upscale the production of solar cells, you are collaborating with a specialized production company. To meet your stringent quality standards, the company has upscaled your production method according to your detailed specifications. The company enforces standard safety protocols, including personal protective equipment for their employees. However, an inspection at the company measured trace particles of your carbon nanomaterial in the air, which suggests their workers may be exposed to low concentrations of potentially harmful particles during the production of your solar cells. The company may have to develop a safer production route. Changes in the production method could affect your final product; how do you deal with this?



Distributed responsibility

One could argue that although researchers and developers have a heavy responsibility for safety, it is unfair and inefficient to put it entirely on their shoulders. Innovation development is segmented into different phases precisely because different actors in the innovation chain each have their specialization and are best suited to deal with issues within their domain of expertise. Therefore, actors such as production companies, distributors, and electricians have to take responsibility for their own part.



Evidence-based decisions

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One could argue that it is not feasible to stop innovation every time a potential risk is identified; development would slow down to a snail's pace. Evidence-based decision making requires evidence. Therefore, making effective and specific adjustments requires a detailed evaluation of whether there is actually an exposure risk, how big that risk is, and where exactly in a process it originates.



C

Safety throughout

One could argue that in order to have a product that is Safe-by-Design, risks needs to be addressed from the design phase onwards. That means that everything from lab procedures, operational use, production, distribution, and disposal should be assessed. Before continuing development, any identified hazards should be resolved, regardless of how big the probability of exposure to that hazard is.



Shared responsibility

One could argue that responsibility for the safety of a product should always be shared between several stakeholders involved in the supply chain. After all, although a certain stakeholder is in the lead for a certain task, others may provide crucial information to resolve safety issues, which could benefit everyone. Nevertheless, there are many practical barriers, and it is a challenge to distribute both the costs and the benefits of such shared responsibility.



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

You have decided that the exposure risks for workers at the company are not your responsibility. In the meantime, the company workers get wind of the inspection agency's reports and seek media coverage for the alleged cover-up of potential harms to their health. Although most of the attention is directed at the company, the issue also casts a shadow on your project.

Resources s	pent:
	points
Uncertainty	reduction:
	points
System awa	areness:
	points

A comprehensive study is launched

You have decided to do more research on the potential risks. Sensitive equipment is used to measure particle exposure throughout different stages in the production process, and a longitudinal study is started to closely monitor the health of the workers involved. This takes up a lot of resources but the project remains mostly on schedule. A few workers try to initiate a protest on the grounds that if there is indeed a health risk, it will only be discovered once the damage is already done...

Resources spent	
	points
Uncertainty redu	uction:
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System awarene	
	points
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Production is halted

Because you want to avoid every risk, you have decided to search for a production method that is completely safe for the workers. After spending many resources, you identify several ways of eliminating exposure risks throughout the production process. This complicates production significantly, because you did not cooperate with the company in this development, you end up with a production method that cannot be transferred to the company without adjustments. This delays your project significantly and demands further investments.



Combining practice and science proves fruitful

You have decided to collaborate with the company in improving its production method. In this way, you take joint responsibility for safety. Your collaboration results in adjustments of the production process to exclude exposure risks to workers, including the provision of protective equipment to shield workers from exposure to any remaining particles. At the same time, the process becomes more cost-effective as well.



Response options

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A. Alert the proper oversight bodies

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- B. Remarket for specific uses
- C. Make a deal
- D. Publish a manifesto

Unexpected interest

Your innovative products have caught the eye of an unexpected industry. A large toy company claims that thanks to the novel possibilities of your solar cells, they can be integrated into many different electronic toys. As a result, they will no longer need expendable batteries. The toy company says it wants to use these new possibilities to launch a line of sustainable toys. Your solar cells were not designed for use in this type of product. Putting them in the hands of young children may raise a host of new potential safety issues...





Info card

Α

Government inspection

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





Info card

'Fool-proof' design

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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 strictly limited to the intended settings and applications. A so-called 'foolproof' design only allows the product to be used as envisioned by its designers and prevents others from using the technology in new, creative, and potentially unsafe ways.





Info card

C

Commercial opportunity

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 to not let anyone profit from that unintended use.





Info card



Manifesto

Some innovators argue that the responsibility for the variety of applications a technology may have cannot fall entirely on the shoulders of its creators. But one can take a clear position on what the technology was designed for, and thus the applications that one does take responsibility for, by publishing a public manifesto on the intended use. Those who then use a technology in some other way than intended carry the burden of responsibility for their own actions.



The exposure risks are thoroughly inspected

The relevant inspection agency commends you for alerting them to the situation. They thoroughly evaluate the exposure risks of your product during frequent handling and damages. Their research demonstrates that the exposure is non-existent if the nanomaterials are in matrix form, but that damage to the solar cells carries a small risk of release and thus exposure. As a result, the authorities develop new regulations to restrict its use in toys and require additional protection for any professionals who work with your products.

Resources	Bent:		
	points points		
Uncertainty reduction:			
-	points		
System awa	areness:		
	points		

Your solar-cells are sold as integrated products

You have decided to only sell the solar cells as integrated products for clearly designated uses. Designing these products and setting up the required infrastructure and partnerships requires an enormous effort. The resulting brand is perceived as highly trustworthy, responsible, and reliable. However, the high standards you maintain prevent you from quickly adapting to newly discovered applications. And the toy company, although significantly delayed, still launches the product line with solar cells from a much less reputable source.

Resources spent:

—(**P**)

- (P

- P P P P points

Uncertainty reduction:

P points

points

System awareness:

A mutually lucrative partnership

The toy company adopts your technology in return for a significant stake in the new sustainable product line. The new toys are cleverly marketed, and the product line sells very well in high-income countries. This provides you with a solid additional revenue stream. In the meantime, scientific studies indicate there may be severe detrimental health effects from exposure to the nanomaterials you used, and the risk of exposure is still unknown. It may be wise to invest in a firm liability insurance policy...

Resources spent:



A clear moral statement

Your manifesto is well received by those involved in the domain of responsible research and innovation. The manifesto, and your adherence to the principles it states, become a prime example for responsible commercial innovation. Although your principled stance creates business opportunities with like-minded organizations, many commercial entities view it as a barrier in collaboration. The toy company maintains its plans but, trying to avoid a PR scandal, they decide to wait for a less high-profile source of the technology.