

Instructions on the use of the e-service for the NIS2 entity list

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1 Version control

| Revision of the Guideline | Publication Date | Changes |
|---------------------------|------------------|-------------------------|
| 1.0 | 27.6.2025 | New guideline published |

2 General

These instructions are intended for users of the NIS2 entity list's e-service for the submission of entity notifications. The instructions contain information on submitting an entity notification in the e-service and general information on e-service functions.

More information:

- Fimea website: [Cybersecurity](#)

2.1 What is the NIS2 entity list?

The NIS2 entity list is a register maintained by Fimea of essential and important entities within the scope of Fimea's supervision under the Cyber Security Act. The Cyber Security Act (125/2025) specifies the entities that must submit their entity information to Fimea's NIS2 operator list.

The e-service for the NIS2 entity list is intended for the following essential and important entities within the scope of the Act:

- Entities manufacturing medicinal substances and medicines
- Entities involved in the research and development of medicines
- Blood establishments
- Pharmacies
- Healthcare sector entities supplying and providing medicines or medical devices as healthcare professionals
- Manufacturers of medical devices and in vitro medical devices for diagnostics

Important entity refers to the operator listed in Annex I or II to the Cybersecurity Act that meets or exceeds the conditions for medium-sized enterprises in accordance with Article 2 of the Annex to [Commission Recommendation](#) 2003/361/EC concerning the definition of micro, small and medium-sized enterprises and provides its services or activities in a European Union Member State.

Essential entity refers to an operator listed in Annex I to the Cybersecurity Act that exceeds the conditions for medium-sized enterprises in accordance with Article 2 of the Annex to [Commission Recommendation](#) 2003/361/EC concerning the definition of micro, small and medium-sized enterprises and provides its services or activities in a European Union Member State.

In the e-services, an entity can submit their entity information and view the information submitted to the NIS2 entity list.

In the e-service for the NIS2 entity list, you can:

- Submit a notification on your entity's entity information referred to in section 41 of the Cybersecurity Act
- Manage the submitted data (submit notifications of change)
- Check your registered information

Entities must submit a notification on any changes to the information referred to in section 41 without delay. A change to the information referred to in subsection 2 shall be notified to the supervisory authority within two weeks and a change to the information referred to in subsection 3 within three months of the date of the change.

2.2 Who can use the e-service for the NIS2 entity list?

Anyone with a Finnish personal identity code and an identification token intended for identification can access the e-service for the NIS2 entity list. **You will always use the e-service on behalf of an organisation, so you must also have the necessary rights to act on behalf of your organisation.**

You do not need a separate Suomi.fi mandate for Fimea's e-submissions if you are acting on behalf of a company or organisation in which you have an official role entered in the Trade Register:

- Managing director
- Substitute for the managing director
- Partner
- Holder of procuration authorised to sign alone for the company/organisation
- Self-employed business operator
- Liquidator

If you do not work in the above-mentioned roles in a company, you must request a mandate for transactions in the Suomi.fi service and the company must grant it to you. Read more in [Acting on behalf of an organisation: Authorisation \(PDF\)](#) and [mandates granted by organisations in Suomi.fi](#).

2.3 Definitions

- **Important entity.** Important entity refers to the entity listed in Annex I or II to the Cybersecurity Act that meets or exceeds the conditions for medium-sized enterprises in accordance with Article 2 of the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises and provides its services or activities in a European Union Member State.
- **Essential entity.** An essential entity is the entity referred to in Annex I to the Cybersecurity Act that exceeds the definition for micro, small and medium-sized enterprises in Article 2 of the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized

enterprises and provides its services or activities in a Member State of the European Union.

- **Manufacturer of a medicinal product.** Manufacturer of a medicinal product refers to pharmaceutical plants that have a licence for the industrial manufacture of medicinal products granted by Fimea in accordance with section 8 of the Medicines Act (395/1987).
- **Manufacturer of the medicinal substance.** Manufacturer of a medicinal product refers to an industrial manufacturer referred to in section 8 of the Medicines Act (395/1987) who manufactures medicinal substances (active substances) used in the manufacture of medicinal products.
- **Manufacturers of medical devices.** Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
 - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
 - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
 - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
 - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
 - and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products for the cleaning, disinfection or sterilisation of medical devices.

"Manufacturer" refers to any natural or legal person who manufactures or fully refurbishes a device or who commissions the design, manufacture or refurbishment of a device and markets that device under their own name or trademark.

- **Manufacturers of medical devices intended for in vitro diagnostics.** In vitro diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:
 - a) a physiological or pathological process or state;
 - congenital physical or mental impairments;

- a predisposition to a medical condition or a disease;
- to determine the safety and compatibility with potential recipients;
- to predict treatment response or reactions;
- to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.

"Manufacturer" refers to any natural or legal person who manufactures or fully refurbishes a device or who commissions the design, manufacture or refurbishment of a device and markets that device under their own name or trademark.

3 Logging in to e-services

Fimea's e-services are available at asiointi.fimea.fi. Log in to e-services through the Suomi.fi e-Identification service in the top right corner of the front page.

Once in the Suomi.fi e-Identification service, you can select the desired identification method. Identification takes place with online banking codes, a certificate card or a mobile certificate. After identification, select the "Continue to service" button.

Then select the "NIS2 operator list" button on the navigation bar and select the "Home and announcements" button from the drop-down menu. Select the company, association or other organisation on whose behalf you wish to use the service. Press the blue "Select and go to the e-service" button and you will be directed to the home page of e-service for the NIS2 entity list.

The system will automatically log out a user if the service is idle for 30 minutes. Always log out of e-services when you stop using the service. Also, clear your browser's history and cache and close all open browser windows. In this way, you can ensure that person who use the same computer later on will not be able to see your data.

4 Navigation in e-services

Use of the service starts on the front page of e-services. You can change the language settings (1) at the top of the screen. You can change the service language from the "Suomi", "Svenska" or "English" buttons.

Identify yourself in the service by pressing the "Log in" button (2).

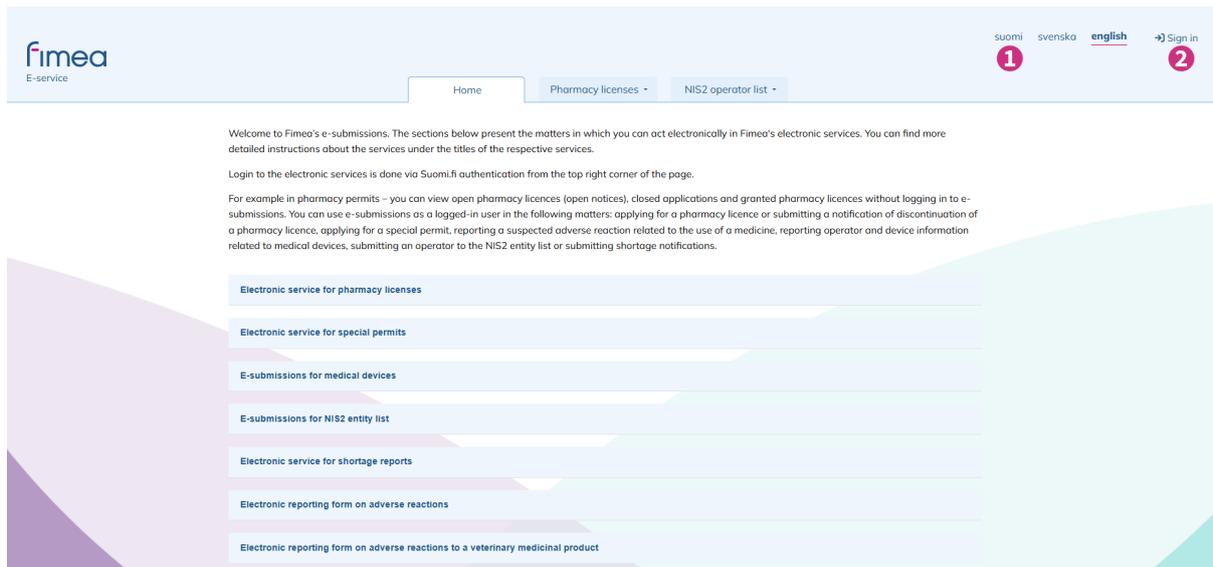


Figure 1. View of the e-services homepage

After identification, the user's name is displayed in the top bar of the home page (3).

Select the "NIS2 operator list" button (4) on the navigation bar and select the "Home and notifications" button (5) from the drop-down menu. Before accessing the NIS2 operator list, you will be directed to identify yourself as a person acting on behalf of a company through the Suomi.fi e-Identification service.



Figure 2. View of the e-services homepage

After identification, you will be able to access the home page of the NIS2 operator list. On the home page, you can submit your entity's first notification if there are no previous notifications. If the operator has previous notifications, you can view the notifications on the home page.

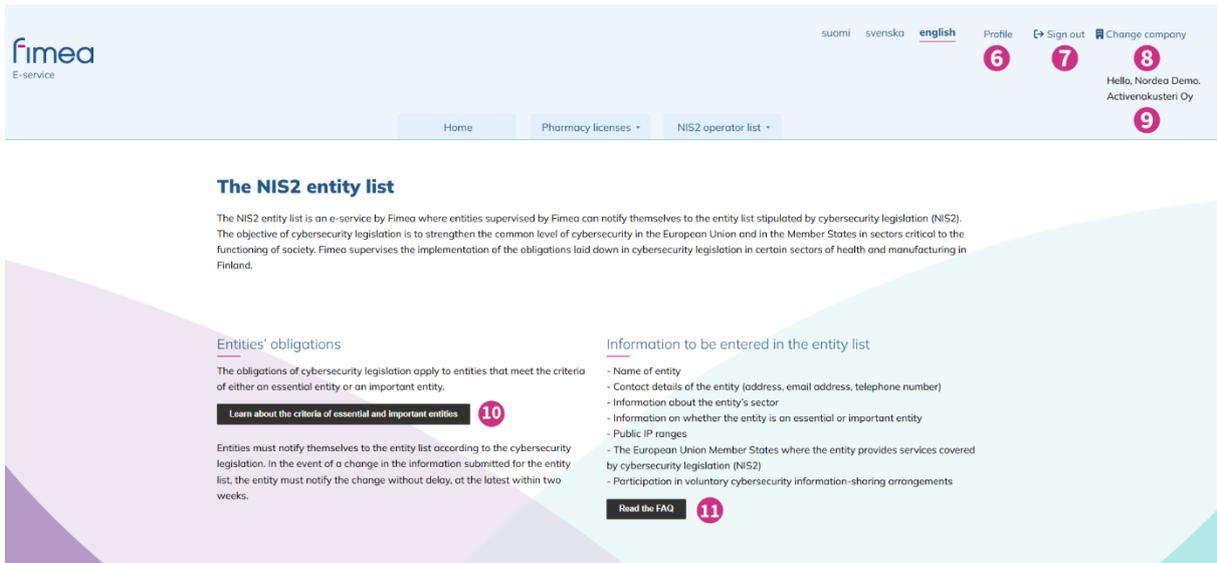


Figure 3. View of the NIS2 operator list e-services homepage

You can view the profile of the logged in user at the top of the home page for the NIS2 operator list e-service (6).

Next to this you can find the "Log out" button (7) for logging out.

There is a button at the top right of the page from which you can change the company on whose behalf you are acting (8).

The top bar contains the name of the user who is logged in and, under this, the company on whose behalf they are acting (9).

Read more about cybersecurity legislation, by clicking on the "Learn about the criteria of essential and important entities" button (10).

Click the "Read the FAQ" button to read the frequently asked questions (11). The button will direct you to the Fimea website.



Figure 4. View of the NIS2 operator list e-services homepage

If an operator has no previous entity notifications, you can submit an entity notification to the NIS2 entity list by selecting the 'Register the operator you represent to the entity list' button (12).



Figure 5. View of the NIS2 operator list e-services homepage

If the operator has previous entity notifications, you can view them by pressing the "Change notification" (13) or "First notification" link (14).

5 Entity list

5.1 An entity's first notification

1. Log in to the e-service for the NIS2 entity list to access the home page of the e-service.
2. Select the "Notify the entity you represent to the entity list" button.
3. After this, a view with the registration form will open. Important information is given above the form on how to fill in the form and the information collected in the entity list. The form's process flow is also shown above the form.
4. Fill in the entity's details. Compulsory fields are marked with a red * - symbol (1). The form will not proceed to the next phase until all compulsory fields have been filled in. When entering the next phase of completing the form, the service will notify you of any missing compulsory information.



Country * 1

Figure 6. View from the entity registration form

The company's name and business ID have been filled in automatically on the form (2 and 3). This data cannot be changed in the e-service for the NIS2 entity list. Instead, the Suomi.fi e-service checks the information in a basic register (trade register, business information system and register of associations) or in the Suomi.fi Authorizations register.



Name of the entity 2

Ageemu Testifirma OY

Business ID 3

7025758-1

Figure 7. View from the entity registration form

The form allows you to move forward or backward using the "previous" (4) and "next" (5) buttons at the bottom of the page.



Previous 4

5 Next

Figure 8. View from the entity registration form

7. Move to the next page of the form from the bottom of the form (5).
8. Fill in information on the sector Select the "Add to" button (6). Select the entity's sector description (7) from the selection boxes. You can select several sectors, sub-sectors and entity types. Then press "Add" (8) to return to the view with sector data.

Figure 9. View from the entity registration form

Figure 10. View from the entity registration form

9. Move to the next page of the form from the bottom of the form (5).
10. Fill in operations-related information. Remember to read the instruction texts on the form carefully.
11. Go to the last page of the form titled "Sending of information."
12. The form will now be saved as a draft. You can still go back to correct the information entered in the draft form by either using the "previous" button (4) or going directly to the home page of the e-service for the NIS2 entity list. To move ahead to sending, select the "Submit" button.
13. Confirm and send the form by selecting the "Send" button. The "Close" button will take you back to the home page of the NIS2 entity list e-service where you can edit the draft form.
14. Once a notification has been sent successfully a "Thank you for the notification!" message will appear on the screen and a button to go to the front page (9). You can see the successfully submitted notification on the front page of the NIS2 operator list. Please note that there may be a small delay in the submission of the notification to the system.

Thank you for the notification!

Your notification has been sent to Fimea. The entity you represent has been notified to Fimea's NIS2 entity list. You can view the details of notifications you submit on the front page of the service. In the event of a change in the information submitted for the entity list, notify the change to the service without delay, at the latest within two weeks. You also have to submit a change notification if the entity you represent no longer meets the criteria of an essential or important entity or if the entity has ceased its activities.

Important information about the processing of notifications

Fimea receives notifications of essential and important entities for the NIS2 entity list and delivers information on them to Finland's single point of contact on cybersecurity as described in the Cybersecurity Act.

Cybersecurity incidents must be reported to the incident reporting application maintained by the National Cyber Security Centre, and the Centre subsequently informs Fimea for supervision purposes. Depending on the situation, an incident is addressed in cooperation by the entity, Fimea and/or cybersecurity authorities.

The Additional information field of this NIS2 entity list is not for urgent cybersecurity matters. Address additional information and urgent enquiries to Fimea's supervision email addresses and kirjaamo@fimea.fi or NIS2-CER@fimea.fi.

To home



Figure 11. View from the entity registration form

5.2 Notification of change to entity information

If an operator’s entity information changes, for example, due to a change of address, sector description or operator’s core criteria, the changes must be reported to the NIS2 operator list without delay, at the latest within two weeks of the change.

1. Log in to the e-service for the NIS2 operator list to access the home page of the e-service.
2. Select the company on whose behalf you are acting in the NIS2 operator list.
3. Open "NIS2 operator list" from the navigation bar and select the "Notify of changes to operator information" page (1) from the drop-down menu.

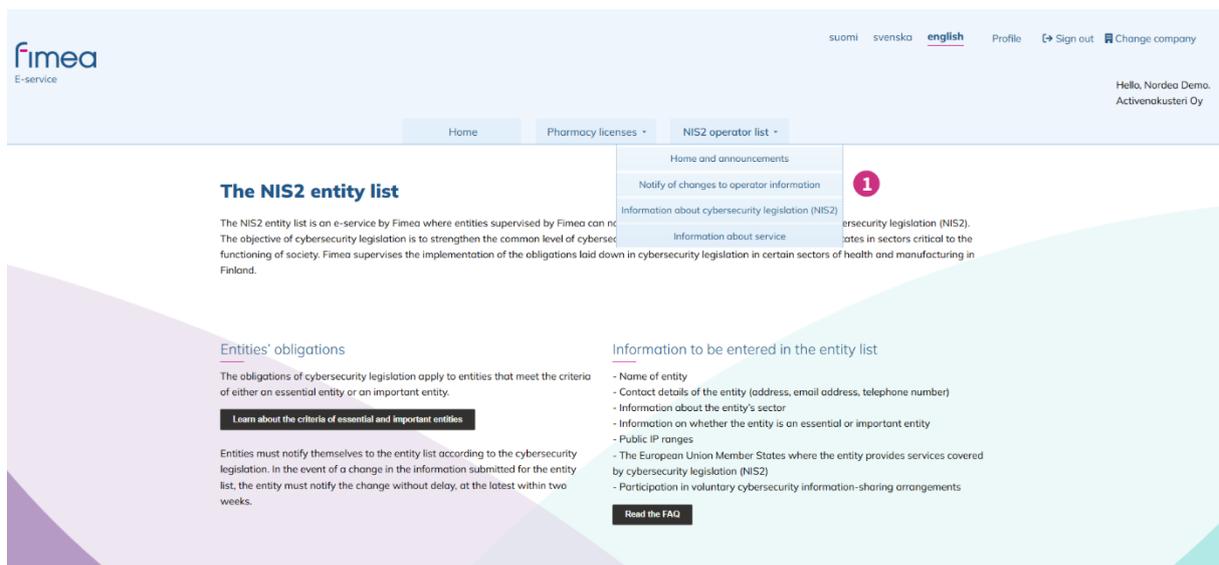


Figure 12. View of the NIS2 operator list e-services homepage

4. Select the "Notify a change to the entity’s information" button (2).

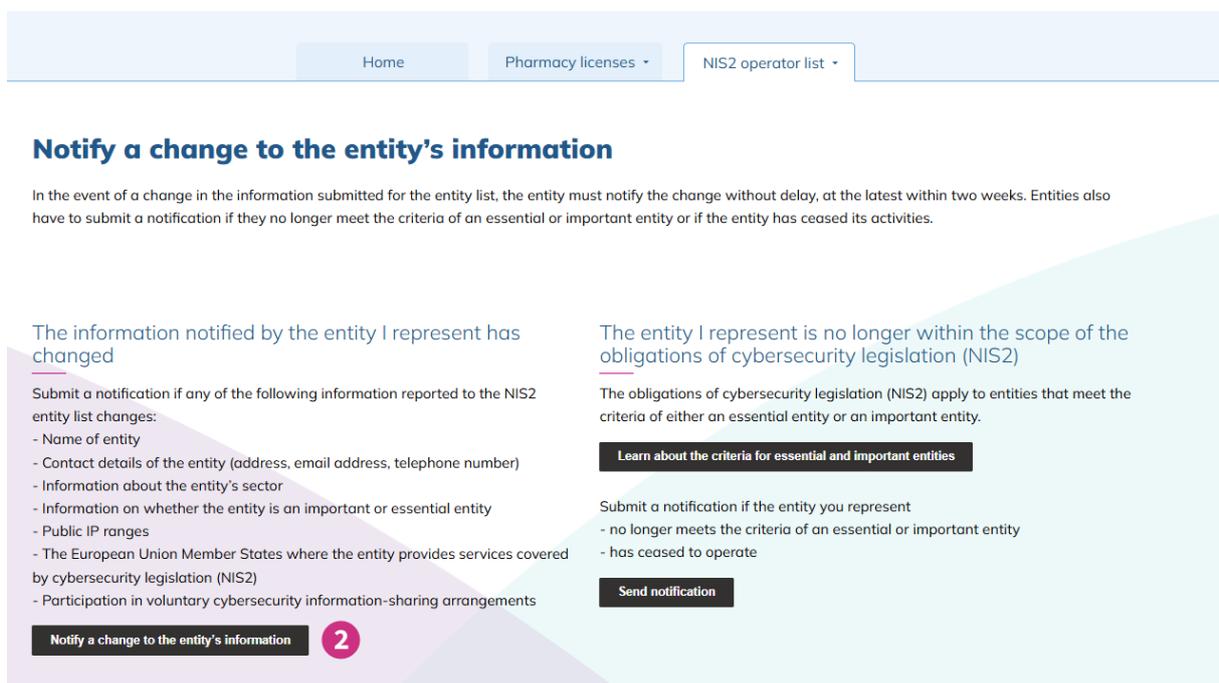


Figure 13. Notify of changes to operator information page

5. After this, a view with the registration form will open. Important information is given above the form on how to fill in the form and the information collected in the entity list. The form's navigation options are also shown above the form.

6. Review and update the changed information on the form. The form has been pre-completed on the basis of the information provided to the NIS2 entity list. Please note that the sector is added to the form manually. The company's name and business ID have also been filled in automatically on the form (3 and 4). The name and business ID of a company cannot be changed in the e-service for the NIS2 entity list. Instead, the Suomi.fi e-service checks the information in a basic register (trade register, business information system and register of associations) or in the Suomi.fi Authorizations register.

Compulsory fields are marked with a red * - symbol (5). The form will not proceed to the next phase until all compulsory fields have been filled in. When entering the next phase of completing the form, the service will notify you of any missing compulsory information.

The screenshot shows two input fields. The first field is labeled 'Name of the entity' with a red circle containing the number 3. The text 'Ageemu Testifirma OY' is entered in the field. The second field is labeled 'Business ID' with a red circle containing the number 4. The text '7025758-1' is entered in the field.

Figure 14. View from the operator information update form

The screenshot shows a single input field labeled 'Country' with a red asterisk and a red circle containing the number 5, indicating it is a compulsory field. The field is currently empty.

Figure 15. View from the operator information update form

7. The form allows you to move forward or backward using the "previous" (6) and "next" (7) buttons at the bottom of the page.

The screenshot shows two buttons at the bottom of the page. On the left is a button labeled 'Previous' with a red circle containing the number 6. On the right is a button labeled 'Next' with a red circle containing the number 7.

Figure 16. View from the operator information update form

8. Once you have updated the changes to the form, move to the last page of the form titled "Sending of information".

12. The form will now be saved as a draft. You can still go back to correct the information entered in the change notification form by either using the "previous" button (6) or going directly to the home page of the e-service for the NIS2 entity list. To move ahead to sending, select the "Submit" button.

13. Confirm and send the change notification form by selecting the "Send" button. The "Close" button will take you back to the home page of the NIS2 entity list e-service where you can edit the draft change form.

14. Once a notification has been sent successfully a "Thank you for the notification!" message will appear on the screen and a button to go to the front page (8). You can see the successfully submitted notification on the front page of the NIS2 operator list. Please note that there may be a small delay in the submission of the notification to the system.

Thank you for the notification!

Your notification has been sent to Fimea. Fimea has received your notification of changes to the entity list information.

You can view the details of notifications you submit on the front page of the service.

In the event of a change in the information submitted for the entity list, notify the change without delay, at the latest within two weeks. You also have to submit a change notification if the entity you represent no longer meets the criteria of an essential or important entity or if the entity has ceased its activities.

Important information about the processing of notifications

Fimea receives notifications of essential and important entities for the NIS2 entity list and delivers information on them to Finland's single point of contact on cybersecurity as described in the Cybersecurity Act.

Cybersecurity incidents must be reported to the incident reporting application maintained by the National Cyber Security Centre, and the Centre subsequently informs Fimea for supervision purposes. Depending on the situation, an incident is addressed in cooperation by the entity, Fimea and/or cybersecurity authorities.

The Additional information field of this NIS2 entity list is not for urgent cybersecurity matters. Address additional information and urgent enquiries to Fimea's supervision email addresses and kirjaamo@fimea.fi or NIS2-CER@fimea.fi.

To home **8**

Figure 17. View from the operator information update form

5.3 Notification of an entity’s removal from the scope of NIS2 obligations

If an operator registered in the entity list no longer meets the criteria for an essential or important entity, or if the operator ceases its operations, a notification must be submitted.

1. Log in to the e-service for the NIS2 entity list to access the home page of the e-service.
2. Select the company on whose behalf you are acting in the NIS2 entity list.
3. Open "NIS2 entity list" from the navigation bar and select the "Notify of changes to operator information" page (1) from the drop-down menu.

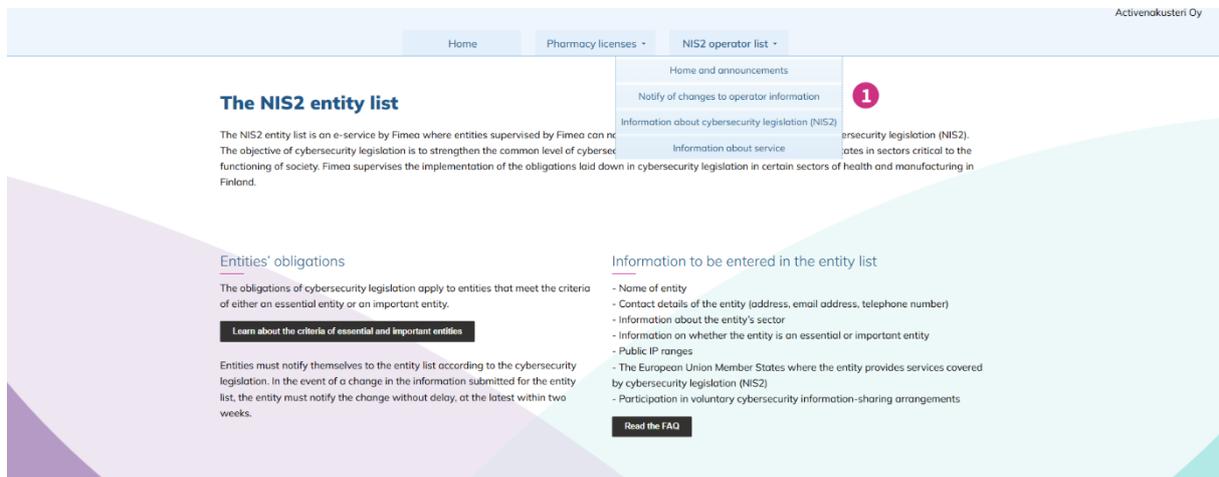


Figure 18. View of the NIS2 operator list e-services homepage

4. Select the "Send notification" button (2).

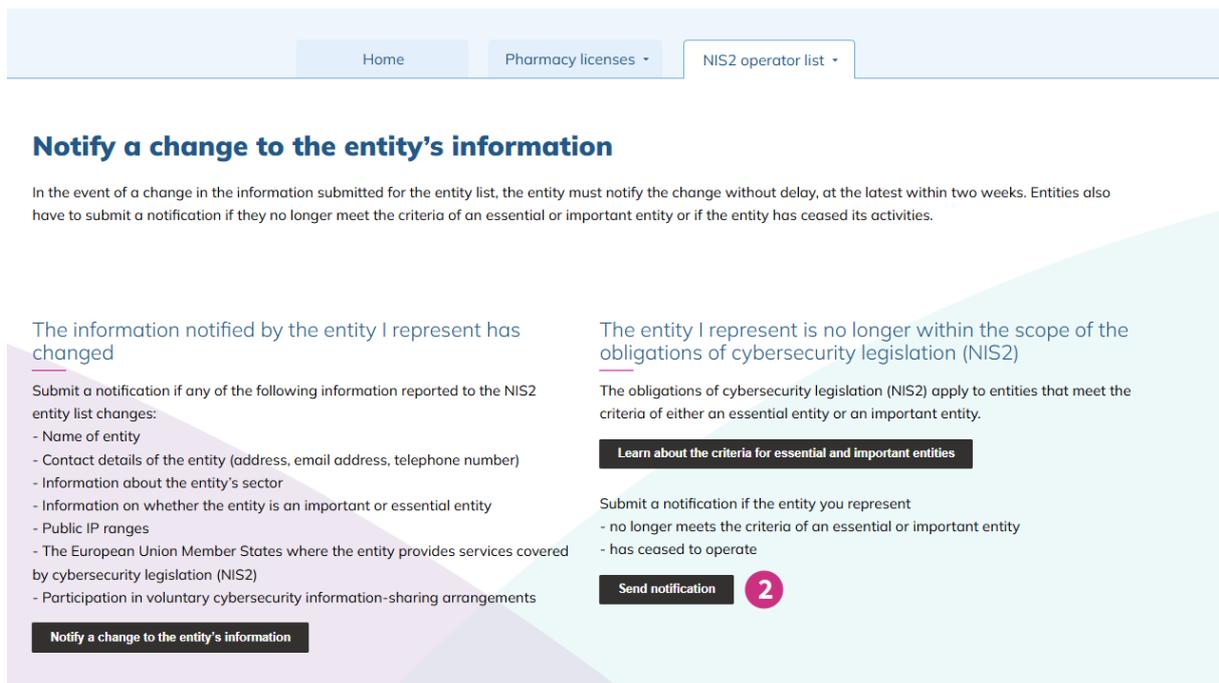


Figure 19. Notify of changes to operator information page

5. Confirm sending of the notification using the "Send" button **(3)**. Select the "Cancel" **(4)** button to return to the home page of the NIS2 entity list e-service.

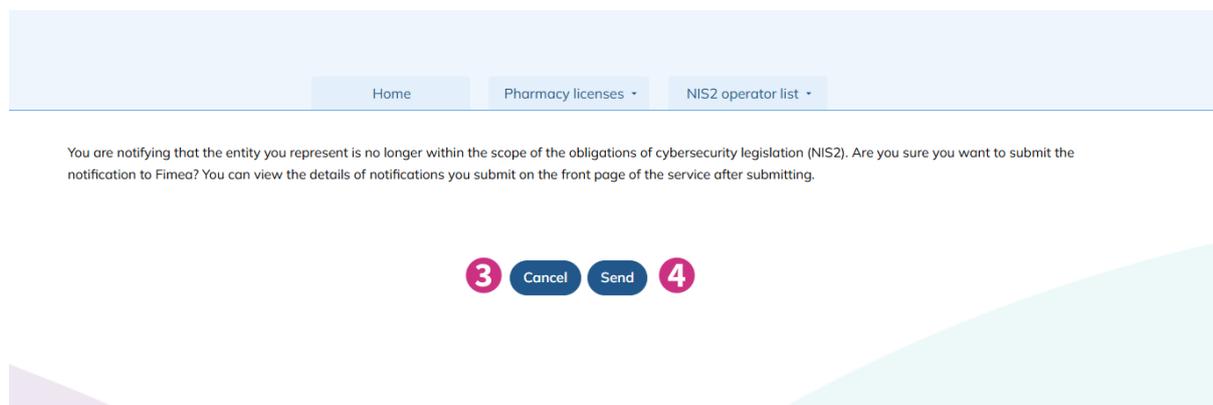


Figure 20. View from the remove operator from the operator list page

6. Once a notification has been sent successfully a "Thank you for the notification!" message will appear on the screen and a button to go to the front page. You can see the successfully submitted notification on the home page of the NIS2 entity list. Please note that there may be a small delay in the submission of the notification to the system

The logo for Fimea, the Finnish Medicines Agency. It features the word "fimea" in a lowercase, sans-serif font. The letter "f" is dark blue, and the letter "i" has a small red dot. The remaining letters "mea" are also dark blue. The background of the page is white with a large, abstract, overlapping purple and lavender geometric shape in the bottom-left corner.

fimea

Lääkealan turvallisuus- ja kehittämiskeskus
Säkerhets- och utvecklingscentret
för läkemedelsområdet
Finnish Medicines Agency